



Proposals for the Smoked Tobacco Regulatory Regime

Public consultation document

2023

Citation: Ministry of Health. 2023. *Proposals for the Smoked Tobacco Regulatory Regime – Public Consultation Document*. Wellington: Ministry of Health.

Published in January 2023 by the Ministry of Health
PO Box 5013, Wellington 6140, New Zealand

ISBN 978-1-991075-05-5 (online)
HP 8661



This work is licensed under the Creative Commons Attribution 4.0 International licence. In essence, you are free to: share ie, copy and redistribute the material in any medium or format; adapt ie, remix, transform and build upon the material. You must give appropriate credit, provide a link to the licence and indicate if changes were made.

Contents

Introduction	1
Background	1
Purpose of this consultation document	2
Structure of this consultation document	2
How to provide feedback	3
Regulatory proposal 1: Smoked tobacco retail application scheme	4
Description	4
Regulatory proposal 2: Low nicotine requirements	15
Description	15
Proposal	15
Regulatory proposal 3: Fees	21
Description	21
Proposal	21
Regulatory proposal 4: Notification requirements	23
Description	23
Proposal	23
Regulatory proposal 5: Youth Vaping	25
Description	25
Proposal	25
Appendix 1: Additional information regarding rural and urban areas	28
Appendix 2: More information on minimum requirements	30
Appendix 3: More information on ranking criteria for smoked tobacco retailers	31
List of Tables	
Table 1: Summary of smoked tobacco product retailer allocation example	8

Table 2: Proposed minimum requirements for approval as a smoked tobacco retail premise to be set out in regulations

10

Introduction

Background

Aotearoa New Zealand is underway in making changes to the types of smoked tobacco products available, and where these can be sold across the country. This is being done through the Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Act, which came into force on 1 January 2023. This means that the Smokefree Environments and Regulated Products Act 1990 (the Act) now:

- restricts the sale of smoked tobacco products (such as cigarettes, cigars, roll your own tobacco and pipe tobacco) to a limited number of approved retail premises. The Director-General of Health will set, by written notice, the maximum number of such retail premises across the country. This is intended to significantly reduce retail availability of smoked tobacco products
- prohibits anyone from selling or supplying smoked tobacco products to people born on, or after, 1 January 2009. This is intended to create a 'Smokefree Generation' to prevent our tamariki, and the generations born after them, from ever taking up smoking
- extends the Act's regulatory powers over the composition of smoked tobacco products, such as nicotine levels, so that only products that meet requirements set out in the Act and in the Smokefree Environments and Regulated Products Regulations 2021 (the regulations) can be manufactured, imported, sold or supplied in New Zealand. This is intended to make smoked tobacco products less addictive and appealing.

To implement these changes a regulatory regime must be established to oversee and monitor the import, manufacture, sale and supply of smoked tobacco products in New Zealand. This consultation document sets out a number of regulatory and operational proposals to this end.

The document also sets out a small number of proposals intended to tighten current restrictions on vaping product safety requirements and packaging, and consider some restrictions on the location of Specialist Vape Retailers (SVR's). These proposals respond to concerns about the appeal and uptake by youth of vaping products, and to ensure that disposable vapes are safe to use. The proposals are not intended to restrict access or availability to vaping products to people who wish to stop smoking and switch to a less harmful product.

Purpose of this consultation document

The Ministry of Health is seeking your views on regulatory proposals that will provide the operational detail needed to establish the new regulatory regime, as well as changes to regulatory requirements for notifiable products¹ (vaping, heated tobacco and now herbal smoking products).

These proposals will inform the development of regulations, written notices and guidance to implement the new provisions of the Act. It is important that the regulatory regime is workable. Your feedback on the proposals is important and will help shape the detail of the new regulatory regime.

In addition, the Act requires us to consult with Māori regarding the process of appointing smoked tobacco retailers, including in determining the maximum number of retail premises and the area to which that number applies (Proposals 1a, b and c).

It is important that the changes we are making to the way tobacco and vaping products are made and sold reflect the aspirations of communities, with a focus on hāpori, iwi, hapū and whānau Māori. This is because of the marked inequities in health caused by greater smoking prevalence among Māori. The **Smokefree 2025 Action Plan** commits to ensuring Māori leadership and decision-making at all levels: this is essential if we are to achieve the equitable outcomes we seek.

Structure of this consultation document

This consultation document has 5 main sets of proposals:

1. Regulatory proposal 1: Smoked tobacco retail scheme (refer to new Part 1B of the Act)
2. Regulatory proposal 2: Low nicotine requirements (refer to new Part 3A of the Act)
3. Regulatory proposal 3: Fees (refer to Part 5 of the Act)
4. Regulatory proposal 4: Registration requirements for smoked tobacco distributors and notifiable product retailers (refer to new Part 1B Subpart 3 of the Act)
5. Regulatory proposal 5: Vaping (refer to new Part 1B Subpart 2 and Part 5 Subpart 1 of the Act).

Each section describes the regulatory proposals and asks a number of questions that will inform and shape the development of final regulations and other instruments. Appendices provide additional information on some of these topics.

¹ Notifiable products are a defined class of products regulated under the Smokefree Act, and include vaping products, heated Tobacco products and now herbal Tobacco products.

How to provide feedback

You can provide feedback in one of two ways:

1. Use our online tool at <https://consult.health.govt.nz/tobacco-control/proposals-for-the-smoked-tobacco-regulato>. This is our preferred way to receive feedback.

Note: With the online tool, you can complete your submission over multiple sessions and save it as you go. If you select 'Save and come back later', you will receive an email with a unique link that will let you return to edit and submit your response. You can share this link with your colleagues if you need them to contribute to or review the submission. Once you have completed your submission, you will be sent a pdf copy for your records

2. Send an electronic submission to smokefree@health.govt.nz using our downloadable Microsoft Word template from the Ministry of Health website at <https://www.health.govt.nz/publication/proposals-smoked-tobacco-products-regulatory-regime>. If you have any issues with the template, please email us at smokefree@health.govt.nz

The closing date for submissions is 15 March 2023 at 5.00pm.

Note that your submission may be requested under the Official Information Act 1982. If this happens, the Ministry of Health will normally release your submission to the person who asks for it. If you consider there are good reasons to withhold it, please clearly indicate these in your submission.

We appreciate you taking the time to make a submission.

Protection from commercial and other vested interests of the tobacco industry

New Zealand has an obligation under Article 5.3 of the Framework Convention on Tobacco Control (FCTC) when 'setting and implementing public health policies with respect to tobacco control... to protect these policies from the commercial and other vested interests of the tobacco industry'.

The internationally agreed **Guidelines for Implementation of Article 5.3** recommend that parties to the treaty 'should interact with the tobacco industry only when and to the extent strictly necessary to enable them to effectively regulate the tobacco industry and tobacco products.

We expect to receive feedback from companies in this industry. We will consider all feedback when analysing submissions.

To help us meet our obligations under the FCTC and ensure transparency, we ask all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry.

Regulatory proposal 1: Smoked tobacco retail application scheme

Description

There are currently no restrictions on where smoked tobacco products can be sold in New Zealand and who can sell them. There are approximately 6,000 tobacco retailers, and these are concentrated in low-income communities, where smoking rates are highest. High retail density has been associated with greater tobacco use, increased youth smoking rates and greater risk of relapse among people attempting to quit. Reducing the retail availability of smoked tobacco products is a focus area of the Government's Smokefree Aotearoa 2025 Action Plan and is key to achieving the Smokefree 2025 goal.

Under the amended Act, from 1 July 2024 smoked tobacco products will only be able to be sold in a limited number of retail premises approved by the Director-General of Health. The Director-General must set a maximum number of such retail premises across the country that is no more than 600. The Act also provides minimum requirements that smoked tobacco retailers must meet, and for criteria and conditions for becoming an approved smoked tobacco retailer to be made in regulations. The Director-General must also determine and publish an application process.

It is intended that retail premises appointed under this process will have a time limited term.

These new requirements are intended to significantly reduce the retail availability of smoked tobacco products in Aotearoa.

Proposals

We are seeking your feedback on the approach we take to inform the development of the smoked tobacco retail application scheme. This is discussed in 3 parts:

- Proposal 1a - the proposed distribution of smoked tobacco retail premises across Aotearoa. This relates to the written notice that must be made by the Director-General under section 20M of the Act to set maximum numbers of retail premises for areas of New Zealand.
- Proposal 1b - the criteria for the Director-General's decision-making, including minimum approval criteria. This relates to key criteria under 20I, and regulation making

powers under 82A of the Act to require the retailer to meet certain criteria before they can be approved.

- Proposal 1c - the approval processes, including a method of ranking applicants and criteria to do so. This relates to requirements under 20L of the Act, including the requirement for the Director-General to publish an application process, and for related requirements to be set via regulations.

The Act has specific requirements to consult with Māori on the maximum number of approved retail premises and the areas for these retail premises, and the application process. Additional information about these requirements can be found in new section 3AB Te Tiriti o Waitangi (the Treaty of Waitangi). Hui will be held to understand Māori views on the consultation, however we also welcome feedback through our online tool.

Proposal 1a – Number of smoked tobacco retail premises and their distribution across Aotearoa

Currently there are around 6,000 retailers of smoked tobacco products in New Zealand. The recent changes to the Act mean that no more than 600 approved retail premises will be permitted to sell smoked tobacco products across the country. In deciding how these stores will be distributed, we have made a number of proposals that we would like feedback on, as follows:

We propose setting a maximum number of retail premises for each area of New Zealand

The Director-General must make a written notice setting a maximum number of retail premises for all of New Zealand, or divide New Zealand into different areas and set a maximum number of retail premises for each area. The total number must be no more than 600.

The purpose of this section is to seek your views on how the Director-General should determine areas and the maximum number of approved smoked tobacco retail premises for each area.

We propose defining areas based on urban or rural settings

Areas could be defined in a number of ways, such as by region, by local council, by iwi boundaries or by small areas such as by postcode, town or suburb.

To achieve the overall purposes of the Act, and to reduce disparities in smoking rates and smoking-related illnesses between New Zealand population groups, and in particular between Māori and other groups, we propose:

- to divide New Zealand into areas based on whether the area is urban or rural, and
- set a maximum number for each rural or urban area.

We propose urban and rural areas are determined as follows:

- **Urban** areas are towns or cities, and their commuting zones. We defined urban areas using information from Stats NZ which includes both small towns and larger cities. We slightly expanded urban areas to include places within an easy driving distance of the boundary of an urban area (the 'urban halo').
- **Rural** areas are all areas outside of the defined urban areas.

We propose to do this because people living in urban and rural areas face different challenges. For example, smoking prevalence is higher in some rural areas and travel time is longer. On the other hand, we have heard concerns about the current clustering of stores in low socioeconomic urban areas. This is contrary to the purposes of the Act: to reduce disparities in smoking rates and smoking related illnesses between population groups.

We propose that there should be a separate maximum for each individual urban or rural area. For example, in Taranaki, there are several urban areas – one city (New

Plymouth), and then some smaller towns, such as Hāwera, and rural areas between these. Each of these would have a separate maximum number of retail premises. This would mean that it is easier to ensure that retailers are spread throughout a region and are not clustered, for example, in lower socio-economic areas.

The final number of areas and the number of retail premises for each area will be set by written notice following consultation. We are interested in hearing how you think areas should be defined.

We propose allocating maximum numbers differently for rural and urban areas

In setting the number of retail premises for an area, the Act requires the Director-General to consider the geographic nature of the area and the estimated average travel time to purchase smoked tobacco products as well as the population size in the area and estimated number of people who smoke.

We propose that in urban areas the key consideration is to reduce availability and avoid clustering of retail premises in lower socio-economic areas. For rural areas the key concern is ensuring that there is still a reasonable level of access, however there is no need to ensure access where none previously existed.

We therefore consider that the number of retail premises should not be determined by the Director-General based entirely on the number of people who smoke, as a strictly proportional model of allocation will result in most stores being located in larger urban centres. The majority of stores would be located in Auckland, and other major urban areas. Many smaller urban areas (such as Wellsford, Kaikōura, Te Anau, Bluff, Coromandel, Featherston, and Hokitika) would end up with no stores at all.

We propose a model in which the number of stores allocated in a particular area is determined, in part by whether an area is defined as urban or rural, as follows:

- **Urban:** The number of stores allocated in these areas will be based on estimated numbers of people who smoke in a particular area. We have adjusted the allocation, so that smaller urban areas (smaller towns) get allocated more stores on a population basis to improve coverage of smaller towns.
- **Rural:** The number of stores allocated in these areas will be based on a defined driving time along the state highway in that area.² Rural allocations will need further refinement based on feedback. In order to ensure accessibility for rural populations not served by a state highway, some adjustments will need to be made to reduce disparities between regions. There are some rural areas with no retail premises because there is no state highway (for example Great Barrier Island, Stewart Island) and a few which might have too many retail premises (for example along SH43 from Stratford to Taumarunui).

Our proposed model has been designed to align with the purposes of the Act but can be tailored to the needs of each rural and urban area, which is why we want to hear from communities about what is important in different areas.

² Other allocation methods for rural areas, such as those based on population or land area were also considered but found to give a less equitable distribution.

Because of the differences between the way we have proposed to allocate retail premises to urban areas (to reduce availability, and avoid clustering in poorer areas) and rural areas (to reduce availability, and ensure that there is still reasonable access, and in particular considering the geographic nature and driving time as required by the Act), it is likely that there will be more premises per person who smokes in rural areas than there are in urban areas.

Changes to the calculations in this model, such as the relationship between the number of people who smoke and the number of stores, the agreed acceptable drive time to an urban area or within rural areas, or any adjustments made to account for overlapping state highways or areas where few or no people live, will change the allocation figures.

Appendix 1 provides more information about how we have defined urban and rural areas.

Summary of proposed model for distribution

Taking these factors into account, Table 1 below provides an example scenario for smoked tobacco retail premises summarised by region. It is likely that the final distribution will need to be adjusted to take into account feedback from consultation, so this is a starting point for discussion only.

In this scenario, Auckland has fewer retailers than, for example, the Waikato, because it is one large urban area, while the Waikato has a number of cities, towns and rural areas each with a separate allocation. This also shows more rural retailers than urban. The number of retailers per person who smokes is higher in smaller urban areas than larger ones.

We have provided a series of maps of New Zealand to show how this scenario might look at a local level. These are provided as a separate document that can be downloaded from the Ministry [website](#).

Table 1: Summary of smoked tobacco product retailer allocation example

Region	Urban	Rural
Northland (Te Tai Tokerau)	14	28
Auckland (Tāmaki Makaurau)	28	5
Waikato	33	57
Bay of Plenty (Te Moana a Toi-te-Huatahi)	23	36
Tairāwhiti/Hawkes Bay (Te Matau-a-Māui)	16	28
Taranaki	9	16
Manawatū/Whanganui	20	21
Wairarapa/Wellington (Te Whanganui-a-Tara)	30	2
Nelson (Whakatū)/ Marlborough (Te Taihu-o-te-waka)	7	10
Tasman (Te Tai o Aorere)/West Coast (Te Tai Poutini)	9	41
Canterbury (Waitaha) /Chatham Islands (Wharekauri / Rēkohu)	34	43

Region	Urban	Rural
Otago (Ōtākou)/ Southland (Murihiku)	27	60
Total (New Zealand)	250	347
	597	

Overall access to smoked tobacco products should reflect geographic requirements and smoking rates.

The number of stores allocated in a particular area should reflect local requirements. For example, people in areas with high smoking prevalence and rural areas should continue to be able to reasonably access smoked tobacco products. Conversely, access to products in more densely populated urban areas should not be too high.

When determining the maximum number and the area to which that number applies, the Director-General must also take into account the views of those consulted.

We are interested in hearing from communities about the overall allocation for your region. This could be in relation to the example allocation in Table 1, and/or any specific feedback in relation to different towns and cities, given the need to significantly reduce the overall number of retailers.

Consultation questions

-
1. Do you agree with having a separate maximum number of smoked tobacco retail premises for each area of Aotearoa?
-
2. Do you agree with the concept that urban and rural areas should be treated differently? If so, do you agree with how we have defined rural and urban?
If not, how else could the geographic nature of the area be taken into account?
-
3. Do you agree with our suggested allocation scenario, as described in Table 1 and the supplementary maps we have produced?
If not, how else would you determine the maximum number of retail premises, bearing in mind the Act allows a maximum of 600 retail premises?
-
4. We are interested in understanding the needs of different areas of Aotearoa. If you have any comments on the number of retailers in your area, please tell us.
What is your area (town, city or rural location)?
-

Proposal 1b – Minimum requirements for approval as a smoked tobacco retailer

Minimum requirements that the Director-General must consider when deciding which retail premises can sell smoked tobacco products are set out in the Smokefree Act.

The Director-General must be satisfied:

- that the applicant is fit and proper and is a New Zealand resident, or for an entity, each responsible person is fit and proper, and the entity is carrying out business in New Zealand or incorporated or registered under New Zealand law
- that retail premises are a fixed permanent structure and appropriate to operate from
- that the applicants security, training, sales, delivery and other business systems meet any requirements in regulations
- that other requirements in regulations are met.

Appendix 2 provides further information about the proposed requirements for a ‘fit and proper person’. The Act requires that the Director-General must have regard to these criteria or requirements when making their consideration.

Further requirements can be set in regulations for the security, training, delivery, other business systems, and other relevant criteria. The requirements proposed are designed to ensure that the retail scheme works as intended. For example, ensuring that there is adequate security will prevent the scheme being undermined by theft or other crimes and protect the health and safety of both customers and staff. These are minimums that any applicant must meet before being approved. We propose the following:

Table 2: Proposed minimum requirements for approval as a smoked tobacco retail premise to be set out in regulations

Criteria	Minimum Requirement
Security systems ³	Applicant must have secure product storage, an operational fog cannon, a suitable alarm system and operational security cameras with recording facility.
Training	Applicant must make sure that all employees involved in sales of tobacco products have training in relation to responsibilities under the Act, including preventing sales to minors/the smokefree generation.
Sales systems	Applicant must keep appropriate records of sales. Applicant must have systems to prevent sales to minors.
Delivery systems	Where a sale involves any aspect of delivery, the applicant must have systems in place to ensure that the delivery is to the person purchasing, and not to a minor or member of the smokefree generation.
Other business systems	None considered at this time.

³ The Ministry is continuing to work with NZ Police to refine security requirements, including clarifying those that are minimum requirements and those that are decision making criteria (see proposal 1c and Appendix 3) and therefore optional but highly recommended.

Consultation questions

1. Do you agree with the proposed requirements for a 'fit and proper person' in Appendix 2?

If you have any comments on these requirements, please let us know.

2. Do you agree with the minimum requirements we have proposed for security systems, training, sales systems, delivery systems and other business systems?

Do you have any other suggestions?

Proposal 1c – Approval processes and decision-making criteria

The Act requires that the Director-General determine and publish a process for applications. In this regard, we are seeking feedback on 2 main parts: firstly, how the application process will be run, and secondly how we will compare applications against each other if there are too many applicants for an area.

Retail application process

The draft smoked tobacco retailer application process is proposed as follows:

1. Applications will be open for a set period of time.
2. The Director-General will review applications against the eligibility criteria discussed in proposal 1b. Applications that do not meet these minimum requirements, will not be considered further.
3. The Director-General will assess and rank all other applications based on the evaluation criteria described below and in Appendix 3.
4. The Director-General may check the information provided in the remaining applications for accuracy (for example, through a site visit).
5. The Director-General will decide on the ranking of the eligible applications taking into account any information identified through the checking process.
6. The Director-General will then approve a number of retailers that is no more than the defined maximum for that area.

Where there are more applicants for an area than the maximum number of retailers for that area, the Director-General will assess and rank applicants based on the evaluation criteria described below in order to determine which applicants will be granted approval. The Director-General does not have to approve the maximum number of retailers and may choose a lower number, or none, where there are not any applicants for a specified area that meet the minimum criteria discussed in proposal 1b.

The Act would not allow for the maximum number in an area to be exceeded, even if another area nearby does not use its full allocation of retailers. This means that if the Director-General approves less smoked tobacco retailers than the number allocated to that area, the remainder would not transfer to any other area.

If there is a tie in ranking between potential stores, the Director-General will approve both applications, unless this would mean that there are more than the maximum number of retail premises for that area, in which case, the Director-General will approve neither application.

Decision making and ranking process

If there are too many applicants in one area, the following criteria could be useful to distinguish between retail applications (Appendix 3 provides further detail). These criteria may be defined in Regulations.

- Business related criteria: criteria like security, sales systems and training, could be used to rank applicants. For example, in terms of sales systems, the business needs to have considered factors such as their supply chain – ensuring that they will have the right amount of stock to service demand. We propose that detailed proposals would be acceptable within an application, to avoid retailers’ incurring costs prior to approval of an application.
- Proximity and location: certain criteria may relate to the location of the retail premise or specific community needs. For example, distance from schools or sports grounds may be relevant. Communities may feel that there are areas where it is less appropriate for smoked tobacco retail premises to operate (such as near schools or marae). Additionally, ensuring that the premises are spread across each area may be important.
- A history of compliance with the Smokefree Environments and Regulated Products Act, by the applicant (the entity or individual) and any responsible people over the previous 5 years may be relevant.
- The nature of the business may be relevant – for example, retail premises selling alcohol, convenience goods and/or groceries might rank lower on this criterion while stores only selling smoked tobacco products may score higher, because we are of the view that selling tobacco products alongside everyday grocery items normalises these products.
- A ‘specialist outlet’ category could allow for a certain number of retail premises specialising in smoked tobacco products that are not cigarettes (eg, cigars) to score higher.

The Director-General may weight the criteria or give them an equal consideration. We are interested in feedback about what criteria is of most importance, or least importance.

Consultation questions

-
1. Do you agree with the proposed application process?

 2. Are there any aspects that need to be clearer?

 3. If you have any changes or additions to the criteria we have proposed, please let us know.

 4. What do you think are the most and least important things to take into account when assessing an application?

Online sales

The Act provides that there may be sales from specified internet sites operated together with a specified retail premises, however the Director General has discretion to consider whether allowing online sales would achieve the purposes of the Act in the particular context.

There may be instances where we need to grant approvals for online sales to ensure that there is adequate access to smoked tobacco products for specific parts of the population. The Act requires that there is a demonstrated need for an online service, for example no approved retail store reasonably available to a population (eg, people in particular remote areas) and it is expected that any approval granted would include conditions that reflect the particular circumstances.

We propose that retailers indicate whether they wish to be considered for selling online when they apply for approval to be a smoked tobacco retailer. If, after granting approval to retailers to be smoked tobacco retailers, the Director General decides that there is a need for online sales, then the Director-General will assess those retailers who have indicated that they wished to be considered for online selling in their application and determine who will be granted approval to sell smoked tobacco products online. As part of this process, the Director General would be able to seek additional information specific to online sales if such information needed to inform their decision.

We propose that regulations are made that describe sales and delivery system requirements that a retailer will need to meet before being approved to provide online sales of smoked tobacco products. For example, to ensure that sales online are not to the smokefree generation (those born on or after 1 January 2009) and that the retailer can meet expected demand.

Retail support

Many current retailers will no longer be able to sell smoked tobacco products. We have heard that for some retailers, smoked tobacco is currently a significant part of their turnover, and they are concerned about the loss of this business. Other feedback we have heard has highlighted the low margin of smoked tobacco products.

While we are not considering direct compensation for loss of smoked tobacco product sales, there may be other support that we could offer. We are interested in understanding what would be useful.

Consultation questions

-
1. Do you have any feedback on additional decision-making criteria and processes for selling smoked tobacco products online?
-
2. Do you have any feedback on possible support for retailers who are no longer able to sell smoked tobacco products?
-

Regulatory proposal 2: Low nicotine requirements

Description

The product approval scheme comes into force on 1 April 2025. This means that from this time only low nicotine smoked tobacco products will be allowed in New Zealand.

The Act prohibits the sale, manufacture, import or supply of smoked tobacco products that have not been approved by the Director-General. The Director-General will only approve products that meet specified criteria, including that the product meets requirements set out in the Act and has been tested in accordance with regulations. This proposal seeks feedback on these proposed regulations.

To reduce the appeal and addictiveness of smoked tobacco products, the Act provides that nicotine levels in the tobacco in smoked tobacco products, must not exceed 0.8mg/g. This maximum applies to each individual product and includes all sources of variability. The Act also requires that regulations are made to determine whether the levels have been exceeded.

Additionally, nicotine must not be present in any other constituent of a smoked tobacco product. Constituents are everything that makes up, is present in, or is emitted from a regulated product. This includes for example the filter or any 'crush ball' within the filter of a smoked tobacco product.

The Act also provides for additional requirements to limit or prohibit other constituents, as well as the ability in certain circumstances to temporarily approve products that do not comply with one or more requirements.

These restrictions will come into force in April 2025.

Proposal

We propose that all smoked tobacco products must meet the product requirements set out below.

Testing method

There are a range of analytical testing methods available to determine the nicotine content in smoked tobacco products. Regulations will include detail about the methodological processes and general testing requirements that will apply. We propose that requirements include reference to analytical chemical methods to determine nicotine content, with a focus on chromatography-based technology, such as:

- a method based on the World Health Organisation (*WHO*)'s *SOP4 – Standard operating procedure for determination of nicotine in cigarette tobacco filler*,⁴ validated to account for the low nicotine levels prescribed
- or alternatively a Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) method, such as CORESTA no. 62 – Determination of Nicotine in Tobacco and Tobacco Products by Gas Chromatographic Analysis.⁵

Other suitable analytical methods, (eg, methods that test the nicotine content of the filler) may be possible. We are interested in feedback on any other suitable methods, and whether it is preferable to mandate the use of one preferred method such as one based on WHO SOP4, or to allow a variety of methods that meet requirements.

We are not considering methods that analyse the content of emissions (smoke) such as ISO 10315:2013, because ISO yield tests are based on the outputs of 'smoking machines' that simulate smoking. This type of test is open to manipulation; and it was used historically in the development of 'light' cigarettes, which communicated a false sense of harm reduction.

We also propose that the regulations make it clear that because the nicotine levels stipulated in the Act are inclusive of all sources of variability, results from testing nicotine levels in accordance with the method (for the purposes of product registration or compliance and monitoring) must never exceed 0.8mg/g for any individual tested product.

Existing reg 63 – Conduct of tests of manufactured cigarettes

We propose that the existing requirements listed in current reg 63 are no longer needed. These relate to certain constituents in cigarette smoke which will not be used in future to, for example, determine the nicotine content.

Current requirements are to test using the following methods:

- for tar, ISO 4387:2000 Cigarettes – Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine
- for nicotine, ISO 10315:2013 Cigarettes – Determination of nicotine in smoke condensates – Gas-chromatographic method

⁴ <https://fctc.who.int/publications/i/item/standard-operating-procedure-for-determination-of-nicotine-in-cigarette-tobacco-filler>

⁵ <https://www.coresta.org/determination-nicotine-tobacco-and-tobacco-products-gas-chromatographic-analysis-29185.html>

- for carbon monoxide, ISO 8454:2008 Cigarettes – Determination of carbon monoxide in the vapour phase of cigarette smoke – NDIR method.

We are interested in feedback as to whether there is any reason to keep these tests (eg, for research or comparative purposes). If so, they will be updated to the current, up-to-date versions.

Other product safety requirements for smoked tobacco products

Colour and smell of smoked tobacco products

We are not proposing changes to the requirements regarding the colour of tobacco.

We propose that current reg 32 (2) is revoked. This regulation allows that the smell of tobacco can include the smell of an additive or flavouring of a kind used before 31 May 2016. This is unclear and hard to interpret.

We propose that instead, smoked tobacco products should only smell of manufactured tobacco, or menthol.

Other constituents of a smoked tobacco product

We propose that the regulations preclude the use of synthetic or natural chemicals that are analogues of nicotine in tobacco filler. Such chemicals could act to undermine the policy by maintaining appeal and addictiveness in low nicotine products.

Similarly, we propose that all parts of a smoked tobacco product other than tobacco leaf or filler should not contain any nicotine-like substances, including any psychoactive substances that could maintain addictiveness.⁶

Parts of a smoked tobacco product include but are not limited to filters, filter papers, other plant material, 'crush balls' or similar inclusions within a cigarette or cigarette package, and attachments sold alongside a smoked tobacco product.

We do not propose introducing requirements for any other specific chemicals in tobacco products at this time, for example tobacco specific nitrosamines, or monoamine oxidase inhibitors. Should these change over time in a manner designed to promote addiction, we will consider regulating them then.

Good manufacturing practices

We are not proposing specific requirements for manufacturing practices; however, we are interested in understanding if there are any specific requirements that would be useful.

⁶ The Act already precludes the presence of nicotine in these constituents.

Product Safety

We propose that some existing regulations relating to product safety requirements for notifiable products are replicated for smoked tobacco products.

These require that systems are in place that enable:

- investigation and resolution of complaints about the products
- recall of a product from sale or supply
- notification to the Ministry of Health of any recall.

Reporting

We propose updating forms under schedule 9 and 10 of the regulations to align with the product information required.

Other product changes

Packaging and product warnings

We propose updating existing packaging requirements for low nicotine tobacco products, so that low nicotine tobacco can be distinguished from existing products.

We propose that the graphic warnings currently displayed on packs (described in Part 1 of the existing regulations) remain unchanged. We propose that the wording of text included as part of the warnings should remain similar in size and style, but we propose reviewing these to ensure that the wording is appropriate for low nicotine smoked tobacco products. Our overall approach to packaging reflects the fact that all smoked tobacco products are dangerous to health, whether or not the nicotine level is reduced.

Additionally, we propose updating Parts 1 and 2 of the regulations to allow for the words 'very low nicotine' to be included on the packaging.

For example, we would update Part 2, Sub part 2 – *Text and other markings that may appear on tobacco packaging*, so that it states that the area on the bottom front of the pack that displays the brand and variant, can include the phrase 'very low nicotine' if the product meets the low nicotine standards.

We are interested in feedback on this proposal, including any evidence regarding the potential behavioural effects of updating the warnings, or any alternative to our proposal, for example, not allowing any differentiation between high and low nicotine products.

Information inserts for products

We seek feedback on whether it would be useful, in accordance with section 52(2) of the Act to require an insert into all smoked tobacco product packs, informing people of upcoming changes to the availability and appeal of smoked tobacco products. The messages on such an insert could focus on encouraging quit attempts and align with quit smoking campaigns developed by Te Whatu Ora.

Application for approval of a Smoked Tobacco Product

Application for approval of a smoked tobacco product

Under the Act, approval of a smoked tobacco product is required before products can be imported, sold or supplied in New Zealand. We propose that regulations should set out additional detailed requirements, and forms for the purpose of applying to seek approval for products.

We propose that an application is required for each brand variant (model) of smoked tobacco products. We propose developing an application form as a schedule to the regulations, which would require the following:

- the applicants name and contact details
- if the applicant is an entity, such as a business, its name and company number or New Zealand Business Number
- the name and contact details of the manufacturer of the product, and the site of manufacture if this is different
- a declaration that the product meets the requirements of the Act and regulations.

In addition, we propose amending the regulations to require the following product specific information:

- a description of the product type, brand, variant and unique product code (eg EAN or UPC number)
- a summary of test results for nicotine and any other constituent required
- a full list of ingredients, including any additives
- an appendix containing a dossier including full test reports, product and packaging images and any other relevant documentation

We propose requiring applications to be accompanied by the relevant fee (see 'Regulatory Proposal 3: Fees' within this document)

Application for temporary approval

The Act allows for the Director-General of Health to temporarily approve the import, supply, manufacture or sale of tobacco that does not meet low nicotine tobacco criteria under some circumstances. These circumstances allow for research and testing, for some niche products.

Under the Act, cigarettes do not meet the requirements for a niche product and cannot therefore be granted temporary approval as a niche product. We propose that regulations should further clarify that products similar to cigarettes, such as mass-produced cigarillos do not meet the criteria for a niche product.

We propose that regulations should set out detailed requirements, and provide forms for the purpose of applying to seek temporary approval of products.

In all cases, applications for temporary approvals will need to describe the products intended to be imported (including volume, brand and variant), as well as the purpose for importing these products.

We propose requiring additional detail tailored to the different types of temporary approvals:

- imports for research and testing purposes – these will require a description and purpose for the proposed research or testing, including rationale for requiring import of non-compliant product
- import of a niche product - this will require evidence that this product is a niche product, not of mass appeal, and not a cigarette, and that no similar compliant product can be sourced.

Consultation questions

-
1. Do you agree that a suitable testing method may include a method based on WHO SOP4, validated to account for the low nicotine levels prescribed?
-
2. Do you have any other suggestions for suitable chemical analytical methods?
-
3. Do you agree with the proposal that the main packaging change should be to allow the words 'very low nicotine' on qualifying smoked tobacco products? If not, why not?
-
4. Do you agree with the proposal to require an insert in smoked tobacco product packs?
-
5. Do you agree with the product application requirements?
-
6. If you have further comments on product application requirements, please write them here.
-
7. Do you agree with the proposed requirements for temporary approvals? If not, why not.
-

Regulatory proposal 3:

Fees

Description

The Act provides for recovering the costs of establishing and operating the regulatory regime from the industry through fees or levies. It allows for regulations to specify these fees and levies.

Proposal

We propose that regulations specify fees for:

- smoked tobacco retail applications
- smoked tobacco product approvals and reassessments for significant product changes
- registrations (for smoked tobacco distributors, general vape retailers, and retailers of other notifiable products).

The following table sets out our proposed fees.

Type of fee	Amount (excl. GST)	What this fee covers
Assessment fee for applications to be an approved smoked tobacco retailer	\$500 - \$2,200	Receive and check application; assess and score against published criteria; undertake internal peer review and final review; calculate application ranking; send final assessment to applicant; publish on approved smoked tobacco retailer register. Note – final costs depend on level of automation, or inclusion of site visits. As a comparison, the fee for assessment as an SVR is \$1,600.
Assessment fee for smoked tobacco product applications	\$13,450	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	Receive and check application; undertake market scan; review product test results; 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

Type of fee	Amount (excl. GST)	What this fee covers
Registration fee (for smoked tobacco distributors, general vape retailers, and retailers of other notifiable products)	\$80	Receive and check annual registration; seek clarifications (if any); review any additional information provided; publish on participant register where relevant

Our proposed fees are based on assumptions around the average effort required to process each application or registration. Each proposed fee is set on a full cost-recovery basis.

Consultation questions

1. Do you agree the Ministry of Health should charge for these processes?

What processes do you suggest we charge for?

2. Do you agree with the level of each of the fees?

If not, how much do you suggest the Ministry of Health should charge?

3. Do you agree with our cost-recovery approach?

If not, what approach do you suggest we use?

Regulatory proposal 4: Notification requirements

Description

New notification requirements for distributors of smoked tobacco and notifiable product retailers commence on 1 October 2023. This means that by this date, distributors and general retailers will need to complete a form to tell the Ministry of Health about their business.

The Act requires that:

- **distributors of smoked tobacco products (distributors)** notify the Director-General of Health that they are distributing smoked tobacco products, and
- **general retailers that sell notifiable products (general retailers)** notify the Director-General of Health that they are selling notifiable products.

We need to ensure that regulations set out the detail of these new notification requirements for distributors and general retailers. These requirements will ensure that all participants in the market are regulated, providing a complete view of the sector for both smoked tobacco and notifiable products. They will also better support compliance and enforcement activities for all regulated products.

Proposal

We propose that regulations require distributors and general retailers 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 of Health's database.

For general retailers, this will mean providing separate applications for each premise (physical address) selling notifiable products.

We propose that regulations require distributors and general retailers to re-notify on an annual basis to ensure that market information is kept up to date, and we propose there will be a small administration fee to do so (see 'Regulatory proposal 3: Fees' above).

We propose that regulations require distributors and general retailers to provide annual returns on their distribution and retail activities in line with other parties and products regulated under this Act.

Consultation questions

1. Do you agree with the proposal that distributors and general retailers be required to re-register annually?

If you do not agree: how frequently should they be required to re-register?

Regulatory proposal 5: Youth Vaping

Description

While the Act now regulates vaping products, youth vaping rates remain high and are increasing.

The Act regulates vaping products so that people who smoke and wish to switch to vaping can access safe vape products with the support and information they need to do so. There are restrictions on how vaping products are advertised, displayed, and packaged and they are not able to be sold to those aged under 18.

The Smokefree Environments and Regulated Products Regulations 2021 set out requirements for how vaping products must look and the messages and information they contain. These requirements are intended in part to limit the appeal of these products, particularly for youth. The regulations also set out safety requirements that products must meet before they are able to be sold on the New Zealand market.

As youth vaping rates continue to rise, we have an opportunity to check whether the current requirements are working to sufficiently reduce the appeal of vape products to our young people.

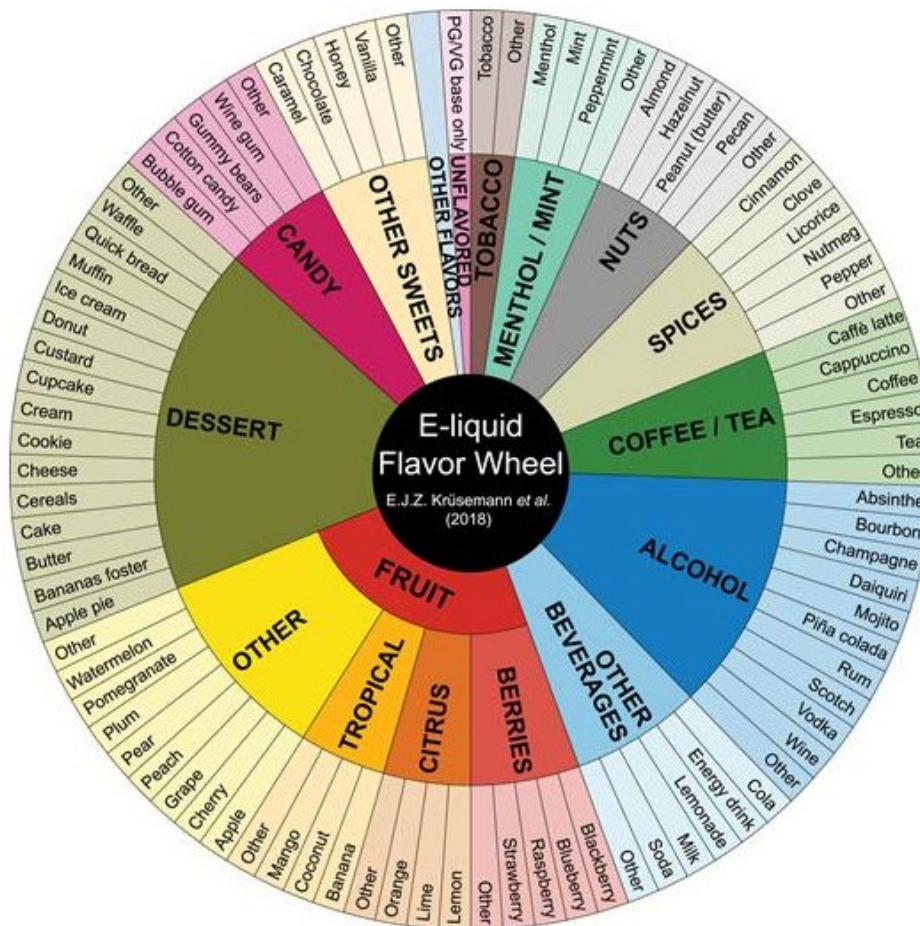
Proposal

We propose **extending vaping packaging and product restrictions** to further improve product safety and reduce the appeal of these products to young people. Our proposals are as follows:

Restricting flavour names

While vape flavours are relatively generic, the naming of flavours in some products appear to be likely to appeal to young people, for example, 'Gummy Bear', 'Bubble Gum' and 'Unicorn Milk'.

We propose that the variant name on a vaping substance or its packaging must only be a description of the product's flavour, and that the flavour must be described using one or more flavours from permitted segments on a prescribed e-liquid flavour wheel, adapted for New Zealand from a published wheel, for example:



We propose that the prescribed flavour wheel exclude flavour descriptions that appear to target young people (such as those under the 'Candy' label in the example wheel above), and that the wheel exclude or replace flavour descriptions that are not common or relevant in New Zealand (such as 'quick bread' and 'bananas foster').

Extending product requirements for vaping products to address single-use safety concerns

Internationally, there has been a dramatic rise in the use of low-cost, single use vaping products (also referred to as 'disposable vapes'), and it is likely that New Zealand will follow this pattern.

These products have high levels of nicotine, and have a number of safety concerns associated with them, including a lack of child safety mechanisms, the inability to inspect for battery damage, nicotine concentration, substance labelling and trackable serial or batch numbers.

We propose the following additional product safety requirements to address concerns relating these single-use products:

- **User safety mechanisms.** We propose that all vaping devices must have a mechanism to prevent the device being activated or accidentally operated by a child.

- **Removeable/replaceable batteries:** We propose requiring 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:** We propose clarifying that 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:** We propose reducing the maximum concentration of nicotine salts allowed in single-use products from 50mg/mL to 35mg/mL (as people can choose to use a lower concentration of nicotine in re-useable devices, but single-use devices have a fixed nicotine concentration that is generally close to the maximum allowed).

We propose clarifying that the requirement for nicotine levels to be displayed on product labels in mg/mL includes single-use products (as they are a vaping substance container as well as a device), and that a percentage figure for nicotine/nicotine salt concentration is not sufficient.

- **Serial/batch numbers:** We propose requiring serial/batch numbers on the single-use devices to ensure they can be traced in the event of a reaction.

Considering proximity restrictions

We also propose setting out **proximity restrictions** relating to where a Specialist Vape Retailer⁷ (SVR) is 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 and sports grounds or other considerations specific to certain communities.

These proximity restrictions would not apply to general vape retailers (eg, dairies, supermarkets, service stations). These stores can only sell three vape flavours and therefore carry a limited product range. In addition, restrictions for general vape retailers would require a legislative amendment as there is currently no existing regulation-making power to do so.

Consultation questions

-
1. Do you agree with the proposal to restrict the flavour names of vaping products to minimise their appeal to youth? If not, why not?

If so, which names do you think should be excluded or replaced on the example e-liquid flavour wheel set out above?

2. Do you agree with the proposal to extend product safety requirements for disposable vaping products? If not, why not?
-

3. Do you agree with the proposal to restrict where Specialist Vape Retailers can be located? If not, why not?

If so, what locations are important to you and why?

⁷ A Specialist Vape Retailer (SVR) is a specific class of R18 retailer that is exempt from some of the restrictions that apply to general vape retailers (for example, SVRs can sell a greater range of flavours).

Appendix 1: Additional information regarding rural and urban areas

Our planning assumption was that the country will be split into a number of geographic areas, with a maximum number of retail premises permitted in each area (up to the country-wide maximum). We also assumed that a different approach will be required for urban areas (towns and cities) compared to rural areas, and a greater proportion of approved retail premises may be needed in rural areas as smoking prevalence is higher in rural areas and travel times are longer.

This appendix further explains our proposal for numbers of retailers in urban and rural areas.

Urban areas

In towns and cities, the maximum number of stores will be based on the estimated number of people who smoke in those areas. Our assumptions are based on urban areas as defined by Stats NZ, and we have assumed that people just outside of these areas can easily travel to the urban area to purchase smoked tobacco products. Therefore, in our proposal 'urban' areas extend an agreed distance in drive time (eg, 10 minutes) along a state highway: the 'urban halo'. This means that we treated areas that are most easily accessed via roads connecting to an urban area as an extension of that urban area.

As towns are often clustered together, our proposal treats any areas that are less than twice the agreed urban halo (eg, 20 minutes) apart as a single urban area ('cluster'): the maximum number of retail premises permitted is based on the total estimated number of smokers in the cluster. Applicants in a cluster will be evaluated together as part of a single urban area: for example, Masterton and Carterton in the Wairarapa. This will not apply to cities, due to their high populations and unpredictable travel times.

Rural areas

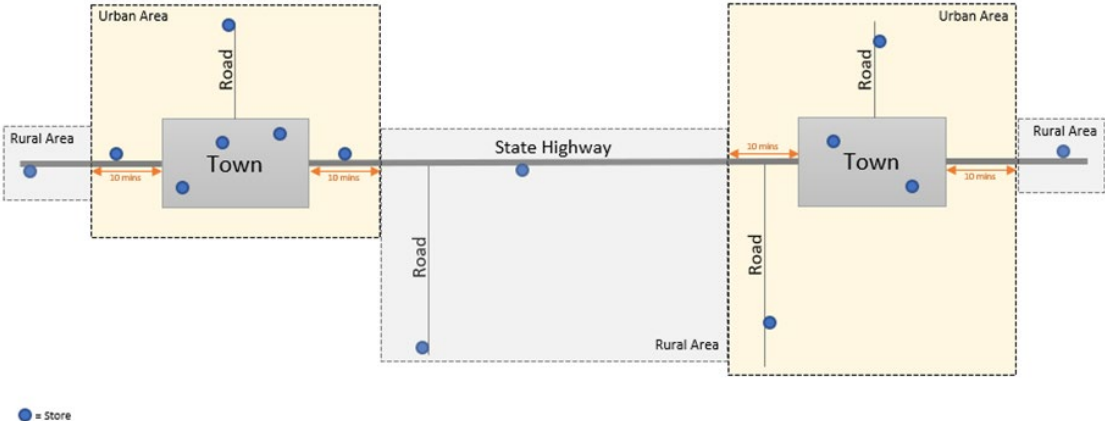
State highway corridors outside an urban area will be treated as rural areas: our proposed maximum number of retail premises in such areas is based on the usual driving time of the state highway in that area. The usual driving times we have assumed for state highways are the times given by Google Maps for a car driving at normal speed limits with uncongested roads. We treated areas most easily accessed via roads connecting to a rural area state highway as an extension of the state highway's rural area.

Some regions have a significantly higher number of state highways covering their rural populations (such as Waikato) than others (such as the greater Wellington region, including the Wairarapa). This skews the rural allocation in favour of those regions with more state highways. We will make some adjustments to ensure accessibility for rural populations not served by a state highway.

Where a state highway passes between regions, we will adjust allocation as appropriate: numbers may be split equally between the regions, or more may be allocated to one region if the majority of the highways and connecting rural roads are in that region.

To ensure accessibility for rural populations not served by a state highway, rural allocations will need further refinement based on feedback. There are some rural areas with no state highway (for example Great Barrier Island, Stewart Island) and a few which might have too many retail premises (for example along SH43 from Stratford to Taumarunui).

Example of Urban and Rural areas with 'urban halo' set at 10 minutes



Appendix 2: More information on minimum requirements

As discussed in Regulatory proposal 1, we are seeking feedback in relation to the minimum requirements that a retail premise would need to meet before the Director-General can appoint them as a smoked tobacco retailer. Some of these are defined in the Act and some can be set through regulations.

The requirements defined in section 20I of the Act include that the Director-General is satisfied that:

- the applicant is a fit and proper person, and that each responsible person is fit and proper
- the applicant is a New Zealand resident or is carrying on business in New Zealand or incorporated under New Zealand law
- the retail premises are a fixed permanent structure and appropriate premises.

Under section 82A of the Act, regulations may be made that include setting fit and proper person criteria for the purposes of section 20I.

We propose to set specific requirements in regulations to explain what a person must demonstrate to be 'fit and proper'. These requirements could include considering:

- any charge or conviction for any offence under the Act, as well as relevant offences under other statutes, such as in relation to the Customs and Excise Act 2018 or the Crimes Act.
- the outcome of any controlled purchase operations and/or other compliance activities by smokefree enforcement officers, if applicable (ie, history of compliance)
- any other court order made against the applicant that may be relevant to the application
- any information collected in the course of a Police investigation that relates to the person's conduct
- any matters disclosed to the Ministry of Health by the Police, New Zealand Customs or Te Whatu Ora in relation to the application, including any objection to the grant of a license; for example, the fact that the person is a member of, or has close affiliations with a gang or organised criminal group
- the person is over the age of 18
- any further matters the Director-General considers relevant.

Appendix 3: More information on ranking criteria for smoked tobacco retailers

Where there are more applicants that meet the minimum criteria than retailers that can be appointed in an area, we propose to assess and rank applicants using additional criteria.

We have divided these criteria into 3 broad categories - location, business and other systems, proximity and locations, and other factors. We are interested in hearing from stakeholders which of these criteria are most important and least important to them, and what, if any criteria, are missing.

We will use feedback from Māori, communities and other stakeholders to refine this ranking and scoring process.

Business and other systems

In terms of business and other systems, we propose the following additional criteria:

Security systems: The minimum we would look for in terms of security systems is secure product storage, an operational fog canon, a suitable alarm system and operational security cameras with recording facilities. In addition, an applicant should demonstrate a comprehensive security system to minimise risks, either in place or proposed in a detailed plan (final approval will depend on this being in place). For example:

- a security system that is regularly maintained, and addresses both stock loss prevention and the safety of staff and customers
- that they have other specific features, such as:
 - an appropriate store layout, ensuring the ability see inside and outside of the store through the front glass windows, and an open store layout with no blind spots and low shelf heights inside
 - for stores with immediate street access, bollards or other external protection to reduce the risk of ram raids,
 - closed circuit television, secure staff areas, controlled entry and panic buttons.
 - additional security features, for example, a solid external roller door, which is secured to the ground when closed, glass security film, interior roller grate/grill,

counter shield either metal or plastic, high quality tobacco safe that is securely bolted to the ground and has increased strengthening against blunt object and power tool attacks

Training: The minimum we would look for in terms of training is evidence that all employees involved in sales of smoked tobacco products have training on premises procedures and processes. In addition, an applicant might demonstrate:

- a good understanding of the types of training required – for example, in relation to responsibilities under the Act and preventing sales to minors/the smokefree generation, security training for all personnel in relation to de-escalation and robbery management.
- detailed information about the programme of training to be provided
- that the training plan is comprehensive and accurate
- that all staff receive initial and regular refresher training
- appropriate records of training are kept and signed by those attending.

Sales systems: The minimum we would look for in terms of sales systems is that there are records and systems in place to prevent sales to minors. In addition, an applicant might demonstrate a supply chain for both current products and low-nicotine products, and a plan for managing fluctuations in demand over time.

Delivery systems: The minimum we would look for in terms of delivery systems is that applicants do not allow any form of delivery, or have systems in place to ensure delivery is only made to the person purchasing, and not to a minor. We have no additional criteria for delivery systems.

Proximity and location

Consultation on the Action Plan and the Bill showed that there was interest in the location of smoked tobacco retailers.

The Act does not include a blanket ban on smoked tobacco retailers in particular locations. However, we are aware that people may consider it inappropriate for smoked tobacco premises to operate at or near certain locations; for example:

- recreational facilities like sports fields, parks or playgrounds
- educational facilities like schools or early childhood centres
- marae
- other areas identified by communities and iwi through this process.

Additionally, within each area, the number of retail premises has been estimated by considering each town and city and rural area. Ensuring that the retail premises are spread across the whole area will be important.

We propose that, in allocating retail premises within given areas, we rank applications based on their proximity to sensitive areas. The definition of 'sensitive' could apply nationally, or there may be some variation based on regional feedback.

Other factors

Finally, we are interested in what other factors would be important to consider in terms of ranking criteria and how we should take this information into account. Other factors might include:

- information about applicant's history of compliance with the Act and the history of any responsible people, over the previous 5 years
- the nature of the business – for example, stores selling alcohol and/or groceries might rank lower on this criterion while specialist tobacconists may score higher. This is because selling tobacco products alongside everyday grocery items normalises these products.
- opening hours. Stakeholders have suggested that opening hours might be a useful factor, however we are interested in feedback on how this could be incorporated and what would be most desirable.
- whether an applicant's premise is a specialist outlet; that is, the applicant sells smoked tobacco products that are not cigarettes (eg, cigars). We propose that, to be considered a specialist store, at least 70% of the turnover from the premise should be from specialist products.