Departmental Disclosure Statement

Smokefree Environments and Regulated Products (Vaping) Amendment Bill

The departmental disclosure statement for a Bill the Government is proposing to amend seeks to bring together in one place a range of information to support and enhance the Parliamentary and public scrutiny of that Bill.

It identifies:

- the general policy intent of the Bill and other background policy material
- some of the key quality assurance products and processes used to develop and test the content of the Bill
- the presence of certain significant powers or features in the Bill that might be of particular Parliamentary or public interest and warrant an explanation.

The disclosure statement was prepared by the Ministry of Health.

The Ministry of Health certifies that, to the best of its knowledge and understanding, the information provided is complete and accurate at the date of finalisation below.

February 2020.

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Part One: General Policy Statement

This Bill amends the Smokefree Environments Act 1990 (the Act) to bring the provisions of the Act up-to-date and to ensure that all regulated products (tobacco smoking products, herbal smoking products, smokeless tobacco products, and vaping products) are adequately covered.

The concept of a 'regulated product' is introduced to incorporate the broader scope of products regulated under the Act. It is intended to provide flexibility so that the amended Act can more readily incorporate reduced-harm products that may come along in future, including those which may not be anticipated at present (in contrast to the significant amendments that have been necessary to incorporate vaping and vaping products).

The Bill aims to take a balanced approach to the regulation of vaping and smokeless tobacco products. It acknowledges that vaping and smokeless tobacco products are less harmful than smoking and that they may help some people to quit smoking. At the same time, it reflects concerns about children's and young people's access to and use of these products.

To protect children and young people from the risks associated with vaping and using smokeless tobacco products, the Bill extends many of the existing provisions of the Act to vaping products and heated tobacco devices (the tobacco component of smokeless tobacco is already regulated).

Part 1 prohibits vaping and the use of heated tobacco products in legislated smokefree areas (ie, indoor workplaces, early childhood centres, schools).

Part 2 extends, to the extent applicable, the existing restrictions on the advertising, promotion, sale, and distribution of tobacco products to all regulated products. This includes placing restrictions on:

- a. the sale, and supply in a public place, of vaping products and heated tobacco devices to people under the age of 18 years
- b. inducements and rewards associated with vaping products and heated tobacco devices, for example, discounts and loyalty points (with some exemptions for specialist vape retailers).

However, the Bill also recognises that smokers need support and advice to successfully switch to a much less harmful product. It, therefore, contains exemptions for vaping products to some of the provisions that apply to tobacco products. It enables all retailers to display products instore, in contrast to requirements that require tobacco products to be out of the public's sight.

In addition, the Bill makes a distinction between specialist vape retailers and generic retailers, such as dairies, supermarkets and service stations. The Bill enables specialist vape stores to be approved as such by the Director-General of Health. The Bill allows an employee of an approved vape store to give advice and recommendations about vaping products to a customer within that place of business. It also enables approved vape stores to:

- a. allow customers to vape within the store for the purpose of sampling products before purchase
- b. give discounts, loyalty points etc
- c. sell vaping products without any restrictions on flavours
- d. use the words 'vape' and 'vaping' in their trading name.

In addition, the Bill allows:

- public health messages approved by the Director-General of Health
- registered health practitioners and other specified health workers to give advice and recommendations about vaping products to patients or clients to support them to switch, thereby reducing the harm to their health caused by smoking.

Part 3 applies provisions enabling standardised packaging requirements to be set in regulations for all regulated products. The intent is to set tailored requirements for different product types that acknowledge their different risk profiles.

This part also retains the existing prohibitions on the import for sale, sale, distribution etc. of tobacco products suitable for chewing or any other oral use (eg, snus).

Part 4 sets out new provisions to regulate the safety of vaping products and smokeless tobacco products. This recognises that, while they are less harmful than smoking, they are not risk-free. This Part is intended to also be suitable for regulating the safety of any products that may be newly regulated in future.

The Bill requires manufacturers and importers to notify a vaping or smokeless tobacco product to the Ministry of Health before marketing it and to certify that the product meets any applicable standards. The notification system is to support rapid follow-up and remedial action should any safety issues arise with a product or product part.

Other provisions in the Bill enable product safety requirements to be set by regulations, require manufacturers and importers to report adverse reactions, and enable the Director-General of Health to issue product recalls, suspend and cancel product notifications, and issue warning statements about products.

Flavours may be used to attract children and young people to vape or use smokeless tobacco products, however, they also seem to be an important factor in supporting smokers to switch. The Bill allows generic retailers to sell only the flavours that are set out in Schedule 2 (ie, tobacco, menthol and mint). There are no flavour restrictions on approved specialist vape retailers. The list of flavours in the Schedule will be able to be amended over time by regulations. The Bill also prohibits the use of colouring substances in vaping liquid as data does not support their safe use.

The product safety regime set out in Part 4 of the Bill will be cost recovered from the regulated industry, consistent with Treasury's Guidelines for Setting Charges in the Public Sector. The Bill enables fees and levies payable to be prescribed by regulations.

In addition to provisions related to the regulation of vaping products and smokeless tobacco products, the Bill:

- a. allows for an assessment tool to be provided in regulations to support a determination of whether a space within a premise, such as a bar, is an open area (where smoking is allowed) or an internal area (where smoking is prohibited). This aims to provide clarity to business owners and Smokefree Enforcement Officers.
- b. enables allowable content for manufacturers' price lists to be set out in regulations to prevent price lists from being used for promotional purposes
- c. repeals the provision that allows an exemption from the Act's advertising and sponsorship prohibitions for multi-national sporting events; a provision that is out-of-date.

The Bill is drafted to commence on the day after the date that it receives the Royal assent. Transitional provisions are provided to give time for existing businesses to adjust, as follows:

- a. six months from Royal assent for the prohibition on sale by a generic retailer of a vaping product or smokeless tobacco product containing a flavour other than a permitted flavour
- b. six months from Royal assent for a manufacturer or importer to notify a vaping or smokeless tobacco product.

Part Two: Background Material and Policy Information

Published reviews or evaluations

2.1. Are there any publicly available inquiry, review or evaluation reports that have informed, or are relevant to, the policy to be given effect by this Bill?

YES

Briefing on achieving the Smokefree 2025 goal for New Zealand [Kaupapa whakamōhio ki te ekenga o te whāinga Auahi Kore 2025 mō Aotearoa]: Report of the Health Committee and the Māori Affairs Committee December 2018: <u>https://www.parliament.nz/resource/en-NZ/SCR_82493/fdd4b1cdd5cc8e1f7a94e425465c124840a7381d</u>

Relevant international treaties

2.2. Does this Bill seek to give effect to New Zealand action in relation to an international treaty?	YES
The Bill supports the implementation of the World Health Organization (WHO) Fr Convention on Tobacco Control:	amework
https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf;jsessionid=B9AD727815	
4A662D29243C3E500870?sequence=1	

2.2.1. If so, was a National Interest Analysis report prepared to inform a Parliamentary examination of the proposed New Zealand action in relation to the treaty?	YES
The National Interest Analysis for the WHO Framework Convention on Tobacco prepared by Ministry of Health and presented to the New Zealand House of Rep accordance with Standing Orders 384 and 385 on 7 October 2003.	
The National Interest Analysis was subsequently published as an Appendix to the Treaty Examination of the World Health Organization Framework Convention on 11 December 2003 (as reported by the Foreign Affairs, Defence and Trade Com Analysis can be accessed on the New Zealand Parliament website at the followin http://www.parliament.nz/en-nz/pb/sc/documents/reports/47DBSCH_SCR2638_treaty-examination-of-the-world-health-organization	Tobacco Control, <i>mittee)</i> . The ng:

Regulatory impact analysis

2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill?	YES
Supporting smokers to switch to significantly less harmful alternatives (January 2019). The report can be accessed on the Ministry of Health website at: <u>https://www.health.govt.nz/about-</u>	
ministry/legislation-and-regulation/regulatory-impact-statements/supporting-smokers-switch- significantly-less-harmful-alternatives	

2.3.1. If so, did the RIA Team in the Treasury provide an independent opinion on the quality of any of these regulatory impact statements?	NO
The Regulatory Impact Statement did not meet the threshold for RIA Team Asses Ministry of Health's Papers and Regulatory Committee reviewed the document an it met the Quality Assurance Requirements.	

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Extent of impact analysis available

2.4. Has further impact analysis become available for any aspects of the	NO
policy to be given effect by this Bill?	NO

2.5. For the policy to be given effect by this Bill, is there analysis available on:	
(a) the size of the potential costs and benefits?	YES
(b) the potential for any group of persons to suffer a substantial unavoidable loss of income or wealth?	NO
Limited information is available in the Regulatory Impact Statement (see section 5 https://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-im statements/supporting-smokers-switch-significantly-less-harmful-alternatives	

2.6. For the policy to be given effect by this Bill, are the potential costs or benefits likely to be affected by:	
(a) the level of effective compliance or non-compliance with applicable obligations or standards?	YES
(b) the nature and level of regulator effort put into encouraging or securing compliance?	YES
Limited information is available in the Regulatory Impact Statement (see section 6 in particular): <u>https://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-</u> statements/supporting-smokers-switch-significantly-less-harmful-alternatives	
The Ministry of Health is seeking additional funding for enforcement and will prepairmplementation plan for Smokefree Enforcement Officers.	are an

Part Three: Testing of Legislative Content

Consistency with New Zealand's international obligations

3.1. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with New Zealand's international obligations?

Officials considered the legislation in relation to New Zealand's international obligations. The purposes of the legislation are consistent with New Zealand's obligations under the WHO Framework Convention on Tobacco Control (see Box 2.2 above).

Consistency with the government's Treaty of Waitangi obligations

3.2. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with the principles of the Treaty of Waitangi?

Officials considered Treaty of Waitangi implications as a normal part of the process to develop the policy and proposals contained in the Bill. None were identified.

Consistency with the New Zealand Bill of Rights Act 1990

3.3. Has advice been provided to the Attorney-General on whether any provisions of this Bill appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990?	YES
Advice provided to the Attorney-General by the Ministry of Justice, or a Bill of Rig section 7 report of the Attorney-General, is expected to be available on the Minis website upon introduction of a Bill. Such advice, or reports, can be accessed on website at:	try of Justice's
http://www.justice.govt.nz/policy/constitutional-law-and-human-rights/human-right	ts/bill-of-rights

Offences, penalties and court jurisdictions

3.4. Does this Bill create, amend, or remove:	
(a) offences or penalties (including infringement offences or penalties and civil pecuniary penalty regimes)?	YES
(b) the jurisdiction of a court or tribunal (including rights to judicial review or rights of appeal)?	NO
New section 81 amends sections 38B to 39 to extend the existing infringement of penalties for tobacco products to cover all regulated products.	fences and

3.4.1. Was the Ministry of Justice consulted about these provisions?	YES
The offence and penalty vetting team at the Ministry of Justice considers the penalties relative vaping products in Part 4 of the Bill to be disproportionately high, given the penalty level for offences related to vaping products in other parts of the Bill. They consider that the penaltie Part 4 should also be set at one-third of the level of the penalties relating to other tobacco products, as is the case for the offences in other parts of the Bill. The Ministry of Health does not consider it appropriate to lower the penalties in Part 4 of t	
Bill. Part 4 contains the product safety regime which protects human health. Breaches have a more serious impact than breaches of other parts of the Act. Therefore, we appropriate that the penalty levels in Part 4 are aligned with the highest level of p exists already in the Act (i.e. penalties for breaching the standardised packaging re	e consider it penalty that

tobacco products).

Privacy issues

3.5. Does this Bill create, amend or remove any provisions relating to the collection, storage, access to, correction of, use or disclosure of personal information?	NO
3.5.1. Was the Privacy Commissioner consulted about these provisions?	N/A

External consultation

3.6. Has there been any external consultation on the policy to be given effect by this Bill, or on a draft of this Bill?	YES
Consultation was undertaken in 2016. See section 2.5 of the Regulatory Impact S https://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-im- statements/supporting-smokers-switch-significantly-less-harmful-alternatives	

Other testing of proposals

3.7. Have the policy details to be given effect by this Bill been otherwise tested or assessed in any way to ensure the Bill's provisions are workable	NO
and complete?	

Part Four: Significant Legislative Features

Compulsory acquisition of private property

4.1. Does this Bill contain any provisions that could result in the	NO
compulsory acquisition of private property?	NO

Charges in the nature of a tax

4.2. Does this Bill create or amend a power to impose a fee, levy or charge in the nature of a tax?	NO
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Retrospective effect

- 1	4.3. Does this Bill affect rights, freedoms, or impose obligations, retrospectively?	NO

Strict liability or reversal of the burden of proof for offences

4.4. Does this Bill:	
(a) create or amend a strict or absolute liability offence?	YES
(b) reverse or modify the usual burden of proof for an offence or a civil pecuniary penalty proceeding?	YES
The Bill extends a range of provisions and associated offences and penalties to a	ll regulated

The Bill extends a range of provisions and associated offences and penalties to all regulated products, including the Act's strict liability infringement offences in clause 81. These offences carry minor penalties (ranging from a maximum \$2,000 to a maximum \$10,000) for minor contraventions of the Act.

The Bill extends a range of provisions to all regulated products, including section 36AAB of the Act which contains a presumption that a defendant (who is not a manufacturer, an importer, or a distributor) is a large retailer. The defendant can rebut the presumption by raising evidence to the contrary. The reverse burden of proof was included because it is more practicable for the defendant to produce its financial records in order to rebut the presumption, than for the prosecution to obtain those records in advance of laying a charge.

Civil or criminal immunity

Significant decision-making powers

4.6. Does this Bill create or amend a decision-making power to make a determination about a person's rights, obligations, or interests protected or recognised by law, and that could have a significant impact on those rights, obligations, or interests?	NO
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Powers to make delegated legislation

4.7. Does this Bill create or amend a power to make delegated legislation that could amend an Act, define the meaning of a term in an Act, or grant	NO	
an exemption from an Act or delegated legislation?		

	B. Does this Bill create or amend any other powers to make delegated islation?	YES
pro	New section 75 amends section 39 to extend the existing regulation-making powers to all regulated products. These powers are necessary to prescribe the detailed requirements that are necessary for the regulatory scheme to be implemented, including:	
a. b. c.	determining whether an area within a premise is an open area (where smoking rather than a closed area (where smoking is not allowed) an application to the Director-General of Health for approval to be a specialist for the associated exemptions to the Act that would allow registered specialist for example display sample products, give advice and recommendations about to customers, and allow customers to vape within the store for the purpose of product before purchasing it the content of price lists given to retailers of regulated products	vape retailer, and vape retailers to ut vaping products sampling a
d. e.	the content of retail (including vending machines and Internet) information and regulated products point of sale health information or warning signs	
f.	testing, and further testing where required by the Director-General of Health for regulated products	
g. h. i.	reporting, including the annual sales information for regulated products that m the Ministry of Health the standardised packaging requirements, including messages and informatio smokeless tobacco products the maximum quantity of smokeless tobacco that may be included in a package	n, for vaping and
j.	the standardised packaging requirements, including messages and informatio products.	-
tob	w section 75 inserts new regulation-making powers related to vaping products a acco products. These powers are necessary to regulate the safety of vaping ar acco products by:	
a. b. c. d. e. f.	prescribing pre-notification requirements prescribing requirements for the notification of vaping and smokeless tobacco specifying the changes to the parts or components of a vaping or smokeless to that will require a new product notification amending the schedule of permitted flavours for vaping products prescribing safety requirements for vaping and smokeless tobacco products enabling amendment of Schedule 2 (which contains the lists of permitted and flavours).	obacco product

Any other unusual provisions or features

4.9. Does this Bill contain any provisions (other than those noted above) that are unusual or call for special comment?

NO