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Minute of Decision

Cabinet

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.

Smokefree Environments and Regulated Products Amendment Regulations 2023

Portfolio

Health

On 21 August 2023, following reference from the Cabinet Legislation Committee, Cabinet:

- 1 **noted** that in May 2023, the Cabinet Social Wellbeing Committee (SWC) agreed to the drafting of the Smokefree Regulations to establish the regulatory regime for smoked tobacco, and to tighten vaping restrictions [SWC-23-MIN-0051];
- 2 noted that in May 2023, SWC agreed to reduce the maximum allowable nicotine salt concentration in single-use vaping products to 35mg/mL [SWC-23-MIN-0051], and that this is expressed in the Smokefree Regulations as a maximum allowable concentration of nicotine of 20mg/mL;
- **noted** that in July 2023, Cabinet agreed to amend clause 15 of the Smokefree Regulations to state that for reusable vaping products that contain nicotine salts, the maximum allowable nicotine concentration is set at 28.5mg/mL [CAB-23-MIN-0305];
- 4 s 9(2)(h)
- 5 **S 9**(2)(b) the Minister of Health took further public health advice from Te Pou Hauora Tūmatanui (the Public Health Agency), Manatū Hauora in relation to the nicotine concentration level for vaping products and regarding the safety requirement for removable batteries for all vaping products (attached at Appendix A to the submission under LEG-23-SUB-0148);
- 6 **noted** the further public health advice from Te Pou Hauora Tūmatanui (the Public Health Agency), Manatū Hauora confirms that the Smokefree Regulations should proceed as previously agreed per Cabinet's policy decisions in May and July 2023 [SWC-23-MIN-0051 and CAB-23-MIN-0305];
- 7 noted that in May 2021, SWC agreed to require that a vaping product and a smokeless tobacco product may not include the depiction of cartoons or toys on its packaging when the Smokefree Environments and Regulated Products Regulations were made in 2021 [SWC-21-MIN-0065];
- 8 **noted** that the Smokefree Environments and Regulated Products Amendment Regulations 2023 give effect to these decisions referred to in paragraphs 1, 2, 3 and 7;

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- agreed to the transitional timeframes for regulations 63A to 63D, regulation 69A, Schedule
 5 and regulations 66 and 70 as set out in paragraph 16 of the submission under
 LEG-23-SUB-0148;
- 10 **noted** that in relation to new subparts 2A and 2B of Part 3 of the principal regulations (as inserted by regulation 6) and new subpart 4 of Part 3 of the principal regulations (as inserted by regulation 8) the Minister of Health has considered the matters set out in section 82(B(2) of the Smokefree Environments and Regulated Products Act 1990;
- 11 s 9(2)(h)
- 12 **authorised** the submission to the Executive Council of the Smokefree Environments and Regulated Products Regulations 2023 [PCO 25668/19.0].

Rachel Hayward Secretary of the Cabinet

s 9(2)(f)(iv)



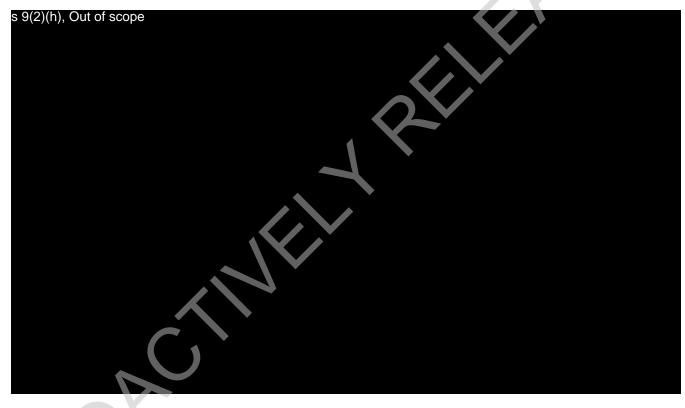
Cabinet

Minute of Decision

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Report of the Cabinet Legislation Committee: Period Ended 18 August 2023

On 21 August 2023, Cabinet made the following decisions on the work of the Cabinet Legislation Committee for the period ended 18 August 2023:



LEG-23-MIN-0148 Smokefree Environments and Regulated Products Amendment Regulations 2023 Portfolio: Health

Separate minute: CAB-23-MIN-0387.01

s 9(2)(h), Out of scope

CAB-23-MIN-0387



Rachel Hayward Secretary of the Cabinet



Cabinet Legislation Committee

Minute of Decision

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Smokefree Environments and Regulated Products Amendment Regulations 2023

Portfolio Health

On 17 August 2023, the Cabinet Legislation Committee:

- 1 **noted** that in May 2023, the Cabinet Social Wellbeing Committee (SWC) agreed to the drafting of the Smokefree Regulations to establish the regulatory regime for smoked tobacco, and to tighten vaping restrictions [SWC-23-MIN-0051];
- 2 **noted** that in May 2023, SWC agreed to reduce the maximum allowable nicotine salt concentration in single-use vaping products to 35mg/mL [SWC-23-MIN-0051], and that this is expressed in the Smokefree Regulations as a maximum allowable concentration of nicotine of 20mg/mL;
- **noted** that in July 2023, Cabinet agreed to amend clause 15 of the Smokefree Regulations to state that for reusable vaping products that contain nicotine salts, the maximum allowable nicotine concentration is set at 28.5mg/mL [CAB-23-MIN-0305];
- 4 s 9(2)(h)
- 5 s 9(2)(h) the Minister of Health took further public health advice from Te Pou Hauora Tūmatanui (the Public Health Agency), Manatū Hauora in relation to the nicotine concentration level for vaping products and regarding the safety requirement for removable batteries for all vaping products (Attached at Appendix A to the submission under LEG-23-SUB-0148);
 - **noted** the further public health advice from Te Pou Hauora Tūmatanui (the Public Health Agency), Manatū Hauora confirms that the Smokefree Regulations should proceed as previously agreed per Cabinet's policy decisions in May and July 2023 [SWC-23-MIN-0051 and CAB-23-MIN-0305];
- 7 noted that in May 2021, SWC agreed to require that a vaping product and a smokeless tobacco product may not include the depiction of cartoons or toys on its packaging when the Smokefree Environments and Regulated Products Regulations were made in 2021 [SWC-21-MIN-0065];
- 8 **noted** that the Smokefree Environments and Regulated Products Amendment Regulations 2023 give effect to these decisions referred to in paragraphs 1, 2, 3 and 7;

- **agreed** to the transitional timeframes for regulations 63A to 63D, regulation 69A, Schedule 5 and regulations 66 and 70 as set out in paragraph 16;
- 10 **noted** in relation to new subparts 2A and 2B of Part 3 of the principal regulations (as inserted by regulation 6) and new subpart 4 of Part 3 of the principal regulations (as inserted by regulation 8) I have considered the matters set out in section 82(B(2) of the Smokefree Environments and Regulated Products Act 1990;



14 **authorised** the submission to the Executive Council of the Smokefree Environments and Regulated Products Regulations 2023 [PCO 25668/16.0].

Rebecca Davies Committee Secretary

Present:

Hon Grant Robertson (Chair) Hon Dr Ayesha Verrall Hon Damien O'Connor Hon Andrew Little Hon Kieran McAnulty Hon Ginny Andersen Hon Willow-Jean Prime Hon Dr Duncan Webb Hon Rachel Brooking Hon Jo Luxton Tangi Utikere, MP (Chief Government Whip) **Officials present from:** Office of the Prime Minister Officials Committee for LEG In Confidence

Office of the Minister of Health Chair, Cabinet Legislation Committee

Smokefree Environments and Regulated Products Amendment Regulations 2023

Proposal

1 I seek authorisation for the submission to the Executive Council of the Smokefree Environments and Regulated Products Amendment Regulations 2023 (the Smokefree Regulations).

Policy

- 2 The Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Act 2022 (the Act) came into force on 1 January 2023. The Act introduced significant changes intended to achieve the following objectives:
 - 2.1 significantly reduce retail availability of smoked tobacco products
 - 2.2 prevent young people from ever taking up smoking
 - 2.3 reduce the appeal and addictiveness of smoked tobacco products.
- 3 The Act has new regulation-making powers to set out the requirements needed to achieve these objectives. Manatū Hauora (the Ministry of Health) developed and publicly consulted on regulatory proposals to establish the regulatory regime to oversee and monitor the import, manufacture, sale and supply of smoked tobacco products.
- 4 The purpose of the Act also provides for the regulation of notifiable products in a way that seeks to minimise harm, especially to young people and children. Manatū Hauora also consulted on regulatory proposals to tighten existing vaping restrictions, to reduce their appeal to young people and children, and those who do not already smoke tobacco products.
 - On 22 May 2023, Cabinet agreed to the key decisions needed to draft the Smokefree Regulations [CAB-23-MIN-0182]. These covered requirements for:
 - 5.1 the smoked tobacco retail scheme (including approval and decisionmaking criteria to become an approved retailer)
 - 5.2 testing requirements and approval processes for low nicotine smoked tobacco products

5

- 5.3 new notification requirements for distributors and retailers
- 5.4 fees to enable the regime to be cost-recovered
- 5.5 extending vaping restrictions by limiting the way flavours can be described, introducing additional product safety requirements and setting proximity restrictions for Specialist Vape Retailers.
- 6 As noted in the preamble of the Smokefree Regulations, in regard to the regulations providing for limits on constituents, product safety requirements and testing of smoked tobacco products I have considered, per section 82B(2) of the Act:

(a) the risks and benefits to the population (including both users and non-users of smoked tobacco products) of regulating the constituent; and

(b) the risks and benefits to Māori (including both users and non-users of smoked tobacco products) of regulating the constituent; and

(c) whether regulating a constituent of a smoked tobacco product will reduce the use of the product by reducing the appeal or addictiveness of the product, including—

(i) the likelihood that existing users of smoked tobacco products will stop using the product; and

(ii) the likelihood that those who do not use smoked tobacco products will start using the product.

- 7 The additional product safety requirements for vaping products include a requirement that a vaping device must have a child safety mechanism and a removable battery, and a maximum allowable nicotine concentration of 20mg/mL for single-use vaping products.¹ This aligns with existing requirements for freebase nicotine vaping products.
- 8 On 17 July 2023, Cabinet further agreed to amend clause 15 of schedule 5 of the Smokefree Regulations to state that for <u>reusable</u> vaping products that contain nicotine salts, the maximum allowable nicotine concentration is set at 28.5mg/mL [CAB-23-MIN-0305]. Freebase nicotine in reusable vaping products is already set at a maximum allowable level of 20mg/mL in the existing regulations and this will remain unchanged.
- 9 For clarity the nicotine concentration has been drafted in the Smokefree Regulations as follows:

¹ This was originally expressed in the consultation paper as a maximum nicotine salt concentration of 35mg/mL, which is equivalent to a nicotine concentration of 20mg/mL for products that use nicotine benzoate for the nicotine salt.

Clause 14 - For a vaping substance that contains nicotine only in salt form and is intended for use in a reusable vaping device, the concentration of nicotine must not exceed 28.5mg/mL.

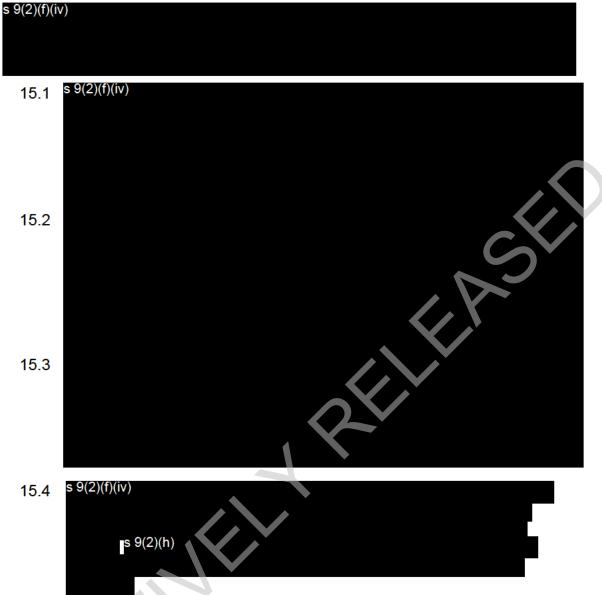
Clause 15 - For all other vaping substances, the concentration of nicotine must not exceed 20mg/mL.

- 10 ^{s 9(2)(h)}
- 11 s 9(2)(h) additional public health advice from Te Pou Hauora Tūmatanui (the Public Health Agency) in relation to the proposed nicotine concentration level for vaping products, and the safety requirement for removable batteries. This advice is contained in **Appendix A.** The Manatū Hauora analysis of the submissions received regarding amending clause 15 is contained in **Appendix B.**
- 12 This additional advice and analysis confirms that Cabinet's decision of 17 July 2023 and Cabinet's earlier decision of 22 May 2023 should proceed and be given effect to through the Smokefree Regulations.
- 13 The Smokefree Regulations also include further amendments to require that both a vaping product and a smokeless tobacco product may not include the depiction of cartoons or toys on its packaging. Cabinet agreed to this decision when the Smokefree (Vaping) Regulations were made in 2021 [CAB-21-MIN-0167] with a transitional timeframe of 12 months following the regulations coming into force. This regulation would have come into force on 11 August 2022, however, this requirement was inadvertently omitted from the regulations that were submitted to the Executive Council at the time.
- 14 Finally, I have asked Manatū Hauora to undertake a full review of the vaping policy across the Smokefree Environments and Regulated Products Act 1990 and the regulations, with a view to providing options for further legislative change.

Timing ^{s 9(2)(f)(iv)}

15 ^{s 9(2)(f)(iv)}

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16 To give industry time to comply, and the Regulator time to implement the new smoked tobacco product testing and application requirements, the new vaping requirements for both flavour descriptions and product safety requirements which includes concentration levels for nicotine substances, and the requirement regarding cartoons and toys for vaping and smokeless tobacco products the following timeframes are provided in the Smokefree Regulations.

| Smokefree regulations | Transitional timeframes | | | |
|--|---|--|--|--|
| Analytical testing methods of smoked tobacco products (Regulations 63A to 63D as inserted by amendment regulation 8) | Any new smoked tobacco product applications for approval must meet the new requirements immediately after the regulations come into force And <i>all</i> smoked tobacco products must meet the testing requirements from 1 April 2025 <i>This allows for a cross over period between current testing</i> <i>requirements and the new requirements.</i> | | | |

| Flavour descriptions (Regulation 69A as inserted by amendment regulation 10) | All new vaping product notifications must meet the new requirements 1 month after the regulations come into force. This gives manufacturers/importers a short amount of time to notify new products that are already in the manufacturing/delivery process. All vaping products that do not meet the new requirements will not be able to be sold 6 months after the regulations come into force. This gives time for manufacturers/importers to update their packaging and retailers to sell through existing product. |
|---|---|
| Product safety requirements (removable batteries, child safety mechanisms and nicotine concentration levels for vaping substances) (Schedule 5 as amended by amendment regulation 16) | All new product notifications for single-use and reusable vaping devices must meet the new requirements 1 month after the regulations come into force. <i>This gives manufacturers/importers a short amount of time to notify new products that are already in the manufacturing/delivery process.</i> All single-use vaping products that do not meet the new requirements will not be able to be sold 3 months after the regulations come into force. <i>This timeframe allows manufacturers/importers time to update their products, and retailers to sell through existing stock that does not meet requirements. This timeframe also recognises 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.</i> All reusable vaping products that do not meet the new requirements will not be able to be sold 6 months after the regulations come into force. <i>This timeframe allows manufacturers/importers time to update their products by young people, the subsequent safety risk posed by not having child-safety mechanisms or removable batteries, and their addictiveness.</i> All reusable vaping products that do not meet the new requirements will not be able to be sold 6 months after the regulations come into force. <i>This timeframe allows manufacturers/importers time to update their products, and retailers to sell through existing stock that does not meet</i> |
| No cartoons or toys (vaping and smokeless tobacco products) (Regulations 66 and 70 as per amendment regulations 9 and 11) | <i>requirements.</i> All vaping and smokeless tobacco products that do not meet the cartoon and toy requirements will not be able to be sold 6 months after the regulations come into force. <i>This new transitional timeframe is not considered to cause any prejudice to manufacturers and retailers.</i> |

21

22 To regulate single-use vaping products in such a way as to minimise harm, especially harm to children and young people, I consider a 3-month timeframe is appropriate given their use by young people. I note that the proximity

s 9(2)(h)

IN CONFIDENCE

restrictions for new approved specialist vaping premises will come into force immediately when the regulations come into force.

Compliance

- 23 The Smokefree Regulations comply with:
 - 23.1 the principles of the Treaty of Waitangi

The changes introduced through the Act seek to fulfil the Government's Te Tiriti o Waitangi obligations, for example by requiring the Director-General of Health to consult with Māori on aspects relating to the smoked tobacco retail scheme and the Minister to consider the risks and benefits for Māori when regulating smoked tobacco products.

Manatū Hauora undertook a number of community hui with Māori to ensure that the Smokefree Regulations will contribute to equitable outcomes for Māori and that the community voice is at the centre of decision making. This feedback has been incorporated where possible in the regulations and will be further considered as the smoked tobacco retail scheme is stood up.

- 23.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993
- 23.3 the principles and guidelines set out in the Privacy Act 2020
- 23.4 relevant international standards and obligations ^{s 9(2)(h)} s 9(2)(h)
- 19.5 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.





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s 9(2)(h)

Regulations Review Committee

25 There are no anticipated grounds for the Regulations Review Committee to draw the Smokefree Regulations to the attention of the House under Standing Order 327.

Certification by Parliamentary Counsel

26 The Parliamentary Counsel Office has certified the Smokefree Regulations as being in order for submission to Cabinet.

Impact Analysis

- 27 A regulatory impact statement was prepared to support the changes in the Cabinet paper Establishing the Smoked Tobacco Regulatory Regime: Report back from consultation and approval to draft Regulations [CAB-23-MIN-0182].
- 28 Manatū Hauora's Quality Assurance panel considered that the regulatory impact statement met the quality assurance criteria.

Publicity

29 Manatū Hauora will communicate the requirements set out in the Smokefree Regulations directly to stakeholders immediately following Cabinet approval.

Proactive release

30 I intend to proactively release this paper, subject to redaction as appropriate under the Official Information Act 1982, following Cabinet approval.

Cost-of-Living Implications

31 There are no expected cost-of-living implications from the proposals in this paper.

Use of External Resources

32 Manatū Hauora has engaged a small number of contractors since 2020/2021 to assist with the Smokefree work programme. From 1 July 2023 all Smokefree policy-related work will be undertaken by fixed-term and permanent staff.

Consultation

- 33 Manatū Hauora publicly consulted on the regulatory proposals informing the development of these Regulations.
- 34 Manatū Hauora has consulted with the following agencies in the development of this paper and the Regulations: The New Zealand Customs Service, the

Ministry of Justice, New Zealand Police, the Ministry of Business, Innovations and Employment (Commerce and Consumer Affairs), Te Puni Kōkiri, the Ministry of Education, the Ministry of Pacific Peoples, the Ministry of Ethnic Communities, Whaikaha- Ministry of Disabled People, Te Aka Whai Ora, Te Whatu Ora, Te Arawhiti, the Parliamentary Counsel Office, the Crown Law Office, the Ministry of Foreign Affairs and Trade, the Treasury, and the Department of the Prime Minister and Cabinet.

Recommendations

I recommend that the Cabinet Legislative Committee:

- 1 **note** that on 22 May 2023 Cabinet agreed to the drafting of the Smokefree Regulations to establish the regulatory regime for smoked tobacco, and to tighten vaping restrictions [CAB-23-MIN-0182];
- 2 note that on 22 May 2023 Cabinet agreed to reduce the maximum allowable nicotine salt concentration in single-use vaping products to 35mg/mL [CAB-23-MIN-0182], and that this is expressed in the Smokefree Regulations as a maximum allowable concentration of nicotine of 20mg/mL;
- 3 note that on 17 July 2023 Cabinet agreed to amend clause 15 of the Smokefree Regulations to state that for reusable vaping products that contain nicotine salts, the maximum allowable nicotine concentration is set at 28.5mg/mL [CAB-23-MIN-0305];
- 4 ^{s 9(2)(h)}
 - s 9(2)(h) took further public health advice from Te Pou Hauora Tūmatanui (the Public Health Agency), Manatū Hauora in relation to the nicotine concentration level for vaping products and regarding the safety requirement for removable batteries for all vaping products (Attached at **Appendix A**);
- 6 **S**^{9(2)(h)} **note** the further public health advice from Te Pou Hauora Tūmatanui (the Public Health Agency), Manatū Hauora confirms that the Smokefree Regulations should proceed as previously agreed per Cabinet's policy decisions on 22 May 2023 and 17 July 2023 [CAB-23-MIN-0182 and CAB-23-MIN-0182];
 - **note** that Cabinet previously agreed to require that a vaping product and a smokeless tobacco product may not include the depiction of cartoons or toys on its packaging when the Smokefree Environments and Regulated Products Regulations were made in 2021 [CAB-21-MIN-0167];
- 8 **note** that the Smokefree Environments and Regulated Products Amendment Regulations 2023 give effect to these decisions referred to in recommendations 1, 2, 3 and 7;

5

- 9 **agree** to the transitional timeframes for regulations 63A to 63D, regulation 69A, Schedule 5 and regulations 66 and 70 as set out in paragraph 16;
- 10 **note** in relation to new subparts 2A and 2B of Part 3 of the principal regulations (as inserted by regulation 6) and new subpart 4 of Part 3 of the principal regulations (as inserted by regulation 8) I have considered the matters set out in section 82(B(2) of the Smokefree Environments and Regulated Products Act 1990;
- 11 s 9(2)(f)(iv) 12 13 s 9(2)(h)
- 14 **authorise** the submission to the Executive Council of the Smokefree Environments and Regulated Products Regulations 2023.

Authorised for lodgement

Hon Dr Ayesha Verrall

Minister of Health

Appendix A – Additional public health advice from Te Pou Hauora Tūmatanui (the Public Health Agency), Manatū Hauora on product safety requirements for vaping products

- 1 This appendix sets out additional public health advice and provides an overview of the consultation regarding the proposed product safety requirements for vaping products in the Smokefree Regulations regarding:
 - 1.1 removable batteries
 - 1.2 nicotine concentration

Removable battery requirement for vaping products

Batteries in vaping products

- 2 All vape devices contain batteries. Batteries in reusable devices are intended to be recharged. With single-use devices, the vaping substance tends to be fully used before the battery is depleted, so operational partially charged batteries are disposed of still inside the empty vape devices. With many devices, the battery is built into the device in a way that does not make it easy for the battery to be viewed or removed.
- 3 There are two distinct risks associated with batteries in vaping products.¹
 - 3.1 The first is where batteries have caused a fire or explosion due to a fault in the battery. This has occurred (around the world) variously during charging, while being carried by a user, or most seriously, during use. While not common, the consequences could be, and at times, have been, severe including resulting in deaths. In New Zealand specifically, ACC has recorded an eight-fold increase in injuries linked to the devices. The yearly number of injuries had risen from 9 in 2016 to 72 in the first 11 months of 2021. The accepted claims for injuries resulting from burns, which ACC said was generally caused by devices exploding or catching fire, had increased steadily each year from fewer than 4 in 2016 to 12 in 2021.²
 - 3.2 The second mode of risk relates to the risk of fire or explosion once vapes have been disposed of. Vapes, with batteries inside, have been crushed causing fires. Several recent instances of this have occurred within recycling bins and trucks in New Zealand.³
- 4 These trends have also been observed internationally. For example, the United States Food and Drug Administration reports that battery-related injury

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<sup>2</sup> Injuries caused by vapes rise steadily - ACC figures | RNZ News, 12 January 2022
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https://www.rnz.co.nz/news/national/459403/injuries-caused-by-vapes-rise-steadily-acc-figures (accessed 9 August 2023).
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¹ Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products, Guidance for Industry, U.S. Department of Health and Human Services Food and Drug Administration Center for Tobacco Products November 2019, https://www.fda.gov/media/133009/download (accessed 2 August 2023).

³ Vape batteries set recycling trucks alight | RNZ News, 24 February 2023

https://www.rnz.co.nz/news/national/484810/vape-batteries-set-recycling-trucks-alight (accessed 9 August 2023).

related to electronic cigarettes increased approximately 100-fold over 2009 to 2017, including two known deaths reported in 2018 and 2019, respectively. Estimates for the number of emergency department visits that are due to battery-related injury vary widely depending on the method and data source. and rates are tending to increase over time. However, estimates ranged from between 680 to 2,000 per year over 2015-2017 in the United States.⁴ The majority of injuries were burn injuries to the upper leg or lower torso (approximately 60-77%, depending on the study), with many of the injuries occurring while the device was in the user's pocket. Injuries to the hands and face are also reported. Scaled for the population of Aotearoa, this would be the equivalent to approximately 10 to 30 emergency department visits per year, not adjusting for age or other demographics. Given the passive nature of adverse event reporting and limitations inherent in health database analyses, it is likely that these incidents are under-reported. The majority of the incidents are potentially avoidable, with modification to the battery design and testing, and public education related to battery safety.⁵

- 5 Requiring batteries to be removable is intended to address concerns around user safety and the risk of explosions/fire at the point-of-use and point-ofdisposal. The ability to remove the battery means it can be checked for swelling or corrosion before use or disposed of separately and safely at the end of its life rather than just being thrown away still inside the device.
- 6 The European Union (EU) has ratified proposals to require all batteries in portable appliances to be removable and replaceable by the end-user, and once that requirement comes into force, all vaping products sold in the EU will need to have removable batteries.⁶ This move by the EU indicates that battery and product manufacturers will need to transition towards removable batteries, which aligns with the proposed product safety requirement.
- 7 Vaping devices with removable batteries are already available on the market globally and in New Zealand, including reusable⁷ and single use⁸ vaping products.

 ⁴ Rossheim ME, Livingston MD, Soule EK, *et al* Electronic cigarette explosion and burn injuries, US Emergency Departments 2015–2017 *Tobacco Control* 2019;28:472-474, https://tobaccocontrol.bmj.com/content/28/4/472 (accessed 9 August 2023); Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products Guidance for Industry (as cited above); ME Rossheim, MD Livingston, EK Soule, HA Zeraye, DL Thombs, Electronic cigarette explosion and burn injuries, US Emergency Departments 2015–2017; Tob Control (2018 0:1–3, https://tobaccocontrol.bmj.com/content/tobaccocontrol/28/4/472.full.pdf (accessed 9 August 2023); Corey, C.G., Chang, J.T. & Rostron, B.L. Electronic nicotine delivery system (ENDS) battery-related burns presenting to US emergency departments, 2016. Inj. Epidemiol. 5, 4 (2018). https://doi.org/10.1186/s40621-018-0135-1
 https://injepijournal.biomedcentral.com/articles/10.1186/s40621-018-0135-1 (accessed 9 August 2023).
 ⁵ Corey, C.G., Chang, J.T. & Rostron, B.L. Electronic nicotine delivery system (ENDS) battery-related burns presenting to US emergency departments, 2016. Inj. Epidemiol. 5, 4 (2018). https://doi.org/10.1186/s40621-018-0135-1
 https://injepijournal.biomedcentral.com/articles/10.1186/s40621-018-0135-1 (accessed 9 August 2023).
 ⁵ Corey, C.G., Chang, J.T. & Rostron, B.L. Electronic nicotine delivery system (ENDS) battery-related burns presenting to US emergency departments, 2016. Inj. Epidemiol. 5, 4 (2018). https://doi.org/10.1186/s40621-018-0135-1 (as cited above).

⁶ See Article 11, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52020PC0798 (accessed 2 August 2023). Article 11 requires that manufacturers shall design appliances, in which portable batteries are incorporated, in such a way that waste batteries can be readily removed and replaced by the end-user or by independent operators.

⁷ For example https://www.vaporesso.com/vape-kits/gen-s (accessed 9 August 2023).

⁸ For example https://www.shosha.co.nz/twist-bar-disposable-vape-with-removable-battery (accessed 9 August 2023).

Consultation on removable batteries

- 8 As part of the broader public consultation on the suite of regulatory proposals, Manatū Hauora consulted on a proposal to require vaping devices to have a removable battery to enable the battery to be inspected (and therefore prevent risk of battery failure/explosion). The consultation document noted that 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. The battery proposal identified and consulted on was proposed to apply to all vaping devices to improve safety, including the safety of single-use vaping products.⁹
- 9 The public consultation period ran for 10 weeks from 4 January to 15 March 2023. Over 2,700 people and organisations engaged with the consultation process, either through a written submission or by attending a hui or fono.
- 10 Numerous respondents agreed with the proposal for removable batteries. For instance, Smokefree Murihuku, Autaki Tupeka Aotearoa, Taranaki Smokefree Coalition, Cancer Society, Smokefree Otago and the Paediatric Society of New Zealand supported removable batteries. Key arguments in support were that requiring removable batteries could reduce the risk of battery failure, explosion and other vape-related injuries. Several submitters were concerned about the public risk of vape devices causing fires and supported removable batteries for this reason. Several submitters also supported removable batteries and new ways of recycling batteries and vape devices to lessen the burden on the environment.
- 11 However, some respondents had concerns about the practical safety and manufacturing implications of implementing the removable battery proposal. Safety concerns generally related to the risk of consumers being able to tamper with or modify the internal workings or circuitry of a product, as well as the heightened risks of accidents due to loose lithium-ion batteries (for instance, if a battery is left in a person's bag or pocket and it reacts with other loose metal such as keys). Communications regarding safe use and disposal of batteries will accompany the regulatory change.
- 12 On 22 May 2023 Cabinet agreed to require removable batteries for all vaping products. Cabinet's decision to allow batteries to be inspected (ie for damage and any signs of wear or deterioration), and safely disposed of, reduces the safety risk that sealed batteries pose. The safety issues described above apply across all vaping products.

⁹ Ministry of Health. 2023. *Proposals for the Smoked Tobacco Regulatory Regime – Public Consultation Document*. Wellington: Ministry of Health. https://www.health.govt.nz/publication/proposals-smoked-tobacco-regulatory-regime. The consultation document states: *"We propose the following additional product safety requirements to address concerns relating these single-use* products: ... **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)."

Nicotine concentration of vaping products

- 13 There are two competing public health considerations around setting the appropriate level of nicotine concentration and any decisions need to represent a considered balance.
 - 13.1 The key public health use of vaping products is as smoking cessation aids. A consideration therefore is ensuring vaping products contain a sufficiently high nicotine concentration to act as effective smoking cessation tools.
 - 13.2 Secondly, we need to consider the risk that products with a high nicotine concentration increase the risk of creating addiction in people who have not previously smoked such as young people and children.
- 14 The below context is important for the decisions regarding the setting of nicotine concentration for vaping products in the Smokefree Regulations.

Types of vaping products and their content

- 15 Vaping products include those that are single-use (or disposable) as well as reusable devices. For reusable devices, the vaping substance can be replaced via a new pod or by refilling the reservoir inside the device.
- 16 Vaping products can use either freebase (unreacted) nicotine or a nicotine salt. Nicotine salts are where nicotine (which is an alkaline substance) is mixed with an acid (such as benzoic acid), to form a salt. This pH correction means that the resulting nicotine salt product is less harsh on the throat, meaning higher levels of nicotine can be tolerated, as well as possibly a different sensory effect on users or nicotine absorption rates compared to freebase vaping products.¹⁰ ¹¹ ¹²
- 17 For a given nicotine concentration in a vaping substance, the concentration of nicotine salt will be higher than the concentration of freebase nicotine. For instance, a nicotine benzoate concentration (the most commonly used nicotine salt) of 50mg/mL is equivalent to a freebase nicotine concentration of 28.5mg/mL.

Vaping as a smoking cessation tool

18 The vast majority of people who smoke want to become smokefree and regret having started smoking.¹³ However, many find quitting very difficult and

¹⁰ Hajek P, Pittaccio K, Pesola F, et al. 2020. Nicotine delivery and users' reactions to Juul compared with cigarettes and other e-cigarette products, *Addiction* 115: 1141–1148,

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7318270/ (accessed 9 August 2023). ¹¹ Leventhal AM, Madden DR, Peraza N, et al. 2021. Effect of Exposure to e-Cigarettes With Salt vs Free-Base Nicotine on the Appeal and Sensory Experience of Vaping: A Randomized Clinical Trial. JAMA Netw Open, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7804919/ (accessed 9 August 2023)

 ¹² O'Connell, G., Pritchard, J.D., Prue, C. et al. A randomised, open-label, cross-over clinical study to evaluate the pharmacokinetic profiles of cigarettes and e-cigarettes with nicotine salt formulations in US adult smokers. Intern Emerg Med 14, 853–861 (2019). https://doi.org/10.1007/s11739-019-02025-3 (accessed 9 August 2023)
 ¹³ Wilson N, Edwards R, Weerasekera D. High levels of smoker regret by ethnicity and socioeconomic status: national survey data. *New Zealand Medical Journal* 2009;**122**(1292):99-100.

continue smoking, despite making multiple attempts to become smokefree.¹⁴ Research has shown that vaping is an effective tool for smoking cessation, and more effective than traditional nicotine replacement therapies.¹⁵ Recent meta-analyses (aggregation) of six studies that compared electronic cigarettes (vaping products) to nicotine replacement as methods for smoking cessation, reported that smokers using electronic cigarettes were 63% more likely to quit smoking for at least 6 months compared to those receiving nicotine replacement therapy.¹⁶

- 19 There is no particular level that has been universally agreed as necessary to support smoking cessation. In 2018, the Technical Expert Advisory Group (TEAG) recommended limits of 36mg/mL concentration of nicotine in a freebase nicotine vaping substance and 60mg/mL maximum concentration of nicotine contained in a nicotine salt vaping substance. Manatū Hauora understand that these recommended limits coincided with what was on the market at the time and that the TEAG's intention was that a current smoker would receive a 'hit' of nicotine that was equivalent to that experienced when smoking a cigarette (or as close as possible given the technology at the time).
- 20 Higher levels of nicotine may better support smoking cessation but the evidence is weak. A meta-analysis on the effectiveness of electronic cigarettes as a tool for smoking cessation identified one study that compared the effectiveness of low- versus high-dose nicotine electronic cigarettes.¹⁷ It reported that smokers receiving high-dose vapes (36mg/mL of nicotine) tended to be more likely to quit smoking compared to individuals receiving low-dose vapes (8mg/mL); however, this result did not reach statistical significance, indicating that further study is needed to confirm this trend. Higher nicotine levels are associated with differences in physiological changes and changes in vaping behaviour.¹⁸
- 21 Some vaping industry representatives have contended that concentrations of 35-50mg/mL are required to help people who smoke to quit. Health and

Chan GCK, Stjepanović D, Lim C, *et al.* A systematic review of randomized controlled trials and network metaanalysis of e-cigarettes for smoking cessation. *Addictive Behaviors* 2021;**119**:106912.

¹⁴ Benowitz NL. Nicotine Addiction. *New England Journal of Medicine* 2010;**362**(24):2295-2303. Chaiton M, Diemert L, Cohen JE, *et al.* Estimating the number of quit attempts it takes to quit smoking successfully in a longitudinal cohort of smokers. *BMJ Open* 2016;**6**(6):e011045.

¹⁵ Hajek P, Phillips-Waller A, Przulj D, *et al.* A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. *New England Journal of Medicine* 2019;**380**(7):629-637.

Hartmann-Boyce J, Lindson N, Butler AR, et al. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2022(11).

¹⁶ Hartmann-Boyce J, Lindson N, Butler AR, McRobbie H, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2022, Issue 11. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub7. (Accessed 08 August 2023). https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub7/full

¹⁷ Cobb, Caroline OAllen, Sophia I. et al. Effect of an electronic nicotine delivery system with 0, 8, or 36 mg/mL liquid nicotine versus a cigarette substitute on tobacco-related toxicant exposure: a four-arm, parallel-group, randomised, controlled trial, The Lancet Respiratory Medicine, Volume 9, Issue 8, 840 – 850, https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00022-9/fulltext

¹⁸ Hiler M, Breland A, Spindle T, Maloney S, Lipato T, Karaoghlanian N, Shihadeh A, Lopez A, Ramôa C, Eissenberg T. Electronic cigarette user plasma nicotine concentration, puff topography, heart rate, and subjective effects: Influence of liquid nicotine concentration and user experience. Exp Clin Psychopharmacol. 2017 Oct;25(5):380-392. doi: 10.1037/pha0000140. PMID: 29048187; PMCID: PMC5657238. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5657238/

research representatives have asserted that 20mg/mL or lower concentration is sufficient. The United Kingdom (UK) has had success in reducing smoking rates with a maximum level of 20mg/mL.¹⁹

- 22 People who smoke often start vaping with higher levels of nicotine and then titrate down over time. There is evidence indicating that with lower nicotine strength liquid, experienced vapers may engage in compensatory puffing, increasing their overall consumption. However, depending on the type of device and experience of the user, some vapers can absorb nicotine levels greater than that delivered by a cigarette, even with very low concentrations of nicotine (e.g. 4mg/mL).²⁰
- 23 Having an effective alternative to cigarettes will be particularly important as the smoked tobacco regulatory regime takes effect. As these new law changes come into force over the next two years and smoked tobacco becomes much less available and contains significantly lower levels of nicotine, people who smoke need access to a less harmful alternative such as vaping.
- 24 The proposed nicotine levels of 20mg/mL (for all vaping devices including single use vaping devices) and 28.5mg/mL for reusable vaping devices using nicotine salts, are closer to what is considered 'high dose' (e.g. 36mg/mL in the study cited in para 20) than 'low dose' (e.g. 4-8mg/mL).

Changing landscape of youth vaping

- 25 While vaping products are only recommended for people who smoke as a cessation support, over the last few years New Zealand has seen a rapid rise in youth vaping. Daily vaping for Year 10s (aged 14-15) rose from 3.1% in 2019 to 10.1% in 2022. Many of those (4.3% of total) were never smokers. There are also large inequities in vaping rates daily vaping rates for Māori in 2022 were particularly high at 21.7%, with Māori girls at 25.2%.
- Single-use devices are popular amongst young people both here and overseas. In New Zealand in 2022, just over half of Year 10 daily vapers used some kind of reusable vape. However, their use had dropped significantly from the previous year, and uptake of single-use vapes was rapidly increasing (9.0% in 2021 to 39.7% in 2022).²¹ This follows similar trends seen in the US and UK. This suggests a significant shift among youth towards predominantly using single-use devices, which tend to be lower cost.
- 27 When using reusable devices, nicotine levels can be titrated downward overtime, to reduce dependence on nicotine. Single-use vaping products do not allow for this gradual reduction as the vaping liquid is integral to the

¹⁹ Nicotine vaping in England: 2022 evidence update summary - GOV.UK (www.gov.uk), Published 29 September 2022 (accessed 9 August 2023).

²⁰ Wagener TL, Floyd EL, Stepanov I, *et al* Have combustible cigarettes met their match? The nicotine delivery profiles and harmful constituent exposures of second-generation and third-generation electronic cigarette users *Tobacco Control* 2017;**26:**e23-e28. https://tobaccocontrol.bmj.com/content/26/e1/e23 (accessed 9 August 2023).
²¹ ASH Year 10 Snapshot Survey 2022: Youth smoking and Vaping in Aotearoa New Zealand – 2023 report for Manatū Hauora, unpublished.

device, and most single-use products have nicotine concentrations at the high end of the range.

- A New Zealand study of Years 9-13 found 75% of those vaping, or 20% of total respondents, are vaping daily or several times a day, and the majority are vaping with high nicotine doses. Of those who reported vaping in the past week, 59.3% were vaping several times a day, and the majority, 79.9%, were vaping at very high nicotine levels (between 24mg/mL–50mg/mL). Of particular note, 54.7% reported that they were vaping at higher nicotine doses than the previous year.²²
- There is evidence that higher nicotine concentrations lead to higher nicotine 29 uptake,²³ and greater nicotine dependence and vaping frequency.²⁴ Studies have shown that for young people, the prevalence of vaping within 30 minutes of waking (a possible indicator of addiction) gradually increases as nicotine concentration increases.²⁵ Young people who vape are more likely to smoke,²⁶ but there are challenges to evaluating the causal relationship. However, a recent meta-analysis and systematic review based on 11 longitudinal studies that evaluated the association between prior vaping and subsequent smoking in adolescents over time, found that young people who vaped regularly were about 3 times more likely to become regular smokers, than those that did not vape.²⁷ Study methodology varied, but all studies adjusted for at least some of the potentially confounding factors that may also lead to smoking, such as the presence of smoking in the household, other alcohol and drug use, or other metrics of susceptibility to future smoking. However, authors noted that unmeasured confounders and other risk factors likely play a substantial role in smoking addiction. Some young people may be using vaping as a smoking cessation tool, and youth smoking has continued to decrease as vaping prevalence has increased.²⁸ However, many young people who vape have never previously smoked.²⁹

639, DOI: 10.1080/10826084.2022.2034876

https://www.tandfonline.com/doi/abs/10.1080/10826084.2022.2034876 (accessed 9 August 2023).

²⁵ Influence of Flavors and Nicotine Concentration on Nicotine Dependence in Adolescent and Young Adult E-Cigarette Users: Substance Use & Misuse: Vol 57, No 4 (tandfonline.com) (as cited above).

²² A 2021 Report in Youth Vaping: The ARFNZ/SPANZ vaping in NZ youth survey, A-2021-report-into-youth-vaping.pdf (asthmafoundation.org.nz) (accessed 9 August 2023).

²³ Dawkins LE, Kimber CF, Doig M, Feyerabend C, Corcoran O. Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects. Psychopharmacology (Berl). 2016 Aug;233(15-16):2933-41. doi: 10.1007/s00213-016-4338-2. Epub 2016 May 27. PMID: 27235016. https://pubmed.ncbi.nlm.nih.gov/27235016/ (accessed 9 August 2023).

²⁴ Elizabeth K. Do, Katie O'Connor, Jennifer M. Kreslake, Samantha C. Friedrichsen, Donna M. Vallone & Elizabeth C. Hair (2022) Influence of Flavors and Nicotine Concentration on Nicotine Dependence in Adolescent and Young Adult E-Cigarette Users, Substance Use & Misuse, 57:4, 632-

²⁶ Staff J, Kelly BC, Maggs JL, *et al.* Adolescent electronic cigarette use and tobacco smoking in the Millennium Cohort Study. *Addiction* 2022;**117**(2):484-494.

²⁷ Chan GCK, Stjepanović D, Lim C, Sun T, Shanmuga Anandan A, Connor JP, Gartner C, Hall WD, Leung J. Gateway or common liability? A systematic review and meta-analysis of studies of adolescent e-cigarette use and future smoking initiation. Addiction. 2021 Apr;116(4):743-756. doi: 10.1111/add.15246. Epub 2020 Oct 5. PMID: 32888234. https://onlinelibrary.wiley.com/doi/10.1111/add.15246.

²⁸ Ministry of Health. New Zealand Health Survey minhealthnz.shinyapps.io/nz-health-survey-2021-22-annualdata-explorer/ w 1275039c/#!/home

²⁹ Ministry of Health. 2023. *Smoking Status of Daily Vapers: New Zealand Health Survey 2017/18 to 2021/22* Smoking status of daily vapers: New Zealand Health Survey 2017/18 to 2021/22 | Ministry of Health NZ

30 While the long-term risks of vaping are not yet clearly known, it is established that vaping is not without risk. For example, surveys of teens have shown increased frequency of respiratory symptoms including productive cough, as well as more severe asthma symptoms among vapers, regardless of smoking status.³⁰ Aside from any long-term risks, any addiction can be a burden and resulting harm can extend to impact on educational attainment, psychological harm, economic harm, environmental harm and cultural harm. A recent systematic review found vaping among young people was associated with reduced mental wellbeing.³¹

Overview of changes to nicotine concentration in the Smokefree Regulations

- 31 Manatū Hauora has currently recommended setting different limits on nicotine concentration levels for reusable vaping devices that use salt versus all other vaping devices including single use vaping devices, balancing trends in youth usage of vapes against ensuring suitable products remain available as cessation support.
- 32 Over time, the direction of travel is likely to be toward consistent, and progressively lower nicotine levels across all devices (that is, regardless of device and the use of nicotine salts or not). Although there is no particular level that has been universally agreed as necessary to support smoking cessation, increasing evidence supports the effectiveness of lower nicotine levels that can both support the Smokefree Aotearoa 2025 Action Plan goal of less than five percent daily smoking prevalence for all population groups, while also minimising harm to young people and children.
- 33 The particular New Zealand context of the impending changes to smoked tobacco products requires a balance to be struck between the needs of people who smoke while protecting young people from harm. Given the rapid developments in this area in terms of new products, changing technologies and shifting trends in use of both smoked tobacco and vaping products, further adjustments will likely be needed in the future.
- 34 The Smokefree Regulations propose a nicotine concentration limit of 20mg/mL for single-use devices³² and 28.5mg/mL for reusable devices using nicotine salts. The process to set or recommend these levels is discussed below.

Reusable vaping products

35 The concentration as currently expressed in regulations states '*The strength* of nicotine salt in a vaping substance must not exceed 50mg/mL'.

 ³⁰ Jonas A. Impact of vaping on respiratory health BMJ 2022; 378 :e065997 doi:10.1136/bmj-2021-065997
 ³¹ Becker TD, Arnold MK, Ro V, Martin L, Rice TR. Systematic Review of Electronic Cigarette Use (Vaping) and Mental Health Comorbidity Among Adolescents and Young Adults. Nicotine Tob Res. 2021 Feb 16;23(3):415-425. doi: 10.1093/ntr/ntaa171. PMID: 32905589. Systematic Review of Electronic Cigarette Use (Vaping) and Mental Health Comorbidity Among Adolescents and Young Adults - PubMed (nih.gov) (accessed 9 August 2023).
 ³² Freebase nicotine in reusable vaping products is already set at 20mg/mL in the existing regulations.

- 36 This caused confusion as to whether the existing regulations restrict the concentration of nicotine salt, or the concentration of freebase nicotine. The industry's understanding was that clause 15 limited the strength of freebase nicotine to 50mg/mL for nicotine salt vaping products, Manatū Hauora understood that clause 15 limited the amount of nicotine salt to 50mg/mL.
- 37 Manatū Hauora conceded to the High Court in judicial review proceedings taken by ALT that the correct interpretation of clause 15 is that the concentration of freebase nicotine in nicotine salt vaping products must not exceed 50mg/mL. This means that vaping products can continue to be sold with a freebase nicotine strength of 50mg/mL unless the Regulations are amended.
- 38 Manatū Hauora considers that 50mg/ml is both higher than necessary for effective smoking cessation, and too high a concentration of nicotine, given the significant increase in youth vaping and the negative impacts of nicotine addiction.
- 39 From 12 to 26 June 2023, Manatū Hauora undertook targeted consultation on nicotine concentration for reusable vaping products containing nicotine salts.
- 40 The consultation process resulted in a large number of submissions that supported and opposed the allowable nicotine concentration to be set as 28.5mg/mL for reusable vaping products containing nicotine salts. Manatū Hauora targeted 194 industry stakeholders, clinical professional groups and non-governmental organisations.
- 41 A total of 4,731 people and organisations made submissions through the consultation process. The vape company Vuse (a subsidiary company of British American Tobacco) emailed its customers a link to the consultation document, offering a free vape to those who responded. This resulted in over 4,000 submissions opposing the proposal.
- 42 Most submissions provided views on whether the concentration level was set correctly (ie, too high or too low). Submissions from key non-governmental organisations, academics and health professionals were mainly in favour of the proposal or were opposed because they thought the proposals were not going far enough (ie, that the nicotine level should be set lower than 28.5mg/mL). Many submissions emphasised that the proposed level was sufficient for those switching from smoking to vaping.
- 43 A summary of the submissions and analysis is provided at **Appendix B**. Following a careful and detailed consideration of the submissions, Manatū Hauora confirmed its policy position that the nicotine concentration in these types of vaping products should be 28.5mg/mL. A higher limit than set in the UK, for example, is appropriate in New Zealand at a time when we are moving towards mandating cigarettes than are non or minimally addictive. On 17 July 2023, Cabinet agreed to amend clause 15 of schedule 5 of the Regulations to state that for reusable vaping products that contain nicotine salts, the maximum allowable nicotine concentration is set at 28.5mg/mL [CAB-23-MIN-0305].

44 Cabinet's decision reflects a compromise between the competing interests that are important in this area, drawing on views given to Manatū Hauora in the consultation. Those interests are enabling vaping products with a sufficiently high nicotine strength to be purchased as a smoking cessation tool and minimising harm to never smokers, particularly to children and young people.

Single-use vaping products

- 45 As part of the broader public consultation on the suite of regulatory proposals, Manatū Hauora consulted on the maximum nicotine level in single-use vaping products to further reduce their appeal, safety risk, and addictiveness to young people. The public consultation period ran for 10 weeks from 4 January to 15 March 2023. Over 2,700 people and organisations engaged with the consultation process, either through a written submission or by attending a hui or fono.
- 46 Submissions showed consistent support for lowering the nicotine content in single-use (disposable) vapes. Some agreed that lowering the nicotine content to the proposed amount of 35mg/mL was enough, however, there was consistent feedback that nicotine levels should be even lower than the proposed amount. Suggestions ranged from 'no nicotine' to 25mg/mL for disposable vapes.
- 47 On 22 May 2023 Cabinet agreed to reduce the maximum allowable *nicotine salt* concentration in single-use vaping products to 35mg/mL [CAB-23-MIN-0182]. Consistent with the way nicotine concentration levels are expressed for reusable vaping products that use nicotine salts, the maximum allowable *nicotine* concentration for single-use vaping products will be set at 20mg/mL. Freebase nicotine in reusable vaping products is already set at 20mg/mL in the existing regulations and will remain unchanged.
- 48 This proposed limit will align with the maximum strength of 20mg/mL set by the United Kingdom, Canada and the European Union for all vape products and is justified given the statistics regarding use of single-use vapes by young people. A lower limit for single use vaping products of 20mg/mL compared to 28.5mg/mL for reusable vaping products containing nicotine salts is appropriate because the nicotine content cannot be changed, and young people are increasingly more likely to use single-use vaping products.





PROPOSAL TO CLARIFY HOW NICOTINE LEVELS FOR VAPING PRODUCTS ARE EXPRESSED IN THE SMOKEFREE ENVIRONMENTS AND REGULATED PRODUCTS REGULATIONS 2021

Analysis of consultation submissions

2023

Released 2023

health.govt.nz

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Table 1: Citizen Space responses by respondent type

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Martin Martin Martin

Introduction

From 12 to 26 June 2023, Manatū Hauora (the Ministry of Health) consulted on the way that the nicotine concentration for reusable vaping products containing nicotine salts is expressed in the Smokefree Environments and Regulated Products Regulations 2021 (the Regulations). Through this consultation, Manatū Hauora aimed to address confusion regarding the interpretation of clause 15 of Schedule 5 of the Regulations relating to vaping products. This clause states that the strength of nicotine salt in a vaping substance must not exceed 50 mg/mL. The Ministry has accepted that the proper interpretation of this clause is that the nicotine strength in vaping products containing nicotine salts must not exceed 50 mg/mL.

Nicotine strength levels for products containing nicotine salts can be described in two ways. It could describe the concentration of the nicotine salt in a vaping substance or as the concentration of 'freebase' nicotine in a vaping substance. The proposal seeks to amend the wording of the Regulations to always refer to the maximum nicotine concentration of a vaping product, rather than the maximum permitted nicotine salt concentration. This approach aligns with the purposes of the Act: to provide for the regulation of notifiable products in a way that seeks to minimise harm, especially harm to young people and children, by making sure products don't contain excessive levels of nicotine, which is the addictive substance in vaping products.

It is important the regulations around vaping products are accessible and easily understood by the public, especially industry and users of products. Regulating the strength of nicotine rather than nicotine salt will be easier for people to understand and cross-check against the labelling on the products. However, retaining a 50 mg/mL level for nicotine strength rather than for nicotine salt strength would mean that vaping products with significantly high levels of nicotine could be sold in New Zealand, increasing the risk of nicotine addiction.

While vaping products can only be legally sold to people aged 18 years and older, the last few years have seen a rapid increase in those under 18 years old using vapes. The estimated percentage of 14- to 15-year-olds, for example, who are vaping daily is currently 10.1%.¹ Daily vaping is more likely to indicate possible addiction to nicotine. Vaping rates are highest for Māori 14- to 15-year-olds and particularly Māori girls (25.2% daily vaping in 2022).² While the trend for youth is currently toward using disposable vapes, at least half still used reusable vapes of some kind (tank or cartridge) in 2022.

The proposed change will increase the protection from the highest levels of nicotine to all youth, which will reduce the likelihood of them becoming addicted.

This document summarises feedback gathered through the consultation on the proposal.

² Ibid.

ANALYSIS OF CONSULTATION SUBMISSIONS ON THE PROPOSAL TO CLARIFY HOW NICOTINE LEVELS FOR VAPING PRODUCTS ARE EXPRESSED IN THE SMOKEFREE ENVIRONMENTS AND REGULATED PRODUCTS REGULATIONS 2021 08-30 11:29:40

¹ Action for Smokefree 2025 (ASH). 2022. ASH Year 10 Snapshot Survey 2022 Topline – Youth smoking and vaping. URL: ash.org.nz (Accessed 24 July 2023).

Methodology

The consultation ran for two weeks from 12 to 26 June 2023 and was launched via an email to targeted stakeholders. The email provided a link to the online consultation platform Citizen Space.

Manatū Hauora created a consultation document setting out the proposal to clarify how nicotine levels for vaping products are expressed in the Smokefree Environments and Regulated Products Regulations 2021 (the Regulations). The proposal was available in both Word and pdf versions on the online consultation platform. Further information on the proposal was emailed to stakeholders on 22 July 2023.

Submissions were returned via the Citizen Space platform or email to the **smokefree@health.govt.nz** inbox.

Data quality assurance

Manatū Hauora asked all respondents to disclose any direct or indirect links to, or funding from, the tobacco industry. This was to ensure we complied with the World Health Organization's Framework Convention on Tobacco Control (FCTC) article 5.3: Protecting tobacco control policies from tobacco industry interference. The implementing guidelines for article 5.3 recommend Governments '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'.

Analysis

Manatū Hauora collated and analysed all submissions received. The consultation asked submitters to respond to the below three questions:

- Do you agree with our proposal to set the maximum allowable nicotine concentration at 28.5mg/mL for reusable vaping products that contain nicotine salts?
- 2. Please explain your reasoning.
- 3. Is there anything else you would like to tell us at this time?

We read all responses to draw out the key themes from each.

We analysed the submissions by respondent type to ensure we captured insights unique to the specific groups. The respondent types are listed below in alphabetical order.

- Community or advocacy organisation
- Government organisation
- Health care provider

2 ANALYSIS OF CONSULTATION SUBMISSIONS ON THE PROPOSAL TO CLARIFY HOW NICOTINE LEVELS FOR VAPING PRODUCTS ARE EXPRESSED IN THE SMOKEFREE ENVIRONMENTS AND REGULATED PRODUCTS REGULATIONS 2021



- Iwi/hapū affiliated and/or Māori organisation
- Medium or large retailer
- Other
- Pacific community or organisation
- Personal submission
- Professional organisation
- Research or academic organisation
- Small retailer
- Tobacco manufacturer, importer or distributor
- Vaping or smokeless tobacco product retailer, distributor or manufacturer.

Results

A total of 4,731 people and organisations made submissions through the consultation process. Of those, 4,723 submissions were made via Citizen Space and eight were made via email.

Limitations

Due to the technical nature of the consultation questions, we intended for this to be a targeted consultation with key stakeholders. On 12 June 2023 an email invitation to submit on the consultation was sent to a list of key stakeholders that comprised tobacco and vaping retailers, manufacturers and importers, non-governmental organisations and health professional organisations inviting them to submit on the consultation. At the same time, we launched the consultation on the online portal called Citizen Space.

Shortly after the consultation had opened, Manatū Hauora was notified that vaping brand Vuse had emailed their customers the following message.

We know you love your Vuse and we want to ensure you can continue to have the freedom to choose the product that's right for you. But we need your help.

The NZ Government has proposed a ban on any nic-salt vaping products with more than 28.5mg/mL of nicotine meaning our 3% (34mg) and 4% (47mg) nic strength is under threat. If this ban goes ahead these products could be off the shelves within 6 months.

If you or someone you know uses 3% or 4% nic products to help you stay smoke free, please share your story via the consultation hub before June 26th (it should only take 5 minutes). This will let the Government know that 3% and 4% vapes help to keep us smoke free.

HAVE YOUR SAY NOW

GET A FREE VUSE GO*

To say thank you for having your say we'll gift you a Vuse Go. Just take a screen grab of your confirmation email making sure to include the response ID, the time received and the email it was sent to, then send this to our Vuse Care Team at **info.nz@vuse.com** to get a promo code for a FREE Vuse Go*.

This email, alongside a post on their website, encouraged their customers to fill out the consultation and offered free vapes to those who did so. Vuse is a brand of British American Tobacco (New Zealand) Limited, which also made a submission. Vuse was mentioned 135 times throughout submissions.

People supporting the proposal often did so because nicotine strengths would be reduced, and those who did not support the proposal often did so because they wanted access to vapes containing very high nicotine levels.

Respondents were asked to indicate whether they were submitting on behalf of themselves or a group, such as a small retailer, health care provider, etc. Respondents had the option of ticking more than one option, and for that reason, some submissions were analysed in more than one of the respondent type categories outlined below.

A large number of submissions were found to have duplicate IP addresses (Internet Protocol address, which indicates a connection to a particular computer network), email addresses and/or content. Though we can expect some duplications, for example, with submissions from people who work together having the same IP address, there was evidence of some respondents submitting multiple times. This may have impacted the findings of the consultation.



Responses by respondent type

Below is summarised submission feedback by respondent type in alphabetical order.

The table below shows the submissions received by respondent type. Most submissions were made by individuals (n=3,360), followed by small retailers (n=1,238) and vaping or smokeless tobacco product retailers, distributors or manufacturers (n=455).

Submitters could select multiple categories, and many of those who identified as vaping and smokeless tobacco product retailers, distributors or manufacturers overlapped with the small retail category.

A summary of the Citizen Space responses received by each respondent type is also provided in the table below.

| Group | Total Number | N= Yes | N= No | N= Not answered | Percentage answered Yes | Percentage answered No |
|--|-----------------|-----------|----------|-----------------------|-------------------------------|------------------------------|
| Personal submission | 3,360 | 422 | 2,933 | 5 | 12.56% | 87.29% |
| Small retailer | 1,238 | 38 | 1,200 | 0 | 3.07% | 96.93% |
| Vaping or smokeless tobacco product retailer, distributor or manufacturer | 455 | 26 | 428 | 1 | 5.71% | 94.07% |
| Medium or large retailer | 74 | 5 | 69 | 0 | 6.76% | 93.24% |
| Not answered | 52 | 8 | 42 | 2 | 15.38% | 80.77% |
| Other | 50 | 10 | 40 | 0 | 20.00% | 80.00% |
| Tobacco manufacturer, importer or distributor | 26 | 3 | 23 | 0 | 11.54% | 88.46% |
| Community or advocacy organisation | 25 | 3 | 22 | 0 | 12.00% | 88.00% |
| Health care provider | 24 | 5 | 19 | 0 | 20.83% | 79.17% |
| lwi/hapū affiliated and/or Māori organisation | 17 | 3 | 14 | 0 | 17.65% | 82.35% |

Table 1: Citizen Space responses by respondent type



ANALYSIS OF CONSULTATION SUBMISSIONS ON THE PROPOSAL TO CLARIFY HOW NICOTINE LEVELS FOR VAPING PRODUCTS ARE EXPRESSED IN THE SMOKEFREE ENVIRONMENTS AND REGULATED PRODUCTS REGULATIONS 2021

| Group | Total Number | N= Yes | N= No | N= Not answered | Percentage answered Yes | Percentage answered No |
|--------------------------------------|-----------------|-----------|----------|-----------------------|-------------------------------|------------------------------|
| Professional organisation | 14 | 2 | 12 | 0 | 14.29% | 85.71% |
| Pacific community or organisation | 8 | 1 | 7 | 0 | 12.50% | 87.50% |
| Government organisation | 7 | 2 | 5 | 0 | 28.57% | 71.43% |
| Research or academic organisation | 6 | 2 | 4 | 0 | 33.33% | 66.67% |

Community or advocacy organisation

Supported the proposal

Of the submissions from community or advocacy organisations who supported the proposal, key reasons were that it would minimise harm from vaping and address current confusion around the wording of the regulations.

Some advocated for lowering nicotine concentration levels further, for example, to 20 mg/mL. One submitter commented that they were not aware of evidence to show that very high nicotine concentration products are needed for vapes to be effective as a cessation device.

Opposed the proposal

Some submitters from this group opposed the proposal as they wanted nicotine concentration limits to be lowered further. One submission recommended all vaping products have the same limit of 20 mg/mL to avoid confusion. Another suggested the nicotine base should be referred to in the regulations.

Some commented that lower nicotine levels could be insufficient to support smokers to switch to vaping. One submission said that most whānau who use stop smoking services prefer a nicotine level of 4% and vape more heavily when the level is lower.

One submission expressed concern that the proposed change could result in harm to adult smokers and young people. Another submitter commented that lower nicotine level products may be smoother and more enjoyable and for that reason may lead to increased youth vaping.

A number of submissions from this group also emphasised that regulations should be better enforced.



Government organisation

Seven submissions indicated that they were made on behalf of a government organisation.

Supported the proposal

The two submissions that agreed with the proposal supported reducing the level of nicotine to reduce the appeal of vaping and the risk to young people.

Opposed the proposal

Some of the submissions that disagreed with the proposal believed this change would disincentivise smokers to make the switch to vaping, and some indicated they did not believe nicotine levels are harmful and may increase youth uptake.

One response stated that vaping is a personal choice.

Health care providers

Supported the proposal

Of the 24 submissions from health care providers, 20.83% supported the proposal. Similarly to previous categories, many submitters chose to select a number of categories or did not clearly affiliate with a healthcare provider, or as a healthcare worker.

The key theme from this group was that the level was adequate for those who want to stop smoking. One submitter in this group commented that they supported the proposal as a way to address youth vaping.

Opposed the proposal

Of the health care providers that didn't support the proposal, some thought the level in the proposal was too low and may be too large a reduction for people currently reliant on higher levels of nicotine. Some raised concerns about people relapsing to smoking or making it more difficult for people to switch from smoking.

Submissions from this group also mirrored concerns by other groups around the potential for growth in the black market and crime.

Iwi/hapū affiliated and/or Māori organisation

Some submitters with iwi/hapū affiliations and/or from Māori organisations supported the proposal. The key reason for support was that less nicotine would reduce the risk of addiction. One respondent expressed support for the proposal as it would reduce the harm from vaping amongst tamariki.

The majority of submitters from this group disagreed with the proposal (14 of 17). They were concerned that decreasing nicotine levels would make vaping a less suitable alternative to cigarette smoking for whānau. Many also stated that adults should have the right to choose what they put in their own bodies.

Some submitters from this group disagreed with the proposal on the grounds that the nicotine limit should be lower, and ideally, vapes should not be available in New Zealand at all.

One submitter disagreed with the proposal as they felt that any nicotine concentration above 20 mg/mL is too high and limiting concentration to 20 mg/mL would better align New Zealand to the limits set in Europe, the United Kingdom and Canada. This respondent stated that youth who vape often have difficulties understanding nicotine concentrates and limiting the concentration might help reduce the risk of addiction.

Medium or large retailer

Of the small number of medium and large retailers that agreed with the proposal (5 out of 74 respondents), many supported nicotine levels being reduced, noting that higher concentrations of nicotine may be more addictive. Most of the respondents in this group seemed to represent independent retailers such as dairies.

The vast majority of medium and large retailers disagreed with the proposal (69). Many raised concerns about impacts to their business and indicated that a large percentage of their sales were products with nicotine concentrations that were higher than the proposed limit.

Some raised concerns that a lower level of nicotine would be less effective for those wanting to use vaping as a tool to quit smoking. Some believed changing the level might cause people to revert to smoking or turn to the black market to purchase higher concentration vapes.

Some respondents felt that there were too many changes already in the regulatory environment and opposed further regulation.



Pacific community or organisation

Eight respondents indicated that they represented a Pacific community or organisation. Of this group, one submitter supported the proposal. This submitter raised concerns about the sale of tobacco and products containing nicotine in general and suggested they should be banned entirely. They were also concerned about the use of these products among youth and teenagers.

The remaining seven respondents from this group disagreed with the proposal, noting that nicotine is addictive but not harmful on its own and that high nicotine vape products are helpful tools for those seeking to quit smoking. Some raised concerns that people might return to smoking if they no longer had access to high nicotine vapes. Some suggested people should be free to make their own choice about whether they vape or not.

Personal submission

In all, there were 3,360 personal submissions. In addition to this, 50 submitters selected the 'other' category, and 52 did not indicate if they were submitting on behalf of themselves or an organisation. For the purpose of this analysis, we have treated these 102 submissions as personal submissions.

Supported the proposal

Of the personal submissions, 12.64% supported the proposal. Many of those who supported the proposal were vapers themselves and felt the proposal would keep products available that are adequate for their own use and for others trying to switch from smoking to vaping.

Many of these submitters commented that a lower nicotine concentration is better for health or less likely to lead to addiction, that high nicotine products are unnecessary and that high strengths make it harder for people to switch to lower doses or quit vaping. Many also suggested that lower nicotine strengths were a good option to help address concerns about young people taking up vaping rather than regulating vapes as smoking cessation products. Some submissions commented that lower nicotine strengths could help stop youth vaping and reduce their likelihood of addiction.

Some individuals supported the proposal as they generally supported tighter regulation of vaping products and the vaping industry. A number commented that vaping companies encourage higher strength products, and some cited the email sent by Vuse. Some submitters commented that the long-term effects of high nicotine vape products are still unknown and regulation of these products is important.

Some individuals supported clarification of nicotine concentration in the proposal and supported New Zealand aligning with international standards. Others who supported the proposal wanted to ban disposable vapes or all vapes. Some recommended vapes be made prescription only.

Opposed the proposal

Of the personal submissions, 87.29% did not support the proposal. Key themes from personal submitters who did not agree with the proposal included negative impacts on individuals and freedom of choice.

Impact on individuals

Key concerns for this group included reducing the effectiveness of vaping as a tool to quit smoking, with many submitters saying only being able to access lower-level nicotine vapes would make the transition from smoking difficult or impossible. Others in this group said that high nicotine levels were key to their transition from smoking and that lowering nicotine strength could cause them to start smoking again. Some submitters from this group commented that they prefer the taste of high nicotine vapes.

Some of this group raised concerns that lower nicotine levels would mean they would need to vape more to get the same 'hit'. Similarly, some raised concerns around an increased cost to vapers who would need to buy more to get the same level of nicotine. Some submitters commented that this would lead to increased waste from vaping products.

Some submitters raised concerns around the negative impact not having access to high nicotine vaping products could have on an individual's anxiety, mental health and general wellbeing.

Freedom of choice

Freedom of choice was mentioned by many submitters in this group. Many submitters viewed the impact of the proposal as penalising vapers and taking away their personal choices. Some commented that people should be able to make their own decisions around what to put in their bodies. Some emphasised there are already low nicotine options available for people to use if they want.

Some respondents from this group felt that addressing youth vaping was being prioritised over supporting people who wish to stop smoking. While many submitters supported changes that reduce harm to youth, many felt that this should not be at the expense of adults who wish to use vaping as a tool to help them quit smoking.

Supported a lower or higher limit

Of the individual submitters who did not agree with the proposal, some supported a lowering of the current maximum nicotine concentration. Some of this group felt 28.5 mg/mL was too high and recommended lower limits, such as 20 mg/mL. Many respondents commented that lower nicotine levels make it easier for people to eventually quit vaping.

Some submitters supported an increase of the current maximum nicotine concentration. Some former smokers felt the current limit was too low to keep them



away from smoking. Some of this group recommended higher limits such as 35 mg/mL, 40 mg/mL or 50 mg/mL.

Supported keeping the current limit

Of the personal submissions that did not agree with the proposal, some wanted levels to remain the same and felt a lower concentration would not be sufficient. Many stated they had tried lower limits and found they were not strong enough, and some supplemented vaping with cigarettes. Some of this group emphasised that keeping nicotine levels stable is important for those trying to remain cigarette free, and others commented that people need the ability to titrate down nicotine levels.

Professional organisation

Of the respondents representing a professional organisation, 14.29% supported the proposal. Many of those supported the impact the proposal could have on protecting young people from high levels of nicotine and nicotine addiction.

Of those respondents disagreeing with the proposal, some preferred a lower limit, for example 18–20 mg/mL.

Some respondents noted that lack of availability of high nicotine vape products might make it difficult for long-term smokers to quit, particularly if they were dissatisfied with a cessation tool. One submitter suggested that a concentration of 28.5 mg/mL might not replicate the sensation of smoking and could make it more difficult to quit.

Some raised concerns about losses to businesses as a result of the changes and noted people might turn to a black market to purchase higher strength nicotine products.

Research or academic organisation

Of the six submitters that indicated they represented research or academic organisations, four did not indicate an affiliation with a specific research or academic organisation in their submission. The remaining two submissions were from The Royal New Zealand College of General Practitioners and the ASPIRE Aotearoa group³ who both supported the proposal.

Supported the proposal

Those who supported the proposal generally supported clarifying the law and agreed with the principle of setting a nicotine limit that provides the best balance between protecting young people from nicotine addiction while also ensuring vaping products

³ ASPIRE Aotearoa is a group of leading smokefree researchers and health providers from Aotearoa New Zealand. Their aim is to provide research to help the government achieve the goals of a Smokefree Aotearoa.

ANALYSIS OF CONSULTATION SUBMISSIONS ON THE PROPOSAL TO CLARIFY HOW NICOTINE LEVELS FOR VAPING PRODUCTS ARE EXPRESSED IN THE SMOKEFREE ENVIRONMENTS AND REGULATED PRODUCTS REGULATIONS 2021 74pljbyi4i 2023-08-30 11:29:40 are effective for helping people who smoke to successfully switch from smoking to vaping.

It was noted that the ambiguity of the current wording in the regulations has contributed to the availability of nicotine salt products with very high nicotine concentrations, which may have contributed to the substantial increase in daily vaping observed in young people. One response stated that the proposal would close a loophole that was being exploited.

It was also suggested that the nicotine limit be set at 20 mg/mL to align with some international standards. One response stated that it was not clear how the 28.5 mg/mL limit was determined.

It was noted that clarifying and enforcing the law would better protect people who do not currently smoke, particularly youth and children, from nicotine addiction.

Opposed the proposal

Some disagreed with any change to allowable nicotine concentration in vaping products. Among those that disagreed, there was a perception that the 28.5 mg/mL expression would be a large reduction, and this might drive people to vape more to compensate for the reduction in nicotine strength.

Small retailer

The vast majority of the 1,238 small retailer submissions did not support the proposal (1,200 compared with 38 supporters).

The small number of responses that did support the proposal had several key themes. Several of these submitters supported the proposal as they believed it would make vaping less addictive, help people quit vaping and lead to improved health. Some supported strong regulation of the vaping industry or banning vapes entirely.

Those who didn't support the proposal generally mentioned the negative impact on small retailers, negative impact on people trying to quit smoking and freedom of choice. A large number of respondents from this group were concerned the proposed change would lead to an increase in black market sales. Some commented that they weren't concerned about the nicotine concentration so long as they could keep selling some vapes.

Impact on small retailers

Submissions from small retailers consistently raised concerns around the impact the proposal could have on their income and ability to sell stock, potential loss of customers and potential business closure. This group frequently commented that there have been too many changes to requirements around sale of vaping products over a short period of time that have negatively impacted small businesses.



Many submitters from this group reported that a significant proportion of their customers use high nicotine strength vapes and that these sales make up a large percentage of their profits. Some emphasised the challenges retailers have faced since the pandemic and commented that they had already spent money on setting up specialist shops or getting licenses.

Impact on individuals

Another key theme in the submissions from this group was the potential impact on exsmokers or people trying to quit smoking. A number of submissions emphasised the positive impact of access to high nicotine concentration vapes on those trying to quit smoking and raised concerns that any change would make it harder for those people to remain smokefree.

A number also raised concerns that people may vape more to get an equivalent effect from their vape. Several stated that smokers need a higher nicotine percentage to come off smoking.

Some submissions from this group stated that the proposed change could negatively impact the smokefree goal as it could cause smoking levels to increase. Some submissions from this group stated that addressing youth vaping should not be prioritised over supporting adults to quit smoking.

Tobacco manufacturer, importer or distributor

Supported the proposal

Of the 26 respondents who indicated they represented a tobacco manufacturer, importer or distributor, only three (11.54%) supported the proposal. Of those three, comments showed support for the clarity that would be provided around how nicotine limits apply to nicotine salt-based substances.

One submitter from this group indicated that it is not always possible to identify the nicotine level within a nicotine salt and said it was not clear how the 28.5 mg/mL limit was determined. This respondent suggested it may be simpler to maintain the 50 mg/mL limit but clearly state that this limit applies to the nicotine salt strength. The respondent gave an example of possible wording for the regulations as: 'If the nicotine in a vaping substance is in the form of a nicotine salt, then the nicotine salt (and not the nicotine component alone) must not exceed a strength of 50 mg/mL'.

One respondent from this group noted they take their obligations under the Act seriously and want to be confident in their compliance with the Act. The respondent felt the regulations should clearly identify whether the proposed amendment would replace the existing limit of 50 mg/mL. They also requested clarification on labelling

requirements if the proposed limit were introduced, especially in cases where the nicotine concentration may not be known.

Opposed the proposal

Of the 26 respondents who indicated they represented a tobacco manufacturer, importer or distributor, 88.46% (23) did not support the proposal. Of that group, many were concerned the proposed nicotine concentration of 28.5 mg/mL would limit attempts to quit smoking.

Some submitters from this group agreed the current limit of 50mg/mL is too high but believed the proposed 28.5 mg/mL is too restrictive and limits consumer choice. Some suggested setting the limit at 35 mg/mL or 40 mg/mL instead.

Some raised concerns about loss of business if these changes were implemented.

Vaping or smokeless tobacco product retailer, distributor or manufacturer

The vast majority of respondents representing vaping or smokeless tobacco product retailers, distributors and manufacturers did not support the proposal (428 out of 455 from this respondent type).

Supported the proposal

Twenty-six submitters from this group supported the proposal and generally felt the proposal is a minor change to the regulations that will improve clarity for everybody and aligns with the intent of the legislation that was introduced in 2021.

Some supported a lower nicotine concentration as they felt this would be less addictive and noted there is no need for vapes to have a higher nicotine strength than that available in cigarettes. Some noted they have seen customers who were never tobacco customers purchasing higher nicotine products and were concerned by the high number of young people consuming vapes. They noted that non-smokers and young people taking up vaping goes against the intention of vapes being introduced as a cessation tool for smokers.

Opposed the proposal

Submitters from this group who disagreed with the proposal frequently commented that customers who purchased '3% or 4% nicotine strength' were ex-smokers who used vaping as a cessation tool. They were concerned that ex-smokers might return to smoking if they could not purchase nicotine at this strength.



One submitter from this group commented that the proposed change could reduce the efficacy of vaping products and have negative consequences, particularly before the very low nicotine cigarette policy comes into force in 2025. This submitter called for a delay on implementing any reductions to current nicotine limits.

Many submitters from this group were also business owners and raised concerns about losses to their business, stating that most of the products they sold had a higher strength than 28.5 mg/mL. However, others stated that consumers might need to purchase more vaping products to compensate for the lower level of nicotine.

Many noted there have been a lot of regulatory changes recently and feared further changes would have negative implications for their businesses. Some said they would need to discard large amounts of product that are above the proposed limits. One commented that having a number of different nicotine limits would make the environment unwieldy for both regulators and consumers.

Some stated that vaping is a personal choice and suggested people should be able to buy whatever nicotine strength they chose. Some stated that consumers may turn to a black market to purchase vapes with higher nicotine strengths. Some also felt crime might increase as a result of the proposed changes.

Some stated there have been too many regulatory changes in a short time, and it would be difficult for retailers and consumers to adjust quickly. One submission stated that the proposed changes would be confusing for consumers, who might not understand the difference between freebase nicotine and nicotine salts. They suggested suppliers should be required to state the strength for nicotine salts, not the freebase nicotine strength in a product containing nicotine salt.

Further feedback and suggestions

Some individual submissions that didn't support the proposal suggested other issues should be prioritised. Some suggested that selling vape products to underage people should be addressed, and the focus should be on age confirmation and regulation of industry. Further to this, some suggested that only specialist stores should be able to sell vape products, and others recommended harsher penalties for those selling to underage people. Some submitters suggested addressing other societal issues, such as alcohol and caffeine use, domestic violence, child poverty and food issues.

A number of submitters expressed frustration around people who use vaping as a tool to stop smoking being penalised in order to address youth vaping. Some commented that personal accountability, parental responsibility and education were key in addressing youth vaping. Several responses commented that the general public is paying for the government's shortcomings in regard to reducing youth vaping and expressed doubt that this proposal would address youth vaping rates.

Some submitters raised concerns about the potential impact on smokefree programmes that encourage smokers to switch to vaping. A number called for vaping products not to be changed further and to focus on the smokefree goal instead.

Some submitters also noted that their preferred flavour isn't available in lower strengths and recommended increased availability of low nicotine and nicotine-free options. Some submitters also emphasised the importance of accurate labelling and of providing more information on ingredients. Another key recommendation was that any changes be communicated clearly.

A small number of submitters commented on manufacturers' ability to dilute the nicotine content of vape products. Others commented that the strength required for the ice range needed to be stronger to achieve the same impact. Some submitters suggested removing any limit on nicotine strength.

Many submissions from retailers mentioned freedom of choice, lack of evidence supporting the proposal and wasting time and resources as key concerns. Some felt other issues should be addressed instead, such as puff count and vape flavours that appeal to children. Some felt parents should take responsibility for their children and teach them the harms of nicotine products. Some submissions suggested making vapes available by prescription only or only through smoking cessation providers.

Retailer submissions also made several suggestions, including keeping high nicotine vape products at specialist vape retailers only and switching the focus to funding quit smoking/vaping programmes to make it easy and free for people to quit. Other suggestions included subsidising retailers impacted by changes and stricter punishment of retailers that sell to underage people.

One submission from an advocacy group recommended the consultation be postponed in favour of a more robust review of evidence, including engagement with a technical advisory group to understand how products deliver nicotine and how people use products to manage withdrawal. Another submitter from this group felt Manatū Hauora needed to be able to adjust nicotine limits as new evidence became available.



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