



# Cabinet

## Minute of Decision

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### Nicotine Concentration in Reusable Vaping Products: Proposed Amendments to Smokefree Regulations

Portfolio                      Health

On 17 July 2023, Cabinet:

- 1        **noted** that Manatū Hauora has consulted on a proposal to regulate the maximum allowable nicotine concentration in reusable vaping products containing nicotine salt and to amend the Smokefree Environments and Regulated Products Regulations 2021 (the Regulations) to bring this proposal into effect;
- 2        **noted** that feedback from clinical professional groups and non-governmental organisations were mainly supportive of the proposal, and that some wished to see even lower allowable nicotine concentrations in vaping products;
- 3        **noted** that the majority of industry stakeholders, and individual submitters, did not support the proposal;
- 4        **agreed** that setting the maximum allowable nicotine concentration at 28.5mg/mL for reusable vaping products that contain nicotine salts will support the continued use of vaping products as a smoking cessation tool to reduce smoking related harm, while reducing the risk of addiction and subsequent potential harm associated with the use of vaping products to young people;
- 5        **agreed** to amend clause 15 of the Regulations to state that for reusable vaping products that contain nicotine salts, the maximum allowable nicotine concentration is set at 28.5 mg/mL;
- 6        **noted** that the amended clause 15 is expected to be submitted to Cabinet on 31 July 2023 as part of the suite of new smoked tobacco and vaping regulations (the proposed Smokefree Environments and Regulated Products Regulations 2023);
- 7        **invited** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to the above paragraphs;
- 8        **authorised** the Minister of Health to approve any necessary consequential changes to the Regulations and other minor and technical amendments as required.

Rachel Hayward  
Secretary of the Cabinet

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Office of the Minister of Health

Chair, Cabinet

### **Amending the Smokefree Regulations: Nicotine concentration in reusable vaping products**

#### **Proposal**

- 1 This paper seeks agreement on how nicotine levels for vaping products are expressed in the Smokefree Environments and Regulated Products Regulations 2021 (the Smokefree Regulations).

#### **Relation to Government priorities**

- 2 This regulatory proposal will strengthen the regulation of vaping products. This contributes to the Smokefree Aotearoa 2025 goal and other Government priorities: namely empowering Māori to achieve better health outcomes, improving equity for Māori and Pacific peoples, and improving child and youth wellbeing.

#### **Executive summary**


- 3 Under the Smokefree Environments and Regulated Products Act 1990, vaping products must meet product safety requirements. These requirements are set out in the Smokefree Regulations and include maximum allowable nicotine strengths for vaping products.
- 4 To address concerns over the way nicotine concentration is expressed in the Smokefree Regulations, and how this is understood by suppliers, Manatū Hauora recently consulted on a proposal to amend clause 15 of Schedule 5 to always refer to the maximum nicotine concentration of a vaping product, rather than the maximum nicotine salt concentration. For reusable vaping products that contain nicotine salts, the consultation proposed that the *maximum allowable nicotine concentration is set at 28.5mg/mL*. This proposal is closer to the maximum nicotine level in the European Union, United Kingdom and Canada (ie, 20 mg/mL).
- 5 The majority of clinical professional bodies and non-governmental organisations who responded to the consultation supported the proposal and/or wanted nicotine concentrations to be even lower. Most industry stakeholders did not support the proposal. Approximately three thousand submissions opposing the proposal were received from individuals, some of whom were incentivised by a vape company offering free vapes to those who responded. Minimal feedback was received to suggest different wording to what was proposed in the consultation.

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6 I recommend that the maximum allowable nicotine concentration is set at 28.5mg/mL for reusable vaping products that contain nicotine salts and that clause 15 of Schedule 5 of the Smokefree Regulations be amended accordingly.

7 s 9(2)(g)(i)



**Background**

8 The Smokefree Environments and Regulated Products Act 1990 requires manufacturers and importers to notify the Ministry of Health of their intention to sell vaping products and smokeless tobacco products before the products can be sold in New Zealand.

9 As part of the notification requirement, these products must also meet safety requirements. These requirements are set out in the Smokefree Regulations and include maximum allowable nicotine strengths for vaping products.

10 The nicotine strength of vaping products containing nicotine salts is set out in clause 15 of the Smokefree Regulations and states that *the strength of nicotine salt in a vaping substance must not exceed 50mg/mL*.

11 There has been dispute, which is the subject of judicial review by one of the major vaping product suppliers, as to whether the existing regulation restricts the concentration of nicotine salt or the concentration of nicotine in products that contain nicotine salts.

12 Manatū Hauora has taken the view that clause 15 refers to the concentration of the nicotine salt. Some industry members have understood clause 15 differently, as a reference to the concentration of freebase nicotine in a vaping substance. This difference in understanding makes a material difference to the overall amount of nicotine permitted in a vaping product, resulting in some more highly addictive products currently available for sale.

13 To address this situation, and consistent with the Government's objective of reducing youth vaping, Manatū Hauora held a two-week targeted consultation from 12 to 26 June 2023 on a regulatory proposal to limit the nicotine concentration levels in vaping products containing nicotine salts (rather than limit the strength of the nicotine salt itself, as per current drafting), and to set the concentration of nicotine in reusable products containing nicotine salt at 28.5mg/mL.

14 Subject to Cabinet's policy approval, I intend to include the amended Regulation in the broader suite of smoked tobacco and vaping regulations going to Cabinet on 31 July 2023 for authorisation to submit to the Executive Council.

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### The regulatory proposal

- 15 The consultation document proposed that the wording of clause 15 of the Smokefree Regulations is amended to refer to the maximum nicotine concentration of a vaping product, rather than the maximum permitted nicotine salt concentration. For reusable vaping products that contain nicotine salts, it is proposed that the *maximum allowable nicotine concentration is set at 28.5 mg/mL*.
- 16 This concentration level of 28.5mg/mL is intended to give enough of a 'nicotine hit' so that people who smoke can use vaping as a smoking cessation tool, while minimising harm to young people by ensuring that these products do not have excessive levels of nicotine.
- 17 This proposal only applies to reusable vaping products. Cabinet has already agreed to amend the nicotine concentration in disposable vapes [CAB-23-MIN-0182]. Information held by the Vaping Regulatory Authority indicates that the proposal is likely to result in less than 5% of the products currently available on the market in New Zealand having to be removed. This means that many vaping products containing nicotine will still be available to people using vaping as a smoking cessation tool.

### Consultation

- 18 An email invitation to make a submission on this consultation was sent to 194 businesses, clinical professional bodies and non-governmental organisations. Of this group, 20 made submissions. Overall, 4731 submissions were received.
- 19 Some of those directly invited to submit encouraged others to also submit. For example, Manatū Hauora is aware of one business providing its customers with a link to the consultation and offering to give a free vape to anyone who made a submission.
- 20 I am disappointed, but not surprised, that free vapes have been offered to encourage people to submit. As the email invitation was targeted, this has resulted in a lack of balance in submissions received.

### Consultation findings

- 21 Generally, people supporting the proposal often did so because they thought nicotine strengths would go down even further (eg, a number of submitters wanted to see nicotine concentration reduced to 20mg/mL in line with the European Union), and those who did not support the proposal often did so because they wanted to continue to be able to purchase higher strength products.
- 22 Key themes that emerged from the submissions included a concern from vapers and ex-smokers that they would have to use lower strength products that would cause them to return to smoking, lessen the effectiveness of vaping as a cessation device, and infringe on their freedom of choice. However, some submissions from vapers and ex-smokers supported the

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proposal as they felt that the proposed concentration was appropriate for those attempting to use vaping as a cessation tool.

- 23 Submissions from key non-governmental organisations, academics and health professionals were mainly in favour (eg, Cancer Society, ASPIRE group, Stroke Foundation, Royal New Zealand College of General Practitioners) or were opposed because they thought the proposals were not going far enough (Asthma Foundation\*, Thoracic Society, Hāpai te Hauora). s 9(2)(ba)(i) opposed the proposal due to concerns regarding the effectiveness of vapes as a quit smoking tool at lower concentrations.
- 24 A large number of retailers raised concerns that the proposal would negatively impact their business and frequently commented that proposed changes would be confusing for customers and criticised the frequency of recent regulatory changes. Other retailers supported the proposal and specifically supported further regulation of vape products and the vaping industry.
- 25 Submissions from manufacturers and distributors and industry associations were nuanced. Some were strongly opposed, while others s 9(2)(ba)(i) sought clarity of the law and were concerned about transitional periods for example. Some submissions from this group showed support for the proposal, specifically for improved clarity and stronger alignment with the existing legislation.
- 26 The proposal did not seek views on whether the nicotine levels should be increased or lowered, rather that stakeholders supported or opposed the wording of the proposal itself, that is, that the maximum allowable nicotine concentration is set at 28.5mg/mL. No submitters provided feedback to suggest different wording to what was proposed, although some proposed reducing the maximum nicotine concentration to 20mg/mL.

### Recommendation

- 27 I propose that clause 15 is amended to reflect the consultation proposal that the *maximum allowable nicotine concentration for reusable vaping products containing nicotine salts is set at 28.5mg/mL.*
- 28 In doing so I have had regard to the submissions, including continuing to support the use of vaping products as a smoking cessation tool to reduce smoking related harm, while managing other risks associated with the use of vaping products, including addiction risks and minimising other potential health risks associated with use of the products. Vaping rates are highest for Māori youth, and Māori girls in particular (25.2% daily vaping in 2022 for 14-15 year-olds), so this is especially important in protecting the health and wellbeing of our young people by reducing the addictiveness of reusable vaping products.
- 29 Concerns have been raised that 28.5mg/mL is an insufficient level to support people who smoke to transition to vaping products and a higher concentration is required to get a 'nicotine hit' that is more comparable to smoking a cigarette. Based on overseas experience where lower concentrations are common (such as in the United Kingdom, Canada and the European Union),

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\*Addendum at time of proactive release: the Asthma Foundation is referred to here in error; the submission was from an individual.

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and the benefit of reducing addiction risk and the uptake of vaping by both youth and non-smokers with its attendant risks, I consider that 28.5mg/mL is an appropriate level. The government will continue to monitor these settings and will consider whether any adjustments are needed later this year.

- 30 I am satisfied that this balances the Government's intent to ensure that adults wishing to stop smoking have access to a less harmful product, while protecting our young people from becoming unnecessarily addicted to these products.

### Cost-of-living Implications

- 31 The proposals in this paper have no cost of living implications.

### Financial implications

- 32 The fiscal impact of this change is unknown given the existing level of analysis, although likely to be minor. However, there will be a cost to industry in adapting products to meet the amended requirements (eg, labelling and packaging).
- 33 Officials will undertake work to incorporate this change and other actions intended to reach Smokefree 2025 into the Treasury's tobacco excise revenue forecast at PREFU 2023.

### Impact analysis

- 34 The Treasury's Regulatory Impact Analysis team has determined that this proposal is exempt from the requirement to provide a Regulatory Impact Statement on the grounds that it has been addressed by existing impact analysis [CAB-21-MIN-0167 and RIS].

### Population implications

- 35 The Smokefree Regulations must align with the purposes of the Smokefree Act to minimise harm, especially to children and young people, and contribute to Government fulfilling its Te Tiriti o Waitangi obligations of improving equity of health outcomes.
- 36 Vaping rates are highest for Māori youth, and Māori girls in particular (25.2% daily vaping in 2022 for 14-15 year-olds). 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. Cabinet has already agreed to limiting the amount of nicotine in disposable vapes [CAB-23-MIN-182]. This proposal to set the amount of nicotine in reusable vapes at 28.5mg/mL will extend protection to all youth from the highest levels of nicotine, reducing the likelihood of nicotine addiction, while at the same time still enabling smokers to switch to a less harmful product.

**Human rights**

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

**Use of External Resources**

38 Manatū Hauora has engaged a small number of contractors since 2020/21 to assist with the Smokefree work programme. Since 1 July 2023 Smokefree policy-related work has been undertaken by fixed-term and permanent staff.

s 9(2)(h)

**Consultation**

40 The Ministry of Foreign Affairs and Trade, the Crown Law Office and the Parliamentary Counsel Office have been consulted. The Treasury and the Department of the Prime Minister and Cabinet were informed.

**Communications**

41 The Ministry will communicate the changes directly with stakeholders in August 2023 following Cabinet approval of the broader suite of Smokefree Regulations.

**Proactive release**

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



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### Recommendations

I recommend that Cabinet:

- 1 **note** that Manatū Hauora has consulted on a proposal to regulate the maximum allowable nicotine concentration in reusable vaping products containing nicotine salt and amend the Smokefree Environments and Regulated Products Regulations 2021 to bring this decision into effect
- 2 **note** that feedback from clinical professional groups and non-governmental organisations were mainly supportive of the proposal and some wished to see even lower allowable nicotine concentrations in vaping products
- 3 **note** that the majority of industry stakeholders, and individual submitters, did not support the proposal
- 4 **agree** that setting the maximum allowable nicotine concentration at 28.5mg/mL for reusable vaping products that contain nicotine salts supports the continued use of vaping products as a smoking cessation tool to reduce smoking related harm, while reducing the risk of addiction and subsequent potential harm associated with the use of vaping products to young people
- 5 **agree** to amend clause 15 of the Smokefree Environments and Regulated Products Regulations 2021 to state that for reusable vaping products that contain nicotine salts, the maximum allowable nicotine concentration is set at 28.5 mg/mL
- 6 **note** that the amended clause 15 will be submitted to Cabinet on 31 July 2023 as part of the suite of new smoked tobacco and vaping regulations (the Smokefree Environments and Regulated Products Regulations 2023)
- 7 **agree** to authorise the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to recommendation 5
- 8 **authorise** the Parliamentary Counsel Office to make necessary consequential changes to the regulations and other minor and technical amendments as required

Authorised for lodgement

Hon Dr Ayesha Verrall

Minister of Health

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