

Hahahahahahahahahahahahah

133 Molesworth Street PO Box 5013 Wellington 6140 New Zealand T+64 4 496 2000

10 November 2023

Morris Lazootin

By email: fyi-request-24188-cc8a5ed0@requests.fyi.org.nz

Ref: H2023031848

Tēnā koe Morris

# Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 21 September 2023 for information regarding the flavour names listed in Schedule 4A of the Smokefree Environments and Regulated Products Amendment Regulations 2023 (the Regulations). You requested:

- "1. Details on the rationale behind the creation of this list.
- 2. Criteria or factors that determined the inclusion or exclusion of specific flavours.
- 3. Information about the individual(s) or entity/entities responsible for finalising this list.

I would appreciate any relevant communications, discussions, and documents that could provide insight into these queries."

In response to questions 1 and 2, Manatū Hauora intends to proactively release key documents relating to the Regulations on the Manatū Hauora website. This will include Cabinet material, briefings, copies of submissions and other decision documents: <a href="https://www.health.govt.nz/about-ministry/information-releases">www.health.govt.nz/about-ministry/information-releases</a>. As the requested information will soon be publicly available, your request is therefore refused under section 18(d) of the Act. However, please see the email correspondence attached which is relevant to question one and two and is not going to be a part of the proactive release.

Please note, the overarching rationale for specifying generic flavour names in the regulations is to limit the flavour descriptions, so flavour names that are appealing to young people cannot be used. This includes names of candy brands, cocktails, soft drinks, energy drinks, and words that are not flavours such as rainbow or burst. Manatū Hauora is not regulating vape flavours or flavour ingredients, rather these are a labelling requirement.

In response to question 3, Manatū Hauora staff, including the policy and regulation team, undertook the analysis and collation of the initial list, and continued to refine and review against specified criteria before the final list was approved by the Director-General of Health.

Please note that legal advice and documents which come under the scope of all three questions are withheld under section 9(2)(h) of the Act, to maintain legal professional privilege.

As you may be aware, on 1 October 2023 retailers of notifiable products must have notified the Director General that they sell notified products at retail. From 21 October 2023, New Zealand Manufacturers and importers of notifiable products must notify vaping products that use permitted flavour descriptions. As per the Smokefree Environments and Regulated Products Amendment Regulations 2023, section 10: A variant name on a vaping product must describe the actual flavour of the vaping product using only 1 or 2 flavour names listed in Schedule 4A. The limit on vaping flavours applies to all new vaping product notifications on and from 21 October 2023. Vaping products that do not comply with those limits must not be sold on and from 21 March 2024.

Retailers, manufacturers and importers must also only notify vaping products that meet product safety requirements including nicotine limits, removeable batteries, child safety mechanisms, and labelling requirements.

For more information on vaping regulation and dates of its implementation, please use the following link: <a href="https://www.health.govt.nz/system/files/documents/pages/hp8804-vaping-regs-timeline.pdf">www.health.govt.nz/system/files/documents/pages/hp8804-vaping-regs-timeline.pdf</a>.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: <a href="mailto:oiagr@health.govt.nz">oiagr@health.govt.nz</a>.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: <a href="mailto:info@ombudsman.parliament.nz">info@ombudsman.parliament.nz</a> or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: <a href="www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests">www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests</a>.

Nāku noa, nā

Jane Chambers

Group Manager, Public Health Policy and Regulation Public Health Agency | Te Pou Hauora Tūmatanui

Appendix 1: List of documents for release

#	Date	Document details	Decision on release		
1	27 June 2023	Email correspondence: Draft Flavour Wheel	Released with some		
1A	N/A	Email attachment: SERPA Flavour Wheel	information withheld under section 9(2)(a) of the Act, to		
2	22 October 2023	Email correspondence: Flavour Wheel	protect personal privacy		
2A	N/A	Email attachment: The role of flavors in attractiveness of electronic cigarettes	Publicly available: https://edepot.wur.nl/537112		
3	24 August 2023	Email correspondence: Ice memo/unintended consequence and managing queries			
3A	29 August 2023	Email attachment: Memo – Policy decision taken to exclude synthetic cooling agents from approved flavours for vaping products	Released with some information withheld under		
3B	N/A	Email attachment: Audit trail to Memo – Policy decision taken to exclude synthetic cooling agents from approved flavours for vaping products	section 9(2)(a) of the Act, to protect personal privacy		
4	27 February 2023	Email correspondence: Vaping submission			
4A	N/A	Email attachment: Whitehall- smokefree-environments- regulations-submission- form_feb_2023.pdf			

That means I'm not sure how we deal with it. I think it's a difficult thing we need to make a decision about. It may not fit well in the wheel, but I don't think we can ignore it. Manufacturers will want or likely find someway to refer to it. It might be better to have it as one of the two flavour descriptors.

From: s 9(2)(a) @health.govt.nz> Sent: Tuesday, 27 June 2023 10:58 am To: s 9(2)(a) @health.govt.nz>; s 9(2)(a) @health.govt.nz>; s 9(2)(a) @health.govt.nz> Cc:s 9(2)(a) @health.govt.nz>; s 9(2)(a @health.govt.nz>; s 9(2)(a) Subject: RE: Draft Flavour Wheel - some feedback His 9(2)(a) Does that mean you support it not being included? Thanks, s 9(2)(a) @health.govt.nz> From: s 9(2)(a) **Sent:** Tuesday, 27 June 2023 9:06 am @health.govt.nz>,s 9(2)(a) To: s 9(2)(a) @health.govt.nz>; s 9(2)(a) @health.govt.nz>s 9(2) @health.govt.nz>

Just adding to the discussion on ice – this is not usually a mint/menthol flavour – just a cooling effect. It is extremely popular with youth. It acts in a similar way to menthol tobacco to mask somewhat the harshness of the nicotine. It might not be considered a flavour, but more of an effect.

@health.govt.nz>; s 9(2)(a)

@health.govt.nz>

Cc: s 9(2)(a)

@health.govt.nz>; s 9(2)(a)

**Subject:** RE: Draft Flavour Wheel - some feedback

 From: § 9(2)(a)
 @health.govt.nz>

 Sent: Tuesday, 27 June 2023 8:14 am

 To: § 9(2)(a)
 @health.govt.nz>; § 9(2)(a)

 @health.govt.nz>;
 \$ 9(2)(a)
 @health.govt.nz>; § 9(2)(a)

 Cc: § 9(2)(a)
 @health.govt.nz>; § 9(2)(a)

 Subject: RE: Draft Flavour Wheel - some feedback

### Thanks s 9(2)

- 1. We specifically took out drinks other than coffee and tea, but if you think cola is needed then we could add it back in by changing the category to Drinks my concern with that is that we could get a lot of requests to add in other drinks as well. We wouldn't necessarily add them in but we'd need to respond to a lot more requests. I've added passionfruit, oat (renaming Nuts to Nuts & Grains) and sweet.
- 2. We excluded ice as it isn't a flavour. If they have to ensure the name accurately describes the flavour then we shouldn't allow things that don't have a flavour. They can presumably use a mint flavour instead of ice.
- 3. Yes definitely. I think we've decided that they can choose one flavour name or a combination of two flavour names for each variant.
- 4. I think we should allow people to request additional flavours but not additional categories so if the flavour they want doesn't fit within the listed categories then we won't consider it.

I've attached a link to the updated version of the flavour wheel in case anyone has any further feedback.

Cheers,

#### s 9(2)(a)

```
From: s 9(2)(a) @health.govt.nz>
Sent: Monday, 26 June 2023 9:00 pm

To: s 9(2)(a) health.govt.nz>; s 9(2)(a)
@health.govt.nz>; s 9(2)(a) @health.govt.nz>; s 9(2)(a)

@health.govt.nz>
Cc: s 9(2)(a) @health.govt.nz>; s 9(2)(a)

@health.govt.nz>; s 9(2)(a)

@health.govt.nz>; s 9(2)(a)

@health.govt.nz>
Subject: RE: Draft Flavour Wheel - some feedback

Hi s 9(2)(a)
```

I have taken a look at the flavour wheel document. I think it looks pretty good really, but I have a couple of questions/comments:

- 1. I have done a quite unscientific survey of websites.... I think that the wheel has most things that we would want. A couple of things to consider adding Cola, passionfruit, some sort of cereal/granola/oat flavour name, generic 'sweet.'
- 2. Also 'Ice' —We haven't got it as a descriptor, and it is a very popular descriptor. However, I understand that 'ice' can be added in a way that is essentially flavourless. I wasn't sure if this was purposeful?
- 3. I think that the flavour wheel document would need to specify how people use it. For example, the fact that there can only be a maximum of two chosen (if this is what we are saying)
- 4. Are we having a process / some way that people can request a flavour be added to the wheel? We haven't really talked about this... it just says that the Ministry will publish.

Regards,

s 9(2)

From s 9(2)(a) @health.govt.nz>

Sent: Tuesday, 20 June 2023 11:12 am

To: s 9(2)(a) <a href="mailto:@health.govt.nz">@health.govt.nz</a>; s 9(2)(a) <a href="mailto:@health.govt.nz">@health.govt.nz</a>;

s 9(2)(a) <u>@health.govt.nz</u>>; s 9(2)(a)

@health.govt.nz>

**Cc:** s 9(2)(a) <u>@health.govt.nz</u>>; s 9(2)(a)

@health.govt.nz>;s 9(2)(a)
@health.govt.nz>

Subject: RE: Draft Flavour Wheel

Hi,

We did some more work on the flavour wheel and would appreciate any thoughts/feedback on this version: SERPR Flavour Wheel.xlsm Refer to Document 1A

Thanks,

s 9(2)(a)

From: s 9(2)(a)

Sent: Thursday, 18 May 2023 6:31 pm

To: s 9(2)(a) @health.govt.nz>; s 9(2)(a)

@health.govt.nz>;s 9(2)(a)
@health.govt.nz>

Subject: RE: Draft Flavour Wheel

Here's the updated flavour wheel now the macros are working again.

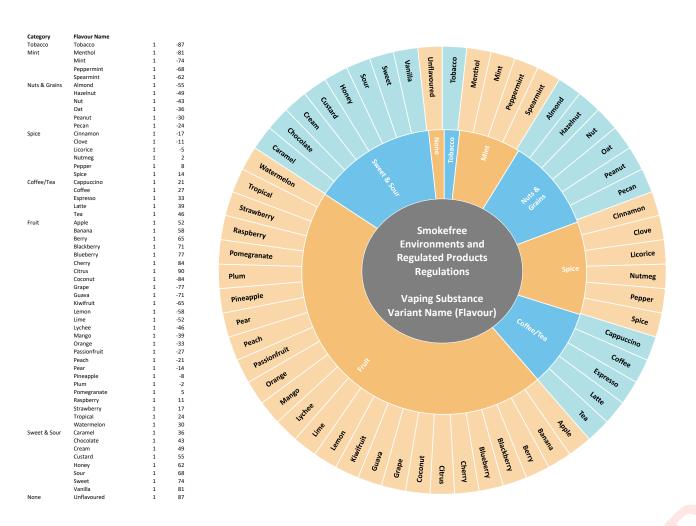
From: s 9(2)(a)

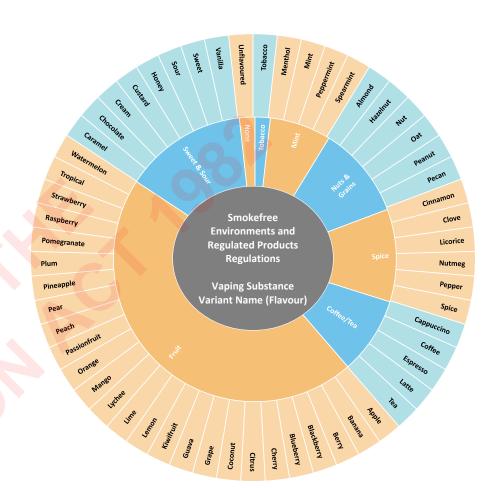
Sent: Wednesday, 17 May 2023 11:08 am

To:s 9(2)(a) <a href="mailto:@health.govt.nz">@health.govt.nz</a>; s 9(2)(a)

@health.govt.nz>; s 9(2)(a)
@health.govt.nz>

Subject: Draft Flavour Wheel





Category
Tobacco
Mint
Nuts & Grains
Spice
Coffee/Tea
Fruit
Sweet & Sour
None

From: @health.govt.nz> s 9(2)(a)

Sent on: Friday, October 20, 2023 3:36:40 AM

To: @health.govt.nz> s 9(2)(a)

**Subject:** FW: Flavour wheel

**Attachments:** Thesis\_Krusemann\_complete.pdf (3.48 MB)



# Refer to Document 2A

Thesis Krusemann c omplete.pdf

From: s 9(2)(a) @hc-sc.gc.ca>

Sent: Saturday, 22 October 2022 1:11 am

To: s 9(2)(a) @health.govt.nz> Cc: s 9(2)(a) @health.govt.nz>

**Subject:** Flavour wheel

See chapter 2, attached, thesis for the flavour wheel I was referring to

Warm regards,

s 9(2)(a)

@health.govt.nz> De: s 9(2)(a)

Envoyé: 2022-10-17 16:34

À:s 9(2)(a) @hc-sc.gc.ca> @health.govt.nz> Cc : s 9(2)(a)

Objet: vaping product packaging

Dear s 9(2) I hope all is well with you.

With our legislation progressing through Parliament, we are turning our minds to regulations. In addition to the regulations needed to implement the smoked tobacco Bill, we considering options to tighten up the regulation of vaping products as youth uptake continues to rise, causing a fair amount of concern in some quarters. Subject to the Bill passing in December, we will be publicly consulting on regulatory proposals in February.

We would be keen on meeting to hear about your experience with your regulatory requirements – primary in relation to packaging, including product or flavour names. I'm not sure that we are entirely up to date with the work you have done in this area, but we would be interested in hearing what you have in place or are considering, as well as whether compliance and enforcement has been a challenge.

And we'd be happy for a general catchup – it's been a while.

Regards

s 9(2)(a)

s 9(2)(a)

Policy and Regulation

s 9(2)(a)

sally.stewart@health.govt.nz

Public Health Agency | Te Pou Hauora Tūmatanui Ministry of Health | Manatū Hauora 133 Molesworth Street Thorndon, Wellington 6011





\*

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From: s 9(2)(a)

Sent: Thursday, 24 August 2023 3:31 pm

To: s 9(2)(a) @health.govt.nz>

Cc: s 9(2)(a) @health.govt.nz>; s 9(2)(a) @health.govt.nz>

Subject: Ice memo/unintended consequence and managing queries

Kia ora s 9(2)(a)

Sorry to dump you with this but I haven't had time the last few days to get around to doing anything about this. We just need to update the memo to include a little bit about how the industry might react, what they are now required to do, and what the impact of this might be. § 9(2) has seen the memo and asked for more to be added about this.

I note we have already received a query about this to the vaping inbox -59(2) just mentioned.

I'm not familiar with the toxicological assessment, or what that means logistically, so can't really write up anything about it.

The risk I see is that we are in effect applying a new trade barrier to industry which is an unintended outcome of the regulations to restrict flavour names. We need to be able to explain what the industry needs to do and why. And probably justify why this is now a requirement when it wasn't something outlined in the consultation etc.

We need to be able to manage and respond to queries and challenges that will come from industry on this issue. might be able to give you a steer if you don't know where to start.

Can I leave that with you to work on? Run it by (2)(a) when you're done, and then update the memo a little to say what we've done.

Just noting it has gone on the webpage today so we will probably want to prepare something soon. I'm around for the arvo so let me know if you have any questions.

Link – Memo to GM on Policy decision taken to exclude synthetic cooling agents from approved flavours for vaping products from SERPR 2023.docx

Audit trail – Audit Trail - Memo to GM on Flavour Wheel.docx

s 9(2)(a) will then want to see the memo again before she signs it. You could also share the wording that is prepared for media queries.

Ngā mihi

s 9(2)(a)

Public Health Policy & Regulation

s 9(2)(a) y@health.govt.nz

Te Pou Hauora Tūmatanui I Public Health Agency Manatū Hauora, 133 Molesworth Street











# Memo

# Policy decision taken to exclude synthetic cooling agents from approved flavours for vaping products

Date:	29 August 202	3
То:	s 9(2)(a)	, Public Health Policy & Regulation
via:	s 9(2)(a)	, Tobacco Regulatory Authority Establishment
From:	s 9(2)(a) Tūmatanui	r Regulatory Products, Public Health Agency   Te Pou Hauora
For your:	Information	

# **Purpose of report**

- 1. This memo informs you of a policy decision taken to exclude non-menthol synthetic cooling agents, a popular additive, from the list of pre-approved flavours for vaping products.
- 2. It is to ensure the decision-making informing the regulatory changes is clear and transparent.

# **Background and context**

- 3. Following Cabinet decisions to regulate flavour descriptions for vaping products, the Smokefree Environments and Regulated Products Regulations 2021, (the Regulations), will include a list of approved flavour names for vaping products. This intends to reduce the appeal of vaping products to young people. This list will also be published on our website.
- 4. The Vaping Regulatory Authority (VRA) and Ope Ōpiki developed the vaping product variant (flavour) list this is a list of approved vaping product flavours, from which notifiers (manufacturers and importers) of vaping products will be able to select up to two flavour names to use as the variant name for their products. The list of flavours is a schedule to the Regulations, and is attached as Appendix one.
- 5. This paper discusses the decision to exclude common descriptors for synthetic cooling agents, such as 'ice', 'polar blast' and 'winter', from the flavour list.
- 6. The Smokefree Environments and Regulated Products Act 1990 (the Act) defines **flavour** as a clearly noticeable smell or taste, resulting from an additive or a combination of additives that is noticeable before or during the use of the product.
- 7. It is the position of the VRA and Ope Ōpiki that a non-menthol synthetic cooling agent is not a flavour, but rather it is an additive that causes a sensation when added to vaping products.



# Current use of synthetic cooling agents as an ingredient in products

- 8. Evidence is still being developed about potential health risks from synthetic cooling agents. This is a developing area, and it remains difficult to identify any appropriate regulation.
- 9. Ice, as a description can be used to describe a mint or menthol flavour (which are flavour names on the proposed list), or it can be used to indicate a synthetic cooling ingredient that has no discernible flavour.
- 10. These cooling agents were developed with external uses in mind (eg, shaving foams) but are used in vaping products to create a cooling sensation for users, similar to that experienced with menthol chewing gum.
- 11. Their presence in vaping products is commonly indicated with wording such as 'ice', 'polar blast', and 'winter'. It can appeal to young people, as the cooling sensation commonly masks the harshness of high nicotine concentrations. Inexperienced vapers may therefore be likely to be able to tolerate higher nicotine concentrations if they contain a cooling agent.
- 12. Synthetic cooling agents can also be purchased separately and added in small amounts to other vaping liquids. This is available in Aotearoa but is much more common internationally.
- 13. It is also noted that vaping products available internationally widely use these chemicals, most of which are sold as fruit-ice hybrid flavours, and that they are popular with youth.<sup>2</sup>

# Decision to exclude synthetic cooling descriptors from permitted flavour names

- 14. The VRA and the PHA Ope Opiki policy team agreed to exclude synthetic cooling descriptors as permitted flavour names on 29 June 23. This is because synthetic cooling descriptors are not flavours, but rather adjectives that are used to describe a sensation.
- 15. This decision is supported by marketing material from manufacturers and vaping substance suppliers, who promote WS-23 (the most commonly used synthetic cooling agent) as odourless and tasteless.<sup>3</sup>
- 16. Biochemically, a cooling agent exerts its effect by interacting with temperature-sensitive receptors in the body, independently from any effects on taste receptors.<sup>4</sup>
- 17. Despite wide-ranging bans on flavouring agents in the U.S and several European jurisdictions, synthetic cooling agents are identified as potential loopholes due to their flavourless profile.<sup>5</sup>
- 18. Mint, menthol, and similar flavour names have been included in the list, for products that have those flavours.

<sup>&</sup>lt;sup>1</sup> https://tobaccocontrol.bmj.com/content/early/2022/04/27/tobaccocontrol-2021-057073

<sup>&</sup>lt;sup>2</sup> https://bmjopen.bmj.com/content/13/3/e068466 & https://academic.oup.com/ntr/article/25/3/524/6995393

https://www.taimacn.com/product/WS-23-Cooling-Agent.html, https://darkstar.co.uk/blogs/darkstar-blog/ws-23-everything-you-need-to-know & https://flavorjungle.com/products/ws23?variant=39650681454650

http://www.afinitica.com/arnews/sites/default/files/techdocs/Menthaol%20article.pdf

https://img.perfumerflavorist.com/files/base/allured/all/document/2014/02/pf.PF 39 03 034 10.pdf

https://academic.oup.com/ntr/article/24/7/1037/6528985

- 19. The new regulations require accurate flavour descriptions to be shown on the product and its packaging using only 1 or 2 approved flavour names from the published list, so 'raspberry ice; or 'iced raspberry', for example, would not be permitted as a variant name regardless of whether the product contains the cooling agent because 'ice' and 'iced' are not approved flavour names.
- 20. However, manufacturers may continue to use cooling agents in their products and may use words like 'ice' or 'iced', 'cold' colours, or depictions of ice or snow, for example, on their packaging to indicate this, provided labelling and packaging complies with all relevant requirements.
- 21. The PHA's view is that non-menthol synthetic cooling agents in vaping substances are non-flavour additives. The Regulations, therefore, require notifiers to carry out a toxicological risk assessment before including them in their products, and to be ready to explain their inclusion to the VRA, on behalf of the Director-General, if needed.
- 22. The policy intention of restricting variant names did not explicitly intend to exclude synthetic cooling agents from being a flavour. However, this is an unintended outcome of the regulatory amendments which may result in some products requiring additional regulatory assessment. Manatū Hauora will consider this further as part of its vaping policy review later this year and prepare materials for public communications should the media or industry raise this issue.

# **Risks and mitigation**

- 23. The vaping sector may frame the requirement to carry out a toxicological assessment as a trade barrier. The sector may also challenge this requirement on procedural grounds as it was not outlined in the proposed regulatory regime change consultation earlier this year. The consequence may be to impact on implementation of the Regulations.
- 24. The VRA does not believe these to be legitimate arguments as:
  - a. Notifiers are already expected to carry out toxicological risk assessments for all non-flavouring additives in products they have notified.
  - b. It is well-established that synthetic cooling agents such as WS-23 are flavourless, and the requirement for notifiers to carry out a toxicological risk assessment on non-flavour additives has been legislated since the introduction of the Regulations in 2021.
  - c. Toxicological information for WS-23 and other synthetic cooling agents are readily available from several manufacturers.
- 25. The VRA will publish guidance for the sector on this matter on its website to try and mitigate the risk of sector push-back.

## Recommendations

<sup>&</sup>lt;sup>6</sup> https://www.health.govt.nz/system/files/documents/publications/proposals for regulation - smokefree environments and regulated products act 1990 22 dec final.pdf



# Document 3A | Yang | Y

# It is recommended that you:

1.	Note	A policy decision was taken that non-menthol synthetic cooling agents (eg, 'ice') are to be excluded from the list of approved flavours for vaping products and will not be added if requested by industry as they do not meet the definition of flavour in the Act.	Noted
2.	Note	Schedule 5, clause 5 of the regulations requires notifiers to carry out a toxicological risk assessment for any additives other than flavours in a vaping substance, and to be ready to explain their inclusion to the Director-General if needed.	Noted

s 9(2)(a)

Signature \_ Date: 30 August 2023

s 9(2)(a)

Public Health Policy & Regulation
Te Pou Hauora Tümatanui | Public Health Agency





# **Appendix one: Vaping Substance Variant Name List**

Category	Flavour Name
Tobacco	Tobacco
Mint	Menthol
	Mint
	Peppermint
	Spearmint
Nuts & Grains	Almond
	Hazelnut
	Nut
	Oat
	Peanut
	Pecan
Spice	Cinnamon
	Clove
	Licorice
	Nutmeg
	Pepper
	Spice
Coffee/Tea	Cappuccino
	Coffee
	Espresso
	Latte
	Tea
Fruit	Apple
	Banana
	Berry
	Blackberry
	Blueberry
	Cherry
	Citrus
	Coconut
	Grape
	Guava
	Kiwifruit
	Lemon
	Lime
	Lychee
	Mango
	Orange

(continued)

Passionfruit
Peach
Pear
Pineapple
Plum
Pomegranate
Raspberry
Strawberry
Tropical
Watermelon
Caramel
Chocolate
Cream
Custard
Honey
Sour
Sweet
Vanilla
Unflavoured

# **Audit and Sign-Out Sheet**



Download and use the <u>correct template</u> from Te Whare and ensure it aligns with our <u>Communication Standards</u> to avoid delay sign-out/approval. Standard Director-General sign-out/approval turnaround is 48 hours. Please build this into your timeframes or talk to DGA if your paper is urgent or you have any other queries.

Title	Memo to Public Health Policy and Regulation Group Manager: Policy decision taken to exclude 'ice' from approved flavours for vaping products.				
Document type	Memo	Commissioned by	Manatū Hauora	Commissioned on	29/06/2023
Due	Select date	Primary contact	Matt Burgess	Reference	2
Pātengi location		Proactive release No number			
Parliment and autoration universal and blook if not needed					

Background and context for reviewers – Leave blank if not needed

It is a file note, and will be sent to DDG for noting, but does not require sign-off.

Audit and Sign Out – By signing below you confirm that you have fulfilled your responsibilities outlined on Page 2					
Role	Name	Title	Directorate/Agency	Date	Signature
Author	s 9(2)(a)	s 9(2)(a), Regulated Products	РНА	3/07/23	s 9(2)(a)
Peer reviewer		s 9(2)(a) , Compliance, Regulated Products	РНА	3/07/23	
Proof-reader		s 9(2)(a), Regulated Products	РНА	15/08/23	
SME		s 9(2)(a) Regulated Products	РНА	28/08/23	
Manager		s 9(2)(a) Regulated Products	РНА	29/08/23	
GM or equivalent		s 9(2)(a) , Public Health Policy & Regulation	РНА	30/08/23	

**Consultation** - You must consult where your document or advice may have an impact eg. with the Public Health Agency, Māori Health, Legal, Communications, Finance, Te Whatu Ora, Te Aka Whai Ora, Te Aho o Te Kahu, Whaikaha, or other relevant agencies, etc.

Role	Name	Title			Directorate/Ag ency	Date
Policy	s 9(2)(a)	S 9(2)(a) Ope Ōpiki, Public Health Policy & Regulation			РНА	15/08/23
					Select one	Select date
PARC Approval papers	– for all Cabinet papers	except APH	Name		Signature	

Group Manager Note		
	Noted	

# **Audit and Sign-Out Sheet**



#### By signing the Audit and Sign-Out Sheet you agree to have fulfilled the expectations and responsibilities below

Author	<ul> <li>Drafts high-quality advice that addresses the peer review and proof-reader points below</li> <li>Adheres to the Manatū Hauora Communications Standards and uses the correct template</li> <li>Considers whether additional consultation is required (see below)</li> </ul>
Peer Reviewer	• Reviews the advice for audience focus, readability, analysis, robust advice, and where necessary, checks that appropriate consultation has happened (see below)
Proof-reader	<ul> <li>Ensures that advice is properly formatted with no spelling/grammatical errors, that the correct template has been used, and the advice meets the Manatū Hauora Communications Standards</li> <li>This may be an EA/PA, the peer reviewer, or someone else</li> </ul>
Responsible Manager	<ul> <li>Ultimately responsible for the document and will have been involved in the commissioning, and is the person to whom the author, peer reviewer and proof-reader are responsible to.</li> <li>This may be a manager, or a Group Manager and it will be the person that your DDG, the DG, or a Minister, will turn to if they need to discuss the advice</li> </ul>
Accountable DDG or equivalent	<ul> <li>Is accountable for the process leading to the final product they sign-out</li> <li>May need to discuss the advice further with the Director-General or Minister(s)</li> </ul>
Consultation	<ul> <li>If applicable, relevant internal parties have been consulted, including finance, legal, policy, clinical, and communications</li> <li>If appliable, necessary external consultation has occurred and is included in paper where appropriate (ie. with Te Whatu Ora, Te Aka Whai Ora, Treasury, other government agencies)</li> <li>Does the document contain surprises for your DDG or the DG? If so, have they been consulted?</li> </ul>

#### Before you start your report - consider the following:

- 1. Why is it being provided is it in response to a request from the Minister or DG, or is it being done at our own initiative?
- 2. What's the context has there been recent public, political or sector interest in the report's subject matter?
- 3. Is this a regular briefing to the Minister or DG if so, what is normally included and what has the Minister previously asked be added?
- 4. Is it related to another piece of work, eg. a Cabinet paper, another report if so, what context should they know?
- 5. What degree of analysis is needed how much commentary do you need to provide?
- 6. Is the Minister or DG already relatively familiar with the subject matter?
- 7. Have you got the correct template (Aide-memoire, Health Report, DG or Minister Memo, Cabinet paper)?

#### Quality of the advice - what to include

- 8. A report should not simply summarise facts but provide Ministers or the DG with information they can use to understand the implications of decisions they're being asked to make. Only make recommendations if some action or decision is required.
- 9. The paper should:
  - meet the intended audience's needs and focus on the Minister or DG's use of material
  - tell a logical, compelling story that is easy to understand
  - be clearly written using active and direct language, and be as brief as possible
  - include information on the scope of the matter/problem
  - include information on risks (what could go wrong and how confident are we in our information?) and risk mitigation (how do we avoid things going wrong?)
  - include information on costs and data (if relevant)
  - contain action-orientated recommendations with no unnecessary noting recommendations
  - indicate who the Minister or DG will be meeting and what Ministry official(s) will be attending (if relevant)
  - contain clear next steps (including who is doing what and by when).

### **Proof-reading**

10. Is the paper consistent with the most recent Ministry's Communication Standards?

From: s 9(2)(a)

Sent: Monday, 27 February 2023 9:59 am

To: s 9(2)(a) @health.govt.nz>; s 9(2)(a)

@health.govt.nz>

Subject: RE: Vaping submission

Môrena, here's the other vape flavour article from the March 2023 issue. Just shows how complex the evidence is around flavours, which we may need to reference in the RIS.

Associations Between E-cigarette Use and E-cigarette Flavors With Cigarette Smoking Quit Attempts and Quit Success: Evidence From a U.S. Large, Nationally Representative 2018–2019 Survey | Nicotine & Tobacco Research | Oxford Academic (oup.com)

#### This one suggests:

- smokers that vape are more likely to make quit attempts/successfully quit
- users of flavoured vapes are more successful than unflavoured or tobacco flavoured vapes
- those who use mint or menthol are as successful as those who use other flavours (fruit/sweet) though they reference the other studies that have suggested these fruit/sweet flavours are more associated with success
- based on their findings they suggest removing flavours aside from mint and menthol would not harm smoking cessation but would remove youth appeal (possibly in conflict with the article I sent Friday about youth liking the cooling properties that menthol presents)
- they reference multiple surveys that suggest if flavours were restricted, a sizeable group of vapers would return to smoking
- limitations of the study include that they didn't really look at how type of vape device interacted with flavours and smoking cessation, and this is US based with a strong history of African American use of menthol flavour, which might make the findings less applicable to us.

And here's a highly relevant but small study looking at how youth perceive vape packaging.

<u>Vaping Flavors and Flavor Representation: A Test of Youth Risk Perceptions, Novelty Perceptions, and Susceptibility | Nicotine & Tobacco Research | Oxford Academic (oup.com)</u>

#### This found:

- middle schoolers (11-14) who view the fruit-flavoured vaping product with flavour colour and flavour image were more likely to consider it fun and interesting and were seen as more susceptible to trying vaping (compared to tobacco flavour colour and image or no colour and image)
- restricting flavour representation on packaging might reduce how fun and interesting youth perceive these products to be and how susceptible they are to using them
- limitations are that it was only 176 children
- they suggested additional research with adult smokers is needed to check how these changes would impact their behaviour. "Future research should also continue to investigate other approaches not tested in this study, such as restricting the descriptors of flavours and selling these and other products in adult-only brick-and-mortar shops."

Ngâ mihi,

s 9(2)(a)

From: s 9(2)(a)

Sent: Friday, 24 February 2023 2:25 pm

To: s 9(2)(a) @health.govt.nz>; s 9(2)(a) @health.govt.nz>

Subject: RE: Vaping submission

Hi again

More for us to discuss.

This is a really difficult article to get my head around, but feels like it could be very relevant to our vaping flavours work. Perceived Sensory Characteristics of Blended and Ambiguous "Concept" Flavors Among Adolescent and Young Adult E-cigarette Users | Nicotine & Tobacco Research | Oxford Academic (oup.com)

If I'm interpreting it correctly, it's saying:

- A cooling sensation is at least as important as whether a flavour profile is sweet or fruity (I'm not sure if we have or can factor this into the flavour wheel)
- Industry suggests removing 'descriptive' flavour names like ice mango, and moving to
   'concept' flavour names like marigold will remove youth appeal (basically the opposite of
   what we're proposing)
- The authors are not convinced this is true, as they say youth are able to find concept flavours that match their preferred descriptive flavours (but raises the question of whether changing it either way would have any effect on youth usage)
- Youth already seem to mostly use descriptive flavours though they acknowledge this could
  be an association with the type of devices they use (ie young people mostly use disposables,
  disposables may mostly have descriptive names etc).
- They suggest the US menthol cigarette ban should be extended to ban cooling agents in vapes, as that effectively masks the harshness of high levels of nicotine (worth discussing).

There are other vape flavour articles in this March 2023 journal that I haven't got to yet, including impact on quit smoking success, so I may share more relevant stuff next week.

Ngâ mihi,

s 9(2)(a)

From: s 9(2)(a)

Sent: Friday, 24 February 2023 12:20 pm

To:s 9(2)(a) @health.govt.nz>;s 9(2)(a)

@health.govt.nz>

**Subject:** Vaping submission

Whitehall-smokefree-environments-regulations-submission-form feb 2023.pdf

Refer to Document 4A

Kia ora kôrua

This is an interesting submission on behalf of what I assume is a vape retailer/organisation. Their answers to questions across the document demonstrate a thorough understanding of our proposals. If you skip to page 14, you can see the responses on youth vaping. I think there's some useful challenges and suggestions to consider when preparing the RIS.

Might be best if we work through the answers together and test the validity. I suspect we can dismiss some of the recs as unworkable, but other challenges may be suitable to list as cons in the RIS. Matt I think we'll really need your expertise re batteries etc.

I'll set up a meeting for Wednesday. Best if you spend 10-15 mins beforehand reading through those 6 pages.

Ngâ mihi,

s 9(2)(a)

Please note, my standard days of work are Mon(9-2.30), Wed (8.30-5.30), Thurs (7.30-3.30) and Fri (9-2.30)

# s 9(2)(a)

@health.govt.nz

Public Health Agency | Te Pou Hauora Tūmatanui Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

K&K&K&K&K&K&K&K&K&K&K&K&K&K&K&K&K&K&K





# Submission form: Proposals for the Smoked Tobacco Regulatory Regime

# **Your details**

This submission was completed by:	(name)	s 9(2)(a)
Email:		
Organisation (if applicable):		Whitehall Limited

# **Additional information**

These questions are optional. We are only asking for your age and ethnicity to help us analyse submissions.

### My age is:

Under 18
18 − 34
35 − 44
45 − 54
55 − 64
65 +
Not applicable (eg, I am submitting on behalf of an organisation or group)

The	ethnicity/ethnicities I identify with	are:			
	Māori Pacific Peoples Asian Other European Other ethnicity				
If ot	her ethnicity, please specify:				
Plea	se provide details of any lwi you m	ight a	affiliate to below.		
Click	c or tap here to enter text.				
l am	, or I represent, the following cated	gory o	or categories: (tick all that apply)		
	Personal submission		Healthcare provider (eg, primary care provider, stop smoking provider)		
	Community or advocacy organisation		Professional organisation		
	lwi/Hapū affiliated, and/or Māori organisation		Tobacco manufacturer, importer or distributor		
	Pacific community organisation		Vaping or smokeless tobacco product retailer, distributor or manufacturer		
	Government organisation (eg, local council)		Small retailer (eg, dairy or convenience store)		
	Research or academic organisation Other (please specify): Click or tap here to enter text.		Medium or large retailer (eg, supermarket chain or large petrol station)		
Pı	rivacy				
sub	·		this consultation, but <b>we will only publish your</b> Il remove personal details such as contact		
If yo	ou do not want your submission pu	blishe	ed, please tick this box:		
	☐ Do not publish this submission.				
	r submission will be subject to requant	uests	made under the Official Information Act (even if		

# **Commercial interests**

Do you have any commercial interests?
$\square$ I have a commercial interest in smoked tobacco products
☑ I have a commercial interest in other regulated products (vaping products, other notifiable products)
☐ I have commercial interests in both smoked tobacco and other regulated products (vaping products, other notifiable products)
☐ I do not have any commercial interests in smoked tobacco or other regulated products (vaping products, other notifiable products)
Commercially sensitive information
We will redact commercially sensitive information before publishing submissions or releasing them under the Official Information Act.
If your submission contains commercially sensitive information, please tick this box:
☐ This submission contains commercially sensitive information.
If so, please let us know where.

# Protection from commercial and other vested interests of the tobacco industry

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

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

The proposals in this discussion document are relevant to the tobacco industry and we expect to receive feedback from companies in this industry. We will consider all feedback when analysing submissions.

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

Please provide details of any tobacco company links or vested interests below.

Click or tap here to enter text.

# Please return this form:

By email to: smokefree2025@health.govt.nz

By post to: Smokefree Consultation, PO Box 5013, Wellington 6140.

# **Consultation questions**

The Ministry of Health is seeking comments on the following.

# Regulatory proposal 1a: Number of smoked tobacco retail premises and their distribution across Aotearoa

This section focusses on how stores that sell tobacco products will be spread across the country. In this section you can tell us if there's anything you think we should know about how areas should be defined, how many stores should be in each area, and anything important about your area.

This proposal relates to the written notice under section 20M of the Act to set a maximum number of retail premises in areas of New Zealand. Currently there are around 6,000 retailers of smoked tobacco products in Aotearoa. The recent changes to the Act mean that no more than 600 approved retail premises will be permitted to sell smoked tobacco products across the country. We propose that New Zealand be divided into areas based on whether they are urban or rural.

We have suggested an example scenario for smoked tobacco retail premises summarised by region. It is likely that the final distribution will need to be adjusted to take into account feedback from consultation, so this is a starting point for discussion only.

1.	Do you agree with dividing Aotearoa into areas and having a separate maximum number of smoked tobacco retail premises for each one?
	Yes
$\boxtimes$	No
2.	Do you agree with the concept that urban and rural areas should be treated differently?
$\boxtimes$	Yes
	No
	If you have any comments on how we have defined rural and urban, or how the geographic nature of the area required by the Act should be taken into account, write them here

The Director General must make a written notice setting a maximum number of retail premises for all New Zealand or divide New Zealand into different areas and set a maximum number of retail premises for each area. Setting a maximum number of retail premises for each area adds an additional layer of complexity and runs a risk of not fit for future purposes over time as population changes and (if the amendment act meets its objective) various areas reach smokefree levels faster than others. Specifying the maximum number of retail premises for New Zealand gives the director general the ability to tweak the distribution of licenced tobacco retailers over time.

3.	, ,		ocation scenario, as described in Table 1 of the lementary maps we have produced?
$\boxtimes$	Yes		
	No		
	<u> </u>		aximum number of retail premises for each area, naximum of 600 retail premises?
	seems to be the best intentions regulations. However, whenever	by th top-oft is cr	ocation of the 600 retail premises with what e Ministry of Health to implement the down, desktop exercises like this are completed, ucial that the Director General retains the nevitable issues arise.
4.	We are interested in understand your area?	ling th	ne needs of different areas of Aotearoa. What is
	Northland (Te Tai Tokerau)		Manawatū/Whanganui
$\boxtimes$	Auckland (Tāmaki Makaurau)		Wairarapa/Wellington (Te Whanganui-a-Tara)
	Waikato		Nelson/Marlborough (Whakatū/Te Tauihu-o- te-waka)
	Bay of Plenty (Te Moana a Toi-		Tasman/West Coast (Te Tai o Aorere/Te Tai
	te-Huatahi)		Poutini)
	Tairāwhiti/ <mark>Ha</mark> wkes Bay (Te		Canterbury/Chatham Islands
	Matau-a-Māui)		(Waitaha/Wharekauri/Rēkohu)
	Taranaki		Otago/Southland (Ōtākou/Murihiku)
	Other/I am not in New Zealand		
	(please specify): Click or tap here to enter text.		
	ener of tap here to enter text.		

# Regulatory proposal 1b: Minimum requirements for approval as a smoked tobacco retailer

This section focusses on minimum requirements for selling smoked tobacco products. In this section you can tell us about who should be allowed to sell and what type of systems you think they should have.

This proposal relates to key criteria under 20I and regulation making powers under 82A of the Act to require the retailer to meet certain criteria before they can be approved.

The Director-General of Health must be satisfied that retail premises are run by people who are 'fit and proper'. Further requirements that need to be met can be set in regulations for security, training, delivery, other business systems, and other relevant criteria. We have proposed some requirements which are intended to ensure that the retail scheme works as intended.

ınter	ided.
1.	Do you agree with the proposed requirements for a 'fit and proper' person in Appendix 2 of the consultation document?
	Yes No
	If you have any comments on the proposed requirements for a 'fit and proper person, please write them here.
	Further clarity should be provided on the proposed approval process and decision-making criteria for instances where an Approved Tobacco Retailer is sold to another party (or) key management personnel / directors change in a smoked tobacco retailer which deems previous assessment of a "'fit and proper' person void.
2.	Do you agree with the minimum requirements we have proposed for security systems, training, sales systems, delivery systems and other business systems?
	Yes No
	Do you have any other suggestions?
	The minimum requirements are rational and given the 6000 small businesses currently participating in a ~ \$2.5b industry (~\$400k per store in annual sales

The minimum requirements are rational and given the 6000 small businesses currently participating in a ~ \$2.5b industry (~\$400k per store in annual sales revenue) are going to be competing for 1 of 600 licenses potentially worth \$4m+ in annual sales revenue per store so it makes sense that the "winners" have appropriate security and business systems in place. Appendix 2 refers to a minimum requirement as being 'any further matters the Director-General considers relevant'. This is clearly a

'catch all' clause, this is a subjective / discretionary requirement which is better suited for the ranking of applications process rather than as a minimum requirement for stores to apply.

# Regulatory proposal 1c: Approval processes and decision-making criteria

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

Here you can tell us what you think is important to consider.

You can find more details on this proposal in the consultation document.

1.	Do you agree with the proposed application process?
	Yes No
2.	Are there any aspects that need to be clearer?
3.	If you have any changes or additions to the criteria we have proposed, please write them here.
	For a typical tobacco retailer to justify the investment and risk required to be at this level would be quite difficult given the intent to introduce VLNC in phase 2 of the Amendment Act which are designed to not be adopted by current smokers.  Although out of scope to this consultation, we are unclear why cabinet made the decision to sequence the reduction of tobacco retail premises prior to the introduction of VLNC

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

Most important criteria to take into account is a history of compliance to the Smokefree Environments and Regulated Products Act.

# **Additional retail questions**

1. Do you have any feedback on additional decision-making criteria and processes for selling smoked tobacco products online?

No feedback, to the best of our understanding the quantity of smoked tobacco products sold online is relatively low.

2. Do you have any feedback on possible support for retailers who are no longer able to sell smoked tobacco products?

5400 small businesses are frantically trying to find a way to hedge the impending \$400k average annual sales revenue loss resulting from removal of smoked tobacco products from their store. A 'natural' reaction for many of these retailers will be to meet consumer demand by considering stocking black market tobacco products, or grey market vaping products.

The best support for these retailers is to:

- 1) Continue regulating vaping products in a risk proportionate way that ensures continued availability of vaping products to these retailers that deliver nicotine to consumers at comparable levels to a combustible tobacco cigarette.
- 2) Review regulations to reconsider alternative non-tobacco reduced harm nicotine products not currently permitted for sale in New Zealand e.g. nicotine pouches.

# Regulatory proposal 2: Low nicotine requirements

From 1 April 2025 only low nicotine smoked tobacco products will be allowed in Aotearoa. This section focusses on the details of testing and product requirements, application processes as well as product packaging updates needed.

You can find more details on this proposal in the consultation document.

1.	Do you agree that a suitable testing method may include a method based on WHO SOP4, validated to account for the low nicotine levels prescribed?
$\boxtimes$	Yes
	No
2.	Do you have any other suggestions for suitable chemical analytical methods?
	Not qualified to make a suggestion.
3.	Do you agree with the proposal that the main packaging change should be to allow the words 'very low nicotine' on qualifying smoked tobacco products?
$\boxtimes$	Yes
	No
4.	Do you agree with the proposal to require an insert in smoked tobacco product packs?
$\boxtimes$	Yes
	No
	If you have any additional feedback on smoked tobacco packaging, please comment here.
	Tobacco importers and notifiers should be permitted to communicate to consumers about very low nicotine cigarettes, both pre implementation and post
	implementation. In addition, Smoked tobacco products should receive a vaping
	advertising exemption that permits brands to recommend a specific nicotine vaping
	product for consumers to transition to.
5.	Do you agree with the product application requirements?
$\boxtimes$	Yes
	163
	No

6.	Do you agree with the proposed requirements for temporary approvals?
$\boxtimes$	Yes
	No
	If you have any comments on the proposed requirements for temporary approvals, please write them here.
	Click or tap here to enter text.

# **Regulatory proposal 3: Fees**

This section focusses on fees for applications, registrations and product approvals.

	You can find	more details	on this pro	posal in the	consultation document.
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1.	Do you agree that Manatu Hauora should charge for these processes?
	Yes No
	What processes do you suggest we charge for?
	Click or tap here to enter text.
_	
2.	Do you agree with the level of each of the fees?
	Yes
$\boxtimes$	No
	If not, how much do you suggest we charge?
	There should be a tiered Smoked Tobacco Retailer Fee based on the stage an applicant progresses to which allows for:  1) Stores which are dismissed from not meeting the minimum requirements 2) Shortlist Fee 3) Success fee (for the 600 successful retailers)
3.	Do you agree with our cost recovery approach?
$\boxtimes$	Yes
	No
	If not, what approach do you suggest we use?
	Click or tap here to enter text.

# Regulatory proposal 4: Notification requirements

This section is about the process for distributors of smoked tobacco products and retailers of notifiable products to tell the Director-General about their business.

You can find more details on this proposal in the consultation document.

1.	Do you agree with the proposal that distributors and general retails be required to re-register annually?
	Yes No
	If you have any further comments (including how frequently registration should be required) please write them here.
	Click or tap here to enter text.

# **Regulatory proposal 5: Youth vaping**

Youth vaping rates are currently increasing. We propose extending vaping packaging and product restrictions to further improve product safety and reduce the appeal of these products to young people, specifically through restricting flavour names and introducing product safety requirements for single use vaping products.

You can find more details on this proposal in the consultation document.

100	and more details on this proposal in the consultation document.
1.	Do you agree with the proposal to restrict the flavour names of vaping products to minimise their appeal to youth?
	Yes No
	If not, why not? If you agree, which names do you think should be excluded or replaced on the example e-liquid flavour wheel set out in the consultation document?
	The consultation document raises concerns over youth vaping and proposes to restrict the flavour names of vaping products to minimise their appeal to youth.
	While flavours are to some extent 'Generic' they play an important role for adult smokers transitioning from smoked tobacco products and are only permitted for sale in R18 SVR retail premises.
	Because of wide range vaping products available (which are designed to appeal to a wide range of adult ex-smoker / smoker's consumer preferences), there needs to be the ability to label product flavours in a way that helps adult consumers navigate to a suitable flavour profile for their needs.
	One of the original intents of the Smoke Free Environments and Regulated Products act was to regulate vaping products in a way that allows for future innovation and segment evolutions.
	Recommendation Rather than prescribing a "permitted list" of flavour descriptors, we recommend introducing a "prohibited" flavour name list; whereby the Ministry of Health can test the assumption that availability of certain flavour names in R18 specialty vape stores such as 'Unicorn Milk' is correlated to the level of youth vaping.
	The benefits of this approach are:
	Much quicker to implement vs blanket product name changes for any flavour descriptors that don't match a name on a constrained flavour wheel.
	Reduces the risk of a defacto flavour ban for any flavour profiles not added to the 'flavour wheel'

Less consumer confusion resulting from flavour descriptor name changes that are not

deemed as appealing to youth.

- 2. Do you agree with the proposal to extend product safety requirements for disposable vaping products?
- No

If you have further comments on the proposal to extend product safety requirements for disposable vaping products, please write them here.

The consultation document raises concerns over youth vaping and proposes to extend product safety requirements for disposable (single use) vaping products.

The current wording and rationale for the proposed extended safety requirements in the consultation document has **no link to reducing the appeal of vaping to youth**, runs a high risk of adverse consequences to other vaping product categories and will result in inexperienced users being forced to switch to vaping products currently reserved for advanced vaping product users who receive extensive product safety education from Specialty Vape Retailers upon sale.

If the Ministry of Health wishes to ban disposables to address concerns over youth vaping and product safety due to the low cost / mass produced nature of single use vaping devices, we recommend regulations are amended to prohibit single use disposables vaping devices rather than introducing new standards that disposable vaping devices cannot comply with to the detriment of reputable reusable vaping devices responsibly distributed in New Zealand.

#### **User Safety Mechanisms**

The consultation document proposes that all vaping devices must have a mechanism to prevent the device being activated or accidently operated by a child.

Introducing a mechanism to prevent a disposable vaping device from being activated or accidently operated by a child will not reduce the appeal of vaping to youth.

A "mechanism" is quite vague but we assume intends refer to anywhere from a simple button to an inbuilt age verification system on the vaping device.

### **Button Mechanism**

If youth do experiment with a vaping product that contains a 'button' mechanism to prevent accidental operation, they will eventually work out how to press the button.

There are several reusable vaping devices (both prefilled and refillable) which don't have a 'button mechanism' sold in thousands of stores that have helped a significant number of ex-smokers successfully switch to vaping (refer to vaping annual returns for qty).

One of the key reasons for these products success in New Zealand is their ease of use. The more complicated vaping devices are to operate, the less effective vaping becomes at lowering smoking rates.

Vaping devices sold in New Zealand already include instructions for safe operation, including warnings to keep devices away from reach of pets or children when not in use.

### **Inbuild Age Verification System**

A small number of vaping products now discontinued (IQOS Veev Gen1, RELX ALPHA & JUUL) have unsuccessfully tried to include a "device lock" which prevents operation of a vaping device until the customer has created an online account with the manufacturer that verifies their age using a passport or drivers licence against a government database, then links the device to the customers account before the device is unlocked.

The primary reason these attempts have been unsuccessful is because the technology isn't compatible with vaping products or feasible at a localised level; Mobile device app stores prohibit any vaping related applications which makes it difficult to connect a vaping device to the internet to complete verification and most vaping devices in New Zealand are international brands sold in multiple markets which combined made it a very unreliable user experience.

As vaping product retailer, we stocked one of these products designed exclusively for New Zealand for a short period of time prior to it being delisted; 1 (one) customer was able to successfully unlock their device unassisted after 1 hour of repeat attempts, the rest had to be assisted remotely over a number of days via email and phone calls with the device manufacturer. Most of the devices we sold were subsequently returned and exchanged for an easier to use alternative device.

Pursuing this path will result in a significant reduction in availability of vaping products and will prevent adult smokers who are not tech savvy or don't have access to a computer from vaping.

Recommendation: Now is not the time to require user safety mechanisms to prevent accidental activation. This will have no improvement to user safety and does nothing to reduce the appeal of vaping to youth.

#### Removable/Replaceable Batteries

The consultation document proposes a requirement that all vaping devices to have a removable battery to enable the battery to be inspected (and therefore prevent risk of battery failure/explosion).

When removal batteries are used properly and as intended by users in vaping devices, there is a very low risk of battery failure and device explosion. However, for inexperienced users not educated in battery safety, removable batteries pose a significantly increased (and unnecessary) safety risk.

Based on ACC injury claims, most vaping battery failure incidents relate to improper care and use by inexperienced users dealing with removable batteries. The vast

majority of Specialty Vape Retailers offer comprehensive education on battery safety to customers and ongoing care is required to ensure battery wraps are maintained to prevent battery failure.

The majority of vaping devices notified in New Zealand contain inbuilt batteries which are securely sealed within. These devices draw significantly less electricity from the battery as compared to devices designed for removable batteries, and the current product safety standards in vaping regulations already require devices to be compliant to New Zealand electrical safety standards.

### Substance container labelling

The proposal to clarify that all vaping products must have the prescribed labels on substance containers, including single-use devices, where the container may be the device makes sense and brings single use disposable vaping products in line with other nicotine vaping products.

Sufficient transition time should be provided to impacted products to comply.

The clarification should specify what prescribed labelling exactly means to remove any ambiguity between the concentration of nicotine S5 Part 1 1(i) regulations and strength of nicotine salts (Email guidance provided to industry) and ensure consumers have a single reference point they can use to compare between products.

### Nicotine concentrations in non-refillable products

The consultation document proposes reducing the maximum concentration of nicotine salts allowed in single-use products from 50mg/mL to 35mg/mL (as people can choose to use a lower concentration of nicotine in re-useable devices, but single-use devices have a fixed nicotine concentration that is generally close to the maximum allowed).

#### Reducing the concentration of nicotine

When assessing policy related to maximum nicotine levels, we urge decision makers to consider the emissions content of nicotine (i.e. the type of device typically used with the vaping substance). The problem with 'reducing maximum nicotine concentrations' is that current (small, low powered) devices will ultimately be replaced with larger, more powerful devices with coils that can vaporise e-liquid in a way that delivers nicotine to consumers at a comparable (or higher) level. While this may appease stakeholders who challenge the maximum nicotine levels, it is ineffective policy that does not directly reduce the appeal of vaping, or the nicotine consumed by people who vape.

The Ministry of Health has previously communicated that 50mg/mL nicotine concentration does not pose any safety risk or concerns to public health but notes that it may result in higher levels nicotine dependency and recognises that availability of vaping products that can deliver a similar level of nicotine to a combustible cigarette helps deliver the governments ambition of Smokefree 2025.

### Ability to choose lower nicotine levels.

Non-refillable nicotine vaping products (including single use disposable vaping products) are already available in multiple levels of nicotine which gives consumers choice and the ability to reduce nicotine intake over time.

Prefilled pods have a fixed nicotine concentration as do e-liquid bottles; Single use disposable vaping devices should not be treated differently.

While we agree that a large proportion of single use disposable vaping devices in New Zealand contain nicotine levels at concentrations close to the maximum allowed, this if the extended regulations permit the sale of single use vaping products, an extended range will follow to meet evolving consumer needs.

### Delivery of Smokefree 2025

To successfully deliver smokefree 2025, smoked tobacco consumers must have access to vaping products that deliver a comparable level of nicotine to deliver a similar level of satisfaction which in turn reduces the risk of fuelling demand for black market tobacco products.

<u>Recommendation</u>: Now is not the right time to be reducing maximum nicotine levels in vaping products.

There is no clear rationale provided in the consultation paper that demonstrates a public health benefit resulting from reducing the maximum nicotine levels for single use disposable vaping products.

This proposal contradicts with the proposal of requiring replaceable batteries in all vaping devices (if single use disposable vaping products had a removable / replaceable battery they wouldn't be a single use disposable vaping product).

3.	Do you agree with the proposal to restrict where Specialist Vape Retailers can be
	located?
	Yes
$\boxtimes$	No

If you have any further comments on where Specialist Vape Retailers are located (including any particular locations that are important to you), please write them here.

The consultation document proposes setting out proximity restrictions relating to where a Specialist Vape Retailer (SVR) is located. This would mean that the Director-General would need to give consideration to where a business intends to operate when deciding to give a person approval to be an SVR. For example, the distance from schools and sports grounds or other considerations specific to certain communities.

Our understanding of the rationale behind this proposal is not necessarily that SVR stores located nearby school are selling to youth (which could easily be addressed by enforcement of the SERPA) but rather that their visibility is in part correlated to the appeal of vaping amongst youth.

### Proximity to Schools

There are approximately 2500 Schools tactically located around New Zealand in "School Zones" which aim to maximise coverage. Many of New Zealand's youth commute to school daily, roam their local area and visit shopping centres. In the process of this normal daily part of life, they pass by a number of that sell products intended for adults stores (not located near schools). Incidental visibility of vape stores to youth is inevitable.

## **Existing SVR Stores**

There are now more than 1000 specialty vape retail premises in New Zealand, with a number of these are already located near schools.

While we agree that in some of the more extreme instances it is inappropriate to have a R18 store located directly beside a school's entrance, however the reality is that due to the tactical location of schools in New Zealand, having some SVR stores located nearby is unavoidable; so any proximity restrictions should account for the area of most student foot traffic (i.e. entrances) rather than a top down distance from the perimeter of a school grounds.

#### Recommendation:

Prior to making a decision to include proximity restrictions, a review should be carried out to assess what this policy would achieve (assuming already approved SVR stores would not lose their licence as a result of this measure).

If a decision is taken to set proximity restrictions, it should set a "minimum criteria" to provide prospective SVR stores some certainty when negotiating a lease. This 'minimum criteria' should be up front, transparent and specific, 'Other considerations specific to certain communities' should not be part of the approval process.