

23 November 2022

Tēnā koe,

We the undersigned represent manufacturers, importers, wholesalers and retailers comprising a significant share of all vaping products sold in New Zealand.

We are contacting you regarding a series of recent emails issued by the Vaping Regulatory Authority (VRA) between 27<sup>th</sup> October and 17<sup>th</sup> November 2022.

### **Context**

While the genesis for the VRA emails remains unknown, the VRA is asserting a new interpretation of what constitutes “nicotine salt” for the purposes of the maximum limits permitted in vaping substances sold in New Zealand, which would result in a nicotine ceiling 50% lower than stated in Regulation and which we maintain is incorrect.

The new interpretation has been put before the industry without warning or consultation after 16 months of previous successful legal product notifications and absence of objections by the VRA of those products permitted sale in New Zealand.

Should the new VRA interpretation be upheld, it will result in a catastrophic disruption to the local vapour industry, with as much as **80 percent of the total market impacted**, including hundreds of thousands of current consumers using vaping to switch from or quit smoking.

Requests to meet and discuss this directly with the VRA have been rejected, and the most recent correspondence suggests they intend to retrospectively cancel the approvals of thousands of products and arbitrarily lower the nicotine ceiling without appropriate consultation that responsible industry members understood they had complied with since its passage in August 2021.

As an industry, we have submitted vaping product notifications to the VRA since August 2021 in compliance with relevant regulation and legislation, transparently and in good faith on the understanding that the publication of a notification by the VRA was confirmation that a product was compliant and legal for sale.

It is widely acknowledged, including by the Ministry of Health, that vaping plays a vital role in helping smokers quit smoking and has helped accelerate the country’s progress towards Smokefree 2025 goals.

Importantly, the Ministry of Health last week celebrated a significant reduction in smoking rates in Aotearoa New Zealand, falling to 8%, from 9.4% in 12 months, one of the lowest smoking rates in the world.

On vaping’s role in helping people quit ASH NZ<sup>1</sup> has also previously expressed specific concerns about setting nicotine strength limits too low “may cause serious harm by making it harder for smokers to get through the early stages of switching, encouraging dual-use with smoking, rendering the products too weak for more dependent smokers”.

The new interpretation being put forward by the VRA:

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<sup>1</sup><https://d3n8a8pro7vhmx.cloudfront.net/ashnz/pages/81/attachments/original/1570154436/SurgeSmokefree2025Report.pdf?1570154436>

- Undermines the success of vaping as a quit tool in New Zealand; putting current vape consumers at risk of relapsing to cigarettes and preventing remaining smokers from successfully switching;
- Risks fuelling product shortages, and the creation of unsafe 'at-home' DIY mixing and black market behaviour and contribute to the further proliferation of illicit and un-notified vaping products in the New Zealand market;
- Is fundamentally at odds with the intent of the Smokefree Environments and Regulated Products Regulations 2021 (Regulations);
- Contradicts the VRA's acceptances of impacted vaping product notifications to date, causing widespread industry, retailer and consumer uncertainty;
- Impacts up to 80% of the current market without appropriate consultation;
- Has no clear scientific basis or rationale setting out the basis for the revised interpretation;
- Is inconsistent with the Government's existing policy position (prior to the change made by the VRA in October 2022) you confirmed in your capacity as Associate Minister of Health on TVNZ Breakfast (October 21<sup>st</sup>) that *"it would make no sense at the moment for [nicotine content of] vapes to be markedly lower than cigarettes and wouldn't support them being used to support quitting"*;
- Will lead to widespread confusion and frustration amongst consumers about vaping products and will force notifiers to mislead consumers about the level of nicotine strength in vaping products;

The VRA email and News article dated 4<sup>th</sup> November stated that all notifications were being reviewed and at that time no issues had been found with 2,374 products (approximately 30% of the market) reviewed. This is impossible to reconcile with their email of 17<sup>th</sup> November deeming approximately 80% of vaping products currently notified would be non-compliant.

### **Our Request**

An issue of this magnitude cannot be resolved through one way communication. The VRA's refusal to meet with impacted stakeholders to discuss this issue falls far short of what is expected of a responsible regulator in any industry and falls short of standards expected for the creation of regulations, in particular, the importance for regulations to "be expressed clearly and precisely, so that people understand what is required to comply with the law"<sup>2</sup>.

We therefore request your support to obtain a meeting between the VRA and industry to discuss the science and interpretations of nicotine salt, with a moratorium on the suspension or cancellation of any product notification for notifiers who have acted in good faith.

Following appropriate industry consultation, should the VRA position remain that it intends to effectively lower the nicotine ceiling, this should be subject to public consultation, open to all impacted stakeholders and consumers, similar to the previous round of consultation on the Regulations.

On 4<sup>th</sup> November, the Ministry of Health stated:

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<sup>2</sup> Standing Order 327(2)(i): [https://www.parliament.nz/en/pb/parliamentary-rules/standing-orders-2020-by-chapter/chapter-5-legislative-procedures/#\\_Toc51754707](https://www.parliament.nz/en/pb/parliamentary-rules/standing-orders-2020-by-chapter/chapter-5-legislative-procedures/#_Toc51754707) [accessed 22 November 2022].

“At this stage, there is no evidence that vaping products being sold in New Zealand have levels of nicotine high enough to significantly increase users’ risk of harm”.

Given the above, any final determinations should allow for a reasonable transition period, in line with the earlier regulations of 12 months. This timeframe will allow for orderly compliance by importers, manufacturers and retailers of both impacted product, and sourcing of new product to meet consumer demand under any new legal framework.

We append additional scientific commentary on the issues raised by the VRA, and the basis for the industry belief that this new interpretation is incorrect and inconsistent with the approach of both local industry, and international scientific standards.

We thank you for your attention.

Sincerely,



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## **APPENDIX 1: Science on Nicotine Salt**

### ***Issue 1: Benzoic Acid***

The VRA states ““benzoic acid” listed as an ingredient in notified products indicates product may contain ‘unreacted benzoic acid’ which is prohibited in vaping substances as a STOT-RE 1 substance”<sup>3</sup>.

The Regulation (Schedule 5, Part 1, Section 12(b)) states “vaping substances must not contain... specific target organ toxicity (STOT-RE) Category 1 substances other than benzoic acid – nicotine salts”.

The local toxicity effects that led to this classification are based on the physicochemical effects from benzoic acid dust<sup>4</sup> and do not apply to solubilised benzoic acid, as found in e-liquids. Benzoic acid content has been listed as an ingredient in many products because nicotine benzoate is not an ingredient but rather the final product; the result of the reaction of nicotine and benzoic acid occurring in the final e-liquid formulation vaped.

Many importers and manufacturers notify, and label vaping products per the ingoing ingredients – whereby both nicotine, and benzoic acid, are ingoing ingredients. The nicotine salt is formed ‘in-situ’ - as such the end vaping substance consumed does not contain unreacted benzoic acid.

This appears to be a misunderstanding by the VRA, or a labelling issue in terms of how ingoing ingredients are declared, versus what is ‘as vaped’ by the consumer.

The same misinterpretation appears to be applied to ‘nicotine salts’ - as these can also be formed ‘in-situ’ where the ingoing nicotine, and ingoing acid, react to form nicotine salt in the final e-liquid or ‘as vaped’ - rather than being pre-mixed and added as a combined single ingredient.

### ***Issue 2: Nicotine Salt***

Regulations, Schedule 5, Part 1, Section 15 provides that: “The strength of nicotine salt in a vaping substance must not exceed 50 mg/mL”.

“Nicotine” and “Nicotine Salt” are not defined in the Smokefree Environments and Related Products Act 1990 or the Regulations, but reference is made in Schedule 5, Part 1, Section 11 to nicotine quality being required to comply with the USP or Ph. Eur. Monograph.

The key issue is whether the word “strength” in Section 15 refers to the concentration of the nicotine in the nicotine salt of a vaping substance (i.e., the concentration of the active ingredient), or whether this refers to the total concentration of nicotine salt in a vaping substance (i.e., the nicotine plus the acid diluent as a proportion of the vaping substance). In our view, the reference to the “strength” of the nicotine salt would be sensibly interpreted to refer to the strength of the nicotine in the vaping product.

Nicotine salt is not something produced separately and added but rather it is formed in-situ, and as vaped by a user. Nicotine salts are formed from a chemical reaction between freebase nicotine

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<sup>3</sup> Email from VRA to all Vaping Retailers dated 27 October 2022.

<sup>4</sup> ECHA RAC (Risk Assessment Committee). Opinion proposing harmonised classification and labelling at EU level of benzoic acid, EC number 200-618-2, CAS number 65-85-0. ECHA/RAC/CLH-O-000000168762-02-F:-9p., 2012. Available at: <https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180a0aef2>

reacting and being pH balanced with an acid, producing a protonated nicotine salt<sup>5</sup>. This reduces the harshness of nicotine and produces a sensorial effect more comparable to that of smoking.

Using one product example of a “3% Nicotine Salt Vaping Substance” : the labelling on the packet indicates the product contains 64.8 mg of nicotine and 36.0 mg of lactic acid in 1.9 mL liquid per pod, having 34 mg/mL nicotine content per pod. The lactic acid referenced on the pack is an ingredient used to produce the final nicotine salt occurring here as part of the manufacturing process. Adding together the nicotine and the lactic acid contents displayed on the pack together does not reflect the actual final active nicotine content in the e-liquid; this will remain 34 mg/mL.

Conversely, the VRA interpretation of (nicotine salt = nicotine + acid) would suggest the above product be labelled as “53.5mg nicotine salt” - which does not give the consumer any indication of how much active nicotine is contained, being 34 mg/mL. Expressing the content of nicotine (expressed as free-base equivalent) used to generate the nicotine salt is the only reasonable way consumers will be informed of the actual amount of nicotine in the final e-liquid formulation they consume.

### ***International approach***

To focus on the active part of the salt molecule is aligned with international approaches and technical standards. For example, as per the recent European Committee for Standards (CEN) document for E-Liquids Ingredients (FprEN 17648:2022(e)<sup>6</sup>, the standard states: “for e-liquids that contain nicotine salt instead of free base nicotine, the indication of nicotine content of the e-liquid shall reflect the nicotine moiety of the nicotine salt and shall not be based on the weight of the total salt added, as the latter would mislead the consumer as to nicotine content of the product.”

This approach to nicotine salts is consistent with the UK and EU. Commentary regarding how New Zealand requirements relate to EU and UK legislation can be found in Appendix A to the “Smokefree Environments and Regulated Products Act 1990: Proposals for Regulations” (available at Appendix A: Product safety requirements (health.govt.nz)). In respect of nicotine salts, it states:

*“The UK legislation does not set a limit specific to nicotine salts. The UK limit of 20 mg/mL of nicotine in nicotine-containing liquid sold for retail applies to nicotine salts as well. Nicotine salts are less alkaline than free-base nicotine, allowing higher concentrations that provide nicotine absorption levels closer to those from smoking cigarettes. Nicotine salts may be an effective alternative for long-term smokers. There is no current evidence that products containing nicotine salts are any more harmful than those with free-base nicotine.”*

The Regulations have taken intentional choice for the limit for nicotine salts to be higher than free-base nicotine to allow for an effective alternative for long-term smokers. This is further evidenced by the work of the E-Cigarette Technical Expert Advisory Group, and the regulatory consultation process.

## **ENDS**

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<sup>5</sup> [\[1\]](#) Talih S, Salman R, El-Hage R, Karaoghlanian N, El-Hellani A, Saliba N, Shihadeh A. Effect of free-base and protonated nicotine on nicotine yield from electronic cigarettes with varying power and liquid vehicle. Sci Rep. 2020 Oct 1;10(1):16263. doi: 10.1038/s41598-020-73385-

<sup>6</sup> [\[2\]](#) FprEN 17648:2022 (E) has been prepared by Technical Committee CEN/TC 437 “Electronic cigarettes and e-liquids”

