



13 September 2016

Tobacco Control Team
Ministry of Health
PO Box 5013
Wellington 6145

Tēnā koe me koutou mā

Re: Submission on Policy Options for Regulation of Electronic Cigarettes (ENDS)

Thank you for the opportunity to provide a written submission on this consultation document.

Regional Public Health (RPH) serves the greater Wellington region, through its three district health boards: Capital & Coast, Hutt Valley and Wairarapa and as a service is part of the Hutt Valley District Health Board.

We work with our community to make it a healthier safer place to live. We promote good health, prevent disease, and improve the quality of life for our population, with a particular focus on children, Māori and working with primary care organisations. Our staff includes a range of occupations such as: medical officers of health, public health advisors, health protection officers, public health nurses, and public health analysts.

This submission recognises for this consultation that the Smoke-free Environments Act 1990 is the primary legislation but RPH's preferred position is that e-cigarettes and nicotine liquids be regulated under the Medicines Act 1981; to achieve further optimal controls for ENDS the Psychoactive Substances Act 2013 should also be considered.

RPH does have concerns that the tobacco industry is involved in the research, development, distribution, marketing and sale of ENDS products. Drawing on decades of public health experience of this industry's practices that have profited from tobacco addiction that have results in global mortality rates of 6 million people per year¹ one needs no reminder that caution is advised. Therefore, RPH would like to see active application of the Framework Convention on Tobacco Control Article 5.3 provisions regarding tobacco industry interference wherever possible.

The team at RPH are happy to provide further advice or clarification on any of the points raised in our written submission. The contact point for this submission is:

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Nā

Peter Gush
Service Manager

¹ The World Health Organization, *Fact Sheet*, June 2016. <http://www.who.int/mediacentre/factsheets/fs339/en/>

Policy Options for the Regulation of Electronic Cigarettes

Consultation submission

Your details

This submission was completed by: *(name)* Shane Kawenata Bradbrook

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Organisation *(if applicable)*: Regional Public Health

Position *(if applicable)*: Senior Public Health Advisor

(Tick one box only in this section)

Are you submitting this:

- as an individual or individuals (not on behalf of an organisation)?
- on behalf of a group, organisation(s) or business?

(You may tick more than one box in this section)

Please indicate which sector(s) your submission represents:

- Commercial interests, including e-cigarette manufacturer, importer, distributor and/or retailer
- Tobacco control non-government organisation
- Academic/research
- Cessation support service provider
- Health professional
- Māori provider
- Pacific provider
- Other sector(s) *(please specify)*:

(You may tick more than one box in this section)

Please indicate your e-cigarette use status:

- I am using nicotine e-cigarettes.
- I am using nicotine-free e-cigarettes.
- I currently smoke as well as use e-cigarettes.
- I am not an e-cigarette user.
- I have tried e-cigarettes.

Privacy

We intend to publish all submissions on the Ministry's website. If you are submitting as an individual, we will automatically remove your personal details and any identifiable information.

If you do not want your submission published on the Ministry's website, please tick this box:

Do not publish this submission.

Your submission will be subject to requests made under the Official Information Act. If you want your personal details removed from your submission, please tick this box:

Remove my personal details from responses to Official Information Act requests.

If your submission contains commercially sensitive information, please tick this box:

This submission contains commercially sensitive information.

Declaration of tobacco industry links or vested interest

As a party to the global tobacco control treaty, the World Health Organization Framework Convention on Tobacco Control, New Zealand (NZ) has an obligation to protect the development of public health policy from the vested interests of the tobacco industry. To help meet this obligation, the Ministry of Health asks all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry. The Ministry will still carefully consider responses from the tobacco industry, and from respondents with links to the tobacco industry, alongside all other submissions. Please provide details of any tobacco company links or vested interests below.

Nil

Please return this form by email to:

ecigarettes@moh.govt.nz by 5 pm, Monday 12 September 2016.

If you are sending your submission in PDF format, please also send us the Word document.

Consultation questions

Although this form provides blank spaces for your answers to questions, there is no limit to the length of your responses; you should take as much space as you need to answer or comment. Feel free to enlarge the boxes or attach additional pages.

Q1 Do you agree that the sale and supply of nicotine e-cigarettes and nicotine liquids should be allowed on the local market, with appropriate controls?

Yes No

Reasons/additional comments:

Regional Public Health's (RPH) preferred position is that e-cigarettes and nicotine liquids be regulated under the *Medicines Act 1981*.

RPH's understanding is that the Ministry of Health is not proposing amendments to the *Medicines Act* but is considering possible amendments to the *Smokefree Environments Act 1990*. The feedback in this submission is in response to these products being categorised under the *SFEA*.

RPH supports the view that Electronic Nicotine Delivery Systems (ENDS) could be used as a tool for smoking cessation. Where appropriate, and with controls in place, ENDS should be used by adult smokers to either switch from smoking tobacco, or used as a smoking cessation tool.

RPH strongly affirms that ENDS for recreational use is not supported in this submission.

Q2 Are there other (existing or potential) nicotine-delivery products that should be included in these controls at the same time? If so, what are they?

Yes No

Reasons/additional comments:

Regional Public Health is aware of tobacco derived products being developed by the tobacco industry that are promoted as 'healthier alternatives' e.g. The *I-Qos Marlboro* brand heat stick; these products are clearly not ENDS.

RPH recommends that:

- Such tobacco-related products remain categorised separately from ENDS.
- RPH believe that there should be a separate section in the *SFEA* that covers heated not burned products, to cover products like those above which are heat sticks. There could be a number of new products that fit this category that do not fit the definition of ENDS e.g. Shisha sticks are an example that is not covered but could be in this category.
- The legal definition for an ENDS device/product is thorough and robust.

Q3 Do you think it is important for legislation to prohibit the sale and supply of e-cigarettes to young people under 18 years of age in the same way as it prohibits the sale and supply of smoked tobacco products to young people?

Yes No

Reasons/additional comments:

Regional Public Health is particularly concerned about the uptake of ENDS by youth in overseas jurisdictions^{2 3} and within the New Zealand context.⁴ RPH would support the suggested age restriction.

Q4 Do you think it is important for legislation to control advertising of e-cigarettes in the same way as it controls advertising of smoked tobacco products?

Yes No

Reasons/additional comments:

Regional Public Health supports the alignment of the *SFEA* with provisions regarding advertising, marketing and promotion. RPH is concerned that there is potential for non tobacco smokers to become vapers.⁵ RPH believes that controlling advertising, marketing and promotion will reduce this risk. Currently ENDS are marketed in the same way tobacco was for decades. The following three advertisements were found on New Zealand ENDS websites.

The new *Therapeutic and Health Advertising Code*⁶, coming into force on 1 September 2016, will provide guidance with some claims made by suppliers (with possible *Fair Trading Act 1986* implications).

Of particular concern is the targeting of youth in advertising.⁷ RPH's experience with the alcohol issue is that something stronger than a *Code of Practice* is likely to be needed and could be included in the *SFEA*.

² Barrington-Trimis J L et al, *E-cigarettes, Cigarettes, and the Prevalence of Adolescent Tobacco Use*, Pediatrics August 2016, VOLUME 138 / ISSUE 2. <http://pediatrics.aappublications.org/content/138/2/e20153983>

³ Filippou T Filippidis et al, Two-year trENDS and predictors of e-cigarette use in 27 European Union member states, *Tob Control* doi:10.1136/tobaccocontrol-2015-052771 <http://tobaccocontrol.bmj.com/content/early/2016/04/20/tobaccocontrol-2015-052771.full>, 24 May 2016.

⁴ White J et al, *Tripling use of electronic cigarettes among New Zealand adolescents between 2012 and 2014*. Journal Adolescent Health 56(5): 522-8. 2015.

⁵ Wills TA et al, *Longitudinal study of e-cigarette use and onset of cigarette smoking among high school students in Hawaii*, *Tob Control* doi:10.1136/tobaccocontrol-2015-052705. 25 January 2016. <http://tobaccocontrol.bmj.com/content/early/2016/01/05/tobaccocontrol-2015-052705>

⁶ Advertising Standards Authority: <http://www.asa.co.nz/codes/codes/therapeutic-health-advertising-code/>

⁷ Campaign for Tobacco Free Kids, *E-Cigarette Marketing Continues to Mirror Cigarette Marketing*, https://www.tobaccofreekids.org/tobacco_unfiltered/post/4974, Jun 2015.

The results* are
clear...

Independent testing trials indicate that:

- ✓ 9/10 people would recommend our product
- ✓ higher proven success vs. patches
- ✓ 57% of participants reduced their intake by more than half

* Elusion — the only supplier to undertake these trials. Read more about the results here.



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GO THE DISTANCE WITH 25% LONGER LASTING CARTS



Q5 Do you think it is important for the SFEA to prohibit vaping in designated smokefree areas in the same way as it prohibits smoking in such areas?

Yes No

Reasons/additional comments:

Agreed. Regional Public Health supports prohibition that aligns with the current *SFEA* legislation for designated areas i.e. workplaces, schools etc. This approach maintains the de-normalisation process of smoking tobacco products and removes any possible confusion about where ENDS can or cannot be used. Although second hand vapour is considered to be much less hazardous than second hand smoke, never-the-less it is desirable not to expose others to vapour.

Q6 Do you agree that other controls in the SFEA for smoked tobacco products should apply to e-cigarettes? For example:

Control	Yes	No	Reasons/ additional comments
Requirement for graphic health warnings	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>Agreed. RPH recognises that there are <u>potential</u> health risks⁸ to consumers so the content of information or warnings will evolve as research is built regarding possible harms, side-effects etc. <i>The US Food and Drug Administration</i> also expect a warning statement on products that nicotine is both present and addictive.⁹</p> <p>Recommend consideration for product warnings that go beyond potential 'health' risks i.e. ENDS product failure – explosions and fires that have resulted in injury or death.¹⁰</p> <p>Recommend all warnings should be in both te reo Māori and English. Consideration for Pacific Island languages should also be made.</p> <p>Recommend consideration for health warnings/information, similar to other nicotine replacement therapy products, that assists consumers with medical requirements and accessing relevant smoking cessation services.</p> <p>Recommend that the <i>National Poisons Centre</i> 0800 number should be on packaging.</p> <p>Alignment with other jurisdictions is recommended.</p>

⁸ Food and Drug Administration, *FDA Warns of Health Risks Posed by E-Cigarettes*, September 17, 2013 - <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm173401.htm>

⁹ Food and Drug Administration, *Nicotine Warning Statement*, <http://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm>, 2016.

¹⁰ US Fire Administration, *Electronic Cigarette Fires and Explosions*, October 2014

Control	Yes	No	Reasons/ additional comments
Prohibition on displaying products in sales outlets	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agreed. Exemptions could be made for Pharmacy and specialist R18 stores that can demonstrate product use and display internally. Note. Retailers selling tobacco products should be prohibited from this exemption clause.
Restriction on use of vending machines	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Disagree. Recommend <u>prohibition</u> of sales from vending machines.
Requirement to provide annual returns on sales data	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agreed. Recommend that information of this nature will provide a dataset that can be used as part of a monitoring mechanism.
Requirement to disclose product content and composition	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agreed. Recommend preference for <u>full disclosure</u> of contents and composition of each product. This will provide consumer information regarding the product whilst also enabling a mechanism to monitor what is going into each brand.
Regulations concerning ingredients (e.g., nicotine content and/or flavours)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agreed. Recommend regulations that are very specific regarding the nicotine content (mg) and the flavours (highly restricted). Recommend <i>SFEA 1990</i> s31 'Limits on harmful constituents' should apply. Flavours should be restricted to one neutral flavour - refer Question 8: Flavours
Requirement for annual testing of product composition	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agreed. Recommend that this testing is at the <u>full cost</u> of the manufacturer/supplier.
Prohibition on free distribution and awards associated with sales	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agreed. As per <i>SFEA</i>
Prohibition on discounting	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agreed. As per <i>SFEA</i>
Prohibition on advertising and sponsorship	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agreed. As per <i>SFEA</i> . RPH recognises that some form of advertising may be applicable in specialised stores e.g. Pharmacy's or R18 ENDS specialist store.

Control	Yes	No	Reasons/ additional comments
Requirement for standardised packaging	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agreed. Recommend that all ENDS packaging aligns with provisions in the proposed <i>SFEA Regulations</i> . This is to minimise brand recognition and association (i.e. between smoked tobacco products and ENDS).
Other	<input checked="" type="checkbox"/>	<input type="checkbox"/>	View 'Other comments' section

Q7 Do you think it is important for legislation to impose some form of excise or excise-equivalent duty on nicotine e-liquid, as it does on tobacco products?

Yes No

Reasons/additional comments:

Agreed. Regional Public Health is supportive of the development of a taxation excise mechanism.

The development of such a regime will be balancing whether ENDS are defined as:

- a tobacco product e.g. the *European Tobacco Products Directive* which would attract tobacco excise; or
- a smoking cessation device where GST only would apply.

RPH recommends that excise tax on tobacco and ENDS be differential in nature as there are concerns that consumer access to ENDS (a product of lower risk than combustible tobacco) could be restricted in part by price.

Q8 Do you think quality control of and safety standards for e-cigarettes are needed?

Yes No

Additional comments:

Area of concern	Yes	No	Reasons/additional comments
Childproof containers	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Devices should be treated as a medical/clinical device and as such made childproof. Child safety issues in terms of children opening and swallowing the contents of nicotine cartridges, which are not generally sold in child resistant containers, with the possible risk of choking or nicotine poisoning or death. Recommend that the <i>National Poisons Centre</i> 0800 number should be on packaging.
Safe disposal of e-cigarette devices and liquids	<input checked="" type="checkbox"/>	<input type="checkbox"/>	At a minimum the provision for point of sale returns for disposal is a possible option however RPH recognises that the ability to influence consumers would be limited.
Ability of device to prevent accidents	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The expectation is that a device should be approved and meet a safety threshold for consumers. Reports of various incidents that are formally ¹¹ and informally ^{12 13} sourced are a concern.
Good manufacturing practice	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Expectation will be that the use of these devices for smoking cessation will require discussions with manufacturers to set a market standard via the MOH.
Purity and grade of nicotine	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Refer above to 'Good manufacturing practice' comment. As a consumer product the expectation is that the purity and grade of nicotine should be of pharmaceutical/medical quality. A mandatory testing regime to ensure that purity and grade is recommended.
Registration of products	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agree. Recommend that a similar registration/licensing framework as described in <i>PSA 2013 Part 2</i> is applied.
A testing regime to confirm product safety and contents purity	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agree. Recommend mandatory independent testing at the cost of the manufacturer.

¹¹ US Fire Administration, *Electronic Cigarettes Fires and Explosions*, October 2014.
https://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf

¹² CNN, http://edition.cnn.com/videos/us/2016/05/19/hole-ripped-in-vaping-mans-tongue-pkg.wten?iid=ob_video_vr2, 2016.

¹³ Info-Electronic-Cigarette, *E- Cigarette Explosions: An In Depth Investigation*, <http://info-electronic-cigarette.com/e-cigarette-explosions-an-in-depth-investigation/>, 2016.

Area of concern	Yes	No	Reasons/additional comments
Maximum allowable volume of e-liquid in retail sales	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agree. Recommend that maximum sizes for refill containers, tanks and cartridges are set. Refer to <i>European Tobacco Products Directive 38</i> . ¹⁴
Maximum concentration of nicotine e-liquid	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Agreed. Recommend that a maximum of 20mg/ml is set. Refer to <i>European Tobacco Products Directive 38</i> . ¹⁵
Mixing of e-liquids at (or before) point of sale	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Disagree. Recommend prohibition. Such a practice would undermine possible registration processes and specifically the integrity of a products quality, safety and content.
Other	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>Manufacturers currently self-regulate what additives / ingredients /flavours/constituents are in ENDS. Regulations are required that restrict or prohibit as needed. RPH recommends:</p> <p>Additives/ingredients: Prohibitions/restrictions are placed on specific additives/ingredients. Preference for <i>Medsafe</i> to determine this alongside the MOH.</p> <p>Flavours: Restricted to ONE neutral flavour. The use of flavours (candy-floss, mango, watermelon etc¹⁶) to attract youth and young adults are prolific in overseas markets and should be highly restricted.¹⁷ RPH reaffirms the position that these ENDS could be used as a tool for smoking cessation where appropriate, and with controls in place. ENDS should be used by adult smokers to either switch from smoking tobacco, or are used as a smoking cessation tool. Options of flavours in this circumstance are not required.</p> <p>Harmful constituents: as within <i>SFEA 1990</i> s31 'Limits on harmful constituents', restricting or prohibiting such constituents is supported by RPH.</p>

¹⁴ Official Journal of the European Union L 127/1, *European Tobacco Products Directive 38*, 29 April 2014.

¹⁵ Ibid.

¹⁶ Vaporfi, <https://www.vaporfi.com/vape-juice/fruit-flavored-e-liquids/>, 2016.

¹⁷ American Lung Association, <http://www.lung.org/about-us/media/press-releases/tobacco-industry-continues-success-in-hooking-kids-with-flavored-tobacco.html>, 2013.

Q9 Are there any other comments you would like to make?

<p>Regional Public Health would recommend the following:</p>
<p>Advertising: RPH would recommend prohibiting the use of the term ‘e-cigarette’ or ‘vaping’ in the store front name of specialist stores as this is a form of advertising and promotion.</p>
<p>Enforcement: If ENDS products are going to be regulated by the <i>SFEA</i> then Enforcement Officers powers and enforcement penalties need to reflect this change.</p>
<p>Importation: Prohibit <u>personal importation</u> of products.</p>
<p>Research/evaluation: RPH would support a research programme that:</p> <ul style="list-style-type: none"> • Peer reviews clinical trials; • Monitors various indicators annually e.g. uptake rates, quit rates, etc.; • Undertakes a longitudinal study regarding how ENDS use among adolescents is related to subsequent smoking behaviour; • Collects and reports on adverse reactions and adverse product failures.
<p>Term - ‘e-cigarettes’: RPH would contend that the use of ‘e-cigarette’ is erroneous. Removing the link with tobacco cigarettes maintains the de-normalisation process that public health has been actively opposing for decades. As stated in Q 1, the consistent use of ENDS is preferred.</p>
<p>‘Termination’ clause: The rationale for this is that the long term health effects are unknown at this point. Therefore, consideration for prohibiting these devices if evidence of adverse health is apparent is strongly recommended. Such a provision could be supported by legislated review periods that occur every five years via independent evaluation.</p>
<p>Tobacco industry involvement:</p> <ul style="list-style-type: none"> • As noted in the consultation document, the tobacco industry continues a strategy of acquiring E-cigarette companies.^{18 19} • Industry involvement in the funding of ENDS research^{20 21} is already evident and is similar to well documented tactics employed re tobacco specific research over decades. • RPH supports the application of the <i>Framework Convention on Tobacco Control</i> Article 5.3 provisions on tobacco industry interference.

¹⁸ Kendell C, *The Battle for the Electronic Cigarette Market*, <http://vaping360.com/the-battle-for-the-electronic-cigarette-market/>, 2014.

¹⁹ Tobacco Tactics, *E-cigarettes*, <http://www.tobaccotactics.org/index.php/E-cigarettes> - 2016

²⁰ R. Polosa et al, Effect of an Electronic Nicotine Delivery Device (e-Cigarette) on Smoking Reduction and Cessation: A Prospective 6-Month Pilot Study, *BMC Public Health*, 11 October 2011, accessed October 2011 .

²¹ Fragerstrom K O et al, *Tobacco harm reduction: The need for new products that can compete with cigarettes*, *Journals Consult: Addictive Behaviours* Vol 39, Issue 3, March 2014 P.507-511. March 2014. <http://www.sciencedirect.com/science/article/pii/S0306460313003729> and Fragerstrom K O et al, *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, *Eur Addict Res* 2014;20:218–225 - <https://www.karger.com/Article/Pdf/360220>

Additional information on sales and use

Q10 Can you assist us by providing information on the sale of e-cigarettes in New Zealand (for example, size of sales or range of products for sale on the local market)?

N/A

Q11 Would the Ministry of Health’s proposed amendments have any impact on your business? If so, please quantify/explain that impact.

N/A

Q12 If you are using nicotine e-cigarettes: how long have you been using them, how often do you use them, how much do you spend on them per week and where do you buy them?

How long have you been using them?	How often do you use them?	How much do you spend on them per week?	Where do you buy them?
N/A	N/A	N/A	N/A