



Policy Options for the Regulation of Electronic Cigarettes Consultation submission

Addendum and Appendix



This Addendum includes appendices to the items referenced on our official submission form, an outline that addresses the specific concerns and objectives in the policy document from the Ministry of Health and the literature references that are noted within.

Addendum to Submission on “Consultation of Policy Options for the Regulation of Electronic Cigarettes”

DECLARATION: Aotearoa Vapers Community Advocacy aka AVCA has NO financial interest or vested commercial interest in the tobacco industry nor in the electronic cigarette manufacturing/import/distribution industry. We are solely a grassroots community organisation that is an umbrella charitable trust board to represent the interests and concerns of users of electronic cigarettes and personal vaporisers that utilise legally produced and imported e-liquid.

INTRODUCTION: AVCA are solely a grassroots community organisation that is an umbrella organisation to represent the interests and concerns of users of electronic cigarettes and personal vaporisers that utilise legally produced and imported e-liquid. Our mission statement is: Educate, Advocate, Inform, Community.

OBJECTIVE: This Addendum to our submission under the above noted consultation is written to specifically address the issues, objectives and concerns held by the Ministry of Health regarding electronic cigarettes and nicotine e-liquid. Also, this addendum will clarify our viewpoint on the noted issues, objectives and concerns as were outlined in the original policy document that was presented for consultation by the Ministry of Health.

It is interesting to note that the concerns presented in the policy document around nicotine e-liquid & nicotine containing e-cigarettes (ENDS) are the same concerns that the Ministry holds around the Drug Utensils Policy.

As such, we believe it would be **best practice to address this issue with the five criteria** that were outlined in that document: **Harm Reduction, Harm Prevention, Proportionality, Cost of Implementation and Ease of Implementation.**

It is with this perspective, we will also address the following objectives and concerns that the Ministry has surrounding e-liquid and e-cigarettes (ENDS), as well as some of the options presented within the National SmokeFree Working Group Background document that was released on 25 August 2016. These comments will follow on from the original MoH document we are addressing and are relevant as this background document is also part of what MoH will be considering in its final decision.

Ministry of Health Policy Objectives and Concerns:

A. Policy Options for E-Cigarette Regulation

BACKGROUND:

The Ministry of Health specifically stated that **“This consultation aims to clarify the legal position, proposed amendments mean that all e-cigarettes - with and without nicotine**

- would be available for sale and supply lawfully in New Zealand...but would be restricted to people 18 years of age and over, advertising of e cigarettes would be restricted and the use of e-cigarettes would be prohibited in areas defined as SmokeFree in SFEA.”

The policy document states the following as the objectives that the Ministry of Health hopes that the submission phase of the process towards legalising nicotine containing e-liquid will help to clarify:

- Reduction of harm from tobacco smoking
- Prevention of harm from e-cigarettes
- Product safety

The policy document also states the following as the areas of concern that the Ministry of Health has with regard to the legalisation of nicotine e-liquid and electronic cigarettes.

** Convention is that the ***AVCA responses will be in bold italic*** after each area of concern. E cigarettes that contain nicotine will be referred to in the foregoing as ***ENDS***.

DISCUSSION:

Nicotine – carcinogenicity, toxicity and harms: *Nicotine is a widely used addictive substance, which has a psychoactive effect and can be lethal in large quantities. On the other hand, the long-term use of small quantities of nicotine in approved nicotine replacement therapy (NRT) products (such as gum, patches or lozenges) is considered to be safe.*

The reference utilised by MoH to the justify above statement comes from a journal article that was a review of previous scientific articles with an emphasis on, as is in the title “dubious self-experiments in the nineteenth century.” Accordingly, In the policy document, MoH references that “The medium lethal dose is estimated to range between 6.5 and 13 mg/kg.”⁽⁶⁾ Current science disproves these figures and results, as discussed below.

Nicotine is no more addictive than that of the caffeine contained in coffee and tea.⁽¹¹⁾ Although nicotine is the main psychoactive agent in tobacco, it has relatively minor health effects - It is not a carcinogen, does not cause respiratory disease and has only minor cardiovascular effects.⁽³⁾ Also, the nicotine used in ENDS, while it may contain small amounts of other chemicals including volatile organic compounds, carbonyls, aldehydes, tobacco-specific nitrosamines (TSNAs) and metal particles, research indicates that they are present at much lower levels than in cigarette smoke.⁽⁴⁾ In normal conditions of use, toxin levels in inhaled ENDS aerosol are below prescribed threshold limit values for occupational exposure, in which case significant long-term harm is unlikely.⁽⁵⁾

Lethal overdose of nicotine is rare as nicotine itself is an emetic and any ingestion of liquid nicotine diluent, such as that used for ENDS would result in vomiting.^(7,8,9) This also coincides with the issues the ministry holds regarding “dual use” of ENDS with combustible tobacco, that it may cause harm does not take into account the concept of “reduced harm” There is no evidence of increased nicotine intake from dual use. Smokers regulate their smoking behaviour in order to maintain the blood concentrations of nicotine within a comfortable range. If those levels get too high, symptoms of nicotine toxicity – such as nausea, headache and dizziness can occur and smoking is then reduced. A recent study found that smokers using ENDS

maintain their intake of nicotine, but reduce their smoke and toxin intake, which results in an overall health benefit, therefore reducing harm through reducing exposure to the toxicants in combustible tobacco⁽¹⁰⁾. It is extremely difficult for someone to have a fatal overdose of nicotine through either ENDS use or through ingesting nicotine containing e-liquid due to nicotine's inherent emetic qualities.

Enforcement: The ministry states that they have been unable to carry out enforcement actions against retailers who are illegally selling/supplying nicotine containing e liquid because of the lack of clarity in the legislation.

When discussing enforcement within the context of currently having a law that is not easily enforced, it would be best to take the approach of harm reduction through proportionality, ease of implementation, cost effectiveness and harm prevention to create enforceable legislation.¹

Proportionality, ease of implementation and cost effectiveness: in this context leads to enforcing the currently in place consumer protection acts for all electrical/electronic equipment (including batteries) that are utilised for vaping; including the manufacture of e-liquids in New Zealand under the current food safety standards – (See AVCA Certification and Consumer Bill of Rights in Addendum) – thereby removing the need for additional legislation.

The legislation that would be required would be to remove the restriction on nicotine e-liquid for retail sale to registered businesses - who can apply for a licence to sell nicotine e-liquid (up to 48mg/4.8%) and said licence will give them the authority to be legally able to retail nicotine e liquid on the open market as a consumer product with an age restriction of 18+.

Promotion to young people: Overseas evidence that promotion of e-cigarettes targeting young people through flavours, packaging may appeal to young people. Local evidence that there is an increase in New Zealand youth trying e-cigarettes from studies in 2014 that DID NOT NOTE whether said use was with nicotine containing e-liquid or non-nicotine e-liquid.

The main issue with youth is harm reduction. One cannot, in an unequivocal manner state that they can prevent youth from uptake or experimentation with any harmful substance of behaviour with 100% guarantee. "Common Liability", as discussed by Bell and Keane, as it relates to the "gateway theory" defines this as the association between youth who are more risk takers and attracted to experimentation and more likely to try anything that seems to be "taboo" be it ENDS, alcohol, drugs, etc.⁴.

With regards to the uptake of "vaping" in previously non-smoking youth, the available evidence does not support the "gateway hypothesis" that ENDS encourages nicotine addiction or uptake by youth. In the UK, daily ENDS use in youth is almost exclusively confined to those who already use combustible tobacco daily and regularly. Less than .2% of youth who have never smoked combustible tobacco have taken up vaping and there is no evidence of progression to smoking in this cohort.^{5,6}

Keeping this in mind, as far as harm reduction and youth: nicotine dependence in youth develops rapidly and over 50% of those youth who smoke daily are already

nicotine dependent. Young people who are already smoking can reduce their harm by switching to ENDS by 95%, as was shown in the Public Health UK Report. ¹¹

Product Safety and Controls: There are no health & safety or quality controls for e-cigarettes available on the local market or from Internet sales which may put users and children at risk. These are listed as: no restriction on nicotine levels, harmful ingredients, labelling, no health warnings, risk of accidental poisoning, child proof containers.

In summary, we request that e juice manufacturers conform to the following: USP/BP Pharma grade diluents (Glycerol and Propylene Glycol), pharma grade nicotine diluent, food grade flavouring agents – all of which must have SDS/MSDS for each ingredient kept on record at each manufacturers facility; food safety certification of both the mixer and the facility where the e liquid is manufactured; batch/lot number tracking for each e-liquid and labelling that outlines ingredients, warnings as well as childproof/tamper resistant bottles and caps.

Please review, in the appendices, the AVCA Consumer Bill of Rights and the AVCA Vendor Certification documents contained therein. Both of these were created in consultation with both the vaping community and the vendors who are associated with the Vape Trading Association of New Zealand, and also reviewed by local consultants with expert knowledge of the NZ legislative framework as it relates to consumer products, pharmacy and medsafe policies and standards.

Impact of vaping on others: The main issue they have here is “renormalisation of smoking” and that “vaping clouds may be a nuisance to others, especially in enclosed spaces”

With regards to the “normalisation” argument see above under Promotion to Young People.

With regards to second hand exposure concerns, the ministry needs to look again at the Public Health UK report that they referenced in their policy document. Contained therein is a review that passive exposure to vapour have generally concluded that the risk to bystanders is very small and that Public Health England found that “ENDS release negligible levels of nicotine into ambient air with no health risks to bystanders.” ⁷

As far as the argument that “vaping clouds could be a nuisance to others especially in enclosed spaces”, unless the government also wishes to regulate the use of body sprays, perfumes, and deodorants which are also a nuisance – and can be a health hazard to those who have respiratory difficulties and disease (unlike second hand vapour which has NO health harms associated with it ^{5,6} therefore this argument is not valid.

The need for future-proofing legislation: “There has been considerable innovation in the production of e-cigarettes since they first appeared on the market and this is expected to continue...New Zealand regulators need to consider developing and implementing regulatory controls that, as far as possible, are fit for purpose...”

If the ministry wants to approach nicotine containing e-liquid and ENDS as a tobacco product, that is not going to making any future submission towards having e-cigarettes certified as a smoking cessation product be feasible within the local manufacturing or market. It will create a bias towards any company with big enough coffers and influence to make any such submission. In this particular instance, the only industry capable of submitting an application due to costs and time constraints would be from a tobacco company and therefore create an imbalance in the open marketplace that is geared towards the tobacco companies and their affiliates.

Illicit drug use: *We have addressed this in our submission to the Ministry of Health through the Drug Utensils Policy consultation process. In summary, we have stated that the vaporisers that are utilised for illicit use are mainly those that utilise a system of vapourisation through utilising “dry herb or wax” vaporisation and NOT liquid diluent vaporisation. The argument that cannabis oil can be utilised in standard open tank vaporising systems is false, as the viscosity of said products would not “wick” through the material that is utilised in standard coil/wick setups – both premade and rebuildable, that are utilised for “vaping.”*

Potential environmental impacts: *“there is limited information on the environmental impacts associated with the production, manufacture, use and disposal of e-cigarette devices and their liquid.”*

The environmental impacts of ENDS use from a consumer’s point of reference is almost nil. Consumers are well aware of safe battery disposal per their own local council’s requirements and bylaws and the vendors who sell the equipment readily accept any equipment that is no longer working for safe disposal through their local councils.

Nicotine e-liquid and nicotine diluent that is available for consumer use vaping is not of a high enough mg amount to cause any negative environmental impacts.⁸ One would need to have access to commercial grade and strength powdered undiluted nicotine powder to have any effect on the environment, and that form of nicotine is not utilised in the creation of nicotine containing e-liquid (it is utilised for other commercial applications, specifically in agriculture).

Tobacco industry involvement: *“there are indications that tobacco industry involvement in the production and marketing of e-cigarettes has been increasing in the last few years. There is no information currently available to quantify the current market share.”*

These particular devices are not sold currently in New Zealand through the vendors who sell electronic cigarettes as their core business. In consultation with the vendors, they have adamantly refused to even consider selling any product that may be manufactured or distributed by any tobacco company, conglomerate or affiliate. Their main supply chain is through non-tobacco vested manufacturers overseas. You may contact them directly with regards to their supply chain and we are confident that they too will address this particular concern in their own submission.

The devices that are being produced and marketed overseas by “Big Tobacco” do contain actual tobacco leaf. The process by which they consider them “vaporisers” is

because they do not directly combust the tobacco leaves, but instead create heat to vaporise the tobacco, and are, in fact, dry herb vaporisers, same as is used for eliciting partaking in cannabis and synthetic cannabis product. These products from tobacco companies are NOT liquid vaporisers that utilise the same technology as those utilised in e-cigarettes.

In conclusion, these devices do, in fact, utilise actual tobacco, are in fact “Dry herb vaporisers” and not liquid vaporisers. The personal vaporisers that are utilized in “vaping” do not contain actual tobacco and the nicotine e liquid utilised may or may not be from the process of tobacco extraction as there are many companies that offer synthetic nicotine for dilution and many e-liquid companies that utilise this synthetic nicotine in their e-liquid.

Controls under SFEA: The Ministry also seeks feedback on whether other controls currently in place under the SFEA for smoked tobacco products should be applied to e-cigarettes and whether there is a need for quality control and product safety. The controls currently in place under the SmokeFree Environment Act (SFEA) were originally devised and implemented with the rationale to prevent harm from exposure to combustible tobacco products, second hand smoke and public health issues that arise from carcinogens and toxicity of second hand smoke and the associated costs in the National Health System.

AVCA’s position regarding the inclusion of nicotine e-liquid and ENDS under the SmokeFree Environments Act is that the criteria for inclusion is weak from a public health perspective, as ENDS do not carry the same risks and harms as do combustible tobacco products, and inclusion in the SFEA is unwarranted, as are the increased taxes and excises that are placed on combustible tobacco products to cover the social cost of those harms within the public health system.

This flies in the face of the Ministry’s concerns about harm prevention and harm reduction.

Effect of SFEA inclusion on Maori Smoking Rates: According to the policy document we are responding to, the Ministry states that the daily smoking rate among Māori is higher than that among the total population (New Zealand Health Survey 2012/13 rates were 35.5 percent and 15 percent respectively), and more Māori women smoke daily than Māori men (New Zealand Health Survey 2012/13 rates were 40 percent and 30.5 percent respectively).

There is currently a very good uptake that is increasing by the day, of Maori towards using ENDS. Inclusion in the SFEA will derail the efforts of those involved in Maori Health, outside the scope of MoH, in assisting more of our people to get off combustible tobacco. Keeping in mind that the Maori cohort has seen the slowest decline in smoking prevalence in the previous five years.

PART 2

B. NSFWG Background Document

The following recommendations were made in the NSFVG background document that was released in support of and to provide background to, the Ministry of Health. Below, we have addressed each preferred option with commentary.

1. Supply and availability of e-cigarettes

Two preferred options are proposed drawing on consultations with members of the NZ smokefree practitioner community from the National SmokeFree Working Group.

Preferred option 1 - Maintain status quo. Sale of nicotine-containing ECs or e-liquids within NZ prohibited, but legal to import for personal use (up to 3 months supply). However, it should be noted that the real status quo is that nicotine-containing EC or e-liquids have been widely available for some time in New Zealand (due to importation by users and illegal sales by retailers).

Preferred option 2 - Allow restricted sale of nicotine-containing e-cigarettes or e-liquids. Continue to allow the importation of nicotine-containing EC or e-liquids for personal use (up to 3 months supply) but also allow sales of nicotine-containing ECs or e-liquids e.g. through pharmacies and/or limited numbers of licensed specialist 'vape' shops (with stipulations about proximity to schools, exclusion of minors from shop, and training/competence for staff in EC technical and ABC cessation support); minimum age of purchase to be same as for smoked tobacco products.

We believe Option 2 is the best practice in accordance with the policy of harm reduction. However, it does come with a caveat – there is no need to make the process more complex than needs be. If the current specialised vape shops register with MPI or MoH (whichever process government decides to follow) there will be no need to create an entirely new subset of “experts”.

The simple solution is to engage with the vape vendors in country already, and the vapers themselves who help each other within the community for no other reason than to share their knowledge and experiences with others. We are concerned that by over-regulation through the use of external “experts”, that the human and grassroots aspect of the community will be lost and then replaced by those whose interests are merely revenue gathering – be it through commercial transactions or taxation.

2. Smoking cessation advice and support for e-cigarettes as quitting aids

Preferred option. There is a strong consensus that smokers quitting using ECs should have access to advice and support. Cessation service providers receive resources and training in use of EC to support quitting, based, for example, on recent PHE advice. Healthcare providers should not recommend or support specific EC products unless these were licensed for cessation through MedSafe.

There are already processes in place, within the community, of which AVCA Vape It Forward participates, that provide resources and training to mentors who support those who wish to switch to ENDS from combustible tobacco. This network is already in place and has been successful in getting 95% of the participants in the program off of combustible tobacco products switched onto ENDS.

Had the individuals who wrote the background document contacted those in the wider New Zealand Vape community, such as AVCA, they would have found that this process has been quite effective.

Of the 95% in the successful group, 40% have already gone off of using nicotine containing e-liquid. Of that 40%, 20% have gone off of using any kind of ENDS in total. It has been so successful that we have been contacted by external cessation providers that cannot advise on ENDS due to MoH restrictions to assist their “hardcore” smokers in switching.

Of the 15 people that have been referred to us from this particular stream, 13 of these people have remained smokefree and are now in the process of cutting down their nicotine levels to reach 0mg. Of the 13, 5 of them started on 18mg and are now down to 6mg; 4 of them started on 12mg and are down to 3mg and the remaining 4 individuals started on 3mg and have remained at that level and have no immediate plans to reduce their nicotine level. (These numbers have been collected and collated by AVCA since the inception of the VIF program in April 2016.)

As well, there is the Vape2Save program run by the Sisters of Mercy in Auckland that also assists individuals with switching from tobacco to ENDS – for budgetary/fiscal reasons (people save money) as well as for health reasons. The particular statistics for this program can be had from Rebecca Ruwhiu-Collins, who is a paid consultant and runs the program for the Sisters of Mercy.

3. Marketing, packaging and consumer information

Preferred option marketing and public information. Commercial marketing of nicotine containing ECs and e-liquids products sold within NZ (if permitted) to be limited to point of sale displays regulated to avoid exposure to children and young people. Information (e.g. leaflets) giving advice to EC users trying to quit should be provided by cessation services and at point of sale. Consider mass media or targeted information campaigns to inform about availability of ECs and potential benefits and harms.

Commercial Marketing should be restricted to adults only. And only in the case of giving them information that they have the option of ENDS for cessation or recreational use in place of combustible tobacco. The information and advice on ENDS devices sold by vape vendors in New Zealand already comes with information and advice – some vendors have leaflets, some vendors have information online and some vendors hold seminars and one day sessions. Also, the vendors of VTANZ refer individuals to AVCA either to the VIF mentoring program or to the facebook groups where they can get support and guidance from the privacy of their own homes. So, in summary, this is already in place.

Preferred option packaging. Packaging requirements for ECs and e-liquids sold within NZ (if permitted) to include minimum standards of child safety, safety warnings (e.g. dangerous to ingest, keep away from children and pets), health warnings and Quitline information, and list of constituents. No packaging or product names would be permitted that are appealing to children and young people.

As noted above and in the appendices, the AVCA Consumer Bill of Rights and the AVCA Vendor certification documents already provide a framework to address packaging and manufacturing guidelines – that were collated from information from experts in the UK, France, the EU and the US for “best practice”

4. Product design/ standards/flavours

Preferred option – Apply existing consumer protection legislation and explore introducing minimum quality and safety standards and excluding additives/flavours (e.g. those shown to be toxic or that make products appealing or palatable for children and young adults) to nicotine containing ECs and e-liquids products sold within NZ (if permitted). To be identified from review of international standards and best practice.

As above please see the AVCA Consumer Bill of Rights and AVCA Vendor Certification documents in the appendices.

5. Use of e-cigarettes in indoor and outdoor workplaces and public places

Preferred option – Use of ECs to be banned in all indoor workplaces and public places (consistent with the 1990 SFE Act), all schools, in cars, and in selected outdoor locations (areas where children predominate e.g. playgrounds, parks) but allowed in other smokefree areas at local discretion and where public consultation suggests this is acceptable. Clear signage should indicate where vaping is permitted, and these areas should be separate to “smoking permitted” areas.

It is our preference that ENDS do not be included in SFEA as they do not cause the same harms as combustible tobacco as outlined previously in this document. Those same harms were the reason behind the creation of the SFEA, and simply, do not apply to ENDS.

6. Tax and excise for cigarettes

Preferred option – *Maintain status quo i.e. no additional tax or excise applied to nicotine-containing ECs and e-liquids.* To be reviewed if there is evidence of substantial uptake of nicotine-containing ECs by children and young people.

We agree that no additional taxation or excise is necessary. We addressed youth using ENDS and “the gateway effect” earlier in this document.

7. Monitoring and research

Preferred option – Ministry of Health develops a framework for monitoring and evaluating emerging evidence on ECs, including their technological evolution and use (internationally and in NZ), and for evaluating the impact of ECs, especially on smoking prevalence in all population groups and progress towards the Smokefree 2025 goal. Use consistent, international best practice methods for measuring and monitoring EC use.

Please see AVCA Consumer Bill of Rights and Vendor Certification document in the appendix.

CONCLUSION:

At the beginning of this Addendum to our submission we stated that we believe it would be best practice to address this issue with the five criteria that were outlined in a previous MoH document that also touched upon Personal Vaporisers and ENDS with regards to Harm Reduction (through utilising ENDS in place of combustible tobacco); Harm Prevention (through quality control of manufacturing, registration of vape vendors, advertising restrictions or packing that do not appeal to children; Proportionality & Cost of Implementation – by utilising existing consumer legislation and provided structures and frameworks contained in the appendices attached herein and the streamlining of advice and expertise through utilising existing resources and not “recreating the wheel”; and Ease of Implementation through utilising the same existing pathways, resources, expertise and knowledge in the vaping community and within consumer protection regulations already in place in New Zealand.

We also believe that this process needs to be inclusive, and by inclusive we mean that those who are tasked with coordinating the efforts to come to some form of agreement/framework/legislation regarding ENDS, need to step outside of their “bubble” and include the wider vaping community in New Zealand, not just academics, government officials and external “experts” who have no interaction with the wider community.

In order to understand what is going on, these people above have to actually participate and engage with the people doing it in order to get a well rounded and objective view of what is going on and the processes by which it has been successful (or not). Those offers to engage and collaborate have been made for well over the past six months, and with the exception of one MP, have not been acted upon.

If there are any further questions regarding our position, or should the Ministry wish to consult with us on this and any future issues as they relate to “vaping” and/or ENDS, please feel free to contact us via email at either:

nsutthoff@avca.org.nz or sdohmen@avca.org.nz

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