

Policy Options for the Regulation of Electronic Cigarettes

Consultation submission

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Policy Options for the Regulation of Electronic Cigarettes

Consultation submission, September 2016

Jenesa Jeram, Policy Analyst, The New Zealand Initiative

1. Introduction

- 1.1 Thank you for this opportunity to submit to this consultation on ‘Policy Options for the Regulation of Electronic Cigarettes’. The proposal to legalise the sale and supply of nicotine e-cigarettes and liquids is a welcome change to the current regulation. While a growing number of people have taken up vaping in New Zealand, the status quo is not working. Vapers who import nicotine e-liquids from overseas risk bringing in unsafe or unknown products, without the same consumer protection under New Zealand legislation. Paradoxically, domestic retailers face more stringent regulations than international retailers, despite the fact it is easier to hold domestic retailers accountable.
- 1.2 I am a Policy Analyst with The New Zealand Initiative, and author of The Initiative’s report on public health and lifestyle regulations *The Health of the State* (April, 2016). The New Zealand Initiative is a public policy think-tank based in Wellington, supported by New Zealand’s leading businesses. The shared vision of The Initiative’s staff and members is to build a free and prosperous New Zealand. I can be contacted at jenesa.jeram@nzinitiative.org.nz
- 1.3 My interest in this consultation stems primarily from my research for *The Health of the State* (available on The New Zealand Initiative’s [website](#)). The report considers public health from two angles. The first is whether the policy’s infringements on personal choice and liberty is justified. The report also looked at the evidence that supports public health policies, such as those around e-cigarettes. *The Health of the State* considers the quality of these studies and points out some of the methodological flaws recognised in those research areas. My research found flaws in many of the studies that purported to show associated risks or harms from e-cigarettes. Given no substantial risks had been established at the time of publication, the report recommended a harm-reduction approach to e-cigarettes. The policy framework envisaged would involve minimal regulation, given the existing coverage of the *Consumer Guarantees Act (1993)* and the *Fair Trading Act (1986)*, and the risk of stifling market competition and innovation of the product.
- 1.4 Since releasing *The Health of the State* report in April, I have remained engaged with overseas developments regarding new research and legislation. Of particular interest are the likely

consequences of the European Union Tobacco Products Directive (EUTPD¹) and the Food and Drug Administration's (FDA) regulatory framework. Despite new studies being released since publication, no research to date has convinced me to rethink my conclusions on the e-cigarette's role in harm reduction.²

- 1.5 Based on the principles of harm reduction and avoiding unnecessary regulation³, the challenge will be balancing the following priorities:
 - 1.5.1 Ensuring reasonable health and safety precautions.
 - 1.5.2 A range of products are available to suit individual needs and preferences.
 - 1.5.3 Regulations should not favour specific businesses by being overly prescriptive.
 - 1.5.4 The products are accessible for vapers (ready access to the product will increase its effectiveness as a cessation tool)⁴.
 - 1.5.5 As a new technology, legislation should not constrain improvements to the model, or constrain the development of similar products.
- 1.6 Whatever regulations are eventually applied to e-cigarettes will no doubt stem from whatever the primary aim of e-cigarette policy is. These are the principles The New Zealand Initiative would recommend:
 - 1.6.1 Regulations should be proportionate with proven individual harm, or increased disease risk.
 - 1.6.2 Any harm should be considered on a net basis, which means considering the benefits of the product, as well as the costs.
 - 1.6.3 Given the long term effectiveness as a cessation tool is still unknown, e-cigarettes should be treated as a consumer product, not a health product. As a consumer product, where possible, further regulations should not be needed, given the already wide-reaching requirements of the Consumer Guarantees Act and Fair Trading Act.

¹ Many of the recommendations suggested in the Ministry of Health's discussion document are similar to Article 20 of the EUTPD. The European Union's regulation of e-cigarettes has been criticised as damaging for both vapers (current and potential) and manufacturers. On the consumer side, the regulations are likely to disincentivise vaping as an alternative to smoking. On the producer side, regulations are likely to increase the costs of production, discourage innovation, and can limit market diversity. Christopher Snowdon, Director of Lifestyle Economics at the Institute of Economic Affairs has reviewed the likely implications for each regulation in Article 20. See Christopher Snowdon (2015) 'E-cigarettes and Article 20 of the Tobacco Products Directive', Epicenter, <http://www.epicenternetwork.eu/wp-content/uploads/2015/09/EPICENTER-Briefing-E-cigarettes-and-Article-20-14th-September-2015.pdf>

² Though new research has been released since publication of *The Health of the State*, many of the studies repeat the flaws in methodology or policy conclusions that I identified in my research.

³ Even with the best intentions, unnecessary regulation, misguided regulation, or poorly designed regulation can sometimes cause more harm than applying no regulations at all. Further, once regulations are put in place, they can become costly and burdensome to lift. For a recent example, consider the 400% increase in the price of EpiPens in the US, due to pharmaceutical giant Mylan enjoying a monopoly protected by FDA regulation. The burden of proof regarding EpiPen safety and effectiveness is so stringent and costly that no other manufacturers have been able to enter the market and compete at the same level.

⁴ As an addictive product, ready access is important to satisfy nicotine cravings, and if access is too limited, vapers trying to quit smoking could easily just switch back to smoking.

2. The risks of over-regulation

- 2.1 When considering examples from overseas, it is important not to repeat their same mistakes. While the legislation in the EU and US will not restrict access to e-cigarettes completely, the EUTPD and the FDA will limit the diversity of products available on the market and reduce innovation.⁵
- 2.2 Equally, it would be a mistake to limit the sale of e-liquids to pharmacies and other specialist shops. In an environment where tobacco cigarettes are available in a variety of places, limiting the availability of e-cigarettes/liquids makes it harder to treat e-cigarettes as a viable alternative to smoking.
 - 2.2.1 Prescription-only availability might also put off potential vapers, because those who would avoid going to the doctor for traditional NRT products would equally avoid going to the doctor for an e-cigarette prescription. It also increases the cost for those who are curious about the product, but not motivated enough to pay for formal advice. There are additional costs for those who need to renew their prescription.
 - 2.2.2 Pharmacy- or ‘specialist store’- only non prescription access can be equally restrictive as pharmacy hours are not as flexible as the many places you can buy tobacco such as at dairies, petrol stations, supermarkets etc. The sheer number of pharmacies or specialist stores is also unlikely to come close to rivalling the number of places tobacco is sold.

3. Other nicotine-delivery products

- 3.1 Products substantially less harmful than smoked tobacco – and not substantially more harmful than other consumer products on the market – should be regulated as normal consumer products. Additional regulation of these products, other than age restrictions to those over 18, will prove counterproductive. The harms caused by reduced access to a safer alternative to smoked tobacco will likely outweigh any benefits of the regulatory regime.
- 3.2 Ideally, the framework allowing e-cigarettes to be sold on the New Zealand market would be flexible enough to incorporate any other product carrying equivalent risk. Examples include smokeless tobacco (snus) and the “heat-not-burn” tobacco products being introduced on international markets.⁶
- 3.3 Delaying legal access to e-cigarettes in order to build a regime able to handle more types of products would harm current and potential e-cigarette users. But failing to incorporate a

⁵ A recent report by think-tank the Reason Foundation emphasised the importance of bottom-up innovation, and is critical of the EUTPD and FDA for limiting competition and innovation. The report also points out the many ways the e-cigarette industry is already self-regulating for safety, making the case for regulating vape products as consumer products. Julian Morris and Amir Ullah Khan (2016) ‘The Vaping Revolution: How Bottom-up Innovation is Saving Lives’, Working Paper, Reason Foundation.

⁶ Such products are not readily available in New Zealand, but have enjoyed popularity overseas. These products use a stick of tobacco rather than an e-liquid, but are similar in that they avoid the harmful toxins associated with combustion. It is likely innovations such as this will continue. See ‘Big Tobacco Wants to Turn Japan’s Smokers into Vapers’ (29 August 2016) *Bloomberg.com*, but note that Japan has a regulatory environment that favours this product over nicotine e-liquids.

wider range of products can harm those current smokers who do not find e-cigarettes an acceptable substitute for smoked tobacco and who would switch to other safer alternatives. Balancing these considerations is not simple.

- 3.4 Our preferred balancing of these considerations would allow a broad array of harm-reduced products onto the market while:
- 3.4.1 Maintaining a watching brief on the evidence regarding risks of novel nicotine- and tobacco-delivery devices;
 - 3.4.2 Establishing a framework for regulating those products that, while less harmful than tobacco, are more harmful than normal consumer products;
 - 3.4.3 If the government wishes to recoup costs to the public health system⁷ by use of an excise regime, any tax imposed should be proportionate to the cost that product imposes;
 - 3.4.4 Bringing products into the new regime as and where warranted.
- 3.5 If the government instead decides to regulate either pure nicotine-based products or other harm-reduced products under the Smoke-Free Environments Act and make them subject to excise⁸, we urge an impartial review of the framework and of evidence on health effects within five years. Excise and regulatory regimes, if imposed, should be proportionate to health risks. If those risks are overestimated when the products are first allowed onto the market, a required review allows correction where, in the alternative, it would be tempting for the government to maintain too-high an excise regime for revenue reasons rather than to compensate for costs imposed on the public health system.

4. Age restrictions

- 4.1 Restriction of sales to those 18 and over is a sensible approach to mitigate some of the concerns around e-cigarettes and the uptake by young people. The legislation will also override the need to specifically design regulations that ensure e-cigarettes are not attractive to young people.
- 4.2 As long as sales and supply are restricted, there is less need for additional legislation to protect young people, such as restrictions around advertising, places they can be sold, or limitations to flavours that are “attractive” to young people.⁹
- 4.3 One of the oft-publicised ‘risks’ of e-cigarettes is the gateway effect: a hypothesised causal

⁷ Although, as *The Health of the State* argues, this reason alone is not justified from an economics perspective. The externalities that matter from an economist’s perspective are those that distort peoples’ choices. For a discussion of what externalities are and are not relevant, see Edgar K. Browning (1999) ‘The Myth of Fiscal Externalities’ *Public Finance Review* 27:1; Jenesa Jeram (2016) *The Health of the State*, The New Zealand Initiative.

⁸ This is not our recommendation, but a consideration of possible outcomes from this consultation.

⁹ Limitations on flavours would especially be nonsensical. There is no such thing as ‘adult’ and ‘kid’ flavours. A study by ASH UK found that while tobacco was the most popular flavour for adult vapers (33%) a significant proportion also preferred fruit flavours (22%) or menthol flavours (22%). Adults should not be restricted from purchasing a product that might be attractive to children, if appropriate age restrictions have already been implemented. ASH UK (2016) ‘Use of electronic cigarettes (vapourisers) among adults in Great Britain’, ash.org.uk

relationship where youth who take up vaping eventually might take up smoking. Because of this risk, there are some who might argue that young people in particular need to be protected. Yet to date, no such effect has been proven, and most of the studies purporting to 'prove' a gateway effect suffer similar flaws.¹⁰

5. Advertising and standardised packaging restrictions

- 5.1 Restrictions on tobacco advertising and packaging were applied once the harms of tobacco smoking had been established. The same restrictions cannot be extended to e-cigarettes, given the different harm profile.
- 5.2 A fair compromise would be to include some limitations on when and where e-cigarettes are advertised to ensure the product does not target young people¹¹. Useful restrictions could include banning images of children using the product in advertisements, restrictions on television advertising for shows predominantly watched by children, and warnings that nicotine is an addictive substance.¹²
- 5.3 Smoked tobacco currently has the market advantage of having customer recognition and loyalty. Restricting e-cigarette advertising to the same degree will simply protect the tobacco industry as the incumbent.
- 5.4 Advertising and packaging restrictions also limit competition between e-cigarette manufacturers and stifle innovation, as manufacturers have no way of letting consumers know how their product is different from others in the market. Some of these innovations are likely to include improvements to the effectiveness and safety of the product.
- 5.5 Finally, restrictions on e-cigarette advertising restrict consumer knowledge and awareness. This is particularly important if the goal of this policy framework is to encourage smoking cessation. Smokers need to be aware that e-cigarettes exist, that there are a range of products and flavours to choose from, and that they could be an effective alternative to smoking for those wanting to quit.

¹⁰ Clive Bates, former director of Action on Smoking and Health (UK) puts forward seven criteria for assessing the reliability of 'gateway effect' studies: 1) Is the term 'gateway effect' clearly defined? 2) Are the reported trends consistent with smoking trends generally? 3) The order in which vaping and smoking initiation happens does not matter, what matters is when vaping causes a smoking habit *that would not have occurred otherwise* (this is known as considering the counterfactual). 4) Are 'smoking' and 'vaping' well defined? (Keep an eye out for experimentation vs regular use) 5) Was there nicotine in the e-cigarettes? 6) Be aware of confounding variables and establishing causation (and the direction of causation). 7) Are the measures of 'susceptibility to smoking' reliable? See Clive Bates (June 10 2016) 'How not to be duped by gateway effect claims', <http://www.clivebates.com>

¹¹ Note that avoiding targeting children is not the same as avoiding advertising anywhere a child might see it. The harm of a child seeing the advertisement and subsequently taking up smoking (worst possible scenario) or vaping (a less harmful, but arguably still undesirable scenario), must be measured against the benefits advertising brings to vaping consumers and would-be consumers.

¹² Though no such warnings are given for coffee advertisements, despite coffee also being an addictive substance.

6. Prohibition of vaping in designated smoke-free areas

- 6.1 Vaping is a healthier alternative to smoking. Regulations should reflect this difference. Current regulations do not prohibit the use of e-cigarettes in smokefree areas, and instead leave it up to private organisations and workplaces to set their own rules. This is a reasonable policy: if the action causes no harm to bystanders¹³, workplaces should be able to set their own rules.
- 6.2 A more questionable policy is Wellington City Council’s approach, where vaping is banned in both outdoor and indoor smokefree spaces. Vaping in large open spaces is unlikely to cause much discomfort, let alone harm, to bystanders.¹⁴ Unlike tobacco cigarettes, there is no side-stream smoke from e-cigarettes, and only vapour is discharged upon exhalation.
- 6.3 There are several flaws with existing studies on the subject, too. These include the fact that establishing a change in air quality is not the same as establishing a change in health effects or risks, and even *if* toxic particles are detected, it is not the same as calculating the increase in risk of disease from these particles.
- 6.4 Banning vaping in smokefree places could have an adverse effect on the effectiveness of vaping as a smoking cessation method. One of the attractive features e-cigarettes have above smoking is that it is more convenient to use in public than smoking. In a society where smoking has become an increasingly socially marginalised activity, no doubt exacerbated by rigorous public health campaigns, vaping could be an attractive alternative.
- 6.5 Action on Smoking and Health (ASH) UK has provided some reasonable advice to private businesses and organisations who are trying to decide whether to allow vaping on their premises.¹⁵
- 6.5.1 They find: “While there have been a number of studies looking at the potential for harm to bystanders from secondhand vapour we have been unable to find any published scientific evidence that identifies harm from indirect exposure to electronic cigarettes.” [these are the findings of this researcher too.]
- 6.5.2 Addressing the question of whether vapers will influence children as ‘role models’, ASH finds: “The available evidence does suggest that, so far, sustained use of electronic cigarettes among children in Britain is limited to those who have already tried smoking. There is evidence of a growth in the number of young people who have tried electronic cigarettes, even among those who have never smoked, **however this one off use does not appear to be translating into regular vaping or regular smoking.**” [own emphasis added]
- 6.5.3 Overall, ASH recognises businesses and workplaces face differing considerations involving image and reputation, working environment, health promotion considerations, and convenience. It should therefore be up to individual businesses to

¹³ Even if the action does cause harm to bystanders, a case could be made that people who voluntarily occupy that premises are willing to take on that risk.

¹⁴ Besides, not even smoking bans in ‘large outdoor spaces’ is as evidence-based as one might think. While there have been studies proving the existence of second hand smoke particles in outdoor spaces, fewer studies have shown how this exposure is harmful to health.

¹⁵ ASH UK (2015) ‘Will you permit or prohibit electronic cigarette use on your premises?’, Briefing document, <http://www.ash.org.uk>

decide their policy.

7. Other SFEA controls for smoked tobacco products that should/should not apply

- 7.1 There is little logical reason for applying the SFEA to e-cigarettes (nicotine-containing or not). While they both contain nicotine, they are not analogous in the harm they cause to the user or to bystanders. If the purpose of the SFEA is to reduce harm, there is not yet any evidence that capturing e-cigarettes in this legislation will achieve that purpose.
- 7.1.1 Given the differences in harm profile, some SFEA regulations are simply irrelevant to e-cigarettes. For example, the requirement for graphic health warnings. Significant harms have not been established, so perhaps smokers-turned-vapers might enjoy images of healthier lungs, unstained teeth etc. on their vape products.
- 7.2 Some SFEA regulations simply increase the burden of the consumer (vapers or would-be vapers).
- 7.2.1 An example is the prohibition on displaying products in sales outlets. Given the wide range of technologies and products that are available/could become available, prohibiting the display of such products could limit new uptake from smokers who are curious about the product, as well as current e-cigarette users who want to explore the range of products available to find something that is right for them.
- 7.3 Some SFEA regulations could be a costly burden on manufacturers. This in turn can protect only those businesses big enough to afford the costs, rather than the businesses who have a superior product.
- 7.3.1 The requirement for annual testing of product composition is an example of this. The Fair Trading Act already prohibits deceptive labelling. If a product containing a nicotine concentration (or other ingredients) is at odds with the product's label, the manufacturer already faces consequences.

8. Free distribution and discounting

- 8.1 There are some circumstances where free distribution would be a positive, and health-affirming option.
- 8.1.1 Charities and NGOs might offer the devices to smokers wanting to quit, especially as the upfront cost might be prohibitive for some would-be vapers. Given the health consequences of smoking, and the increasing financial consequences of the current excise regime, e-cigarettes offer an alternative that could improve both health and alleviate poverty.¹⁶
- 8.1.2 Retailers might offer free trials of new devices or flavours for those consumers who are unsure about whether the product is for them.

¹⁶ This is a point made in *The Health of the State* and by political parties across the political spectrum from New Zealand First (<http://nzfirst.org.nz/news/tobacco-tax-all-about-money-not-public-health>) to the Act Party (<http://www.act.org.nz/posts/free-thoughts-tobacco-tax-0>). Smoking excise has harmed the poor disproportionately.

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- 8.1.3 Manufacturers might offer free samples of products as a taster and means of attracting new customers from their competitors, and differentiate themselves in the market.
- 8.2 Discounting ought to be left to the discretion of retailers. It is reasonable to assume there will be instances when discounting makes good business sense. For example, discounting could apply to unpopular products, in order to make way for newer products. It could also be a way to reward loyal customers, and could even be the incentive ‘non-committal’ vapers need to make a stronger transition from smoking to vaping.

9. Excise tax

- 9.1 There should not be an excise duty on nicotine e-liquids. None of the standard reasons for an excise tax, namely the existence of externalities¹⁷, would apply in the case of e-cigarettes.¹⁸ If anything, it is likely that any excise tax would cause potential vapers to overestimate the risks of vaping, and would postpone or stop their transition from smoking.
- 9.2 Vaping does not affect bystanders the same way smoking does. There are no proven harms caused by secondhand vapour, and the activity does not produce the same litter.
- 9.3 There is no evidence of population-wide risks of re-normalising smoking. However, the claim is not very convincing. First, because smoking and vaping are sufficiently different activities. But more importantly, it sets a worrying precedent for banning any risky activity if it has the unproven potential to encourage others to take on that risk (or in this case, an even riskier activity). The risk of re-normalising smoking would have to be taken into account at a ‘net harm’ level, so the risk of people taking up smoking would have to be balanced with the benefits of the number of people who quit smoking.
- 9.4 There is no evidence that the activity imposes disproportionate costs on the health system. While vaping is not a risk-free activity¹⁹, there has not yet been any established risk of death

¹⁷ The standard reasons are often referred to in ‘economic terms’ as externalities. That is, smokers should be taxed because of the external costs they impose on others. But the term ‘externalities’ is often bastardised from its economic definition. While it has come to mean ‘anything that affects anyone or anything else’, the economic definition of the term is much more narrow. For an externality to be relevant, the party must be affected to such a degree that they would be willing to pay to change the outcome.

¹⁸ Note that *The Health of the State* questions whether the current rates of excise tax on tobacco are even justified, given the revenue gathered is well in excess of health costs to the state, and despite aggressive measures, the smoking rate is now barely responding. See Jenesa Jeram (2016) *The Health of the State*, The New Zealand Initiative.

¹⁹ Given New Zealanders voluntarily participate in all manner of risky activities from mountain biking, to driving, to rugby, it would seem odd to impose an additional tax on vaping even if a minor risk had been proven.

or disease from vaping that is high enough to warrant an excise tax.²⁰

- 9.5 Some excise taxes are proposed on the basis it could be a useful signaling tool. However, it is unclear what message the government would want to send in this case. A similar argument has been made in New Zealand as justification for a sugar tax, where its real value might be symbolic rather than functional. Given vaping is a safer alternative to smoking, it is unclear why the government would signal the activity is undesirable, especially to smokers who have or who may have switched to vaping.
- 9.5 Just because nicotine is addictive, establishment of addiction is not a harm that warrants excise, and might not even be a harm at all.²¹ There are some who would argue that there is no rational explanation for smoking or participating in an addictive activity. However, a basic understanding of welfare economics will demonstrate that such a state of being is impossible. There are may be harms and risks involved in an activity, but that does not mean there are zero benefits. No person will voluntarily undertake an activity from which they derive no enjoyment or benefit.
- 9.5.1 Because of the physical harm that smoking causes, and the enjoyment derived from nicotine (and for some, the action of vaping itself), e-cigarettes could be the most optimal choice for smokers from a welfare economics perspective. This applies in a situation where they would prefer smoking to abstinence, but harm reduction to smoking. For those who have no intention of quitting nicotine, vaping is the optimal choice for these people. Besides, surveys revealing that smokers actually ‘want to quit’ should also be treated with some scepticism. This is the difference between stated versus revealed preferences, where it is the revealed preference that matters.²²
- 9.6 On a purely fiscal note, the costs of tax administration must also be taken into account. Even if the hypothetical excise tax were not a significant burden or disincentive for vapers, the costs of tax administration would need to be taken into account. If the expected revenue of the tax is low, then the costs to government for administering the tax might outweigh any fiscal gains.

²⁰ There is only one case where an excise on vaping might be justified to recoup costs borne through the health system, and it is an absurd case. If smokers were to quit smoking entirely through the aid of vaping, they are likely to improve their health and life expectancy. While that is a gain for the individual, and for public health, there is evidence that shows that it is the healthy and long-living that wind up costing the health system more in end of life care. This, combined with a reduction in excise revenue collected, could leave the government coffers worse off. In case it is not obvious, it is not our recommendation to thus impose a tax. The point is that the so-called ‘costs to the health system’ justification cannot be made for vaping.

²¹ Carl V. Phillips is a researcher in epidemiology and economics and has worked extensively on tobacco control and harm reduction. On addiction, Phillips argues that “While it gets discussed as if it were a biomedical concept –because it has implications for health and sometimes involves biological pathways –ultimately it describes behaviour, not physiology. Thus it can *only* be analysed via economics.” See Carl V. Phillips (2016) ‘Understanding the basic economics of tobacco harm reduction’, IEA Discussion Paper No.72.

²² More strongly, Carl V. Phillips argues that “the naïve claim that taxes should be proportional to the risk seems to be motivated by a rudimentary understanding of the economics, with the assumption being that consumers completely ignore health costs when making a decision, and thus consumption would be [zero] in the absence of taxes.” Ibid.

10. Other quality controls and safety checks

- 10.1 The importance of separate and wide reaching legislation to ensure safety risks are mitigated is likely overstated as opposed to the alternative: doing nothing. The e-cigarette market still operates like any other market, and may face even stricter expectations of safety by their customers. There is a natural incentive for producers of e-cigarettes to establish themselves as a safe and credible brand in order to attract a loyal customer base. Given many people take up vaping because of the decreased potential harm, consumers may use ‘established safety’ as a key determinant in their choice of brands. There are also ‘opt-in’ options for producers who do want to differentiate their products, such as voluntary codes of conduct, voluntary independent testing, and other industry association standards of quality.
- 10.2 Some of the proposed standards in the Ministry of Health’s discussion document are difficult, if not impossible to meet.
- 10.2.1 For example, it is impossible to design childproof containers. It is unclear how any container could be completely childproof (as opposed to the more feasible and common child-resistant packaging). It would make good sense for nicotine-containing e-liquids to be child resistant. It would be difficult, however, to make the actual e-cigarette device child resistant without making the device extremely difficult to refill.²³
- 10.2.2 The same could be said for ‘ability to prevent accidents’.
- 10.3 While the registration of products sounds like a reasonable request, there seems no obvious case why there should be stronger registration requirements for these products than for other addictive products like different grades of coffee or for coffee machines.
- 10.3.1 If there is to be a registration process it should not be overly time consuming or costly, as this can discourage improvements and innovation in the sector. Even small fixed costs can be a hassle for smaller businesses who offer a range of products or flavours as a large number of small costs soon add up.
- 10.3.2 This could potentially be the case in the United States under FDA regulations. Under the system, any improvements, including safety improvements (including the removal of ingredients that have since been found harmful), to a product must go through a pre-market tobacco application process that could take up to two years and cost at least US \$5 million.²⁴
- 10.3.3 If improving products is to likely incur further registration costs, there are fewer incentives to improve the product. More worryingly, it could also disincentivise health and safety improvements.
- 10.4 A testing regime to confirm product safety and contents purity has the potential to be costly and prohibitive to smaller businesses in the market.

²³ The first generation of e-cigarettes (cigalikes) might technically satisfy the need to prevent leakage, but given innovations in the technology that have occurred since then, not all vapers would find the first generation technology preferable or effective.

²⁴ A vocal and evidence-based critic of the FDA regulations is Michael Siegel, Professor in the Department of Community Health Sciences, Boston University School of Public Health. See Michael Siegel (2016) ‘FDA Bans Safety Improvements in E-Cigarettes and American Lung Association Supports this Unprecedented Regulatory Blunder’, <http://tobaccoanalysis.blogspot.co.nz>

- 10.4.1 The case for such a regime is not obvious, beyond the requirements of the Fair Trading Act.
- 10.4.2 If there is to be a process, it is recommended New Zealand does not follow the FDA example. Pre-market applications, such as the US FDA's Pre-market Tobacco Applications are lengthy documents that require a high burden on proof on applicants. As well as proving general safety, the FDA's regime requires a risk and benefit assessment on effectiveness as a cessation tool and its likely impact on third parties. In many cases, this data simply isn't available. Not only does such a regime favour those larger companies who can invest in the application process, it is excessive compared to testing on other consumer products.
- 10.5 Some 'safety' regulations designed to protect the consumer might just be an inconvenience, and could make vaping a less attractive or convenient alternative to smoking.
 - 10.5.1 Limiting the maximum allowable volume of e-liquid in retail sales is an example. This regulation has the potential to harm e-cigarette users by limiting the availability of the product, thus increasing the likelihood users could switch back to tobacco cigarettes if they run out of e-liquid. The ability to stock up on e-liquid, especially if the user anticipates they will not be able to conveniently purchase the product, is an important consideration.
 - 10.5.2 Limiting the maximum concentration of nicotine in e-liquid is another potential inconvenience. While in principle this seems like a good safety requirement, choosing the "right" level of nicotine will differ from vaper to vaper, just as smokers differ in their habits. If nicotine concentrations are set too low, then vapers might compensate by either dual use or returning fully to smoking. Heavy smokers will require more nicotine. The delivery mechanism also matters, as does the frequency of use in determining how much nicotine is absorbed by the body.