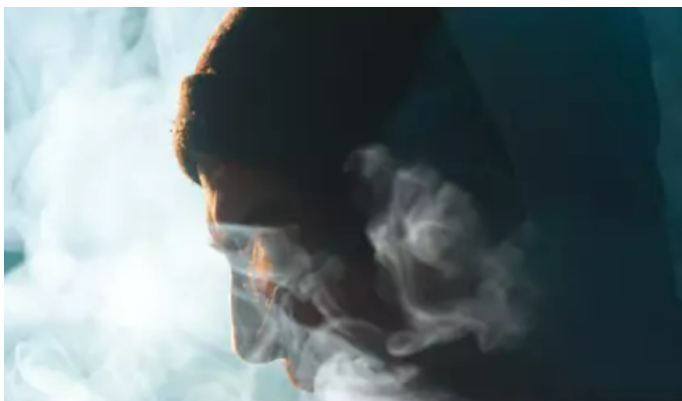


Smoke, heat or vapour? Ideas for risk-proportionate regulation to make World Smokefree Day irrelevant by 2025

30 May 2018

Richard Edwards, Anaru Waa , Janet Hoek, Louise Thornley , Nick Wilson



World Smokefree Day is an apt day on which to propose some ideas that may greatly increase momentum for the achieving Smokefree Aotearoa 2025. Tobacco and vaping products such as e-cigarettes vary greatly in their likely adverse health effects and overall impact on population health. Reflecting this, the Ministry of Health announced in May that it will investigate ‘risk-proportionate’ regulation for tobacco and vaping products. This blog discusses public health considerations in developing the new regulatory framework, and proposes key features of a risk-proportionate approach. We argue the framework should aim to minimise harm and maximise benefits to population health by accelerating progress towards New Zealand’s Smokefree 2025 goal. As well as clarifying the appropriate regulatory approaches to vaping products, we see an overwhelming need for much stronger regulation of smoked tobacco products, as these are vastly under-regulated in relation to the harm they cause.



Background to the risk-proportionate regulatory approach

On March 12, Judge Butler rejected the Ministry of Health’s (MoH) claim that Philip Morris (NZ) Ltd had contravened the 1990 Smoke-free Environment Act by illegally selling an oral tobacco product. The product in question was ‘HEETS’, a tobacco heat stick designed for use with the ‘IQOS’ ‘heat-not-burn’ device; the judgement effectively made such products legal for sale. This decision, together with Hon Nicky Wagner’s proposed e-cigarette regulation Members’ Bill, increased pressure to clarify the regulatory framework for nicotine-containing e-cigarettes (ECs) and similar devices, and may have contributed to the Ministry’s announcement on risk-proportionate regulation of tobacco and vaping products.

[Note: For simplicity, we use ‘ECs’ here to describe all generations of vaping devices, which include heat ‘e-liquids’, commonly containing nicotine, to create an aerosol.]

There is a strong case, from a public health perspective, to introduce a new regulatory framework for these products. Progress towards Smokefree 2025 is far too slow. We need to do much more, particularly to reduce smoking among Māori and Pacific peoples [1-3]. That said, smoking prevalence among adults is decreasing (Table 1), and the decrease accelerated modestly among Māori and young people between 2011/12 and 2016/17 [*]. There were also profound decreases among NZ adolescents: between 2011 and 2017 the prevalence of regular smoking among Year 10 Māori children reduced from 18% to 11% and daily smoking from 10.3% to 5.3% [4, 5].

Table 1 Trends in current smoking prevalence in 2006/7, 2011/12 and 2016/17 (NZ Health Survey) - with the largest reductions marked in bold italics

Population group	Current smoking prevalence (%) (at least monthly)			Mean annual prevalence reduction 2006/7-2011/12	Mean annual prevalence reduction 2011/12-2016/17
	2006/7	2011/12	2016/17		
New Zealand adults	20.1	18.1	15.7	0.40	0.48
Māori adults	42.1	40.2	35.3	0.38	0.98

Pacific adults	27.1	25.9	24.5	0.24	0.28
Adolescents and young people (15-24 years)	23.4	21.4	15.4	0.40	1.20

This continuing decline in smoking prevalence, despite only minor tightening of some aspects of regulation of smoked tobacco products (mainly regular tax increases, a ban on point-of-sale displays and some local extensions in smokefree public places) and relatively constrained availability of ECs, suggests that more robust regulation of smoked tobacco products and greater availability of ECs should accelerate progress towards a Smokefree Aotearoa by 2025.

SMOKEFREE AOTEAROA 2025 PLAN

1. Make tobacco products less affordable:

- Raise tobacco tax by 20%
- Introduce a minimum retail price for all tobacco products

2. Make tobacco products less available:

- Support retailers to move away from selling tobacco in the next 3 years, and then cap the number of retailers
- End tobacco sales in bars and pubs
- Introduce a cut-off birth date for legal purchase of tobacco, to create future 'tobacco-free' generations

3. Make tobacco products less appealing and less addictive:

- Remove additives and flavours that enhance taste or appeal (e.g. menthol, sugar)
- Reduce nicotine content to very low levels so they are no longer addictive

4. Do more of what we already do

Such as:
enhanced targeted smoking cessation, mass media campaigns and moving to greater availability of e-cigarettes

Proposed approach to risk-proportionate regulation

We support the idea of a risk-proportionate regulatory framework, which would bring much-needed clarity and an opportunity to enhance regulations and policies to facilitate achieving the Smokefree 2025 goal. However, the framework must prioritise the health of the public over commercial interests. We propose the following over-arching aim: To reduce smoking-related harm to minimal levels by facilitating achievement of New Zealand's Smokefree 2025 goal – minimal smoking prevalence for all peoples in Aotearoa, including Māori and Pacific peoples.

The framework should aim to create an environment that maximises prompts to quit and support for smokers trying to quit, or if they are unable or unwilling to quit, to switch to

lower-harm alternative products. Equally, regulation should minimise the chance of adolescents, young people or adult non-smokers experimenting with or becoming addicted to any nicotine-delivery products, particularly the most hazardous smoked tobacco products.

The framework should include these critical features:

1. **Comprehensive policies** such as (but not limited to): taxation and price, distribution and supply, marketing, packaging and health warnings, safety standards, and product design and composition (including nicotine content and flavours).
2. Regulation proportionate to risk for **all types of nicotine-delivery consumer products** to ensure the least harmful products are the most affordable, accessible and appealing to smokers, while the most harmful smoked tobacco products are the least affordable, accessible and appealing to both smokers and young people at risk of starting to smoke.
3. A **robust and responsive system for monitoring progress** towards the Smokefree 2025 goal, evaluating the impacts of policies and regulations, and making appropriate changes in response to evaluation.

The framework must strengthen regulation of the most harmful smoked tobacco products. This approach will end the current untenable position where the supply, distribution, product composition, and design of tobacco products is essentially unregulated.

Regulatory options

We outline in Table 2 suggested options for key areas of regulation for ECs/e-liquids and smoked tobacco products. Our proposed options for regulating ECs will no doubt attract discussion and debate. We see this as appropriate given the uncertainty over the impacts of ECs on population smoking prevalence and the potential pros and cons of different regulatory approaches [6, 7]. The smoked tobacco regulations are largely drawn from the ASAP action plan published last year. Heat-not-burn products are discussed separately below.

Some of the measures (e.g. reductions in supply of smoked tobacco products) will require a staged introduction and an implementation plan. This detail is not set out in the table but is included in the ASAP action plan. Some measures would be subject to positive outcomes from consultation (e.g. with pharmacists regarding sale of ECs or tobacco products) or would require appropriate training (e.g. vape shop staff in smoking cessation referral pathways, and pharmacy staff in advising new users of vaping products).

Table 2. Options for proportionate regulation of smoked tobacco products and nicotine-containing e-cigarettes and e-liquids

Regulation/ policy area	E-cigarettes and e-liquids	Smoked tobacco products
Taxation and excise	<p>No application of excise/taxation – unless required to deter youth initiation (e.g. if monitoring identifies youth uptake as a serious problem).</p> <p>Availability of lower-cost ECs will encourage switching from smoked tobacco and provide smokers who cannot or do not want to quit with a cheaper alternative source of nicotine.</p>	<p>Continue planned regular tobacco tax increases, with essential complementary measures, such as mandated retail price and differential increases in RYO tobacco taxation.</p> <p>Potential adverse impacts of tobacco tax on continuing smokers should be minimised by allocating additional revenue to supporting smokers to quit (particularly smokers on low incomes) and other tobacco control measures.</p>
Retail availability	<p>Restrict device and e-liquid sales to (i) licenced specialist vape shops which would be R18 and have cessation support materials and referral available and (ii) pharmacies trained in EC user initiation and support.</p> <p>Aim for ECs/e-liquids to be more widely available than smoked tobacco products for smokers, whilst ensuring new users receive high quality quitting support and/or referral, and expert advice and support about purchase and use of ECs/e-liquids.</p>	<p>Phased ending of sales of smoked tobacco products in dairies, supermarkets and petrol stations. Replacement with greatly reduced (5% of current numbers approximately) number of retail outlets (e.g. specialist stores or pharmacies) selling smoked tobacco products.</p> <p>Aim for marked reduction in availability of smoked tobacco products with sales restricted to fewer more secure and compliant (e.g. with age of purchase laws) retailers.</p>

Regulation/ policy area	E-cigarettes and e-liquids	Smoked tobacco products
Packaging and warning labels	<p>Make e-liquids available in child-proof containers with packaging that does not appeal to children or adolescents.</p> <p>Provide information on packaging to convey to smokers potential benefits of switching whilst informing all potential users about addictiveness and uncertainty about long-term health effects.</p>	<p>Continue current plain (standardised) packaging and enhanced health warnings with frequent rotation and introduction of new warnings to maintain impact.</p> <p>Disallow new smoked tobacco product innovations (e.g. capsule cigarettes) unless proven to reduce harm.</p> <p>Consider specific on-pack warnings to dispel incorrect beliefs about RYO.</p>
Age of purchase/ sale	<p>No sales to children and adolescents (<18 years) with enforcement funded and facilitated through licensing of specialist retailers.</p> <p>Consider creating pathway for established <18 years smokers to access nicotine-containing ECs/e-liquids.</p>	<p>Consider increasing age of purchase to 21 years or introducing a tobacco free generation to progressively raise legal age of sale and reduce access of youth and young adults to smoked tobacco products.</p>
Flavours and additives	<p>Review evidence and consult on evidence for toxicity and impact of e-liquid flavours on EC use among adolescents and young people, and on smokers and quitters using vaping products. Implement regulations as appropriate.</p> <p>MoH to have power to stop sales of e-liquid flavours where there is evidence that they preferentially appeal to or encourage non-smoking youth to use ECs.</p>	<p>Ban all flavours and other additives (e.g. menthol) that enhance appeal and tolerability of smoked tobacco products.</p> <p>Aim to make smoked tobacco products less palatable and appealing, particularly to youth and young adults.</p>

Regulation/ policy area	E-cigarettes and e-liquids	Smoked tobacco products
	Review evidence and consult over whether maximum nicotine concentration/dose limit is required and implement regulations as appropriate.	Consider introducing regulation to require all smoked tobacco products are 'very low nicotine content', as proposed by US Food and Drugs Administration [8].
Nicotine content	Aim to ensure ECs and e-liquids are effective and safe replacement nicotine delivery devices for smokers switching to ECs or using them to quit.	Aim to minimise addictiveness of cigarettes for youth and young adults, and make smoked tobacco products ineffective nicotine delivery devices for existing smokers – prompting quitting or switching to ECs.

Smoking cessation advice

We recommend guidelines and best practice are developed and disseminated for using ECs as a cessation aid, and the MoH engage with established smoking cessation providers to discuss integration of ECs within their services, as is consistent with their tikanga or kaupapa. There should also be support for community-based initiatives and cessation support implemented in new settings (e.g. probation and Iwi-based services) to encourage and assist smokers to quit through ECs (and other means).

Other regulatory issues and monitoring and evaluation

The table does not include assessment processes for developing quality and safety standards for ECs, or for deciding which nicotine-delivery products should be allowed for sale. These decisions are subject to pending guidance from the Electronic Cigarette Technical Expert Advisory Group. The table also does not address where ECs and smoked tobacco products may be used; these questions will also require careful consideration prior to policy development. Finally, implementation of the framework will require appropriate data collection systems and regular high-quality studies to monitor patterns of use (uptake, quitting, switching etc) and source of supply of smoked tobacco products, ECs and other alternative nicotine delivery products among smokers, ex-smokers, and adolescents and young adults.

Heat-not-burn products

We have not addressed regulation of heat-not-burn products in table 2. Data are still emerging on the possible role for these products in helping smokers to quit – or switch – and their relative harm [6]. As a result, there is greater uncertainty regarding policy and regulation for these products than for ECs.

We see many reasons for caution by governments:

1. Preliminary evidence from emissions (and similar) studies suggest these products will be less harmful than smoked tobacco products, but more harmful than ECs [6, 9];
2. The current research base is heavily reliant on studies funded or carried out by the tobacco industry, and requires replication from independent studies [6, 9];

3. These products are currently dominated by the tobacco industry without the strong independent sector that characterises the EC market;
4. These devices (and some of the newer EC products like JUUL) may have strong appeal to and uptake among adolescents and young adults [10], though current data are limited [9, 11];
5. Devices like IQOS are relatively expensive 'premium products' that may be less likely to be used by financially-disadvantaged smokers to quit or substitute for smoked tobacco products.

Our preferred option would have been to keep these products out of the NZ market until (i) the impact of greater availability of ECs has been assessed; (ii) there is clearer evidence of health effects of heat-not-burn products; and (iii) there is more evidence of the impact of heat-not-burn products on smoking prevalence. However, the recent Court ruling has removed that option. We therefore suggest a stronger regulatory framework is required for heat-not-burn products compared to ECs.

Such a framework could include additional restrictions on point-of-sale advertising and displays, and consideration of standardised packaging and higher levels of excise/taxation than ECs. Alternatively, new regulations could simply disallow their sale (in the same way as oral tobacco is not permitted to be sold). In any event, the Ministry of Health should conduct regular reviews of the scientific evidence on the relative harms and impacts on smoking prevalence of these products; and revisit decisions about their availability and regulation as appropriate.

No doubt there will be other new products. For example, JUUL is currently generating considerable interest as a potentially very effective alternative nicotine delivery device but with concerns about youth uptake [10]. This product (and similar products) will require careful evaluation to assess where they fit on the risk continuum and to determine appropriate regulations.

Conclusions

In summary, progress towards SF2025 is far too slow. We need to do much more, particularly to reduce smoking among Māori and Pacific peoples. We welcome the Ministry's intention to develop a risk-proportionate regulatory framework and look forward to discussing its nature and detailed content.

The new framework is an opportunity to strengthen the regulation of smoked tobacco products and intensify policy measures to encourage smokers to quit and discourage children, adolescents and young adults from starting to smoke.

At the same time, a new framework must ensure that ECs (and possibly other lower-harm alternative products) are relatively more affordable, accessible and appealing to smokers who wish to switch to these products. The specific regulatory measures for ECs that will result in the most positive impacts on health can be debated. However, the framework outlined in this blog (or something similar) would be a key step towards finally ending the wholly-preventable epidemic of smoking-related inequality, suffering and death in New Zealand. We believe it would greatly accelerate progress towards achieving the 2025 Smokefree Aotearoa goal and by doing so make World Smokefree day gloriously irrelevant, at least in New Zealand.

Footnotes:

[*] Declines in smoking among Māori and young people were greatest between the last two data points (2015/16-2016/17), so need to be viewed with caution.

Acknowledgements:

Thank you to the following who were consulted and provided comments and suggestions for this blog: Mihi Blair and the Hāpai Te Hauora team, Robert Beaglehole, Tony Blakely, Boyd Broughton, Julian Crane, Shayne Nahu, George Thomson and Ben Youdan. These individuals may not agree with every proposed measure included in Table 2.

Authors: *Richard Edwards, Anaru Waa, Janet Hoek, Louise Thornley, Nick Wilson. ASPIRE 2025, Department of Public Health, University of Otago, Wellington*

References

1. Ball J, Stanley J, Wilson N, Blakely T, Edwards R: Smoking prevalence in New Zealand from 1996-2015: a critical review of national data sources to inform progress toward the Smokefree 2025 goal. *NZMJ* 2016, 129(1439):11-22.
2. van der Deen F, Wilson N, Blakely T: A continuation of 10% annual tobacco tax increases until 2020: Modelling results for smoking prevalence by sex and ethnicity. *NZMJ* 2016, 129(1441):94.
3. van der Deen FS, Wilson N, Cleghorn CL, Kvizhinadze G, Cobiac LJ, Nghiem N, Blakely T: Impact of five tobacco endgame strategies on future smoking prevalence, population health and health system costs: two modelling studies to inform the tobacco endgame. *Tob Control* 2017: Published Online First: 24 June 2017.
4. ASH New Zealand: National Year 10 ASH Snapshot Survey 1999-2011, Factsheet 2: Youth smoking in New Zealand by ethnicity In. Auckland: ASH New Zealand; 2012.
5. ASH New Zealand: 2017 ASH Year 10 Snapshot. Auckland: ASH New Zealand; 2018.
6. McNeil A, Brose LS, Calder R, Bauld L, Robson D: Evidence review of ecigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England; 2018.
7. National Academies of Sciences E, and Medicine.: Public health consequences of e-cigarettes. Washington, DC: The National Academies Press; 2018.
8. US Food and Drug Administration: Tobacco Product Standard for Nicotine Level of Combusted Cigarettes: Advance notice of proposed rulemaking *Fed Regist* 2018, 83 (52):11818-11843.
9. Liu X, Lugo A, Spizzichino L, Tabuchi T, Pacifici R, Gallus S: Heat-not-burn tobacco products: concerns from the Italian experience. *Tob Control* 2018: Published Online First: 26 January 2018.
10. Willett JG, Bennett M, Hair EC, Xiao H, Greenberg MS, Harvey E, Cantrell J, Vallone D: Recognition, use and perceptions of JUUL among youth and young adults. *Tob Control* 2018: Published Online First: 18 April 2018.
11. Tabuchi T, Gallus S, Shinozaki T, Nakaya T, Kunugita N, Colwell B: Heat-not-burn tobacco product use in Japan: its prevalence, predictors and perceived symptoms from exposure to secondhand heat-not-burn tobacco aerosol. *Tob Control* 2017: Published Online First: 16 Decem

Source URL:

<https://www.phcc.org.nz/briefing/smoke-heat-or-vapour-ideas-risk-proportionate-regulation-make-world-smokefree-day>