

Response ID ANON-UPHM-27V6-F

Submitted to Proposals for a Smokefree Aotearoa 2025 Action Plan
Submitted on 2021-05-29 16:37:55

Your details

1 What is your name?

Name:

§ 9(2)(a)

2 Contact details

Email:

§ 9(2)(a)

Phone number:

§ 9(2)(a)

3 What is your organisation & role?

Organisation name:

22nd Century Group, Inc

Organisation address:

500 Seneca Street, Ste 507, Buffalo, New York 14204, United States

What is your role?:

Regulatory Compliance Manager

4 Additional organisation information

Other (please specify)

Other:

United States

Tobacco manufacturer, importer or distributor

5 What is your age?

Not applicable

6 What ethnicity/ethnicities do you identify with?

Prefer not to say

Other ethnicity:

Focus area 1. Strengthen the tobacco control system

1 What would effective Māori governance of the tobacco control programme look like? Please give reasons.

What would effective Māori governance of the tobacco control programme look like? Please give reasons.:

Recognising the profound health disparities that cigarette addiction creates or compounds in vulnerable or minority communities in New Zealand, as in the US, we believe that this is a question for Māori to define.

National Government must ensure that the governance framework proposed by Māori is robustly funded to meet its tobacco control objectives and is ring-fenced to ensure effective, immediate and permanent health gains for Māori and other peoples.

2 What action are you aware of in your community that supports Smokefree 2025?

What action are you aware of in your community that supports Smokefree 2025?:

As a US based plant biotechnology company, we are aware of numerous developments in the US health policy and regulatory landscape that are consistent with the Smokefree 2025 Action Plan.

Ministry of Health Manatū Hauora will already be aware that the US Food and Drug Administration is pursuing its Comprehensive Plan for Nicotine and

Tobacco Regulation [<https://www.fda.gov/tobacco-products/ctp-newsroom/fdas-comprehensive-plan-tobacco-and-nicotine-regulation>].

The four pillars are 1) reducing nicotine in cigarettes to minimally or non-addictive levels 2) providing ready access to cessation support 3) Alternative nicotine products for adult consumer 4) A high focus on youth prevention. In fact, both the reduced nicotine content proposals under consideration in the Action Plan by Aotearoa New Zealand and those in the United States are grounded in a vast evidence base which predominates with independent studies conducted using reduced nicotine content products made by 22nd Century Group, Inc, using 22nd Century's proprietary reduced nicotine content technology.

The US FDA has also recently committed to eliminating menthol from highly addictive cigarettes to address one component of health disparities caused by or compounded by smoking in the US, particularly among African-Americans. 22nd Century Group has publicly voiced its support for this measure [<https://www.xxiicentury.com/investors/news/press-releases/detail/431/22nd-century-group-welcomes-ban-on-menthol-cigarettes-and>]; however, 22nd Century Group believes that in addition to this, a reduction of nicotine to minimally or non-addictive levels in cigarettes will have a far greater public health impact and save millions of lives in the US alone.

Tragically in the US, as in Aotearoa New Zealand and other nations, there are profound health disparities lived by people of our vulnerable and minority communities, with cigarette smoking prevalence a key factor and indicator. It is distressing to read in the Discussion Document that lung cancer mortality among Māori women is over four times that of non-Māori women (Ministry of Health Manatū Hauora, 2018).

22nd Century believes that a prompt introduction of regulations requiring reduced nicotine will be a key tool for swiftly reducing and ultimately eliminating such appalling disparities

[<https://www.xxiicentury.com/investors/news/press-releases/detail/435/22nd-century-vp-of-regulatory-science-to-present-on-health>]. We respectfully submit alongside this response a recent presentation given by 22nd Century Group, Inc. on this key area.

FDA's Acting Commissioner, Dr Janet Woodcock, confirmed at a recent press briefing on FDA's menthol proposals that requiring reduced levels of nicotine in tobacco products is still under consideration by the US FDA. [28 min, 11s into speech; <https://www.youtube.com/watch?v=JlcUKbTFeF4>].

There is overwhelming support among public health, medical and tobacco control organizations, for reducing the level of nicotine in cigarettes to minimally or non-addictive levels

[https://www.acponline.org/acp_policy/letters/joint_letter_to_fda_re_tobacco_product_standard_for_nicotine_level_combusted_cigarettes_anprm_2018.pdf and Willett et al, 2021, <https://academic.oup.com/eurheartj/advance-article/doi/10.1093/eurheartj/ehab245/6284113>]

3 What is needed to strengthen community action for a Smokefree 2025? Please give reasons.

What is needed to strengthen community action for a Smokefree 2025? Please give reasons.:

Empowering community leaders and resourcing them accordingly. The tobacco taxation revenues provide ample opportunity for substantial funding of community led initiatives.

4 What do you think the priorities are for research, evaluation, monitoring and reporting? Please give reasons.

What do you think the priorities are for research, evaluation, monitoring and reporting? Please give reasons.:

A high focus must be given to vulnerable and minority communities with significantly higher prevalence of smoking. Moreover, to ensure ultimately that a Smokefree Aotearoa is achieved, youth product use must continue to be monitored and reported.

22nd Century Group, Inc. as the leader in reduced nicotine content tobacco technology, has provided tens of millions of research cigarettes for clinical investigations by public health experts, conducted largely under US Federal Government Health Agency grants.

Should Ministry of Health Manatū Hauora seek to conduct any such research itself or in partnership with other health stakeholders, 22nd Century Group, Inc. is fully prepared to discuss opportunities to provide reduced nicotine content cigarettes, on customary terms, for studies by public health researchers.

5 What else do you think is needed to strengthen New Zealand's tobacco control system? Please give reasons.

What else do you think is needed to strengthen New Zealand's tobacco control system? Please give reasons.:

A National recognition that cigarette addiction must now become part of New Zealand's past not its future. The Māori, for example, had no cultural history of smoking tobacco until it was brought into their communities by Europeans, with deadly consequences for hundreds of years.

[<https://www.smokefree.org.nz/smoking-its-effects/facts-figures>]

Focus area 2. Make smoked tobacco products less available

1 Do you support the establishment of a licensing system for all retailers of tobacco and vaping products (in addition to specialist vape retailers)?

Yes

Please give reasons.:

The Discussion Document cites Robertson et al 2016, stating that "An estimated 5000 to 8000 retail outlets sell tobacco in New Zealand". The uncertainty in this number of outlets will be a barrier to Tobacco Control. Given the profound public health impact of tobacco on public health, knowing and limiting where tobacco is sold is not unreasonable. Any revenues from licensing should maintain the system of licensing, with any surplus directed at community tobacco control initiatives.

2 Do you support reducing the retail availability of smoked tobacco products by significantly reducing the number of retailers based on population size and density?

Yes

Please give reasons::

Tobacco Products are unlike any other consumer goods – highly addictive and responsible for the deaths of 1 in 2 people who smoke, when used as intended. To place this in context, the case fatality rates for Ebola is also 50%. Given this, they cannot be treated to the usual market norms. Limiting the number of retailers reduces the exposure of youth to tobacco product or tobacco marketing impressions. Wherever highly addictive cigarettes are sold, alternative products should also be available to adult smokers.

3 Do you support reducing the retail availability of tobacco products by restricting sales to a limited number of specific store types (eg, specialist R18 stores and/or pharmacies)?

Yes

Please give reasons::

Without a reduced nicotine content requirement for cigarettes that renders cigarettes minimally or non-addictive, we believe that highly addictive cigarettes should only be available in specific stores.

4 Do you support introducing a smokefree generation policy?

Yes

Please give reasons::

If this policy is combined with other policies in this Action Plan, such as requiring a reduction in nicotine content in cigarettes to minimally or non-addictive levels, it will result in a generationally and globally significant public health achievement.

In isolation, however, this is not a sufficient or rapid enough public health solution, as such a policy does not assist adults who currently smoke, half of whom will die prematurely as a result of addiction to cigarettes.

5 Are you a small business that sells smoked tobacco products?

No

Please explain any impacts that making tobacco less available would have on your business that other questions have not captured. Please be specific.:

Focus area 3. Make smoked tobacco products less addictive and less appealing

1 Do you support reducing the nicotine in smoked tobacco products to very low levels?

Yes

Please give reasons::

Kei te rangatira, tēnā koe, Dear Sir, Dear Madam;

22nd Century fully supports Aotearoa New Zealand in its proposal to reduce the nicotine in smoked tobacco products to very low levels. The evidence is overwhelming that this proposal will lead to profound reductions in smoking and smoking prevalence.

22nd Century Group, Inc, seeks to eliminate tobacco addiction, not to maintain it.

As a leading plant biotechnology company and the World's leading authority on reduced nicotine tobacco, we are fully prepared to play our role in advancing public health in Aotearoa New Zealand

The Need for Reducing the Nicotine in Cigarettes

With 1 in 2 people who smoke losing their lives to diseases arising from smoking, highly addictive cigarettes have no equal among legal consumer products. To place this in context, the case fatality rates for Ebola is also 50%.

As set out in the Proposals for a Smokefree Aotearoa 2025 Action Plan, almost half a million New Zealanders still smoke, with disturbingly high levels of smoking prevalence in Māori communities. There is an urgent need for step-changes in tobacco regulatory policy in Aotearoa New Zealand, and around the rest of the World, to address cigarette addiction in general, while ensuring that minority communities or vulnerable groups are not left behind from public health advances.

We strongly believe, based on the dozens of clinical trials and more than \$100 million of independent science conducted to understand the public health benefits of reduced nicotine content cigarettes, that proposals to reduce the nicotine in smoked tobacco products to very low levels represent one of the most significant public health opportunities of the modern era: by any country.

The Science Supporting Reducing the Nicotine in Smoked Tobacco

22nd Century Group is well placed to comment on the science supporting the reduced nicotine in cigarettes and other smoked products. 22nd Century is a leading plant biotechnology company focused on technologies that alter the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering, gene-editing and modern plant breeding. Our primary mission in tobacco is to reduce the harm caused by smoking by bringing our proprietary reduced nicotine content tobacco cigarettes – containing 95% less nicotine than conventional cigarettes – to adult smokers in the U.S. and International markets.

For almost a decade, we have provided reduced nicotine content tobacco cigarettes to public health agencies and leading academic researchers for studies to inform health policy development, further details of which are provided below. In December 2019, following a comprehensive review of the supporting science, the US FDA permitted for sale two of 22nd Century's reduced nicotine products under the Moonlight® brand, stating that these products were “appropriate for the protection of public health”. These products, menthol and non-menthol variants of the same product, have a nicotine content of ~0.5 mg/g of tobacco. This level of nicotine in the authorized products is at least 95% less nicotine in the tobacco than typical commercial cigarettes. Furthermore, 22nd Century Group has also submitted an application to the US FDA for a modified exposure authorization to permit the sale of the same products above, but with statements in the marketing material that describe the product. The intention here is to communicate to adults who smoke, with an interest in reducing their exposure to nicotine, that the product contains 95% less nicotine than other products in the US market.

22nd Century Group commits to providing any additional detail or data that may be useful to Manatū Hauora Ministry of Health in pursuit of the Smokefree Aotearoa 2025 Action Plan and related action plans on Māori and Pacific health and well-being.

Given the sheer volume of scientific data in support of this particular plan proposal, the summary response here will be accompanied by separate submissions of other materials and references.

22nd Century believes that reduced nicotine content (RNC, also known as VLNC or very low nicotine content) cigarettes containing only minimally, or non-addictive levels of nicotine will enable people to either stop smoking or to never develop the addiction to smoking. Independent clinical trials have shown that 22nd Century's proprietary RNC cigarettes enable smokers to disassociate the act of smoking from the rapid intake of nicotine. Accordingly, smoking consumption is reduced, withdrawal symptoms are lessened, and many more smokers attempt to quit. RNC cigarettes are so promising that research published in the May 2018 edition of The New England Journal of Medicine estimates that in the first year after implementation of the US FDA's own proposed plan to limit cigarettes in the US to minimally or non-addictive levels of nicotine, approximately 5 million people would stop smoking and, in as few as five years after implementation of the FDA's plan, more than 13 million people would stop smoking [<https://www.nejm.org/doi/full/10.1056/NEJMSr1714617>]. The US Centers for Disease Control reported that in 2019, around 34.1 million people smoked in the US, an adult prevalence of 14%; the above suggests a 14.6% reduction in the number of people smoking in year one of reduced nicotine requirements vs baseline and a 38.1% reduction within 5 years.

As a component of a Smokefree Aotearoa Action Plan, we believe that the scientific literature shows that New Zealand would likely also see such a profound relative reduction in smoking prevalence when enacted alongside other measures proposed in the Action Plan. Accepting of course that the US and Aotearoa New Zealand's population and society have many differences; a loose comparison, however, would suggest that smoking prevalence in New Zealand by the single measure of reducing nicotine in cigarettes to minimally or non-addictive levels could potentially be reduced from the current 11.6% to only 7% within five years of implementation, and much lower still when combined with other measures in the Action Plan. For example, the large study conducted in New Zealand by Walker et al found that when reduced nicotine content cigarettes were available in addition to Quitline support (8 weeks of NRT – lozenges or gum and behavioural support) that quit rates were higher at 6 months than in the group receiving only Quitlines support. [<https://pubmed.ncbi.nlm.nih.gov/22594651/>].

At the same time as reduced nicotine content cigarettes requirements are introduced to Aotearoa New Zealand, it will be essential to ensure that there is sufficiently high focus on Māori, Pacific peoples and those living in the most disadvantaged communities that have the highest smoking prevalence, so that all people may move ahead and enjoy the achievement of a Smokerfree Aotearoa.

Reducing Nicotine Content in Cigarettes is Feasible

The Action Plan Regulatory Impact Statement is correct; reducing nicotine in tobacco to levels that would be minimally or non-addictive is feasible. Moreover, this is not simply at a theoretical or early-stage feasibility, but commercially and at scale.

22nd Century is a publicly traded plant biotechnology company with an important mission: To Reduce the Harm Caused by Smoking. The Company's genetic engineering technology, non-GMO technologies and plant breeding expertise allows it to regulate the level of nicotine (and other nicotinic alkaloids) in the tobacco plant. Because of this unique technology, 22nd Century is able to grow tobacco with significantly less nicotine than tobacco used in conventional cigarettes. 22nd Century has an extensive intellectual property portfolio of issued patents and patent applications relating to tobacco plants, as well as hemp/cannabis plants. Nicotine is produced in the roots of the tobacco plant by the linking of compounds derived from nicotinic acid and putrescine. Nicotine is one of many nicotinic alkaloids in tobacco, but it is the most prevalent, making up 85-95% of the total of nicotinic alkaloids in typical commercial tobacco plants. Our proprietary technology allows 22nd Century to decrease the biosynthesis of nicotine and other nicotinic alkaloids in tobacco plants. This enables us to regulate nicotine content in tobacco plants without adversely affecting other leaf compounds important to a tobacco plant's characteristics, including taste and aroma.

In 2011, 22nd Century developed the SPECTRUM® line of research cigarettes in collaboration with independent researchers and officials from the National Institute on Drug Abuse (NIDA), the FDA, the National Cancer Institute (NCI) and the Centers for Disease Control and Prevention (CDC). The main SPECTRUM® product line consists of a series of cigarette styles that vary in nicotine content – from very low (~0.4 mg/g tobacco) to relatively high nicotine contents and yields. SPECTRUM® products are available in 24 styles, in both regular and menthol versions, with 8 levels of nicotine in their tobacco. The amount of nicotine in the various styles of SPECTRUM® cigarettes is controlled by blending conventional nicotine content tobacco and RNC tobacco. The lowest nicotine level SPECTRUM® cigarettes contain only the tobacco used in our Moonlight® and VLN® products, discussed in more detail below. Over the past decade, 22nd Century has grown, manufactured and delivered over 30million of our proprietary products via Research Triangle Institute (RTI) and NIDA for use in dozens of well-designed and conducted independent studies, funded largely under Federal health agency grants. It is the output of this vast body of scientific research that has informed the policy intent of the US Food & Drug Administration

[<https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-dramatically-reduce-smoking>]

and <https://www.federalregister.gov/documents/2018/03/16/2018-05345/tobacco-product-standard-for-nicotine-level-of-combusted-cigarettes>] FDA has also conducted an assessment of the science that supports the policy in a comprehensive presentation that we also submit to the Ministry of Health Manatū Hauora, as well as our detailed response to FDA tobacco product standard proposal ("Advanced Notice of Proposed Rule Making, or ANPRM").

Should Ministry of Health Manatū Hauora seek to conduct any such research itself or in partnership with other health stakeholders, 22nd Century Group, Inc. is fully prepared to discuss opportunities to provide reduced nicotine content cigarettes, on customary terms, for studies by public health researchers.

Scope of the Action Plan

22nd Century Group, Inc. wishes to inform Manatū Hauora that the Company's RNC technology is currently applicable to traditional, widely used cigarette tobaccos, including burley, Oriental, and bright/flue-cured varieties. However, 22nd Century Group's technology also could be made applicable to other tobaccos.

Supplying the New Zealand tobacco industry with tobacco containing very low levels of nicotine is eminently feasible. Since tobacco plants produce a prodigious number of seeds, 22nd Century can produce sufficient quantities of the Company's proprietary RNC tobacco seed for the entire Aotearoa New Zealand market in just one growing season: the supply of RNC seed for RNC tobacco production is not a limiting step in adoption of requirements for reduced nicotine tobacco products. For example, one tobacco plant yields more than 100,000 seeds; fewer than 25 acres of RNC tobacco plants will provide sufficient RNC seed to grow enough RNC tobacco to make 258 billion cigarettes – which would equate to a 12-month supply for the entire U.S. cigarette market.

22nd Century is willing to license the use of the Company's RNC tobacco and technology to ALL interested companies.

Every company will be able to comply with the new requirements that all cigarettes sold in the Aotearoa New Zealand contain only minimally or non-addictive levels of nicotine. The opportunity to license the use of 22nd Century's RNC tobacco and technologies on customary terms eliminates any argument by tobacco companies that contend it is not feasible to comply with the new nicotine reduction rule in Aotearoa New Zealand.

As described in greater detail herein, the case for enacting a national nicotine policy as envisioned by the Ministry of Health Manatū Hauora is compelling, feasible, and vitally urgent for the protection of public health.

Setting the mandated level for reduced nicotine content cigarettes.

Based on the Company's RNC tobacco growing experience, 22nd Century submits that the mandated level should be set at a target nicotine content level of 0.5 mg nicotine per gram of tobacco (dry weight) as measured in the tobacco filler itself. By its very nature, tobacco is an agricultural crop. Tobacco characteristics cannot be controlled to the same level of precision that is achievable in drugs or medical devices. Variations will occur based on growing conditions, location, and curing conditions. Therefore, the nicotine standard set by NZ should also allow for some variation. A nicotine target of 0.5 +/- 0.2 mg per gram of tobacco (dry weight) falls within the range suggested by well-known scientists, including Dr. Eric Donny (0.4 mg/g), Dr. Dorothy Hatsukami (0.4 to 0.5 mg nicotine per gram of tobacco/ and Dr. Neil Benowitz (0.6 mg per cigarette). Based on the fact that cigarettes contain only 0.7 grams of tobacco, 22nd Century's proposed maximum level of nicotine content of 0.7 mg/gm (0.5 +/- 0.2) tobacco would result in a cigarette containing 0.49 mg nicotine per cigarette. In 2015, The New England Journal of Medicine published "Reducing the Nicotine Content to Make Cigarettes Less Addictive." Donny et al., concluded that data from the study suggests, as compared with cigarettes of conventional nicotine content, low nicotine cigarettes were "associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events." Therefore, a nicotine content range of 0.5 +/- 0.2 mg/g is achievable and does not impact the "non-addictive or minimally addictive" properties of 22nd Century's RNC tobacco.

We believe that establishing the necessary testing capability for verification purposes within Aotearoa New Zealand is readily achievable and 22nd Century can provide Ministry of Health Manatū Hauora with its own experience of testing methodologies for assessing low levels of nicotine within tobacco products, examples submitted separately.

Reduced Nicotine Content Cigarettes Have Already Been Authorized for Marketing and Sale by the US Food & Drug Administration (FDA).

Following a comprehensive review by the US FDA of the submitted scientific literature from 22nd Century Group - much of which was conducted independently under Federal health agency grants by leading academic public health experts, in December 2019 FDA permitted for sale two reduced nicotine products under the Moonlight® brand. These products, menthol and non-menthol variants of the same product, have a nicotine content of ~0.5 mg/g of tobacco. This level of nicotine in the authorized products is at least 95% less nicotine in the tobacco than typical commercial cigarettes. In announcing its decision

[<https://www.fda.gov/news-events/press-announcements/fda-permits-sale-two-new-reduced-nicotine-cigarettes-through-premarket-tobacco-product-application>];

FDA stated:

"Following a rigorous science-based review of the premarket tobacco product applications (PMTAs) submitted by the company, the agency determined that authorizing these reduced nicotine products for sale in the U.S. is appropriate for the protection of the public health because of, among several key considerations, the potential to reduce nicotine dependence in addicted adult smokers, who may also benefit from decreasing nicotine exposure and cigarette consumption. The agency determined that non-smokers, including youth, are also unlikely to start using the products, and those who experiment are less likely to become addicted than people who experiment with conventional cigarettes."

We encourage Ministry of Health Manatū Hauora to review the full findings of FDA's Technical Project Lead (TPL) in their report on the scientific review and findings [<https://www.fda.gov/media/133633/download>]. Indeed, we would add, respectfully, that given the US and Canada's shared public health interest in advancing similar proposals, that Ministry of Health Manatū Hauora may benefit from dialogue with FDA's Center of Tobacco Products and Health Canada, if it has not already done so.

We also provide alongside this submission an update of the scientific literature that has been published since the original PMTA application, which we have also provided to the US FDA as part of the ongoing monitoring and evaluation obligation that the FDA has placed on us. Of particular note in this document are the studies that consider the potential effects on vulnerable communities, such as people with pre-existing mental health conditions, people living with HIV and people with substance use disorder. The findings are highly supportive of a nicotine reduction policy supporting such groups

within society. For reasons of copyright and document purchase terms, papers not fully available in the public domain and their summaries are redacted.

Furthermore, 22nd Century Group has also submitted an application to the FDA for an authorization to permit the sale of the same products above with statements in the marketing material that describe the product. The intention here is to communicate to adults who smoke with an interest in reducing their exposure to nicotine that the product contains 95% less nicotine than other products in the US market. This application is under the Modified Exposure Order process which sits within the Modified Risk Tobacco Product (MRTP) pathway [<https://www.govinfo.gov/content/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>]. Of note, we are not seeking to make modified risk claims: all cigarettes can cause disease and death. The product toxicology is essentially the same; the pharmacology of the product with such profound reductions in nicotine is not. The product in the application for a modified exposure order, intended to be sold under the VLN® brand, is the same as the authorized Moonlight® product, discussed above.

We understand that this application is in its final stages of review, and we await FDA's decision on this application, which would enable to communicate the product attributes to adult smokers. We note that the necessity for such claims would be reduced or obviated in a marketplace where nicotine had been reduced and capped in all cigarettes.

The MRTP pathway requires full disclosure of all data submitted to FDA to be made publicly available, save for items which are commercially confidential. The full record of our MRTP application can be accessed here [<https://www.fda.gov/tobacco-products/advertising-and-promotion/22nd-century-group-inc-modified-risk-tobacco-product-mrtp-applications>].

By way of introduction to the MRTP, 22nd Century also submits its executive summary accessible here

[https://syndication-files.s3.amazonaws.com/mrtpa/22century/Section%20III%20Executive%20Summary_MAIN_Redacted.pdf]

This document and accompanying materials provide detailed comprehensive insights into the science supporting the Smokefree Aotearoa 2025 Action Plan.

22nd Century fully supports the Proposal for a Smokefree Aotearoa 2025 plan, in general and specifically on reducing nicotine content.

To close, we wish to re-iterate the conclusions of an assessment of a reduced cigarette nicotine policy by leading New Zealand public health experts Richard Edwards, Janet Hoek and Nick Wilson (members of ASPIRE2025 and the Department of Public Health, University of Otago, Wellington) and Chris Bullen (National Institute of Health Innovation at the University of Auckland),

[<https://blogs.otago.ac.nz/pubhealthexpert/reducing-nicotine-in-smoked-tobacco-products-a-pivotal-feature-of-the-proposals-for-achieving-smokefree-aotearoa-2025>]

"A mandated VLNC policy for Aotearoa NZ is a critical component of the Government's proposed action plan which will give a realistic chance of achieving the Smokefree 2025 goal, and realising the many benefits of health improvement, enhanced equity, and cost-savings that would follow. There is a compelling logic and growing evidence base supporting this approach, and NZ can potentially draw on ongoing developments with implementation of this policy in the USA. Robust monitoring and evaluation will be critical to assess the policy's impact, and to ensure people who smoke are supported to quit or move to other nicotine sources. Submissions for the action plan are open. We encourage all individuals and organisations who are concerned about enhancing the health of New Zealanders and who support the need to protect future generations and help people who smoke to quit, to make submissions in support of this important measure."

And we agree. 22nd Century Group, Inc, seeks to eliminate tobacco addiction, not to maintain it.

We sincerely hope that we may apply our unique biotechnology as part of the wider proposals to enable Māori, Pacific and other peoples to achieve a Smokefree Aotearoa.

Thank you for your review and consideration of our response and the associated materials, please do not hesitate to contact me if I can be of any further assistance.

Nāku noa, nā, Yours Sincerely,

§ 9(2)(a)

§ 9(2)(a)

Vice President, Regulatory Affairs
22nd Century Group
500 Seneca Street
Buffalo, New York

2 Do you support prohibiting filters in smoked tobacco products?

Yes

Please give reasons::

There is no public health benefit to maintaining cigarette filters on highly addictive cigarettes. Society has witnessed 100s of millions of deaths globally since filters were widely introduced; they are an unnecessary component of an intrinsically defective product.

Filters continue to provide a false and misleading reassurance to people that the product has been limited in some manner. In fact, filters allow sufficient rapid nicotine delivery into the brain to create and sustain addiction, ensuring the chronic and compulsive of smoke containing thousands of harmful chemicals that result in disease sadly death.

The arguments 'Big Tobacco' makes for maintaining the status quo on filters are neither necessary nor sufficient justification for their ongoing use on products that kill 1 in 2 people when used as intended. Reasons proffered by Big Tobacco include – "prevent pieces of tobacco from entering the mouth" and "give a different taste to the smoke". [Source, Philip Morris International-sponsored site <https://www.worldnoashtray.com/en.html/>].

Filters have been used to subvert smoke testing methods for nicotine and tar yields for decades - misleading countless consumers in the process; as

carriers for novelty features, such as “crushballs” or features to “engage” consumers with functions such as twistable filters or novelty inclusions such as “carbon”.

While tobacco companies will talk about Cellulose Acetate filters as “bioplastics” made from “wood cellulose”; they often neglect to mention that the cellulose is plasticised during manufacture using triacetin and the final butt that is littered also contains numerous other chemicals.

The final product filter is more robust than cellulose acetate alone, physically persists in the environment, is toxic to aquatic life and an ingestion risk for marine life. Over 4.5 trillion butts are littered globally each year [https://www.thetruth.com].

With or without a filter prohibition, a reduced nicotine content policy would lead to smokers reducing their consumption, increasing quit attempts and smoke free days reducing the numbers of filters in use.

An alternative to filter prohibition could include a levy on each cigarette filter or heated tobacco stick as an unnecessary single-use plastic pollutant; proceeds from which could be invested into community tobacco control initiatives.

3 Do you support allowing the government to prohibit tobacco product innovations through regulations?

Yes

Please give reasons::

There is no foreseeable public health benefit to allowing innovations in highly addictive combustible cigarettes.

Such innovations are invariably part of a brand marketing strategy used to appeal to new smokers and to reassure existing smokers of their addiction generally and brand choice specifically.

Moreover, existing cigarettes in Aotearoa New Zealand and in fact globally are intrinsically defective products as they are 1) highly addictive and 2) highly toxic.

As banning products is not in consideration by the Action Plan, the greatest and most rapid public health advance that can be made towards a Smokefree Aotearoa 2025 is to require all cigarettes to contain minimally or non-addictive levels of nicotine, coupled with other measures in the Action Plan.

Suitably regulated alternative products to highly addictive cigarettes should, subject to oversight and monitoring by public health bodies and other health stakeholders, be able to incorporate innovations over time when, and only when, such innovations are in-line with the objectives of the Smokefree Aotearoa 2025 Action Plan and associated action plans

Please also see response in b) above.

Focus area 4. Make tobacco products less affordable

1 Do you support setting a minimum price for all tobacco products?

Yes

Please give reasons::

We believe that minimum pricing for highly addictive combustible cigarettes is reasonable and necessary as part of the wider proposals set out in the Smokefree Aotearoa 2025 Action Plan.

However, we would qualify this by adding that the authorities of Aotearoa New Zealand should also have the flexibility to deploy differential pricing and taxation measures for alternative products, as this flexibility may accelerate achievement of a Smokefree Aotearoa, alongside other measures in the Action Plan.

General comments

1 Of all the issues raised in this discussion document, what would you prioritise to include in the action plan? Please give reasons.

Of all the issues raised in this discussion document, what would you prioritise to include in the action plan? Please give reasons.:

As a priority within the proposals within the Action, regulatory advancement must include reducing nicotine in cigarettes. This one measure alone would take Aotearoa New Zealand within striking distance of achieving its Smokefree ambition and protects future generations from initiating cigarette addiction. Moreover, it is enabling for people who smoke to reduce their exposure to nicotine, cigarette consumption, as well as increasing quit attempts without compensatory smoking behaviour and minimal or no withdrawal symptoms. This one measure will accelerate achievement of a Smokefree Aotearoa and reverse the tragic and appallingly high levels of addiction, health impacts, deaths caused by cigarettes to the once tobacco-free Māori and other peoples.

There is also a compelling socioeconomic case for ending cigarette addiction. Imagine the cost of a typical packet of cigarettes purchased each day for several decades; the result is huge sums of money that are lost from families and communities, particularly from low income groups for an unneeded, and as stated in the Discussion Document, an unwanted addiction.

The tobacco industry is adept at accommodating minor regulatory shifts in the interests of profit over people. In this regard, to achieve material public health advancements by reducing smoking prevalence, we encourage NZ to rapidly enact all of the proposals set out in the Action Plan at the soonest opportunity that each can be enacted.

Investing heavily in minority community tobacco control initiatives, reducing nicotine in cigarettes, banning misleading and environmentally damaging cigarette filters and a Smokefree generation amongst other proposals are bold moves which will be met with lobbying, front groups and potentially legal challenges. The resistance by industry should be experienced not as a cause of concern, but as a sign that viable proposals that will reduce smoking are being tabled.

Moreover, in moving forward, NZ sends a signal around the globe that NZ once again is leading the world in the interest of its citizens, to eliminate smoking, and to defend its citizens from the corporate interests of those that would sell addiction and death.

22nd Century Group, Inc. is committed to eliminating cigarette addiction and reiterates its support for all proposals within the Smokefree Aotearoa 2025 Action Plan.

2 Do you have any other comments on this discussion document?

Do you have any other comments on this discussion document?:

22nd Century welcomes the advancements in public health policy that the Ministry of Health Manatū Hauora is proposing. As the leading plant experts in reduced nicotine tobacco technology we are fully committed to supporting New Zealand Smokefree 2025. We have considerable expertise and capability that we are prepared to provide to the Ministry of Health Manatū Hauora as it looks to advance this critical National initiative.

22nd Century is a leading plant biotechnology company focused on technologies that alter the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering, gene-editing and modern plant breeding. Our primary mission in tobacco is to reduce the harm caused by smoking by bringing our proprietary reduced nicotine content tobacco cigarettes – containing 95% less nicotine than conventional cigarettes – to adult smokers in the U.S. and international markets.

For almost a decade, we have provided reduced nicotine content tobacco cigarettes to public health agencies and leading academic researchers for studies to inform health policy development.

In December 2019, following a comprehensive review of the supporting science, the US FDA permitted for sale two of 22nd Century's reduced nicotine products under the Moonlight® brand, stating that these products were "appropriate for the protection of public health". These products, menthol and non-menthol variants of the same product, have a nicotine content of ~0.5 mg/g of tobacco. This level of nicotine in the authorized products is at least 95% less nicotine in the tobacco than typical commercial cigarettes.

Furthermore, 22nd Century Group has also submitted an application to the US FDA for a modified exposure authorization to permit the sale of the same products above, but with statements in the marketing material that describe the product. The intention here is to communicate to adults who smoke, with an interest in reducing their exposure to nicotine, that the product contains 95% less nicotine than other products in the US market.

22nd Century Group commits to providing any additional detail or data that may be useful to Ministry of Health Manatū Hauora in pursuit of the Smokefree Aotearoa 2025 Action Plan and related action plans on Māori and Pacific health and well-being.

Declarations, publishing submissions and privacy

1 Publishing submissions

You may publish this submission

2 Official Information Act responses

Remove my personal details from responses to Official Information Act requests

3 Do you have commercial interests?

I have a commercial interest in tobacco products

4 Commercially sensitive information

This submission does not contain commercially sensitive information

If your submission contains commercially sensitive information, please let us know where.:

5 Protection from commercial and other vested interests of the tobacco industry

Please provide details of any tobacco company links or vested interests below.:

22nd Century is a leading plant biotechnology company focused on technologies that alter the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering, gene-editing and modern plant breeding. Our primary mission in tobacco is to reduce the harm caused by smoking by bringing our proprietary reduced nicotine content tobacco cigarettes – containing 95% less nicotine than conventional cigarettes – to adult smokers in the U.S. and international markets.

For almost a decade, we have provided reduced nicotine content tobacco cigarettes to public health agencies and leading academic researchers for studies to inform health policy development. In fact, both the reduced nicotine content proposals under consideration in the Action Plan by Aotearoa New Zealand and those in the United States, as well as the World Health Organisation are grounded in a vast evidence base which predominates with independent studies conducted using reduced nicotine content products made by 22nd Century Group, Inc, using 22nd Century's proprietary reduced nicotine content technology.

In December 2019, following a comprehensive review of the supporting science, the US FDA permitted for sale two of 22nd Century's reduced nicotine products under the Moonlight® brand, stating that these products were "appropriate for the protection of public health". These products, menthol and non-menthol variants of the same product, have a nicotine content of ~0.5 mg/g of tobacco. This level of nicotine in the authorized products is at least 95% less nicotine in the tobacco than typical commercial cigarettes.

Furthermore, 22nd Century Group has also submitted an application to the US FDA for a modified exposure authorization to permit the sale of the same products above, but with statements in the marketing material that describe the product. The intention here is to communicate to adults who smoke that the product contains 95% less nicotine than other products in the US market.

22nd Century Group commits to providing any additional detail or data that may be useful to Ministry of Health Manatū Hauora in pursuit of the Smokefree Aotearoa 2025 Action Plan and related action plans on Māori and Pacific health and wellbeing.

Our strategic intention is to eliminate cigarette addiction not to maintain addiction; we stand ready to provide support to, or partnership with, other stakeholders who also seek to end the current health crisis and the appalling health disparities caused by highly addictive cigarettes.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

21 June 2021

Tobacco Control
Population Health and Prevention
Ministry of Health

British American Tobacco (NZ) Ltd
PO Box 2618
Auckland 1140
New Zealand

Tel 0800 228 690 (Retailer)
Tel +64 (0)9 357 9430 (General)
www.batnz.com

BY EMAIL: tobacco@health.govt.nz

SALE OF TOBACCO PRODUCTS IN NON-STANDARDISED TOBACCO PACKAGING

We refer the Ministry of Health (**MOH**) to articles by *Stuff*, on 2 and 6 June 2021, titled “Auckland black market tobacco: Dairies selling illegal smokes for organised crime groups” and “Holy smokes: illicit tobacco sold in Auckland church fundraisers” (copies **attached**).

These articles highlight a number of types of illicit tobacco that do not comply with New Zealand’s standardised tobacco packaging laws. In particular:

- The 2 June 2021 article mentions that tobacco packets, branded “Double Happiness” and “Louis Vuitton” are sold in dairies, and were recently purchased from a business in Papakura, Auckland.
- The 6 June 2021 article mentions that chopped tobacco is being sold in clear zip-lock bags.

As you know, under the Smokefree Environments and Regulated Products Act 1990 (**SERPA**), it is an offence to sell tobacco products at retail that are not in the required standardised packaging. Section 51(2)(c) of the SERPA says that retailers (other than large retailers) selling such products are liable for a fine not exceeding \$50,000.

Based on a KPMG report, illicit tobacco comprised approximately 11.5% of total tobacco consumption in New Zealand in 2019, representing an 8.4% increase in volume since 2018. This means that in 2019, over one in ten cigarettes consumed was illicit, with an estimated loss of approximately \$290 million in Government excise revenue.¹

A progressive approach to Smokefree 2025

In the context of the MOH’s recent proposed Smokefree Aotearoa 2025 action plan consultation, we recommend that all proposed tobacco control measures consider the impact of reducing the smoking incidence across both the legal and illicit tobacco markets.

Tobacco control policies should be balanced with immediate action against illicit tobacco while introducing new tools in the tobacco harm reduction toolkit to achieve a Smokefree Aotearoa 2025. Some specific examples include:

¹¹ KPMG (2020), Illicit tobacco in New Zealand, 2019 Full Year Report. Available [here](#).

- direct efforts by the Government to robustly track, monitor and report frequently on smoking incidence of both the legal and illicit market;
- remove the personal manufacturing allowance that allows individuals to manufacture up to 30 cigarettes a day for their personal use;
- expand the remit of controlled purchase operations to include enforcement action against retailers that sell illicit tobacco, along with the ability to issue an infringement notice; and
- allow the marketing of oral nicotine pouches as a 'notifiable product'.

Reasons for action against illicit tobacco

Currently, the cheapest BATNZ 20s cigarette pack is priced at \$29.50 (\$24.76 of which comprises taxes paid to the Government). The 2 June 2021 article references a cash sale at \$22.00. This pricing difference between legal and illicit tobacco creates an incentive for adult smokers to seek out illicit products and reduces any cost-based incentive to quit smoking (or shift to alternative nicotine products). We encourage the MoH to seek further information from the journalist and urge action against the retail sale of illicit tobacco products.

The chopped tobacco offered for sale in communities indicates the personal manufacturing allowance legislation is unworkable as there is little to deter growers who abuse the personal manufacturing exception for personal gain. It is also incapable of enforcement without weighing the amount of dried tobacco each person uses over the course of a year. Permitting individuals to grow an unlimited amount of tobacco (but only manufacture up to 5kg), undermines tobacco control measures to achieve Smokefree Aotearoa 2025. Removing this personal allowance legislation will also ensure New Zealand is in step with OECD countries, that do not have this allowance.

By addressing illicit tobacco, the Government has a better opportunity to achieve its Smokefree Aotearoa 2025 goal. If BATNZ can be of assistance, for example, by providing information about stores that may be selling illicit tobacco products, please let us know.

We look forward to the MOH's response.

Kind regards,

s 9(2)(a)

British American Tobacco (New Zealand) Limited

Response ID BHLF-UPHM-2Q2A-G

Submitted to Proposals for a Smokefree Aotearoa 2025 Action Plan

Submitted on 2021-06-07 09:18:58

Your details

1 What is your name?

Name:

§ 9(2)(a)

2 Contact details

Email:

§ 9(2)(a)

Phone number:

§ 9(2)(a)

3 What is your organisation & role?

Organisation name:

Imperial Brands Australasia

Organisation address:

P O Box 39-400, Wellington Mail Centre, Lower Hutt 5045

What is your role?:

Corporate Affairs Manager

4 Additional organisation information

New Zealand

Other:

Tobacco manufacturer, importer or distributor, Vaping or smokeless tobacco product retail, distribution or manufacture.

5 What is your age?

Not applicable

6 What ethnicity/ethnicities do you identify with?

Prefer not to say

Other ethnicity:

Foreword from the Associate Minister of Health

Part A: Context and history

Part B: Proposed Smokefree Aotearoa 2025 Action Plan

Focus area 1. Strengthen the tobacco control system

1 What would effective Māori governance of the tobacco control programme look like? Please give reasons.

What would effective Māori governance of the tobacco control programme look like? Please give reasons.:

Māori governance of tobacco control programmes should emphasise input from Māori smokers. There is a high proportion of Maori smokers and mainstream harm reduction measures to date have been less effective for these people

2 What action are you aware of in your community that supports Smokefree 2025?

What action are you aware of in your community that supports Smokefree 2025?:

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We have noted a strong emergence of consumer led quit support programmes, predominantly based around vaping as harm reduction alternatives to combustible tobacco. Retailers within the restrictive regulatory framework available to them play a critical role in supporting consumer choice. The proposals presented in the Action Plan have a potential for a detrimental effect on that role and will instead shift smokers to illicit markets - and further away from harm reduced alternatives.

3 What is needed to strengthen community action for a Smokefree 2025? Please give reasons.

What is needed to strengthen community action for a Smokefree 2025? Please give reasons.:

As per 1.b) above

The discussion document refers to increasing funding for social and mass media campaigns, and we note that in the recent 2021 Budget announcement, funding has been allocated specifically for this purpose. We strongly encourage the use of education and communications as alternatives to the other heavy handed proposals contained in the discussion document

4 What do you think the priorities are for research, evaluation, monitoring and reporting? Please give reasons.

What do you think the priorities are for research, evaluation, monitoring and reporting? Please give reasons.:

Research into and evaluation of the effectiveness of individual control measures that have been implemented to date is mandatory. As an example, Vaping legislation has only recently been introduced, and regulations are still to be finalised. As smokers choose to quit or reduce harm through alternative products such as vaping, it is paramount that effectiveness and impact of this measure is thoroughly evaluated in 6 SMOKEFREE ENVIRONMENTS AND REGULATED PRODUCTS ACT 1990: PROPOSALS FOR REGULATIONS advance of new proposals.

Over the past 15 years product display bans, excise increases and plain packaging were control measures that have been implemented, each promising to reduce smoking rates by levels that, had they borne true, seen NZ's goal of Smokefree 2025 coming to fruition. However, despite those measures, the evaluation of effectiveness has only been undertaken on Excise.

The proposals outlined in the Smokefree 2025 Action Plan also make sweeping expectations on outcomes, yet the most recently introduced measure - regulating vaping - and one that has the most potential to succeed has not even had an opportunity to be fully implemented let alone evaluated, and then determined whether and what further measures may be required

5 What else do you think is needed to strengthen New Zealand's tobacco control system? Please give reasons.

What else do you think is needed to strengthen New Zealand's tobacco control system? Please give reasons.:

Strengthening of compliance and enforcement. As an example, we are concerned that the consultation document states:

"Some of the ideas proposed in this consultation document will also contribute to an increase in illicit trade in tobacco (eg. cigarettes that have not had tax paid on them). While the Government has recently strengthened action to reduce illicit trade at the border, further measures will be necessary"

While these further measures are not outlined, it is concerning that there is acceptance of the impact on illicit trade that these proposals will have. With KPMG UK1s 2019 report¹

that New Zealand's illicit tobacco consumption had grown to 11.5% of total tobacco consumption, this is a significant portion of the smoking population which is only set to increase further by these proposals.

Growth in illicit trade means that more smokers are becoming criminalised and will increase the risk of smokers interactions with criminal networks

Focus area 2. Make smoked tobacco products less available

1 Do you support the establishment of a licensing system for all retailers of tobacco and vaping products (in addition to specialist vape retailers)?

No

Please give reasons.:

We support penalties for the small minority of retailers who sell tobacco to children and for criminals who trade in smuggled or counterfeit products.

However, we do not believe it is necessary for retailers to have a licence to sell tobacco.

Retailer licensing won't prevent illegal sales.

Notwithstanding the above, should a licensing scheme be implemented it must commence from a standpoint that those who currently and responsibly sell tobacco products be licensed first

2 Do you support reducing the retail availability of smoked tobacco products by significantly reducing the number of retailers based on population size and density?

No

Please give reasons::

There is no justification for implementing measures that would limit the accessibility or availability of tobacco products. It is unproven, untested, unnecessary, and unreasonable. Rather than such measures being based on sound public policy or compelling evidence, they are based purely on emotive speculation and pressure from tobacco control groups.

No credible evidence

There is no credible evidence to support the view that limiting the accessibility and availability of tobacco products would reduce the consumption of tobacco products or smoking initiation.

Increased trade in illicit trade, reducing taxation

Measures that seek to limit the accessibility and availability of tobacco products would eliminate legitimate purchasing opportunities. As demand for tobacco products is unlikely to decline at the same rate, there is a danger that consumers would increasingly turn to illicit goods which are often readily available, thus creating greater exposure to illicit networks while reducing future excise payments to government and bypassing current legislation intended to protect consumers such as age restrictions.

Negative impact on tobacco consumers and retailers

Such measures are likely to have a severe impact on smokers and retailers, especially small independent ones which are already under considerable pressure in the current economic climate. Depending on the exact nature of this proposal, small retailers would struggle to pay punitive licence fees or be banned from stocking tobacco products altogether if government were to reduce the number or type of retail outlets that could sell tobacco products. Given that tobacco products sales account for a significant portion of sales and profit, there is a high likelihood that a considerable number of small retailers may be driven out of business. Furthermore, consumers are very likely to be confused as to where they can still purchase

legitimate tobacco products and may turn to more readily available illicit products, thus reducing legitimate retail sales and shop owner profitability/viability.

Competition concerns

The proposal to ban certain types of retail outlets from selling tobacco products raises serious competition concerns. It would disadvantage an entire retail channel and re-distribute these volumes and profits to other channels.

3 Do you support reducing the retail availability of tobacco products by restricting sales to a limited number of specific store types (eg, specialist R18 stores and/or pharmacies)?

No

Please give reasons::

As per 2.b) above.

Small independent retail stores and convenience outlets are accessible to consumers in terms of proximity and hours of operation. Proposals to re-direct these sales to R18 only premises and/or pharmacies is neither practical nor warranted

4 Do you support introducing a smokefree generation policy?

No

Please give reasons::

We support sensible, evidence-based regulation of tobacco products. The proposal to introduce a smokefree generation is neither of these things. It represents an ideological objective to restrict the free choice of New Zealanders that is unnecessary, impractical and potentially even counterproductive.

The central tenet of the proposal is that a restriction of supply will –contrary to the fundamental principles of economics –result in a contraction in demand. The concept that curtailing supply automatically cancels demand is both logically and factually absurd.

Demand will not be affected by a reduction in one channel of supply. Consumers search either for a new method of supply or, more likely, avail themselves of an existing alternative. Years of successive excise increases have given rise to a substantial illegal tobacco market in New Zealand and this policy will only further strengthen demand for illicit product.

There are also a number of practicality and workability concerns associated with this policy.

The policy will likely see a significant increase in the compliance burden placed upon small business retailers who are already struggling against unprecedented headwinds. The proposal's enforcement will inevitably fall on small businesses who would now be tasked with regulating a new tiered definition of adulthood.

The impracticality of the proposal is evident when third party supply is considered.

5 Are you a small business that sells smoked tobacco products?

No

Please explain any impacts that making tobacco less available would have on your business that other questions have not captured. Please be specific.:

We distribute our tobacco products nationally and our retailer partners range from large supermarkets to small independent corner dairies. Many of these businesses will be making their own individual submissions on the level of these impacts. Whereas smokers can avail themselves of alternative outlets, or alternative reduced risk products, retailers impacted by these proposals can not avail themselves of alternative revenue and profitability that will be foregone on a legal product. The consequential impact particularly for small stores is that many such stores would be forced to close, further contributing to economic and social burden being placed on communities. Many small retail stores also have homes connected to their store placing additional uncertainty on their families livelihoods also.

The Associate Minister is aware of the significant burden that these proposals would have on small retailers in particular referencing this in the foreword of the consultation paper, and must carefully consider the wider social and economic impacts of these decisions carefully.

Focus area 3. Make smoked tobacco products less addictive and less appealing

1 Do you support reducing the nicotine in smoked tobacco products to very low levels?

No

Please give reasons::

No cigarette is considered safe. This proposal could perversely alter perceptions of both smokers and non smokers of reduced level nicotine cigarettes as being safer. We are of the view that the Government's goal should be to significantly reduce combusted cigarette consumption, not to cease all nicotine consumption by virtue of a de facto ban on nicotine products. It is axiomatic that transitioning consumers of nicotine to less harmful sources is a net positive to public health and a significant step forward in combating combusted cigarette use.

New Zealand adults should continue to have the right to purchase and use those legal products in the manner they deem suitable for themselves and to not be deprived of that right by ineffective measures.

We also note that the proposal aims to reduce the number of young people initiating smoking – a group who are already under the Government's Smokefree 2025 goal of less than 5%, yet impacts all other aged smokers severely.

Smoker behaviour

Several studies agree that individual users have differing sensitivities to nicotine and addiction. There is no single threshold of nicotine sufficient to sustain or prevent addiction. Some studies suggest that 0.4-0.5mg/g of nicotine in the cigarette rod would not sustain addiction for most smokers, although there is no clear consensus regarding a threshold of nicotine addiction at this point in time. Importantly, any threshold will likely also be impacted by individual differences in non-physiological (eg. behavioural) aspects of smoking. No two people smoke for the same reasons. Determining a universal threshold which suits all smokers is complex and it is important that these inter-individual differences are understood and any wider implications fully considered prior to implementing any formal regulation or policy.

Reduced nicotine will only ultimately drive smokers to smoke more, and/or exacerbate the illicit tobacco market

Technical achievability

Technical achievability stands as a significant hurdle to implementation. While there have been attempts by manufacturers to market denicotinised cigarettes and by other stakeholders to develop and grow tobacco with reduced nicotine levels, these products have yet to find success in their respective markets. Manufacturers cannot currently reach a potential target of 0.04% without modifying the tobacco's structure and undermining its quality. The only current solution is to create new varieties of tobacco

2 Do you support prohibiting filters in smoked tobacco products?

No

Please give reasons::

No cigarette is considered safe. The proposal to prohibit filters only makes them more unsafe for anyone who continues to smoke, either while quitting or without the intention to quit.

Product features are used in cigarettes to reduce key constituents in line with regulations and consumer preferences. Unfiltered cigarettes will only fuel the demand for filtered cigarettes from illicit traders.

The role of filters

A charcoal filter is a standard cellulose acetate filter which has charcoal segments incorporated into it. This aids absorption of some toxicants into the filter during smoking, reducing the exposure of the smoker to some harmful substances, such as carbonyls. The degree of this effect is dependent on the smoking behaviour.

Filter ventilation comes in many types of filter using different raw materials, filter shapes and contents:

- a. Filter ventilation is one of the design tools used by manufacturers to lower emission levels to comply with mandatory maximum yields within current regulations.
- b. Most modern products, especially those with tar yields of 10mg and below, incorporate filter ventilation into their design. Compliance with current regulations that mandate maximum yields of vapor phase components, for example CO, cannot be achieved without it.
- c. Blocking of 100% of the ventilation holes in a cigarette filter does not occur in human smoking. Smokers may modify their smoking behaviour when smoking products of different tar yields, but a higher uptake of tobacco emissions is caused by increased puff volumes rather than by ventilation blocking.
- d. While filter ventilation does not make products safer, it has been shown to be a viable design tool to lower levels of biomarkers of exposure for most smokers.

3 Do you support allowing the government to prohibit tobacco product innovations through regulations?

No

Please give reasons::

A regulatory power to prohibit product innovation does little more than potentially impact opportunities for harm-reduced products, and circumvents appropriate public consultation on legitimate product developments in response to consumer demands. Clearly, product innovations that increase appeal or attractiveness of tobacco products would be managed through existing frameworks

Focus area 4. Make tobacco products less affordable

1 Do you support setting a minimum price for all tobacco products?

No

Please give reasons::

While the proposal provides no detail on what price such a measure might be set at, regardless we make reference to the Ministry of Health's Ernst & Young 2018 report regarding the impact of excise increases on smokers:

10 percent of respondents overall and 19 percent of Māori reported that, in the month prior to the survey, their household had gone without something else that they needed
2021 is the first year in a decade that a 10% pa adhoc tobacco excise increase has not

been applied, and we note that both the Government and Opposition committed to no further increases, supporting making less harmful products – notably vaping – available and regulated to support cessation.

New Zealand is only second to Australia as the market with the highest level of excise tax on tobacco products. It's no coincidence that these markets have also had increasing issues with illicit tobacco. Approximately 80% of the cost of a packet of cigarettes is taken by the Government as excise and gst revenue – providing a quasi of minimum pricing and a separate price control mechanism is not justified.

A pack of 20 cigarettes is already around \$30, with illicit tobacco products significantly less, and therefore likely to be even more attractive should a minimum price regime be implemented.

Focus area 5. Enhance existing initiatives

General comments

1 Of all the issues raised in this discussion document, what would you prioritise to include in the action plan? Please give reasons.

Of all the issues raised in this discussion document, what would you prioritise to include in the action plan? Please give reasons.:

The Government receives circa \$2b revenue from tobacco excise annually. Only a small proportion of this is diverted to the Health budget for tobacco control SMOKEFREE ENVIRONMENTS AND REGULATED PRODUCTS ACT 1990: PROPOSALS FOR REGULATIONS 13

initiatives. We support proportionate and evidence-based regulation, but also believe that education can support and in some cases mitigate the need for regulatory tools to be implemented. The discussion document refers to increasing funding for social and mass media campaigns, and note that in the recent 2021 Budget announcement, funding has been allocated specifically for this purpose. We strongly encourage the use of education and communications as alternatives to the other heavy handed proposals contained in the discussion document.

2 Do you have any other comments on this discussion document?

Do you have any other comments on this discussion document?:

We would like to summarise our submission.

According to SmokeFree NZ, smoking rates have declined by almost 40% since 2006. The rate of decline is because of stronger tobacco controls that restrict access to cigarettes; better education to stop people from taking up a nicotine addiction; changing societal attitudes to smoking and stronger awareness of personal health; and, adoption of reduced risk products and e-cigarettes supported by a harm reduction approach to smoking cessation.

These factors have helped put New Zealand on the cusp of attaining a smokefree generation. Smoking rates for young adults are already below 5%, the mandated target for Smokefree 2025.

However, despite the known health risks, heavy cost, and social stigma, there remains a small part of the population insistent on smoking. This is a problem especially acute for Māori and Pacific people in low socio-economic areas who remain stubbornly overrepresented in smoking rates.

Decades of outdated tobacco control policy measures have not work for this cohort. In fact, they cause more harm by forcing them into deeper impoverishment (through excise) and into criminal networks (unchecked growth in illicit tobacco).

To make New Zealand smokefree, those smokers must receive effective cessation support.

The outdated thinking is being replaced by the modern concept of harm reduction, embraced by THR advocates in NZ and internationally. Reduced risk products, recently made legal in New Zealand, are incredibly effective among smokers who have otherwise been unable to quit and are the main contributor to decline in smoking in recent years.

The Smokefree Action Plan must take account of these modern realities. Legislating for a smokefree generation, while noble, is at best misguided and unnecessary given a generation of never smokers is already emerging.

Existing smokers, especially Maori and Pacific groups, will bear a heavy burden for these good intentions outlined in the action plan. Perversely, if implemented in full, the action plan will cause more health, economic, criminal harm to these groups.

Instead, we recommend the Government continue embracing harm reduction as the 14 SMOKEFREE ENVIRONMENTS AND REGULATED PRODUCTS ACT 1990: PROPOSALS FOR REGULATIONS

most effective way to get existing smokers to give up cigarettes. These would include:

Good regulation of reduced risk products that make RRP as accessible and available to smokers as cigarettes.

More money invested in education and awareness raising to inform people of the dangers of smoking and the options available to smokers (NRTS, RRP) to quit

Declarations, publishing submissions and privacy

1 Publishing submissions

You may publish this submission

2 Official Information Act responses

Remove my personal details from responses to Official Information Act requests

3 Do you have commercial interests?

I have commercial interests in tobacco and vaping products

4 Commercially sensitive information

This submission does not contain commercially sensitive information

If your submission contains commercially sensitive information, please let us know where.:

5 Protection from commercial and other vested interests of the tobacco industry

Please provide details of any tobacco company links or vested interests below.:

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Response ID ANON-UPHM-2Q9A-Q

Submitted to Proposals for a Smokefree Aotearoa 2025 Action Plan
Submitted on 2021-05-28 21:05:09

Your details

1 What is your name?

Name:

§ 9(2)(a)

2 Contact details

Email:

§ 9(2)(a)

Phone number:

§ 9(2)(a)

3 What is your organisation & role?

Organisation name:

JT International (Asia Pacific) Ltd

Organisation address:

42F Tower 1, Times Square, 1 Matheson Street, Causeway Bay, Hong Kong

What is your role?:

Scientific and Regulatory Affairs

4 Additional organisation information

Other (please specify)

Other:

Asia Pacific Region

Tobacco manufacturer, importer or distributor

5 What is your age?

55 – 64

6 What ethnicity/ethnicities do you identify with?

Asian

Other ethnicity:

Focus area 1. Strengthen the tobacco control system

1 What would effective Māori governance of the tobacco control programme look like? Please give reasons.

What would effective Māori governance of the tobacco control programme look like? Please give reasons.:

2 What action are you aware of in your community that supports Smokefree 2025?

What action are you aware of in your community that supports Smokefree 2025?:

3 What is needed to strengthen community action for a Smokefree 2025? Please give reasons.

What is needed to strengthen community action for a Smokefree 2025? Please give reasons.:

4 What do you think the priorities are for research, evaluation, monitoring and reporting? Please give reasons.

What do you think the priorities are for research, evaluation, monitoring and reporting? Please give reasons.:

5 What else do you think is needed to strengthen New Zealand's tobacco control system? Please give reasons.

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What else do you think is needed to strengthen New Zealand's tobacco control system? Please give reasons.:

Focus area 2. Make smoked tobacco products less available

1 Do you support the establishment of a licensing system for all retailers of tobacco and vaping products (in addition to specialist vape retailers)?

No

Please give reasons::

• Per se JTI is not against a licensing system for all retailers, especially if it is proven to further address youth access to tobacco; however the following question (add question number / section) demonstrates that in this specific case, licensing is meant to reduce the number of retailers which JTI opposes as explained in the following

2 Do you support reducing the retail availability of smoked tobacco products by significantly reducing the number of retailers based on population size and density?

No

Please give reasons::

- Retail availability is a key measure to prevent illicit trade, and therefore the presence on the market of uncontrolled tobacco products that are easily sold to minors
- Prohibition, as demonstrated in the past, is ineffective in reducing the consumption of harmful products
- Proper enforcement of existing regulation, especially those which prevent minors from purchasing tobacco products, are key to the success of health policies
- Arbitrary restrictions on the number of retailers who can sell tobacco products would undermine fundamental freedoms to conduct legitimate business activities in the country and reduce employment opportunities

3 Do you support reducing the retail availability of tobacco products by restricting sales to a limited number of specific store types (eg, specialist R18 stores and/or pharmacies)?

No

Please give reasons::

- Retail availability is a key measure to ensure the absence of illicit trade, and therefore the presence on the market of uncontrolled tobacco products that are easily sold to minors
- Prohibition as demonstrated in the past is a non-effective measure to tackle consumption reduction of products that represents a risk to health
- Enforcement of regulation, especially those protecting minors are key for the success of health policies
- Specialization can create undue economic advantages to specific sectors fostering monopolies

4 Do you support introducing a smokefree generation policy?

Not Answered

Please give reasons::

5 Are you a small business that sells smoked tobacco products?

No

Please explain any impacts that making tobacco less available would have on your business that other questions have not captured. Please be specific.:

Focus area 3. Make smoked tobacco products less addictive and less appealing

1 Do you support reducing the nicotine in smoked tobacco products to very low levels?

No

Please give reasons::

JTI recognizes the risks of smoking and that tobacco products should be regulated; however, regulation should be based on scientific evidence, and it should be appropriate to achieve legitimate public policy objectives. JTI understands the responsibility of the New Zealand Government to introduce effective policy to improve the health of its population. Nonetheless, health disparities subsist between certain demographics in the New Zealand population, and these disparities occur despite the same tobacco products being available to all. The use of tobacco products is not a driver of health disparity, merely a symptom. Therefore, reducing the nicotine in smoked tobacco products to very low levels is unlikely to resolve these health issues within the New Zealand population, but will remove the choice of smokers to smoke a legal product and drive them towards illicit trade.

JTI deems that a proposal for nicotine reduction in cigarettes is not based on sound scientific evidence and will likely not achieve New Zealand's public

policy objectives of preventing people from becoming tobacco users and enable smokers to quit smoking. The "Proposals for a Smokefree Aotearoa 2025 Action Plan" suggests that "Reducing nicotine content to minimal levels would likely decrease the number of young people trying smoking as they would not expect to get a hit from nicotine. It should also stop the progression to addiction among those who do experiment and prevent relapse in people who are trying to quit smoking." (Ministry of Health. 2021. Proposals for a Smokefree Aotearoa 2025 Action Plan: Discussion document. Wellington: Ministry of Health)

All scientific studies available to date, which were conducted on small samples of volunteer participants who smoked during controlled laboratory procedures, do not conclusively establish that reducing the nicotine content of cigarettes would sustain definitive smoking cessation in the general smoking population. The 2020 U.S. Surgeon General Report on Smoking Cessation noted: "[...] evidence is suggestive but not sufficient to infer that VLNC [very low nicotine content] cigarettes could reduce smoking and nicotine dependence and increase smoking cessation [...]" (U.S. Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.). Additionally, a 2018 WHO report titled, "Consultation of Tobacco Addictiveness Reduction Measures" concluded, "[T]here was no consensus among participants about the merits or demerits of a nicotine or tobacco addictiveness reduction policy." (Report: Consultation on Tobacco Addictiveness Reduction Measures, Berlin, Germany, 15–16 May 2018. Geneva; World Health Organization and the Secretariat of the WHO Framework Convention on Tobacco Control, WHO; 2018).

A dramatic reduction, or prohibition, of nicotine in cigarettes would constitute a de facto ban on the sale of the vast majority of conventional cigarettes currently available on the market in New Zealand, including JTI products. The results emanating from human clinical studies clearly indicate that a significant proportion of consumers, if not virtually all, in real-life settings, do not choose to smoke very low levels of nicotine cigarettes (VLNC). Tellingly, the vast majority of smokers appraised VLNC cigarettes as less satisfying and do not accept the taste characteristics delivered by nicotine-free cigarettes. A 2020 paper published by produced by the Dutch National Institute for Public Health and the Environment (RIVM) considered agricultural and manufacturing techniques that can be applied to reduce the nicotine content of tobacco. The authors conclude, "Most of the available techniques are successful in reducing nicotine levels, sometimes to levels lower than 0.4 mg / g. However, in almost all cases, the resulting tobacco leads to a less satisfactory smoking experience. Although reduction of nicotine to a non-addictive level is feasible from a technical perspective, it is not clear whether such measures could be successfully implemented." (Havermans, A., et al., (2020). Feasibility of Manufacturing Tobacco with Very Low Nicotine Levels. Tobacco Regulatory Science 6: 405-415) Meanwhile, a significant proportion of smokers do not even express a desire to quit smoking. As a result of a significant lack of low nicotine cigarette product acceptance, a substantial portion of smokers will likely try to turn to illicit products to obtain the cigarettes they wish to smoke. As a result, we believe that serious repercussions for governments will result from a dramatic reduction of nicotine in cigarettes, should such a regulation be enacted.

The "Proposals for a Smokefree Aotearoa 2025 Action Plan" suggests that "Even for smokers who are not currently considering quitting, using very low nicotine cigarettes can lead them to reduce the number of cigarettes they smoke per day and be more likely to contemplate, make and succeed at a quit attempt." (Ministry of Health. 2021. Proposals for a Smokefree Aotearoa 2025 Action Plan: Discussion document. Wellington: Ministry of Health) It is unclear, however, whether reducing the number of cigarettes smoked per day significantly increases the probability of a successful quit attempt and prolonged abstinence both in smokers who do not intend to quit and in smokers who intend to quit. A myriad of endogenous and exogenous factors combine to determine why a given individual begins smoking, continues to smoke, tries to quit, fails in those quit attempts, and perhaps eventually achieves smoking cessation. Scientific studies, including population surveys and clinical studies, have identified numerous variables as being associated with successful quit attempts, including but not limited to motivation and self-efficacy.

It is our view that smoking behavior is complex and uniquely individual; it cannot be explained simply by the psychopharmacological effects of nicotine, including the amount of nicotine a smoker obtains. The principal reasons that adult smokers report for difficulty quitting smoking are behavioral and situational factors, not physiological factors related to nicotine withdrawal and tolerance. It is important to point out that smoking does not compromise a smoker's free will to undertake a quit attempt and pursue that effort. As a result, all smokers can stop smoking if they choose to.

2 Do you support prohibiting filters in smoked tobacco products?

No

Please give reasons::

Cigarette filters are used to offer consumers a range of taste intensities. This allows manufacturers to meet consumer preferences when they are purchasing their legal product of choice. In the absence of accepted filtered cigarettes, a significant portion of smokers will turn to illicit trade to obtain the cigarettes they wish to smoke.

Cigarette filters are the most effective tool in reducing gas phase compounds in cigarette smoke. Smokers of filtered cigarettes are generally exposed to lower yields of smoke constituents compared to smokers of non-filtered cigarettes; however, there is no safe cigarette.

Increased smoke constituent exposure in addition to a rise in the purchase of illicit cigarettes, is strong evidence that banning cigarette filters is unlikely to result in benefits to public health.

JTI recognizes the unique and precious natural environment found in New Zealand. It is clear that cigarette filters should be prevented from reaching that natural environment. JTI is making considerable efforts to develop reduced bioplastic cigarette filters while continuing to meet both regulatory constraints and smokers' expectations. Even though the microfibers produced during breakdown of current cellulose acetate filters completely dissolve (in contrast with microplastics that originate from fossil fuel-based plastics), cigarettes should be thrown away by using appropriate waste disposal. This involves changing consumer behavior - ensuring that the people who choose to smoke also choose to dispose of their cigarette butts responsibly. Banning cigarette filters will not prevent consumers from littering.

3 Do you support allowing the government to prohibit tobacco product innovations through regulations?

No

Please give reasons::

Tobacco products are subject to a high level of illicit trade. Product innovation is key to differentiate legitimate products from illegal ones, especially in a plain packaging environment, in which tobacco product producers operate in New Zealand

Declarations, publishing submissions and privacy

1 Publishing submissions

You may publish this submission

2 Official Information Act responses

Remove my personal details from responses to Official Information Act requests

3 Do you have commercial interests?

I have commercial interests in tobacco and vaping products

4 Commercially sensitive information

This submission does not contain commercially sensitive information

If your submission contains commercially sensitive information, please let us know where.:

5 Protection from commercial and other vested interests of the tobacco industry

Please provide details of any tobacco company links or vested interests below.:

I work for Japan Tobacco International

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