

Consultation questions

The Ministry of Health is seeking comments on the following proposals for a smokefree Aotearoa 2025. You can find more information about these proposals in the discussion document which can be downloaded from - <https://www.health.govt.nz/publication/proposals-smokefree-aotearoa-2025-action-plan>.

Focus area 1: Strengthen the tobacco control system

- a). What would effective Māori governance of the tobacco control system 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.

- b). 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>]

- c). 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.

- c). 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.

- d). 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

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

Yes No

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.

b). 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 No

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.

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

Yes No

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.

d). Do you support introducing a smokefree generation policy?

Yes No

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.

e). Are you a small business that sells smoked tobacco products?

Yes No

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

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

a). Do you support reducing the nicotine in smoked tobacco products to very low levels?

Yes No

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 wellbeing.

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/NEJMs1714617>]. 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 Manatu 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,



John Dafydd Pritchard
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b). Do you support prohibiting filters in smoked tobacco products?

Yes No

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.

c). Do you support allowing the Government to prohibit tobacco product innovations through regulations?

Yes No

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

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

Yes No

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.

Final questions

- a). 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.

- b). 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 wellbeing.