Feedback on the draft Act amending the Tobacco Act and the State Fees Act – JDM/26-0826

Submission by Smoke Free Sweden (SFS),
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1. **About the Authors:** We are a collective of global physicians and experts with a focus on harm reduction science and policy across diverse areas, including alcohol, tobacco, food, drugs, HIV, and Covid-19. In collaboration with Smoke-Free Sweden (SFS)[1], we champion harm reduction as a vital public health tool. Our mission is to prevent and control diseases and premature deaths associated with various lifestyle habits and substance abuse, encompassing tobacco and drugs. SFS strongly endorses tobacco control, aligning with the Framework Convention on Tobacco Control (FCTC)[2], and places specific emphasis on tobacco harm reduction (THR) as a paramount public health strategy (Article 1d of the FCTC)[2].

2. **Thank You for Listening:** We appreciate the opportunity to be part of the ongoing dialogue and express our gratitude for involving stakeholders. Our thanks go to the Estonian government, the Minister of Justice and the Minister of Social Affairs, for their commitment to this public engagement.

We make this submission in response to the circulated draft act amending the Tobacco Act and State Fees Act. While we commend Estonia for its decision to pursue regulation rather than prohibition, we are concerned that certain provisions in the draft Act may have unintended consequences. In this submission, we first discuss the potential of tobacco harm reduction before looking at the importance of flavours and higher nicotine limits to allow effective public health gains. Finally, we share how this fits into a risk-proportionate regulatory approach – one that Sweden has successfully adopted.

3. **THR Products are Here to Help, Not Hinder:** Rather than focusing on the often-unattainable total cessation of smoking as the only option, THR products offer a harm-reduced alternative for smokers. The smoke free products greatly expand the range of options to quit smoking without reducing or compromising any of the more traditional options.

The reduced harm of the nicotine within these products has also been well researched. A report titled “No Smoke, Less Harm”[3] writes that ‘although nicotine may cause dependence, it does not cause disease. Studies have long established this fact, and nicotine has been used in pharmaceutical formulations for decades. Therefore, as a harm-reduction tool, nicotine is an extremely useful substitute for combustible tobacco.” Moreover, the report goes on to share that the dependence that may be caused by nicotine can be compared to a caffeine dependence. Citing a study by Dr Karl Fagerstrom,

the report shares how 'the degree of dependence was compared between snus, cigarettes, nicotine replacement therapy (NRT), electronic cigarettes and coffee. Dependence on traditional cigarettes and snus seem to be relatively similar, while NRT was rated lower and coffee lowest. Since the prevalence of caffeine use in all forms is more prevalent than nicotine, there might be more people in society that are heavily dependent on caffeine.'

4. **Proof of THR Effectiveness:** Contrary to popular misconceptions, the effectiveness of THR has been proven in various cities and across various studies. We highlight Sweden's success to show THR as a model for effective public health practices, achieving a 61%[8] lower rate of male lung cancer deaths when compared to the EU. No other country in the European Union is even close to replicating Sweden's current tobacco control success – being officially smoke-free with a daily smoking rate of just 3.7%. The influence of harm reduction in this achievement is clear. Evidence supporting Sweden's tobacco harm reduction strategy is outlined in the report "Saving Lives Like Sweden"[4] and "The Swedish Experience"[5] by international experts.

   "It's about combining tobacco control with harm minimisation," explains Dr Delon Human, one of the report's authors. "There are no risk-free tobacco products, but e-cigarettes, for example, are 95% less harmful than cigarettes. It is far better for a smoker to switch from regular cigarettes to e-cigarettes or nicotine pouches than to continue smoking."

   The benefits of Sweden's strategy are enormous. Sweden's example clearly shows the importance of embracing harm reduction on any journey to becoming smoke-free.

   Evidence of Tobacco Harm Reduction benefits can also be seen in the report "Prevent Disease, Save Lives: An Introduction to Oral Nicotine Delivery Systems"[6] as well as "Saving Lives".[7] These reports emphasize the importance of also considering the greater impact of vaping in the country, which has already contributed to a significant reduction in smoking rates. Other reports also highlight the impact of oral nicotine pouches in Sweden on oral health and a drop in women's smoking rates. [9]

5. **The Proposed 4 mg/g Nicotine Limit Is Inconsistent with International Standards and Would Undermine the Harm-Reduction Potential of Nicotine Pouches**

   The draft Act's proposed nicotine content limit of 4 mg/g for oral nicotine pouches falls significantly below the standards already adopted or recommended by leading international and regional standards bodies. Several national assessment bodies have converged on limits for oral pouches in a band around 20 mg per pouch:

   - The **Swedish Institute for Standards (SIS/TS 72:2024)**[10] sets a ceiling of 20 mg per pouch — reflecting the experience of Sweden, which has the world's lowest smoking rate and the highest uptake of oral nicotine products.

- The **British Standards Institution (BSI, PAS 8877:2022)**[11] specifies 20 mg per pouch as the limit for tobacco-free nicotine pouches.
- The **German Federal Institute for Risk Assessment (BfR)**[12] recommends a ceiling of 16.7 mg per pouch

A typical nicotine pouch weighs between 0.5 and 1 gram. At 4 mg/g, the Estonian proposal would cap pouches at 2–4 mg of nicotine per unit — five to ten times below the internationally recognised threshold. This is not a modest adjustment; it is a limit that would render the regulated product category unable to serve the population it is intended to reach.

Heavier, more dependent smokers — precisely those who stand to benefit most from switching — require per-unit nicotine delivery that meaningfully substitutes for cigarette-level intake. Products capped far below this threshold are poorly accepted by this population: users either reject the category entirely or compensate by using multiple low-dose pouches simultaneously, multiplying consumption without reducing overall nicotine intake. Neither outcome advances public health.

Estonia is encouraged to align with the international consensus and adopt a limit that supports real substitution away from cigarettes, rather than one that effectively restricts the regulated market to doses too low to function as a credible harm-reduction tool.

6. **The Restriction on Flavours Does Not Align with Real-Life Preferences**

The draft act's proposal to limit permitted flavours to tobacco and menthol can significantly damage the appeal of harm-reduced products for the smokers it hopes to serve. Flavours are not a peripheral concern — they are a core driver of product acceptability for adult smokers seeking to switch. Recent research in 2026 found that 60% of ex-smokers who vape in Great Britain marked fruit as their preferred flavour.[13]

The role of flavours in helping smokers switch is neither new nor unknown. Research by Konstantinos Farsalinos[14] and others documents that flavours are essential for encouraging smokers to transition away from combustible tobacco, and that banning flavours is unlikely to meaningfully reduce youth uptake while significantly hindering adult switching.

We welcome the introduction of a positive list of permitted flavouring and scenting substances for vapour products, to be established through secondary legislation. This approach — permitting a defined range of assessed substances rather than prohibiting all non-tobacco, non-menthol flavours — is precisely the kind of risk-proportionate mechanism we advocate for. We urge the Ministry to extend the same logic to nicotine pouches and other tobacco-related products covered by the Act. If the regulatory framework already recognises that flavour substances can be assessed, listed, and permitted for vapour products, there is no principled basis for applying a blanket flavour

restriction to other product categories. A consistent, substance-based approach across all product types would be both more coherent and more effective.

7. **Recommendation: The Role and Benefits of Harm Reduction**

   Harm reduction is a critical component of any comprehensive tobacco control strategy. By focusing on reducing harm for adult consumers who smoke, Estonia can better address the complex challenges of tobacco and nicotine use and improve public health outcomes. Research, and Sweden's own experience, indicates that offering less harmful alternatives, such as vapes or nicotine pouches, can significantly reduce the health risks associated with nicotine use. It is important that these alternatives are, and remain, acceptable, accessible and affordable.

   In supporting harm reduction strategies, we also recommend that Estonia align any lobbying transparency measures to those consistent with its existing obligations under the EU Tobacco Products Directive rather than introducing disclosure requirements that exceed the EU standard without clear evidence that the additional burden is justified and proportionate.

In conclusion, we urge the Estonian Ministry of Social Affairs to consider the following amendments to the draft Act. First, the proposed 4 mg/g nicotine limit for oral nicotine pouches should be revised to align with the internationally recognised standard of up to 20 mg per pouch — the threshold Sweden itself applies, and which reflects the dosing necessary for nicotine pouches to function as a genuine alternative to cigarettes. Second, the restriction on flavours should be reconsidered, particularly when NRT gum also contains fruit flavours. Limiting products to tobacco and menthol will reduce their effectiveness as switching tools for adult smokers. Third, any lobbying disclosure requirements should remain proportionate and consistent with the EU Tobacco Products Directive, rather than introducing a sector-specific regime that exceeds the regional standard.

Sweden's path to smoke-free status was not accidental. It was the result of accessible, well-regulated, and adequately dosed alternatives becoming the norm for people who would otherwise have continued smoking. Estonia has an opportunity to lead by example in the region — adopting a regulatory framework for nicotine products that is evidence-based, risk-proportionate, and designed to work. Risk-proportionate regulation recognises that not all nicotine products carry the same harm profile, and that restricting access to less harmful alternatives does not reduce nicotine use — it redirects it, toward cigarettes or the unregulated market. We urge Estonia to adopt a framework that reflects this principle and gives adult smokers a genuine, well-regulated alternative to continued smoking.

Thank you,
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About the authors

- **Professor Marewa Glover (New Zealand)**

  Professor Marewa Glover is one of New Zealand's leading tobacco control researchers. She has worked on reducing smoking-related harm for 31 years. She is recognised internationally for her advocacy on tobacco harm reduction, and locally was a Finalist in the New Zealander of the Year Supreme Award in 2019 recognising her contribution to reducing smoking in NZ. In 2018, Prof. Glover was appointed Tobacco Section Editor for the Harm Reduction Journal. That same year she also established the Centre of Research Excellence: Indigenous Sovereignty & Smoking, an international programme of research aimed at reducing smoking-related harms among Indigenous peoples globally.

- **Dr Gintautas-Yuozas Kentra (Kazakhstan)**

  Dr. Gintautas-Yuozas Kentra is a cardiologist and Deputy Chairman of the Council and member of the Expert Council of the Densaulyk ULL, which is the Harm Reduction Association of Kazakhstan, focusing on the institutionalisation of harm reduction in non-communicable diseases.

- **Carissa During (Sweden)**

  Carissa During is a director of Considerate Pouchers Sweden, a global consumer advocacy group set up to represent pouchers around the world. She studies clinical psychology at Uppsala University in Sweden. She uses nicotine pouches as an alternative to smoking and is keen that the world should know how successful pouches have been in helping Sweden get smoking rates to the lowest in Europe.

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