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By email: sum@sum.dk, cfma@sum.dk, mnen@sum.dk

Subject: Excessively strict limits on nicotine pouches – a major public health error

I write again to express concern about the excessively restrictive regulation of nicotine products that are, beyond any reasonable doubt, far safer than smoking. I understand the government has set a limit of 9 mg of nicotine per pouch from 1 July 2025 to be fully implemented by 1 April 2026.

I am an independent public health expert based in the United Kingdom and former Director of the UK's leading anti-smoking organisation, Action on Smoking and Health. I have no conflicts of interest regarding the tobacco, nicotine or pharmaceutical industries.

Summary of concerns

1. If the measure aims to protect young people, it will fail. The limit will not affect youth uptake, as most youth would use less nicotine than 9mg to begin with. It will, however, harm adults who smoke and require more nicotine in more potent formats to successfully switch.
2. Some young people would otherwise smoke, and they benefit from switching to pouches by diverting away from smoking or, to a lesser extent, from vaping.
3. Young people benefit from the improvement in the health and welfare of significant adults in their lives, and the benefits of pouches to adults are shared with youth through the family.
4. The limit of 9 mg per pouch cuts through the middle of products sold lawfully in Europe and means that users of these products will need to change their behaviour:
    - Current or potential pouch users may smoke or vape instead.
    - Users may source pouches cross-border or via informal suppliers that source legally sold products outside Denmark.
    - Access illegal pouch products sold by criminal networks in Denmark with unknown strength and ingredients. Such networks also generally sell other illicit products, such as narcotics.
    - Create new unlawful supply chains that are likely to include young people as sellers, not just users. This is an established feature of the supply of illicit drugs.
    - Create risky workarounds – for example, adding nicotine liquids to pouches or simply placing two or more in the mouth at once.
5. It is premature to set such aggressive limits. It would be better initially to set a higher limit (15-20mg) that does not trigger harmful unintended behavioural responses and to establish product quality standards that protect users from contaminants and rogue ingredients.
6. No one is protected from any risks when the products are supplied illegally or potential users end up smoking instead.
7. I have found no impact assessment that articulates these serious regulatory risks.

1. Insights from Sweden's record in reducing smoking through snus

Achieving significant public health gains through low-risk alternative nicotine sources. Sweden has achieved the lowest smoking prevalence in the European Union by some distance – 8% compared to Denmark at 14% and the EU average of 24% in 2023.[1] This success has happened because Swedish users of nicotine generally use oral tobacco ("snus"), and this has been steadily displacing smoking for several decades,[2] with similar effects evident in Norway.[3] Among younger people, snus has diverted new users away from smoking. As a result, Sweden has demonstrably lower rates of tobacco-related disease and premature death in the populations that use snus. The ban on oral tobacco in the European Union has prevented replicating the Swedish experience in many other member states. This ban is likely to have caused thousands of avoidable deaths over the three decades it has been in place. The availability of non-tobacco nicotine pouches creates both the opportunity to address that serious public health error and the risk of replicating the mistake through prohibition or excessive restrictions on product design.

Snus provides proof-of-concept for nicotine pouches. The data for snus (oral tobacco) offer a powerful proof of concept for tobacco harm reduction: epidemiological evidence "*provides scant support for any major adverse health effect of snus*"[4] [5] and also that switching from cigarettes to snus reduces the risk of cancer and heart disease, and the risk in switchers being similar to that in those who quit cigarettes.[6] A recent paper estimates that 3,000 premature deaths annually are avoided through snus use in Sweden.[7] One estimate suggests among men over the age of 30 years, 355,000 lives per year could have been saved if the other European Union countries had matched Sweden's tobacco-related mortality rate.[8] If that could be achieved, even partially, with pouches rather than snus, it would be a substantial public health success for Europe and go some way to compensating for the policy failure of the EU snus ban. The ban on snus in the European Union has no basis in science or ethics and should have been reversed long ago.[9] [10] Policy decisions about nicotine pouches must be informed by the experience gained with snus. We have known since at least the early 1990s that modern smokeless tobacco carries a negligible mortality penalty,[11] and we should expect well-regulated oral nicotine pouches to be safer still.

Proportionate regulation is the critical requirement. The most urgent tobacco and nicotine policy challenge for Denmark is to reduce smoking, especially in adults who find it hard to quit. Nicotine pouches offer a significant opportunity. The most urgent policy challenge for the European Union is not to replicate the failure of the snus ban through prohibition or excessively restrictive regulation of oral nicotine pouches. In both cases, the critical task is to establish proportionate regulation that exploits the harm reduction opportunity while providing appropriate consumer protection.

Excessive regulation or prohibitions will have harmful unintended consequences. While experience in Sweden and elsewhere shows that it has been possible to shift from high-risk to low-risk forms of nicotine, there is no evidence that it is possible to eliminate nicotine demand or that a subset of young people will somehow stop using nicotine, just as they are unlikely to stop using alcohol or caffeine. Our aim should be to reduce the harm to the extent possible, not to try to prohibit these substances or impose excessively restrictive regulation. Trying to do this through regulator-imposed supply constraints will be ineffective and counterproductive. Experience so far suggests that supply-side constraints on safer forms of nicotine have three main effects:

1. Increased smoking or other adverse behavioural responses

2. More illicit trade, nurturing unregulated supply and criminality
3. The use of potentially risky workarounds by consumers or suppliers

Unintended consequences are the *main* consequences of regulating safer nicotine products. Any policy proposal should be assessed in light of these harmful, unintended, but foreseeable consequences. Even a slight relative uptick in smoking would be sufficient to outweigh any plausible benefits from the regulation of snus or oral nicotine pouches.

2. The proposed nicotine limit of 9 milligrams per pouch is too low

The harm reduction case for pouches. There is strong evidence that nicotine pouches dramatically reduce the exposure to hazardous chemicals associated with smoking. [12] [13] [14] [15] Even if it is too soon to have long-term disease epidemiology for pouches, we have compelling evidence of very low exposures and no sign of novel risks. It follows by analogy to snus that disease risks will be very low. Given adequate nicotine delivery and a pleasant sensory experience, these products can replicate the public health success of snus at no cost to the state and with the consent (rather than coercion) of nicotine users.

***Regulators* are now the main risk**. The most critical risk to this proposition is that regulators in Denmark or the European Union will intervene to make the nicotine pouches alternative less attractive relative to continued smoking or smoking initiation. There is considerable scope for regulation to cause harm compared to *not intervening*. I agree that a limit on the nicotine contained in oral nicotine products should be set, not least to stop products with very high levels – Russian products with over 200mg of nicotine have been found. However, great care should be taken not to set this too low, triggering perverse unintended consequences.

The limit, as specified, is too low. There is no need to artificially impose a lower level than necessary with the risk that some heavier smokers would find the pouch alternative to smoking unsatisfactory. The risk to youth is minor, and there is no evidence from the effects of snus that higher nicotine is a causal reason for snus uptake. It is much more likely that the recent youth uptake of snus in Nordic countries is a rejection of smoking and, therefore, highly beneficial. In fact, for young people who would otherwise become smokers, a higher nicotine level may be desirable. The risks of setting a level that is too low (causing more smoking among adults or youth) are greater than setting a limit that is too high (risk of poisoning). The goal should be to set limits that accommodate the range of *mainstream* snus products already on the market. It is essential to understand the products that adults use and not restrict their choices unnecessarily. It is essential to reference the use of products already on sale in the market for snus to calibrate the impact of restrictions on pouches. Norwegian researchers Vedøy & Lund show the following:[16]

> *In all snus products combined, the nicotine content per gram snus (mg/g) increased from 16.3 to 24.1, while nicotine per serving (mg/s) was stable around 13.0.*

However, the figures above reflect the market weighted *average*. The mainstream snus market studied in Norway shows a *range* that goes up to around 35 milligrams per gram and 20 milligrams per serving, as shown in the figures below:

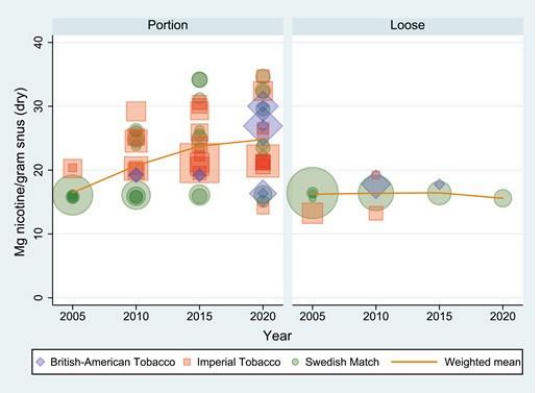

Figure 1. Distribution and weighted mean of milligrams nicotine per gram dry snus (mg/g) 2005, 2010, 2015, and 2020 across product type and manufacturer. Marker shape denotes manufacturer, and marker size denotes market share, Vedøy, T. F., & Lund, K. E, 2022.

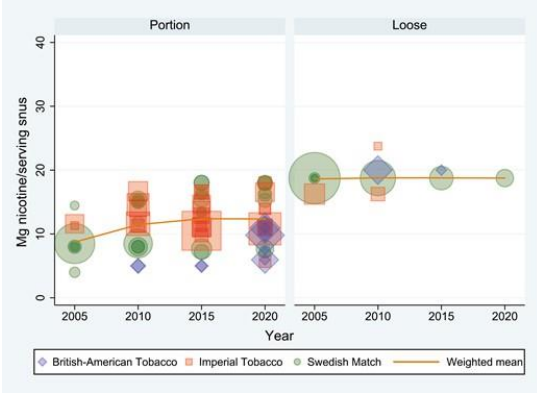

Figure 2: Distribution and weighted mean of milligrams nicotine per serving (mg/s) snus in 2005, 2010, 2015, and 2020 across product type and manufacturer. Marker shape denotes manufacturer, and marker size denotes market share, Vedøy, T. F., & Lund, K. E, 2022.

The range in this market exceeds the proposed limit for nicotine concentration of 9 mg by approximately twice. It would be, therefore, a very intrusive standard. To my knowledge, there is no data suggesting that the existing snus market in either Norway or Sweden with the range of nicotine content shown in the figures above is creating problems. On the contrary, it should be assumed that this range meets most consumer demand. Setting a much lower threshold renders the regulation vulnerable to unintended consequences.

3. Proposed alternative approach

I would like to suggest a two-part alternative to the proposal:

1. **Set the threshold relatively high initially**. The nicotine threshold is set at a relatively high level *initially*; for example, 20 milligrams per serving. The aim would be to eliminate dangerous rogue products with irresponsibly high levels of nicotine without disrupting the mainstream market that is responsible for Sweden's success. The Swedish Standards Institute (Svenska Institutet för Standarder) defines a reasonable model for a standard of this nature and sets a threshold of 20 milligrams per serving.[17] It also defines measurement methodology and sets limits for pH and water content. A riskier approach would be to set a standard at a lower maximum nicotine content per serving based on a notional toxicity threshold suggested by Germany's Bundesinstitut für Risikobewertung, a standard of 16.6mg nicotine per serving.[14] Setting any lower threshold *increases* the risks of adverse consequences (more smoking, illicit trade, workarounds) arising from banning products already used by adult consumers. ***It is not inherently cautious to set a lower threshold***.
2. **Monitor the development of the market and lower thresholds over time if justified.** The impact of the initial threshold should be assessed in a market survey (i.e. what products are available and who is using them), and this would then form the basis for a possible future lowering of the nicotine threshold, providing the Minister is satisfied it will not trigger harmful unintended consequences. Under such a system, the Minister would have powers to set nicotine thresholds through secondary legislation and under conditions specified in the law (e.g. following a market survey).

Such an approach would deal immediately with rogue high-nicotine products with no risk of unintended consequences, provide a basis for a well-managed market meeting adult consumer

needs, and support future regulatory development based on evolving learning and insight or responding to innovation.

I hope the comments are helpful as you consider the benefits and risks of this regulation and determine the appropriate policy response. Please let me know if I may be of further assistance or if I can clarify any aspects of this letter.

Yours sincerely,

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