



European Tobacco Harm Reduction Advocates

Memo for European Commission Seminar (10th February 2022)

Emerging tobacco and nicotine products in tobacco control policies

Introduction

European Tobacco Harm Reduction Advocates (ETHRA) welcomes the opportunity to participate in a European Commission seminar on Emerging tobacco and nicotine products in tobacco control policies. We represent the interests of those most directly affected by such policies either as current consumers of these products or as smokers who may in future switch from high-risk to low-risk products and benefit from potentially life-saving reductions in health risks.

About ETHRA

ETHRA is a partnership of 25 consumer associations in 17 European countries, representing approximately 27 million consumers across Europe and supported by scientific experts in the field of tobacco control or nicotine research. We are mostly ex-smokers who have used safer nicotine products, such as vapes and snus, to quit smoking and to remain smoke free. ETHRA is a voluntary organisation of committed advocates for better policy to support tobacco harm reduction. *We are not funded by the tobacco or vaping industry.* Our mission is to give consumers of safer nicotine products a voice and to ensure that the full harm reduction potential of safer nicotine products is not hindered by inappropriate regulation. ETHRA is listed in the EU Transparency Register at: [354946837243-73](https://ec.europa.eu/transparency/regexp1/index.html?value=354946837243-73).

Summary of the main issues

1. **The most significant European Union public health wins (and failures) will be in tobacco and nicotine policy.** Tobacco smoking is the single largest avoidable health risk, and the most significant cause of premature death in the EU, responsible for nearly 700,000 deaths every year - more than obesity, alcohol, road accidents, drug misuse and HIV *combined*. Around 50% of smokers die prematurely (on average 14 years earlier). The number of smokers in the EU remains high – 25% of the overall EU-27 population and 20% of young Europeans aged 15-24 smoke. A sustained effort to reduce smoking will deliver major public health gains in cancer, cardiovascular and respiratory disease as well as multiple welfare and economic benefits. However, well-intentioned but poorly designed measures aimed at suppressing low-risk products will have the effect of increasing smoking, promoting relapse and preventing switching. *The main risks in tobacco and nicotine policymaking for emerging low-risk tobacco and nicotine products are the perverse but foreseeable consequences of poorly designed policies.*

EU TRANSPARENCY REGISTER: 354946837243-73

2. **The critical policy distinction is between smoked and smoke-free nicotine products - not between tobacco and non-tobacco.** By far the largest cause of death and disease is *smoking* - the inhalation of toxic products of combustion. The critical distinction for public health purposes is between smoked products (cigarettes, hand-rolled, cigars etc.) and smoke-free products (vaping, heated tobacco, nicotine pouches, snus). Sweden has the lowest rates of smoking in the developed world (and a substantially lower burden of disease as a result) because of snus, an oral tobacco product. There has been a 44% decline in cigarette sales in Japan in just five years (2015-20) as heated tobacco products have disrupted the cigarette market. *The Commission should focus on helping Europe's smokers move away from combustion products by whatever measures work, including by switching to smoke-free tobacco products.*
3. **Avoid regulation that protects the cigarette trade.** According to Eurobarometer, 25% of European Union (EU-27) adults were smokers in Aug/Sept 2020. This is despite decades of product regulation, taxation and marketing restrictions. Tobacco harm reduction works because committed smokers willingly choose to switch from cigarettes to new, low-risk smoke-free nicotine products. This shift functions through consumer choice in the internal market rather than via the healthcare system or smoking cessation clinics. Measures that make these products less appealing to smokers (for example, flavour bans), more expensive (excessive taxes), less accessible (marketing restrictions), or unable to match the satisfying nicotine delivery of cigarettes (nicotine caps) are little more than regulatory protections to the cigarette trade. *If the internal market is allowed to work without being rigged in favour of cigarettes, tobacco harm reduction will deliver a high level of health protection in response to a major public health issue.*
4. **Implement risk-proportionate regulation.** For tobacco harm reduction to be successful for public health, two conditions must be met. (1) The smoke-free products must have a much lower risk to the user's health than smoking. We know this to be the case beyond any reasonable doubt, through studies showing that exposures to toxicants in blood, saliva and urine are much lower and close to non-users for many toxicants. (2) That the smoke-free products will displace smoking. There is good evidence from multiple sources to support this: randomised controlled trials, observational studies, population data trends, market data and analysis, and thousands of compelling user testimonials. It is reckless rather than precautionary to impose excessive regulation on these products as if nothing is known about them. The misapplication of the precautionary principle would favour the products that we know with absolute certainty are extremely harmful. *The right approach is 'risk-proportionate' regulation, with the strongest controls reserved for the most dangerous products, cigarettes, and regulatory, fiscal and communications measures aligned to encourage migration from high-risk to low-risk products.*
5. **Focus on securing major public health gains for adults.** The big prize for public health is to avoid potentially millions of cancers and heart and lung disease episodes in Europe among adult smokers. Youth vaping is a natural public and political concern, but it should be kept in perspective, especially in Europe, where there are relatively low levels of youth vaping. It is also possible *that youth vaping is beneficial to public health*: emerging evidence suggests that vaping has been a diversion away from smoking for those adolescents most likely to smoke and therefore those young people most at risk. American and UK data show that most youth vaping is infrequent, and that frequent vaping is concentrated among those who would otherwise smoke. Compared to other youth risk behaviours, vaping is not especially harmful, and it may be beneficial to the young people most at risk of smoking. Finally, the main driver of youth smoking is parental smoking - if we can address adult smoking, we may see a multi-generational payback from well-designed EU policy. *The European Union institutions should focus their energies on capturing the public health opportunity to encourage adult smokers to quit smoking or switch to lower risk alternatives like vaping.*

Specific recommendations

The European Union should implement 'risk proportionate regulation' to facilitate the efficient operation of the internal market in consumer nicotine products. At present that market is dominated by the incumbent harmful cigarette trade. Emerging smoke-free tobacco and nicotine will disrupt the dominance of cigarettes by giving smokers an easier path to smoking cessation. The EU should avoid policies that inhibit this switching behaviour and effectively sustain the cigarette trade.

1. *Remove the 20mg/ml cap on e-liquid nicotine strength.* This measure has no scientific basis and simply works to limit compact product designs that use lower volumes of higher strength liquids at lower power that work effectively to help smokers in the initial stages of switching. There is no evidence to support this measure and experts criticised the justification for it at the time it was introduced. The limit is an arbitrary and pointless regulatory barrier to beneficial innovation and creates a regulatory protection for the cigarette trade.
2. *Lift the ban on snus.* Through widespread use of snus for nicotine consumption, Sweden and Norway have very low levels of smoking and, as a result, low levels of smoking-related disease. Epidemiology shows snus use carries negligible risks and effectively displaces smoking, including among young people. The 1992 ban remains in place despite a vast body of evidence that snus use, where permitted, has significant benefits to public health. There is no scientific, economic or ethical reason to deny EU citizens access to this product. Any regulation should focus on toxicity standards for all smokeless tobaccos.
3. *Protect the diversity of flavours in smoke-free products.* A wide range of flavours is intrinsic to the appeal of vaping products and therefore to their potential to draw smokers or would-be smokers away from cigarettes. We support controls on hazardous ingredients that protect consumers or product *descriptors* that appeal to youth. However, we strongly oppose measures intended to make the products themselves less pleasurable or satisfying for consumers, including bans on broad classes of flavourings. Experience from the United States suggests e-liquid flavour bans have the (predictable) effect of increasing adolescent smoking. Any broad ban on flavoured products will also trigger black market activity and do-it-yourself mixing with food flavourings.
4. *Adopt risk-proportionate taxation.* The revised Tobacco Excise Directive should allow for member states to set zero excise duties on smoke-free products to maximise the economic incentive to switch from high-risk to low-risk nicotine use. A *maximum* allowable rate for smoke-free tobacco or nicotine products should not exceed half the lowest equivalent rate for combustible tobacco products in any member state. This allows a range of taxation options to member states while retaining a risk-proportionate basis to excise duties to improve the functioning of the EU internal market. ETHRA partners will make the case for zero excise duties in each member state.
5. *Redesign health warnings as risk communications.* Health warnings on emerging smoke-free tobacco and nicotine products should be redesigned to support informed consumer choice, and therefore to facilitate the functioning of the internal market. Risk communications should stress risk relative to smoking and that it is a good choice to switch from high-risk to low-risk products. There is evidence that the current warnings cause excessive alarm and deter smokers from switching from high-risk to low-risk nicotine products.
6. *Allow controlled advertising of smoke-free emerging tobacco and nicotine products.* Consumers will only switch to low-risk products if they are aware of them. Advertising for smoke-free products functions as anti-smoking advertising and member states should be free to take advantage of promotion of smoking cessation via advertising. The Tobacco Advertising Directive should be

revised to limit bans on advertising, sponsorship and promotion to combustible tobacco products and brands. It is only the death toll from smoking that justifies the ban on tobacco advertising.

7. *Remove restrictions on tank and refill container size.* The Tobacco Products Directive (Article 20(3)(a) technical restrictions on tank size (2ml) and refill container size (10ml) have no basis in health protection or consumer protection, but increase the number of refills, user inconvenience and packaging waste. To our knowledge, no other consumer product has limits on container size imposed as risk mitigation measure. A more realistic and practical approach would require: (1) child resistant packaging, (2) warning labelling and (3) advice on what to do if exposed.
8. *Regulate nicotine pouches.* Nicotine pouches could play a significant role in migration from smoking for many users. Pouches allow for very low risk and unobtrusive nicotine use without emissions. It is important for consumer confidence that such products are regulated for consumer protection reasons and are brought into the EU framework for regulation of nicotine products. The guiding principles should be consumer protection and risk-proportionality.

This presents a summary of our views in a way that we hope will stimulate discussion. When the appropriate opportunity arises, we will write with a more detailed account of the case for these measures.

ETHRA looks forward to participating in the Commission's seminar on new and emerging products. We hope it generates a thoughtful debate about options to make the internal market function with a high level of health protection. Using tobacco harm reduction to radically disrupt the entrenched cigarette market would be an effective way to do that.

If we can be of further service or you would like to follow up on any of the points raised in this letter, please contact Damian Sweeney [damians76@live.ie] [+353 86 8505931].

Yours sincerely