Evidence brief 4: Policies for novel and emerging products

Policymaking for novel and emerging smoke-free tobacco products is complicated by the following:

- These products are far safer than the dominant tobacco products (cigarettes).[1]
- These products function as substitutes for the dominant high-risk tobacco products (cigarettes).[2]
- Policies to address youth vaping and smoking can cause more harm than good *to young people*.[3]
- Regulatory interventions can trigger unintended consequences that the regulator may not expect or want, such as switching back to smoking, engaging in illicit trade, or finding workarounds.
- Full or partial prohibitions do not cause banned products to disappear; they change how they are supplied and by whom. Governments lose regulatory, fiscal, and legal control to criminal networks.

Five questions every public health official should ask when a new nicotine policy is proposed:

1. **What is the problem this policy is trying to address?** Policymakers should be focused on the objectives of the FCTC[4], the SDGs[5] and the Parties' own public health goals, such as those of the E.U.[6] That will generally mean tackling the non-communicable disease burden, which is driven almost entirely by *smoking*. Most evidence suggests novel and emerging products would reduce smoking and reduce the burden of disease, contributing to meeting tobacco policy objectives.
2. **What evidence supports the proposed policy?** For example, the WHO routinely backs prohibitions of novel and emerging tobacco and nicotine products,[7] giving India an award for prohibition of ENDS and heated tobacco products in 2019.[8] However, there has been no evaluation of this law, its effects on supply and demand, and any unintended consequences. Yet obvious concerns arise about illicit trade and protection of the cigarette trade. Do flavour bans work? Do marketing restrictions protect the cigarette trade? Have the standard policymaking disciplines been applied, for example, impact assessment, cost-benefit analysis, feasibility, risk assessment, and equity assessment?[9]
3. **What trade-offs are created by this policy?** If the policy is designed to protect youth from nicotine uptake, does it harm adults by reducing smoking cessation? Is it designed to protect adolescents who would never use nicotine at the expense of adolescents who would otherwise smoke? Does the policy punish poor or disadvantaged people who continue to smoke or use nicotine, aggravating inequities? Do efforts to control access to ENDS make it relatively easier to access cigarettes?
4. **What are the likely and foreseeable unintended consequences?** Policies do not always create the changes policymakers hope for and can make matters worse. Will the policy cause some ENDS users to return to smoking,[10] some smokers never to switch, and some young people to smoke instead of vaping?[11] Will it trigger black market supply[12] and engage young people in criminal networks? Will it punish people for looking after their own health at their own expense? Will it cause users or suppliers to adopt workarounds that might introduce novel risks?[13]
5. **Who disagrees and why?** Unlike the U.N. Framework Convention on Climate Change, the WHO and FCTC secretariat carefully curate which stakeholders are permitted entry as observers to the COP meetings.[14] American billionaires fund many so-called civil society organisations to promote prohibitionist policies. Effective policymaking demands officials seek out credible contrary perspectives, especially those excluded from the meetings. This does not mean adopting the views of the tobacco industry but recognising there is a substantial body of credible independent public health experts who support tobacco harm reduction[15] [16] and dispute the WHO analysis of ENDS.[17]

Clive Bates, *The Counterfactual*, January 2024

An expert perspective. As the Royal College of Physicians (London) puts it:[18]

> *If [a risk-averse and precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer-friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.*

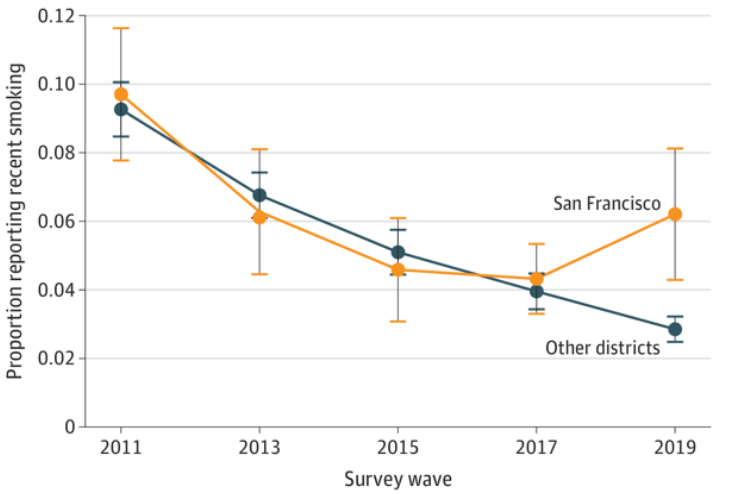
For specific policies, policymakers should be aware of the following.

Outright prohibitions of novel and emerging products. Prohibitions trigger various responses, including illicit supply, switching to products not banned (cigarettes), and workarounds (making and selling DIY products).[19] Illicit trade can involve young people in criminal supply, as WHO was forced to admit as the ban on tobacco in Bhutan unravelled in 2020.[20] [21] The main argument against such proposals is not merely the harmful unintended consequences but the ethics of denying people at risk of serious disease the lawful right, the information, and the means to switch to much safer, smoke-free products while keeping the most dangerous products widely available on the market.[22] [23]

Taxing ENDS. A substantial body of evidence shows that ENDS and cigarettes are economic substitutes. This means that when the price of ENDS increases, the demand for ENDS falls, and the demand for cigarettes rises, all other things being equal,[24] including for youth,[25] and young adults.[26] It is, therefore, not possible to analyse the impact of an ENDS tax without also accounting for the effect on alternatives to ENDS, including cigarettes. One U.S. estimate suggested a "*proposed national e-cigarette tax of $1.65 per millilitre of vaping liquid would raise the proportion of adults who smoke cigarettes daily by approximately 1 percentage point, translating to 2.5 million extra adult daily smokers*."[27] A tax on ENDS protects and promotes the cigarette trade and can easily do more harm than good.

Banning flavoured ENDS. Tobacco harm reduction works by encouraging consumers of cigarettes to switch their product choice from smoking to much safer, smoke-free products. Smoke-free products must appeal to smokers to compete with cigarettes. One example of this appeal is the wide range of flavourings of ENDS.[28] A ban on flavours makes alternatives to cigarettes less competitive with cigarettes and, in doing so, protects and aids the cigarette trade. One study showed that when vape flavours were banned in San Francisco, cigarette smoking increased *among high school students*:[29]

Figure 1. Past-30-Day Smoking Rates Among High School Students Younger Than 18 Years



A recent U.S. study by independent academics showed that ENDS flavour bans had the average effect of increasing smoking: [30]

> "*We find a trade-off of 15 additional cigarettes for every 1 less 0.7 mL ENDS pod sold due to ENDS flavor restrictions*".

A survey of French consumers found that half said they would source flavours illegally, and about one-quarter said they would return to smoking.[31] Several academic studies have identified risks with flavour bans: Posner et al. (2021)[32] found that one-third of e-cigarette users would be likely to switch to cigarettes. Gravely *et al.* (2021)[33] examined possible responses to flavour restrictions in the United States, Canada, and England, finding that 28.8% would access their preferred flavours via illicit means and 17.1% would stop vaping and smoke instead.

Controlling nicotine strength. Proposals to limit nicotine strength are based on a misunderstanding that strength reflects nicotine exposure or 'addictiveness'. In reality, *users* control their exposure to nicotine through a widely understood process known as nicotine titration.[34] Note this also applies to alcohol – people drink smaller quantities of whiskey than beer. This titration effect has been well-documented in smokers for several decades.[35] [36] The user's puffing pattern and possibly their choice of device will change to achieve a desired nicotine intake, for example, by puffing more deeply or more often – a process known as 'compensation'. By adjusting their puffing patterns, users consume lower volumes of higher-strength liquid. But a nicotine strength limit also means that users will consume higher volumes of lower-strength liquid using more energy – potentially creating higher exposures to toxicants generated by heating liquids.[37] [38] [39] As with alcoholic spirits, the strength of nicotine in ENDS is self-limited by consumer acceptability and the excessive harshness of high-strength products. Any limits imposed on nicotine characteristics should focus on pharmacokinetics – the peak nicotine concentration in the brain (C_{max}) in the brain and how quickly to reach it (T_{max}). As long as these characteristics show lower abuse liability (e.g. C_{max}/T_{max}) than cigarettes, there is no case for imposing controls.

A rational approach to ENDS product regulation. Multiple factors drive vaping uptake, not just flavours. In studies reporting the stated motivation of teenage users, *harm reduction* is an important reason for young people to use ENDS,[40] [41] [42] as well as a wide range of psychosocial factors. A flavour ban stops the lawful supply of flavoured products, *but it does not stop the demand*. It follows that many young people will simply find ways around the prohibition or take up smoking. Control of flavours should focus on *descriptors* (packaging, branding, and trademarks that describe the flavour), a form of marketing. Not the flavour sensation itself.

Banning disposables. Disposable single-use ENDS products have risen rapidly among adults and adolescents in several jurisdictions. They are important in reaching poorer smokers because they are low-cost, have no upfront cost, are easy to use, and deliver an immediately satisfactory alternative to cigarettes. They offer the easiest exit route from smoking and work well for people experiencing various forms of disadvantage. A ban on these products would create barriers to vaping uptake and create a regulatory barrier to entry that protects the cigarette trade. These products would not disappear but become part of extensive illicit trade – informal estimates suggest illegal products account for around 50% of the vape market in the U.K. and U.S.

Banning the advertising and promotion of novel and emerging products. Advertising has multiple functions, including introducing new designs and products, gaining market share, building premium brands, and raising consumer awareness. Almost all ENDS advertising functions as "anti-smoking advertising" as it is trying to draw users towards an alternative to smoking. Banning advertising favours incumbents (the

cigarette trade) and penalises entrants and innovators (ENDS) who need to build their competitive position against cigarettes. There is some evidence that suggests that bans on advertising ENDS reduce the number of smokers who quit,[43] and increase demand for cigarettes.[44]

Oral nicotine pouches. Oral nicotine pouches represent perhaps the safest form of alternative low-risk nicotine product as they do not create an inhalable aerosol or involve chemical decomposition arising from heating. The risk profile for products made by reputable manufacturers is likely to be similar to nicotine replacement therapy,[45] though they may be more effective in delivering nicotine at doses satisfactory to smokers. Pouches offer the same harm reduction model as snus,[46] showing how low-risk products can drive out high-risk products in Sweden and other Scandinavian and Nordic countries.[47] [48]

The right overall approach: risk-proportionate regulation. The aim of tobacco and nicotine policy should be to realise the vast benefits of displacing cigarettes with far less risky products. Advocates of tobacco harm reduction are not opposed to the regulation of safer alternatives to nicotine. The aim should be to take the toughest, most restrictive measures to address the risks of smoking to the user and bystander. The focus for regulation of safer nicotine products should be on consumer protection (chemical, electrical, and thermal safety and reliable information) and limiting youth uptake through measures to ensure responsible supply, retailing and marketing. The table below provides an overview of a regulatory system

An outline of a risk-proportionate regulatory system for tobacco and nicotine

Measure	**Cigarettes, hand-rolling tobacco, and other combustibles**	**Vaping, heated and smokeless tobacco and oral nicotine**
Overall aim	Reduce appeal and deter use	Consumer protection
Taxation	Relatively high taxes	Low or zero tax (sales tax only)
Advertising	Prohibit other than within trade	Control themes and placement
Warnings	Graphic warnings depicting disease	Messages encouraging switching
Public places	Legally mandated controls	Up to the discretion of the owner
Plain packaging	Yes	No – control imagery
Risk communication	Major risks to health	A far safer alternative to smoking
Age restrictions	No sales to under-21s	No sales to under-18s
Flavours	Ban characterising flavours	Control flavour *descriptors*
Product standards	Control risks and reduce appeal	Control safety risks to the user

Focus of regulation. The appropriate risk-based distinction in regulation is between “combustible” and “non-combustible”, not between tobacco and non-tobacco or between traditional and novel products. Non-combustible tobacco products are much closer in risk characteristics to non-combustible non-tobacco products than to combustible tobacco products because smoke inhalation is the dominant problem.

References

1 Evidence Briefing 1: ENDS use is far safer than smoking, Clive Bates, Counterfactual, January 2024 [link]

2 Evidence Briefing 2: ENDS use reduces smoking, Clive Bates, Counterfactual, January 2024. [link]

3 Evidence Briefing 3: ENDS use and youth, Clive Bates, Counterfactual, January 2024. [link]

[4] FCTC Article 3: *Objective* "protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke". [link]

[5] Sustainable Development Goal Target 3.4. "*Reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being*" [link]

[6] *Europe's Beating Cancer Plan* [link] and *Healthier Together* action on non-communicable disease [link], Accessed 8 November 2023.

[7] Clive Bates, Prohibitionists at work: how the WHO damages public health through hostility to tobacco harm reduction, The Counterfactual, 7 November 2021 [link]

[8] World Health Organisation, Dr Harsh Vardhan conferred WHO award for leadership in tobacco control, 2 June 2021 [link] "*Dr Harsh Vardhan received the award for spearheading the Government of India's legislation to ban e-cigarettes and heated tobacco products in 2019*."

[9] For example, UK government policymaking guidance includes*: Managing Public Money* [link], HM Treasury *The Green Book* (policy appraisal) [link] and the Better Regulation Framework [link]

[10] Li, D., et al. (2022). Impact of the FDA flavour enforcement policy on flavoured electronic cigarette use behavior changes. *Tob Control*, 31(Suppl 3): s176-s183 [link].

[11] Friedman, A. S. (2015). How does electronic cigarette access affect adolescent smoking? *J Health Econ*, 44, 300-308. [link]

[12] Wong, L. P., et al. (2017). E-Cigarette Users' Attitudes on the Banning of Sales of Nicotine E-Liquid, Its Implication on E-Cigarette Use Behaviours and Alternative Sources of Nicotine E-Liquid. *J Community Health*, 42(6), 1225-1232. [link]

[13] Kerber, P. J., et al. (2023). Effects of E-Cigarette Flavor Enhancing Capsules on Inhalable Aerosols. *Chem Res Toxicol*, 36(1), 8-13. [link]

[14] Clive Bates The WHO tobacco control treaty meetings are closed bubbles of cultivated groupthink – a comparison with the UN climate change treaty, The Counterfactual. 8 November 2021. [link]

[15] Beaglehole, R., Bates, C., Youdan, B., & Bonita, R. (2019). Nicotine without smoke: fighting the tobacco epidemic with harm reduction. *The Lancet*, *394*(10200), 718–720. [link]

[16] 100 independent experts in tobacco and nicotine science, policy, and practice. Letter to Heads of Delegation Parties to the FCTC Ninth Conference of the Parties. October 2021 English, Français, Español, Deutsch

[17] Britton, J. et al. UK Centre for Tobacco and Alcohol Studies (2016), Commentary on WHO report on ENDS and ENNDS, October 2016 [link] [PDF]

[18] Tobacco Working Group. Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 [link]

[19] International Network of Nicotine Consumer Organizations (INNCO), 10 reasons why blanket bans of e-cigarettes and HTPs in low- and middle-income countries (LMICs) are not fit for purpose [link] Press release, 16 March 2021 [link]

[20] World Health Organization. Country Office for Bhutan. (2020). *The big ban: Bhutan's journey towards a tobacco-free society*. World Health Organization. Country Office for Bhutan. [link]

[21] Clive Bates, The Evil Twins (Prohibition and Illicit trade), *Tobacco Reporter*, 1 February 2022 [link]

[22] Knowledge Action Change, The right to health and the right to tobacco harm reduction — Global State of Tobacco Harm Reduction, June 2022. [link]

[23] Kozlowski, L. T. (2002). Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. *Nicotine & Tobacco Research*, *4*(Suppl_2), S55–S60. [link]

[24] Selya, A., et al (2023). Meta-analysis of e-cigarette price elasticity. *F1000Research 2023 12:121*, *12*, 121. [link]

[25] Abouk, R. et al. (2023). Intended and unintended effects of e-cigarette taxes on youth tobacco use. *Journal of Health Economics*, *87*, 102720. [link]

[26] Friedman, A. S., & Pesko, M. F. (2022). Young Adult Responses to Taxes on Cigarettes and Electronic Nicotine Delivery Systems. *Addiction*. [link]

[27] Pesko, M. F., Courtemanche, C. J., & Maclean, J. C. (2020). The effects of traditional cigarette and e-cigarette tax rates on adult tobacco product use. *Journal of Risk and Uncertainty*, *60*(3), 229–258. [link]

[28] Farsalinos, et al. (2023). Patterns of flavored e-cigarette use among adult vapers in the USA: an online cross-sectional survey of 69,233 participants. Harm Reduction Journal 2023 20:1, 20(1), 1–14. [link]

[29] Friedman, A. S. (2021). A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California. *JAMA Pediatrics*. [link]

[30] Friedman, A. et al. (2023). *E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales*. SSRN [link]

[31] AIDUCE, SOVAPE, La Vape du Coeur and FIVAPE, Communiqué : Première synthèse de l'enquête MERCI LA VAPE – 40000 réponses + 1 alerte sanitaire, 3 November 2023 [link] Full report (French) [PDF link]

[32] Posner H, Romm KF, Henriksen L, Bernat D, Berg CJ. Reactions to Sales Restrictions on Flavored Vape Products or All Vape Products Among Young Adults in the United States. Nicotine Tob Res. 2021 https://bit.ly/30aAdOn

[33] Gravely S, Smith DM, Liber AC, Cummings KM, East KA, Hammond D, et al. Responses to potential nicotine vaping product flavor restrictions among regular vapers using non-tobacco flavors: Findings from the 2020 ITC Smoking and Vaping Survey in Canada, England, and the United States. *Addict Behav*. 2021 https://bit.ly/3oRuSo3

[34] Dawkins LE, Kimber CF, Doig M, Feyerabend C, Corcoran O. Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects. *Psychopharmacology (Berl)* 2016;233(15–16):2933–2941. [link]

[35] Benowitz NL, Hall SM, Herning RI, Jacob P, Jones RT, Osman AL. Smokers of Low-Yield Cigarettes Do Not Consume Less Nicotine. *N Engl J Med*. 1983 Jul 21;309(3):139–42. [link]

[36] Russell MAH, Jarvis M, Iyer R, Feyerabend C. Relation of nicotine yield of cigarettes to blood nicotine concentrations in smokers. Br Med J. 1980 Apr 5;280(6219):972–6. [link]

[37] Kośmider L, Kimber CF, Kurek J, Corcoran O, Dawkins LE. Compensatory Puffing With Lower Nicotine Concentration E-liquids Increases Carbonyl Exposure in E-cigarette Aerosols. *Nicotine Tob Res* 2018 [link]

[38] Kosmider L, Cox S, Zaciera M, et al. Daily exposure to formaldehyde and acetaldehyde and potential health risk associated with use of high and low nicotine e-liquid concentrations. *Sci Rep* [Internet] 2020;10(1):6546. [link]

[39] Dawkins L, Cox S, Goniewicz M, et al. 'Real-world' compensatory behaviour with low nicotine concentration e-liquid: subjective effects and nicotine, acrolein and formaldehyde exposure. *Addiction* 2018;113(10):1874–1882. [link]

[40] Shiffman S. Sembower MA. PATH Data: Harm Reduction is Teens' Top Reason for Using e-cigarettes, Poster SRNT, Florence March 2017 [link]

[41] Ambrose BK, Day HR, Rostron B, Conway KP, Borek N, Hyland A, et al. Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014. *JAMA*. American Medical Association; 2015 Nov 3;314(17):1871. [link]

[42] Nicksic NE et al. Reasons to use e-cigarettes among adults and youth in the Population Assessment of Tobacco and Health (PATH) study. *Addict Behav* 2019;93:93–99. [link]

[43] Dave, D. et al. (2019). Does e-cigarette advertising encourage adult smokers to quit? *Journal of Health Economics*, *68*, 102227. [link]

[44] Tuchman, A. (2019). Advertising and Demand for Addictive Goods: The Effects of E-Cigarette Advertising. *SSRN Electronic Journal*. [link]

[45] Azzopardi, D., Liu, C., & Murphy, J. (2021). Chemical characterization of tobacco-free "modern" oral nicotine pouches and their position on the toxicant and risk continuums. *Drug and Chemical Toxicology*. [link]

[46] Patwardhan, S., & Fagerström, K. (2022). The New Nicotine Pouch Category: A Tobacco Harm Reduction Tool? *Nicotine and Tobacco Research*, *24*(4), 623–625. [link]

[47] Lund, I., & Lund, K. E. (2014). How has the availability of snus influenced cigarette smoking in Norway? *International Journal of Environmental Research and Public Health*, *11*(11), 11705–11717. [link]

[48] Ramström, L., Borland, R., & Wikmans, T. (2016). Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. *International Journal of Environmental Research and Public Health 2016, Vol. 13, Page 1110*, *13*(11), 1110. [link]