

Thank you for this opportunity to contribute to this proposal. New Nicotine Alliance Ireland is a consumer-led organization representing the interest of consumers of safer nicotine products, we are unaffiliated to any industry.

Smoking is one of the leading causes of preventable death in the EU, but it's not nicotine that causes the harm from smoking it's the delivery method, the combustion of tobaccoⁱ. E-cigarettes don't contain tobacco and do not involve combustion, and are a vastly safer alternative to smoking. The Royal College of Physiciansⁱⁱ and Public Health Englandⁱⁱⁱ have both stated that vaping poses less than 5% the risk of smoking and should be recommended to smokers as a viable method of smoking cessation.

Population level data from Ireland has provided solid evidence of the benefits of vaping in reducing smoking prevalence. In 2015 and 2016 smoking prevalence had stagnated at 23%, however as vaping became more popular smoking prevalence decreased at the fastest rates in history, falling 6% in just 3 years. 38% of those who successfully quit smoking used vaping compared to only 15% that used pharmacotherapy like nicotine replacement therapy^{iv}. Evidence from a recent Cochrane review^v backs up the much higher efficacy of vaping compared to traditional nicotine replacement therapies, as does the results of a randomised control trial by Hajek et al^{vi}.

Smoking prevalence in the Netherlands is high, 21.7% in 2019, and only fell 2.4% from 2016^{vii}. Compare this to the figures from Ireland where, with the help of vaping, smoking prevalence fell 6% in the same timeframe (Department of Health, 2019). There remains a large number of people in the Netherlands that could benefit from extra supports in their attempts to quit smoking, vaping can provide this support. The proposal to restrict e-cigarette flavours will not further your goals of becoming smoke-free by 2040, as you will be removing an effective tool that people use to quit smoking.

Flavours are of key importance to adults who use e-cigarettes to quit smoking and remain smoke free. A study of almost 18000 people, published in The Journal of the American Medical Association^{viii} concluded that vaping non-tobacco flavours was 2.3 times more effective than vaping tobacco flavours.

Adult preference for fruit flavours over tobacco, and migration away from tobacco to fruit flavours is also evident in data from the Netherlands, this data was based on adults that had completely switched from smoking to vaping^{ix}. The importance of this data shouldn't be overlooked as these are the people that will be targeted, and the most negatively impacted, if a ban on non-tobacco flavours comes into force.

Another important role flavours play is to prevent a relapse to smoking. A study by researchers at Penn State^x found that adult preference for tobacco flavours decreased over time, and migration to sweet flavours occurred in long term users. Discussing their findings Professor Ding Du said that many participants indicated that using sweet flavours over a longer period of time was an important factor in avoiding relapse to smoking.

Flavors are an important element in NRT's too, for the reason that the product must be palatable and attractive enough that the user will continue to use it. To remove flavours from e-cigarettes is short-sighted and self-defeating, if reducing smoking is the intention. We suggest that instead of removing flavours, you regulate the branding and descriptors used to market these products. Like alcohol, nicotine products are intended for adult use, regulating branding and packaging to reflect this is a more effective strategy that protects the gains e-cigarettes may offer while discouraging take up by underage users.

While recognizing the need to prevent youth initiation, we feel a ban on non-tobacco flavors will only reduce the appeal and effectiveness of e-cigarettes to current smokers. Flavours are not the main driver of youth e-cigarette use, curiosity is. However, flavours play a vital role for adults that use e-cigarettes as a smoking cessation tool. A flavour ban will be disastrous for these people and drive many back to smoking. This was the case in California when a flavour ban was put in place. Comparing the before and after of the flavour ban in San Francisco, cigarette smoking increased in 18- to 24-year-olds from 27.4% to 37.1%^{xi}

Prohibition risks illegal products supplying the market. Part of the rationale for the measures to restrict e-cigarette flavours mentioned EVALI. It is telling that EVALI was entirely an effect from illicit THC carts and did not happen with regulated nicotine vapour products. Here in the EU, we have had no cases of EVALI from e-cigarettes. Removing the option to purchase flavoured products legally may urge some users to either buy from unregulated sources or try adding flavours themselves with unintended consequences. While all flavours are regulated for use in vapour products under TPD, what's available off the shelf is not regulated for such use. The cause of the so-called EVALI outbreak was an additive which was oil-based, a substance that is not miscible with water soluble nicotine e-liquid.

Regressive regulations, such as restricting e-cigarette flavours, risks driving people back to smoking and encouraging a black market. E-cigarette flavours are very important for adults who are on their journey to quit smoking, this is very clear. Removing the preferred flavour options from these adults will not advance the goal of a smoke-free Netherlands by 2040, in fact it will hinder progress and render it little more than a pipe dream. However, if regulated in a sensible manner, e-cigarettes will increase quitting sufficiently to make this goal attainable.

ⁱ Russell MA. The future of nicotine replacement. *Br J Addict*. 1991 May;86(5):653-8. doi: 10.1111/j.1360-0443.1991.tb01825.x. PMID: 1859935.

ⁱⁱ Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP, 2016.

ⁱⁱⁱ McNeill, A. *et al.* (2018) 'E-cigarettes and heated tobacco products: evidence review Annual update of Public Health England's e-cigarette evidence review by leading independent tobacco experts.', *Public Health England*, pp. 1–243. Available at: <https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review>.

^{iv} Department of Health (2019) *Healthy Ireland. Summary Report 2019*. Available at: <https://assets.gov.ie/41141/e5d6fea3a59a4720b081893e11fe299e.pdf>.

^v Hartmann-Boyce, J. *et al.* (2020) 'Electronic cigarettes for smoking cessation', *Cochrane Database of Systematic Reviews*, (10). doi: 10.1002/14651858.CD010216.pub4.

^{vi} Hajek, P. *et al.* (2019) 'A randomized trial of E-cigarettes versus nicotine-replacement therapy', *New England Journal of Medicine*, 380(7), pp. 629–637. doi: 10.1056/NEJMoa1808779.

^{vii} Bommel , J. and Willemsen, M. (2020) 'Kerncijfers roken 2019', *Trimbos-instituut: Utrecht, The Netherlands*.

^{viii} Friedman, A. S. and Xu, S. Q. (2020) 'Associations of Flavored e-Cigarette Uptake with Subsequent Smoking Initiation and Cessation', *JAMA network open*, 3(6), p. e203826. doi: 10.1001/jamanetworkopen.2020.3826.

^{ix} Havermans, A. *et al.* (2019) 'Nearly 20 000 e-liquids and 250 unique flavour descriptions: an overview of the Dutch market based on information from manufacturers', *Tobacco Control*, p. tobaccocontrol-2019-055303. doi: 10.1136/tobaccocontrol-2019-055303.

^x Penn State Health. (2020). Research suggests adults – not just teens – like electronic cigarette flavours. Available at: <https://pennstatehealthnews.org/2020/02/research-suggests-adults-not-just-teens-like-electronic-cigarette-flavors/>

^{xi} Yong Yang, Eric Lindblom, Ramzi Salloum, Kenneth Ward. The impact of a comprehensive tobacco product flavor ban in San Francisco among young adults. *Addict Behav Rep.* 2020 Jun; 11: 100273