

Thank you for the opportunity to comment on this consultation. Our contribution outlines why restricting e-liquid flavours will be detrimental to Dutch public health.

European Tobacco Harm Reduction Advocates (ETHRA) is a group of 22 consumer associations in 16 European countries, representing approximately 27 millionⁱ 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.

The stated rationale for the proposed flavour restrictions is to achieve a smoke-free generation by 2040, and to provide a public health benefit. We believe that the proposal is counterproductive to that aim. Severely limiting the products which people use to remain smoke-free will only prolong smoking and have a negative effect on public health.

Vaping is proven to help people quit smoking and remain smoke-free

As ex-smokers we are painfully aware of how difficult it can be to quit smoking and many of us could only quit using vaping products after other methods had failed us. Vaping is indeed a popular and effective method of quitting smoking for adults and this is borne out by data from Belgium, France, Ireland, and the UKⁱⁱ. Evidence from randomised control trials (RCT) also support the efficacy of vaping for smoking cessation. A large scale RCT by Hajek et al found vaping to be almost twice as effective as nicotine replacement therapyⁱⁱⁱ. An ongoing Cochrane review and meta-analysis finds that vaping is 67% more effective than NRT's^{iv}.

Switching from smoking to vaping is beneficial to health

Switching from smoking to vaping has been shown to provide significant benefits for respiratory and cardiovascular health.

The primary cause of harm from smoking is combustion. As vaping does not involve combustion the relative risk is vastly lower than smoking. Discussing the relative risks of vaping compared to smoking, the UK Royal College of Physicians stated in its 2016 report *Nicotine Without Smoke*^v that: *“the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.”* Public Health England stated in its 2018 evidence review that the cancer potencies of e-cigarettes were largely under 0.5% of the risk of smoking^{vi}.

Expert opinion^{vii} from an assessment of published research on the respiratory system and e-cigarettes stated: *“growing evidence supports the relative safety of EC emission aerosols for the respiratory tract compared to tobacco smoke.”* A RCT published in the *Journal of the American College of Cardiology* found significant improvements in cardiovascular health within one month of switching from smoking to vaping^{viii}.

The Decree for regulating e-cigarette flavours raises concern of dual use, however quitting smoking can be a long process and it is very common for smokers to dual use when they first start vaping but to then quit smoking entirely.

A wide variety of flavours is crucial for winning over smokers

Having a wide variety of flavours is intrinsic to the success of vaping products: the ability to tailor vaping to individual tastes plays a very important role in its effectiveness at drawing people away from smoking. The evidence in this area is clear, showing that whilst many people start vaping with a tobacco flavour, over time they gravitate towards fruit, dessert, and sweet flavours^{ix}. Disassociation with the taste of tobacco, as well as enjoyment of the product being used, are very important factors for adult smokers to avoid relapse to smoking.

An analysis of the Dutch e-cigarette market by Havermans et al^x also highlighted the importance of non-tobacco flavours for Dutch smokers. The researchers concluded that *“adults who completely substituted the use of conventional cigarettes by e-cigarettes have often initiated e-cigarette use with fruity flavours rather than tobacco flavours, or switched from tobacco to non-tobacco e-liquid flavours over time.”*

A recent study published in JAMA^{xi} concludes that *“adults who began vaping non-tobacco flavored e-cigarettes were more likely to quit smoking than those who vaped tobacco flavors.”*

The same study also found that flavours are not associated with youth smoking initiation: *“Relative to vaping tobacco flavors, vaping non tobacco-flavored e-cigarettes was not associated with increased youth smoking initiation but was associated with an increase in the odds of adult smoking cessation.”*

Research by RIVM^{xii} emphasises that flavours in e-cigarettes contribute to users switching completely to e-cigarettes and recommends that: *“Ideally, regulation should allow marketing of e-liquid flavors that stimulate smokers and dual users to keep or start using e-cigarettes.”*

It must also be noted that nicotine gums come in a range of flavours, an important characteristic in their efficacy. A German study^{xiii} from 2011 stated *“Product characteristics of nicotine gums, such as crunchiness, sweetness and flavour, appear to be crucial for the expectations that smokers have in the likelihood that any particular nicotine gum will help them to quit smoking.”*

The explanatory memorandum states that e-cigarettes are mainly used by adults who smoke, have smoked and/or want to quit smoking. Banning or restricting flavours will have a disastrous effect on smoking cessation, effectively removing the products responsible for huge reductions in smoking prevalence from the market. Non-tobacco flavours help to disassociate smokers from the taste of tobacco and so lessen the chances of relapse to smoking.

Vape flavour bans create black markets

The added danger with limiting or banning flavours is that consumers are then forced to use the black market to obtain the product they need (or go back to smoking). This was the experience in Estonia where a flavour ban and high taxation led to an explosion of black-market products, reported to account for 62-80% of all sales^{xiv}. In response, Estonia recently amended its flavour legislation.

States in the USA that have banned flavours have also seen thriving black markets develop as ex-smokers seek out the only products that have successfully kept them smoke free. Black market sales of flavoured vaping products are reported^{xv} to be a regular occurrence in car parks around Long

Island New York. Prohibition hasn't eliminated the product; it has simply driven it underground and criminalised those whose only crime is wanting to remain, or become, free from cigarette smoking.

Vape flavour bans increase smoking

A study^{xvi} looking at the impacts of a flavour ban in California found that while flavour bans may reduce overall use of vapour products, they also may increase cigarette smoking. Comparing before and after the ban, cigarette smoking increased in 18- to 24-year-olds from 27.4% to 37.1%.

Banning flavours can increase health risks

There are also health risks associated with banning flavours, as consumers turn to unregulated products or mix their own e-liquids with food flavourings not suited for vaping. Oil based flavours in particular could present a significant health hazard. Inexperienced vapers driven to mix their own flavoured liquids may not be aware that e-liquid flavourings are water soluble, and in their desperation could add oil-based food flavourings to their liquids, without realising the inherent danger this poses.

The dangers of inhaling oil-based solutions are highlighted in section 2.2 (*Harmfulness of e-cigarettes*) of the exploratory memorandum, albeit in a highly misleading way. EVALI was caused by vitamin E acetate used in illicit THC products^{xvii}. However, this compound was never, and could never be used in nicotine e-liquid. E-liquid is a water-soluble solution (hydrophilic), vitamin E acetate is non-water soluble (hydrophobic) used in oil-based solutions. Added to that, vitamin E acetate is already a banned substance under the TPD.

Equally misleading is the inclusion of Diacetyl in the exploratory memorandum, with reference to a risk of bronchiolitis obliterans (popcorn lung) from vaping. Bronchiolitis obliterans is an extremely rare disease that was found **only** in a group of popcorn factory workers. Cancer Research UK^{xviii} had this to say *"There's no good evidence that e-cigarettes could cause the lung condition called popcorn lung. There's been no confirmed cases of popcorn lung reported in people who use e-cigarettes."* Diacetyl is also a banned substance under the TPD.

Use of vapour products among never smoking youth is rare and does not lead to nicotine dependence

We appreciate that there are concerns about youth initiation but there is no evidence that non-smoking young people are becoming dependent on vaping nor that vaping is leading to young people smoking.

The exploratory memorandum discusses youth use of e-cigarettes in the USA, described as an 'epidemic'. However, an examination of the National Youth Tobacco Survey 2019^{xix} found that frequent use of e-cigarettes among tobacco naïve young people was rare. A further study of National Youth Tobacco Survey data concluded that vaping was a diversion away from smoking^{xx}. Youth smoking in the USA is at historically low levels and continuing to fall.

A recently published study^{xxi} on nicotine use by young people in the USA concluded that *"Among US high school students, increases in the prevalence of nicotine product use from 2012 to 2019 do not appear to have been accompanied by a similar increase in the population burden of nicotine*

dependence. This may be at least partly attributable to a shift in the most common product of choice from cigarettes (on which users are most dependent) to e-cigarettes (on which users are least dependent)."

In the Netherlands, Jongeren en riskant gedrag^{xxii} from TRIMBOS shows that youth smoking rates are low and continue to decline, from 2.1% in 2017 to 1.8% in 2019. Jongeren en riskant gedrag also shows that youth vaping is in decline:

"Between 2015 and 2019 there was a decrease in the percentage of young people aged 12 to 16 who have ever used an e-cigarette; from 34% in 2015 to 25% in 2019." (p. 81)

The Netherlands has therefore performed exceptionally well in regard to youth smoking and youth vaping, as prevalence is low and moving downwards for both.

Dutch adult smokers the collateral damage

We are surprised and concerned to see that the rationale given for the restriction of flavours is that it will provide a public health benefit by discouraging the use of e-cigarettes. These measures will in fact have the opposite effect by negatively impacting adult smokers the most. Adult smoking prevalence in the Netherlands is high, at 21.7%^{xxiii}. This 21.7% represents a lot of people who could benefit greatly from switching to a less harmful product.

The cost of smoking is not only felt in terms of health, but also economically. Smoking is very expensive and smoking prevalence is highest in the more disadvantaged socioeconomic groups. Vaping is cheaper than smoking and so offers smokers an alternative which is not only less harmful but also less expensive. Making vaping less attractive to smokers by limiting flavours will keep more people smoking, and spending money on cigarettes.

Conclusions

Vaping is far less risky to health than smoking. Making these products less attractive to adult smokers and restricting their availability will have a negative effect on public health by perpetuating smoking. The Royal College of Physicians has warned of the unintended consequences of overregulating vaping products:^{xxiv}

"if a risk-averse 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."

(section 12.10 page 187)

There are no circumstances in which it is better to smoke than to vape and so keeping vaping products attractive for smokers, to encourage them to switch, can only be a win for public health. Having a wide variety of flavours is crucial to vaping's success at winning over dependent smokers.

We share your commitment to health prevention and promotion but banning flavours will not serve that purpose.

ETHRA is listed in the EU Transparency Register at: 354946837243-73.

References

ⁱ Estimate of 27 million consumers provided by ECigIntelligence/TobaccoIntelligence. The actual figure is likely to be far higher because the data for smokeless tobacco is taken from research (Leon et al 2016) using data gathered in 2010 in only 17 countries

ⁱⁱ Interview on Tobacco Products Directive: notes by ETHRA, pps 8-9 Impact of e-cigarettes on smoking cessation. Available at: https://ethra.co/images/ETHRAs_notes_on_TPD_interview.pdf

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^{vi} 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>.

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^{xii} KA Romijnders, Erna JZ Krüsemann, Sanne Boesveldt, Kees de Graaf, Hein de Vries, Reinskje Talhout. E-Liquid Flavor Preferences and Individual Factors Related to Vaping: A Survey among Dutch Never-Users, Smokers, Dual Users, and Exclusive Vapers. *Int J Environ Res Public Health*. 2019 Dec; 16(23):4661

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^{xiv} Baltic Times, Estonian FinMin looking into prospect of lowering excise duty for e-cigarettes 25 Nov 2019

^{xv} Filter, Vape Bans Are Creating a Thriving Illicit Market 8 July 2020

^{xvi} 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

^{xvii} Blount, B. C. et al. (2020) 'Vitamin E Acetate in Bronchoalveolar-Lavage Fluid Associated with EVALI', *New England Journal of Medicine*, 382(8), pp. 697–705. doi: 10.1056/nejmoa1916433.

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