

IEVA Contribution to the Draft Amendment of the Tobacco and Smoking Products Order

IEVA would like to express its concerns regarding the Draft Amendment of the Tobacco and Smoking Products Order for regulation of e-cigarette flavours, presented by the Ministry of Public health, Welfare and Sports.

According to the statement of grounds submitted by the Dutch authorities, the draft amendment intends to ban flavours other than tobacco in e-liquids in order to "reduce the temptation for young people and former smokers to purchase e-cigarettes", and that this measure is "justified by the need to protect public health". The statement also claims that, in order to achieve the objective of a smoke-free generation by 2040, "preventing smoking in general and helping current smokers quit are more likely to be achieved if e-cigarettes are less attractive."

IEVA is concerned by this Draft Amendment, which effectively bans the use of flavouring additives in e-liquids by presenting an exhaustive list of 16 flavouring additives that are allowed.

IEVA believes the **proposed flavour ban is not proportionate to the objective** pursued, as the measure strongly fails to be:

- Appropriate, i.e. a suitable mean to attain the objective with a reasonable connection between the aim and the measure;
- Necessary, i.e. Member States should choose the means which least restrict the free movement of goods.

Moreover,

- The Tobacco and Smoking Products Act (*Tabaks- en rookwarenwet*) already fully regulates the market and prevents adolescents under 18 years old from buying such products (Article 8).
- The ban will lead to a rise in black market activity.
- It will put at risk tens of thousands of jobs and would lead to a reduction in government revenues by reducing tax collection.¹

¹ Vaping in Europe, a market on the rise. The results of the Eurispes study, <u>URL</u>

Overall, IEVA respectfully calls on the Dutch government to refrain from keeping this draft amendment as it is and to re-examine it in the light of the information we provide in this contribution.

1. Introduction of a flavour ban on e-liquids

Proposed measure: To make e-cigarettes less attractive, this draft Ministerial Order now bans additives that create flavours other than tobacco flavours in liquids containing nicotine, nicotine-free liquids and other e-cigarette components. This will ban the production and sale of e-cigarette flavours other than tobacco. This helps reduce the temptation for young people and former smokers to purchase these e-cigarettes.

IEVA considers that the foreseen flavour ban does not adequately serve the policy objectives targeted by the Dutch authorities.

1- Vaping products are less harmful alternatives than smoking

<u>Claim</u>: "Mounting scientific evidence indicates that e-cigarettes are harmful, addictive and attractive. [...] Due to the harmful effects of inhaling chemicals in liquids for e-cigarettes and the addictiveness of nicotine e-cigarettes, reducing the attractiveness of e-cigarettes offers health benefits. For this reason, regulating flavourings for e-cigarettes is justified by the need to protect public health."

The Dutch authorities, in their explanatory memorandum, only provide one source (a 2015 RIVM investigation) to justify the harmful effects of e-cigarettes, despite claiming the existence of "mounting scientific evidence". Yet many independent and publicly funded studies have in fact highlighted the harm reduction potential of e-cigarettes: a report commissioned by Public Health England found that using e-cigarettes is **95% less harmful than smoking** combustible cigarettes,² and a study financed by the prestigious Institut Pasteur, confirmed that vaping is significantly less carcinogenic than smoking and constitutes an acceptable replacement for traditional tobacco.³ Other sources pointing to the harm reduction potential in vaping can be found in studies by the Royal

³ Dusautoir et al., "Comparison of the chemical composition of aerosols from heated tobacco products, electronic cigarettes and tobacco cigarettes and their toxic impacts on the human bronchial epithelial BEAS-2B cells", Journal of Hazardous Material, Vol. 401, 2021, URL

² McNeil et al., "Evidence review of e-cigarettes and heated tobacco products 2018", <u>URL</u>

College of Physicians⁴ or published in the British Medical Journal.⁵ Overall, e-cigarette reduced the risk of cancer for smokers.

IEVA regrets that the Dutch authorities neglect the positive effects of e-cigarettes with particular flavour profiles, wrongly assuming that "it is not known to what extent the e-cigarette is less harmful".

2- E-liquid flavours play an important role in encouraging adult smokers to quit smoking

<u>Claim</u>: "[H]elping current smokers quit are more likely to be achieved if e-cigarettes are less attractive."

Peer reviewed and publicly-funded studies showed, in fact, the opposite: **e-liquids** flavours do play a critical role in helping adult smokers to switch to vaping from traditional tobacco. When it comes to the relationship between vaping and smoking initiation, a recent study by the Yale School of Public Health, based on more than 17,000 respondents aged 12 to 54, concludes that "adults who began vaping non-tobacco flavoured e-cigarette were more likely to quit smoking than those who vaped tobacco flavours". On the contrary, flavours are in fact more important for adult smokers and ex-smokers than ever: a study published in the Harm Reduction Journal concludes that "restricting access to non-tobacco e-cigarette flavours may discourage smokers from attempting to switch to e-cigarettes."

Moreover, a flavour ban might convey the misleading message that traditional tobacco and vaping products pose similar health risks, thereby spreading current misconceptions regarding the comparative risks of these products, and discouraging smokers from switching to vaping.

Finally, it is important to note that the European Parliament considered, in its <u>report on strengthening Europe in the fight against cancer</u> adopted in February 2022, that "electronic cigarettes could allow some smokers to progressively quit smoking".

⁴ "Nicotine without smoke: tobacco harm reduction", UK Royal College of Physicians, 28/04/2016, <u>URL</u>

⁵ William E-Stephens, "Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarette with those of tobacco smoke", BMJ, 04/08/2017, <u>URL</u>

⁶ "Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation", Yale School of Public Health, 05/06/2020, URL

⁷ Russell, C., McKeganey, N., Dickson, T. et al. "Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA". Harm Reduction Journal 15, 33 (2018), <u>URL</u>

3- Vaping products are not a gateway to smoking combustible tobacco

Claim: "E-cigarette use also appears to make young people more likely to start smoking tobacco compared to young people who do not use these products. [...] [The proposed flavour ban] helps reduce the temptation for young people and former smokers to purchase these e-cigarettes."

The authorities, again, use selective evidence to back up the claims that vaping "appears" [sic] to make young people more likely to smoke.

The Yale School of Public Health study mentioned in the previous point concluded that "vaping non-tobacco-flavoured e-cigarettes was **not** associated with increased youth smoking initiation but was associated with an increase in the odds of adult smoking cessation". As stated by Professor Riccardo Polosa: "Removing flavours will not affect the rates of youth cigarette use. But it will certainly reduce the number of options available for those adults who seek to quit smoking for good and find flavoured e-cigarettes effective".

4- Vaping is a tool for Europe to meet its public health policy objectives

The European Commission presented its <u>Beating Cancer Plan</u>, in February 2021 setting out a new EU approach to cancer prevention, treatment and care. One of its laudable objectives is to create a "**Tobacco-Free Generation**", reducing the smoking prevalence in the EU to 5% by 2040. As there are more than 112 million smokers in the EU, this objective entails that **90 million Europeans need to quit smoking**.

Vaping has been proven to be 95% less harmful than combustible tobacco and significantly less carcinogenic (see point 1) and could help **meet the Beating Cancer Plan's goals - bearing in mind that 91% of smokers can't or don't want to quit smoking**, at least in the short term. ¹⁰ Public health policy should exploit the harm reduction potential offered by e-cigarettes

⁸"Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation", Yale School of Public Health, 05/06/2020, <u>URL</u>

⁹ Riccardo Polosa, "Harm reduction is a flavoured journey in global tobacco control", Catania Conservation, 11/09/2020, <u>URL</u>

¹⁰ No Tobacco Day: la via possibile della riduzione del rischio, Eurispes. URL

5- E-liquids are dependent on flavours to be produced

E-liquids are produced with different flavours. Tobacco flavours are not made out of tobacco leaves, but rather with various recipes mixing different flavours such as vanilla, liquorice, or wood. Banning flavours that are not tobacco will severely restrict the number and variety of e-liquids put on the market.

2. Legal justification of the measure

IEVA would also like to express serious doubt regarding the legal justification of the measure.

IEVA believes the ban on e-cigarette products with particular flavour profiles will amount to a **quantitative restriction in the sense of article 34 of the TFEU** (Treaty on the Functioning of the EU), as the banned products can legally be marketed in other Member States. This would therefore create a difference of treatment and access for e-cigarette and associated products shops.

As the Ministry of Health, Welfare and Sports states in its explanatory memorandum, such restrictions can only be allowed when a number of conditions is met. The proposal must:

- be justified by imperative requirements in the general interest;
- be suitable for securing the attainment of the objective which they pursue;
- not go beyond what is necessary;
- be accessible and foreseeable; and
- be applied in a non-discriminatory manner.

IEVA considers that theses conditions are not met, for the following reasons:

1- The measure seems unlikely to be justified under article 36 of the TFEU that allows for restrictions in imports or exports of goods on grounds of protection of health and life of humans.

IEVA considers that the scientific basis on which the Dutch flavour ban is based does not take into account the full picture, but is instead selective in choosing the scientific studies that support the authorities' position. **The Netherlands do not thoroughly demonstrate that the products in question pose a genuine threat to public health,** which should therefore prevent them from introducing such a flavour ban under article 36 of the TFEU.

Moreover, as many studies (cited above) prove that vaping is significantly less harmful than vaping and indicate that a flavour ban is likely to discourage smokers from abandoning combustible tobacco, the Draft Amendment cannot be deemed to meet the criteria of suitability for attaining the objective that the Government pursues (protecting public health).

Furthermore, the Draft amendment is **not justified by imperative requirements**: The explanatory memorandum from the Ministry even admits that the rate of young people in the Netherlands having tried vaping products has decreased between 2015 and 2019). As explained above, it cannot be considered as suitable to attain the objectives it intends to reach due to the negative impact it would have on smoking rates. Finally, **the government's proposal cannot be deemed proportional**: the consequences it would have on the vaping industry are extreme compared to the claimed public health benefits, as explained below.

3. Flaws in the list of permitted tobacco-flavour substances and its consequences for the vaping industry

The RIVM (the Dutch National Institute for Public Health and the Environment), on which work the Draft amendment is based, has published two reports regarding e-liquid flavours.

The first presented a list of 23 substances used to create tobacco-flavoured e-liquids that would be allowed on the Dutch market. After thorough analysis, the Dutch trade association of producers and distributors of vaping products, <u>Esigbond</u>, has warned the Ministry of Health, Welfare and Sport that this list includes carcinogenic substances, such as isophorone and pyridine, that are known to be harmful by the e-cigarette industry and therefore not used. The Ministry of Health, Welfare and Sport hence asked the RIVM to review the 21 remaining substances.

The RIVM then published a second report after carrying out additional research. It found that among the 21 remaining substances, 7 were hazardous or irritating, leaving 16 on the updated list. The analysis performed by RIVM could not determine whether 20 of the substances on the list were harmful or not. Their judgement was solely based on assumptions. As a result of their analysis, the RIVM suggested two options to the Ministry: (1) banning all 16 substances, leaving no option to manufacture any e-liquids, or (2) allowing only the 16 remaining substances.

Consequences of the chosen option for the Dutch vaping industry: The Ministry has opted for the second option in order to keep the e-cigarette available for smokers who want to quit. However, with the limited list of 16 substances, none of the current tobacco-flavoured e-liquids that are being marketed by registered vape shops in the Netherlands can be manufactured anymore. This option would therefore force the industry to start new development processes to determine (with no guarantee of success) whether an acceptable and marketable tobacco-flavoured e-liquid can be produced using only these 16 ingredients.

Although the RIVM claims that 23% of the e-liquids with tobacco flavour would remain available with the remaining substances, this is in fact not the case and this option could outright ban all e-liquids in the country.

Risking the ban of all flavoured e-liquids in the Netherlands is an extreme measure that would gravely impact the vape shops SMEs in the country. IEVA strongly argues against it, and notes that its consequences are not proportional to the public health goals that the government intends to reach.

Conclusion

Against this background, IEVA respectfully calls on the European Commission to examine the proportionality of the flavour ban proposed by the Netherlands, and encourage national authorities to adopt measures adapted to the pursued aim and based on thorough scientific evidence.

About IEVA

The Independent European Vape Alliance (IEVA) is a trade body that brings together Europe's small and medium sized producers and retailers of vaping products. The vast majority of vaping companies are run by self-funded entrepreneurs who saw a problem in society, cigarette smoking; and created vaping products as part of the solution. We are independent and not influenced by tobacco companies. We remain available anytime for any further questions or comments you may have:

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