

IEVA Contribution to the Ministerial Decree Amending the Tobacco and Smoking Products Order

IEVA would like to express its concerns regarding the ministerial decree Amending the Tobacco and Smoking Products Order, presented by the Ministry of Public Health, Welfare and Sports.

According to the statement of grounds submitted by the Ministry, the decree intends to "extend existing tobacco product rules to heated tobacco products" in accordance with the Delegated Directive (EU) 2022/2100 amending the Tobacco Product Directive (TPD) of 2014.

The statement also states that the Ministry takes the opportunity to "clarify the implementation of Article 7(6) of the Tobacco Products Directive", by applying Article 7(6) to electronic vapour liquids (e-liquids). The Ministry publishes a list of additives including substances that they claim facilitate the uptake of nicotine, such as TRPM8 receptor agonists.

IEVA is concerned by this ministerial decree, which effectively **bans e-liquids** by forbidding the use of essential and indispensable substances for their production.

IEVA believes that the extension of the additive list, originally targeting heated tobacco products (HTP), **to e-liquids, runs several risks**:

- The effective ban of e-liquids in the Dutch market will lead to a boom in black market activities with dangerous, non-compliant products
- It will lead to a rise in smoking rates
- It will put at risk <u>tens of thousands of jobs</u> and would lead to a reduction in government revenues by reducing tax collection

Overall, IEVA respectfully calls on the Ministry of Public Health, Welfare and Sports to refrain from extending the prohibited additive list to e-liquids as it is and to re-examine it in the light of the information we provide in this contribution.

1. TRPM8 additives do not facilitate nicotine uptake and banning them is not required by TPD

Ministry's proposed measure: "[The] prohibition [of additives] also applies to nicotine-containing liquid for e-cigarette [...] and to non-nicotine containing liquid. [...] The list elaborates on the prohibition of additives with carcinogenic and/or mutagenic and/or reprotoxic characteristics, additives that facilitate inhalation, stimulate nicotine absorption or increase the addictive effects of tobacco products or e-cigarettes."

The list notably bans TRPM8 receptor agonists, such as menthol-related substances, which are common additives in e-cigarettes liquids.

Bernhard-Michael Mayer, professor of pharmacology and toxicology at the University of Graz, explains that while TRPM8 receptor agonists mask the airway irritation caused by tobacco smoke, they have the opposite effect in nicotine-containing aerosols: They increase the perceived irritation and harshness produced by the inhalation of most e-liquids, as shown by <u>Rosbroo, K.& Green</u>. Another study (<u>Ni, Ogura & Lin</u>) further demonstrates that TRPM8 receptor agonists increase airway irritation caused by propylene glycol and nicotine, thereby hampering the inhalation of e-liquids with or without nicotine.

Contrary to what the Ministry asserts, this extending the list of forbidden additives to e-cigarettes is **not** required by Article 20 (3) (c) of the TPD, because TRPM8 receptor agonists are not included in the scope of Article 7(6): indeed, they do not "facilitate inhalation or nicotine uptake".

2. Ministry of Public Health makes misleading references to Belgian and German legislation

Ministry's justification: "In a number of other European countries, such as Belgium and Germany, a list of banned additives has already been included in national legislation implementing and interpreting Article 7(6) and Article 20(3)(c) of the Tobacco Products Directive. The Belgian and German lists are therefore sources for the Dutch list of banned additives."

The Ministry's claim is misleading. While Belgium did include a <u>list of prohibited additives</u> in its national legislation, the prohibition is only applicable for tobacco products for smoking, and <u>not</u> for e-liquids. The <u>Royal Decree on the manufacture and marketing of electronic cigarettes</u>, which transposes Article 20 (3) of the TPD into Belgian legislation, does <u>not</u> ban additives that facilitate inhalation or nicotine uptake.

Germany's legislation on prohibited additives is similar to Belgium's. The Tobacco Products Ordinance includes a <u>list</u> of banned additives for tobacco products, which bans chemicals that facilitate inhalation or nicotine uptake, such as menthol-related substances. However, the same legislation also contains a <u>second list</u> dedicated to e-liquid, which does <u>not</u> ban the aforementioned substances, and therefore allows the use of TRPM8 receptor agonists such as menthol.

For both countries, **the list of forbidden additives for tobacco products does not necessarily extend to e-cigarettes**, as TRPM8 receptor agonists are only banned for smoking tobacco. The Dutch ministerial decree indiscriminately applies the substances prohibition for tobacco products to e-liquids, while misleadingly claiming to follow other EU Member States' examples.

Moreover, equating both lists would convey the false 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. **IEVA therefore calls the Dutch Ministry to create two separate lists and to exempt e-liquids from TRPM8 receptor agonists prohibition**.

3. Additive ban will severely impact the vaping industry and cause a black market boom

Currently, the vast majority of e-liquids are manufactured using one or several of the additives contained in part 4 the list published by the Ministry of Public Health, Welfare and Sports ("Additives that facilitate inhalation and nicotine uptake").

A ban of the aforementioned additives will not only **outlaw virtually all the e-liquids currently placed on the Dutch market**, but also restrict the range of e-liquids that can legally be created so severely that it would basically amount to **full ban of e-liquids**. Such a ban in the Netherlands is an extreme measure that would gravely impact the vape shops SMEs in the country, threatening their very existence.

Beyond their economic consequences for both SMEs and governmental fiscal revenues, banning e-liquids will create a **rise in black markets selling non-compliant and potentially dangerous products**. In Estonia, the Parliament actually introduced a <u>bill</u> to roll back a ban on e-liquid flavours, stating that due to the use of black market products, "the health risk of consumers has increased significantly, which was until then mitigated by the mandatory laboratory control of electronic cigarette liquid established in the EU Tobacco Product Directive".

The consequences of this ban are not consistent with the public health goals that the Dutch government intends to reach.

4. Additive ban will lead to rising smoking rates and will threaten public health

Many independent and publicly funded studies have highlighted the **harm reduction potential of e-cigarettes**: a <u>report</u> commissioned by Public Health England found that using e-cigarettes is 95% less harmful than smoking combustible cigarettes, and a <u>study</u> financed by the prestigious Institut Pasteur, confirmed that vaping is significantly less carcinogenic than smoking and constitutes an acceptable replacement for traditional tobacco. Other sources pointing to the harm reduction potential in vaping can be found in studies by the <u>Royal College of Physicians</u> or published in the <u>British Medical Journal</u>. Overall, e-cigarette reduced the risk of cancer for smokers.

Vaping products also play a **critical role in helping adult smokers to switch to vaping from traditional tobacco**. Studies by the <u>Yale School of Public Health</u> or by the <u>Harm</u> <u>Reduction Journal</u> highlight the smoking cessation potential of e-liquids. 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".

For these reasons, we can expect that **implementing the ban of additives contained in the list will deprive smokers from a safer alternative** and lead to a **rise in tobacco smoking rates**, therefore doing more harm to public health.

Conclusion

Against this background, IEVA respectfully calls on the Ministry of Public Health, Welfare and Sports and the Dutch government to re-examine the extension of the additives prohibited for tobacco products to e-liquids, especially for TRPM8 receptor agonists. IEVA invites the Ministry to follow the examples of Belgium and Germany and create separate and distinct lists, for tobacco products on one side and e-liquids on the other.

We 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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