A Scientific Argument Against the 16-Compound Restrictive List and for Expanded Flavouring Provisions Including Natural Tobacco Extracts

Submission to the Responsible Regulatory Department of Estonia

Executive Summary

The proposed regulation restricts tobacco-flavoured e-liquid formulations to 16 specified flavouring compounds. This submission argues on scientific, sensory, and public-health grounds that this list is structurally incapable of recreating the flavour profile of cured tobacco or tobacco smoke, and that its implementation will undermine rather than advance smoking cessation objectives.

We argue that firstly, tobacco flavour is an emergent property of thousands of trace constituents. As Rodgman and Perfetti (2013) documented, tobacco and tobacco smoke contain over 5,500 identified chemical constituents spanning terpenoids, esters, norisoprenoids, pyrazines, furanones, organic acids, phenolics, lactones, and Maillard reaction products. The sensory experience smokers recognise as 'tobacco' arises from the integrated contribution of these compounds at trace concentrations not from a handful of synthetic isolates.

Secondly, natural tobacco extracts provide the full authentic flavour spectrum and should be permitted. Tobacco extracts (NETs) contain the complete volatile and semi-volatile profile of cured tobacco leaf. They are already used commercially in e-liquids and offer the only viable pathway to a genuinely tobacco-like flavour.

Lastly, such restrictive ingredient list will only hamper our company's honest goals. ENVA was founded for one reason: to help people who smoke cigarettes find a realistic alternative they can actually stick with. We know from years of research and from the experiences of our own customers that the single hardest thing about switching from combustible cigarettes is the sensory gap. A product that doesn't satisfy what a smoker expects tobacco to taste like is a product they abandon and when they abandon it, they go back to smoking.

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Our recommendation: Expand the permitted list to include natural tobacco extracts and additional compound classes genuinely present in tobacco (pyrazines, phenolics, maltol, furaneol, vanillin, menthol), with concentration-based controls rather than follow the misguided restrictive list set precedent by Netherland's regulatory body.

We believe our approach aligns with the purpose of Directive 2014/40/EU. The Directive restricts characterizing flavors because they attract non-users, especially youth. A product that tastes like tobacco is only relevant to people who already use tobacco; a product that tastes like mango or cotton candy is relevant to everyone. We want our product to be relevant only to existing adult smokers looking for an alternative. We really appreciate your time to take into our considerations and are available to answer any questions you may have.

Part 1: The Chemical Architecture of Tobacco Flavour

1.1 The Scale of Tobacco's Chemical Complexity

Tobacco is not a simple botanical. Rodgman & Perfetti's The Chemical Components of Tobacco and Tobacco Smoke (2nd ed., CRC Press, 2013) documents over 5,500 identified constituents in tobacco and its smoke. These span a remarkable diversity of chemical classes which can be summarised in the table below:

Chemical Class	Representative Compounds	Sensory Contribution
Terpenoids & norisoprenoids	α-Ionone, β-ionone, damascones, damascenones, neophytadiene	Floral, fruity, woody, green
Pyrazines	2,6-Dimethylpyrazine, 2-ethyl-5-methylpyrazine, trimethylpyrazine, acetylpyrazine	Roasted, nutty, toasted, earthy
Phenolics	Guaiacol, 4-methylguaiacol, phenol, cresols, eugenol	Smoky, medicinal, spicy, clove-like
Furanones & pyranones	Maltol, ethyl maltol, furaneol, cyclotene	Sweet, caramel, burnt sugar
Pyridines	Pyridine, 3-ethylpyridine, 3-acetylpyridine, nicotyrine	Tobacco-like, burnt, roasted
Organic acids	Acetic acid, isovaleric acid, hexanoic acid	Sour, cheesy, sharp
Amadori compounds	Fructose-proline, fructose-asparagine	Odourless precursors to pyrazines, furans

Critically, the sensory impact of these compounds is governed not merely by presence but by odour activity values (OAV) the ratio of concentration to odour threshold. A compound present at parts-per-billion can dominate the aroma if its threshold is low enough. Guaiacol, for example, has an odour threshold of approximately 0.021 mg/L in water; 2,6-dimethoxyphenol (the phenolic on the permitted list) has a threshold of approximately 1.85 mg/L, approximately 88 times less potent. Replacing guaiacol with 2,6-dimethoxyphenol is not a like-for-like substitution.

1.2 The Maillard Reaction: The Thermal Engine of Tobacco Aroma

Tobacco flavour does not exist in the raw leaf. It is created through two sequential processes. First, curing and aging, enzymatic and non-enzymatic reactions between the leaf's sugars (25–50% dry weight), amino acids (12–25% nitrogenous content), and lipids produce Amadori compounds, Strecker aldehydes, and norisoprenoids. Second, combustion/pyrolysis at 600–900°C in the burning zone, these precursors undergo Maillard reactions, caramelisation, and thermal cracking to generate the heterocyclic volatiles (pyrazines, pyridines, furans, phenols) that define smoke aroma.

Amadori compounds, odourless intermediates accounting for 2–3% of tobacco dry weight, are particularly important. Their thermal degradation produces 'large amounts of flavour-related products, including aroma-active aldehydes, ketones, acids, pyrazines, pyridines, and other odorants' (Li et al., 2024). **The permitted list contains no Amadori compounds, no pyrazines, and no Maillard-reaction products.**

1.3 The Pyrazine Triad and Roasted Character

Wu et al. (2026), analysing cigar tobacco smoke, identified what they term the 'pyrazine triad' (methyl-pyrazine, 2,6-dimethyl-pyrazine, and 2-ethyl-5-methyl-pyrazine) as the chemical engine of 'roasted almond and toasted bread aromas, establishing the dominant charred nutty character.' These compounds exhibit direct transfer efficiencies of 40–50× from leaf to smoke, meaning they are thermally generated in large quantities during smoking.

The proposed list contains zero pyrazines. Pyrazines are: naturally present in roasted coffee, chocolate, nuts, and bread; formed from the Maillard reaction between amino acids and sugars, a reaction central to all heated food; GRAS flavouring compounds widely used in the food industry; and essential to the 'roasted' and 'nutty' dimensions of tobacco smoke. **Without pyrazines, any e-liquid will lack the roasted, toasted, earthy backbone that smokers associate with tobacco smoke.**

Part 2: The Case for Natural Tobacco Extracts (NETs)

2.1 What NETs Are and How They Work

Natural Extract of Tobacco (NET) e-liquids use cured tobacco leaf that is macerated, steeped, or extracted to transfer the leaf's native volatile and semi-volatile compounds into the e-liquid base. The extract contains native compounds such as norisoprenoids, terpenoids, and Maillard products already formed during curing (pyrazines, furans, pyrroles, Amadori compounds).

The extract provides the integrated, balanced profile that 16 isolated synthetic compounds cannot replicate.

2.2 Why NETs Were Excluded (And Why That Reason Is Insufficient)

The Pennings methodology, the methodology Netherlands regulators based their ingredient list on, excluded all plant extracts at Criterion 3: 'Flavouring ingredients that are mixtures defined as a distillation or extraction product from plant material are excluded. The composition of such substances... is not consistent as it depends on the composition of the plant source material... It is therefore not possible to establish conclusively through analytical chemical research whether an e-liquid contains a particular extract.'

The concern is that analytical laboratories cannot verify whether an e-liquid contains 'tobacco extract' versus 'cocoa extract' because both are complex mixtures. This problem is solvable through: certificate-of-analysis requirements (quantifying key marker compounds); nicotine and alkaloid fingerprinting (tobacco extracts contain characteristic alkaloid profiles); and exclusion of non-tobacco plant extracts (permit only Nicotiana species extracts).

The analytical challenge should be put onto the manufacturers to prove their case and compliance. When regulators ban NETs, they force manufacturers to attempt the impossible: recreating a 5,500-compound botanical profile from 16 synthetic molecules.

Part 3: The Consequence — What Happens When E-Cigarettes Cannot Satisfy Smokers

3.1 Evidence from Flavour Ban Evaluations

Studies such as Rubenstein et al. (2025) conducted a laboratory choice task with 88 adult dual users. When the only e-cigarette available was tobacco-flavoured, participants chose combustible cigarettes more often. We see this problem too often in regions that have banned other flavours. Our goal at ENVA is to recreate authentic tobacco flavours derived from NETs to hopefully convince users that have would have gone back to combustible cigarettes to choose the less harmful product.

Our product that is aimed to faithfully recreate the sensation of taste of a tobacco cigarette is only aimed for adult smokers to present them with a reduced harm alternative that they use on the daily. Such flavours are only relevant to our target users as they are not attractive to users that are looking for sweet and fruity flavours.

Part 4: A Proposed Science-Based Alternative

The goal of tobacco-flavour regulation should be to permit formulations that provide sensory satisfaction equivalent to combustible tobacco for adult smokers seeking to switch; do not create distinctively sweet, fruity, or candy-like flavours that appeal to youth; are based on compounds genuinely present in tobacco or tobacco smoke; and are manufactured with quality controls and concentration limits.

First, permit natural tobacco extracts. Tobacco extracts derived from Nicotiana tabacum or Nicotiana rustica should be permitted under standardised conditions.

Second, expand the synthetic compound list to include authentic tobacco constituents. Pyrazines, phenolics, furanones, vanillin derivatives, pyridines, lactones, and traditional casing ingredients (cocoa, licorice extracts) should be permitted with concentration caps.

Third, maintain prohibitions on youth-appeal flavours. Fruit-flavour isolates, candy and dessert profiles, bubblegum, cotton-candy, and high-concentration sweeteners should remain prohibited. Pyrazines and guaiacol are no more appealing to youth than 3-ethylpyridine or isovaleric acid. In fact, pyrazines and phenolics are harsh, bitter, and astringent at concentrations that would be used in tobacco e-liquids.

DECLARITION

We respectfully request that the governing body review this submission in accordance with the principles established in Directive 2014/40/EU and the Estonian Tobacco Act, and we are available to provide any additional information or clarification that may be required. We are happy to provide samples of our product for your expert panels to judge whether our products only produce tobacco flavors.

Key Peer-Referenced Citations:

1. European Parliament and the Council of the European Union. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC. European Union. 2014 Apr 29. https://health.ec.europa.eu/system/files/2016-11/dir_201440_en_0.pdf
2. Rodgman A, Perfetti T. The Chemical Components of Tobacco and Tobacco Smoke, Second Edition. CRC Press; 2013. https://www.researchgate.net/publication/294261056_The_Chemical_Components_of_Tobacco_and_Tobacco_Smoke_Second_Edition
3. Li W, et al. The dynamics of microbial community structure and metabolic function in different parts of cigar tobacco leaves during air-curing. Frontiers in Microbiology; 2024. https://pmc.ncbi.nlm.nih.gov/articles/PMC11669699/
4. Wu X, et al. Formation and transfer patterns of key aroma compounds in cigar tobacco. Food Bioscience; 2026. https://www.frontiersin.org/journals/chemistry/articles/10.3389/fchem.2026.1755255/full
5. Rubenstein D, et al. Restricting choice of e-cigarette flavor and device type increases choices for combustible cigarettes. Drug and Alcohol Dependence. 2025;320. https://pubmed.ncbi.nlm.nih.gov/41343944/

Authorisation and Sign-Off

This submission is prepared by our lab scientist and researcher in response to the public consultation on proposed restrictions to e-liquid flavouring compounds. The signatory confirms that the information provided herein is accurate to the best of our knowledge, and that this submission represents our genuine scientific and regulatory position.

Shenzhen GreenSound High-tech Co., Ltd. 2026-July-28

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