

ANAFE contribution to TRIS notifications 2022/508/NL

1. Introduction

ANAFE – Confindustria (hereafter “ANAFE”) is the national trade association that has been representing the Italian industry of electronic cigarettes since 2013. Today, ANAFE brings most of the Italian firms producing devices and inhalation liquids.

The Association, which has been part of IEVA (Independent European Vape Alliance) since 2019, has closely monitored the development of relevant legislation and the so-called new generation products and, since its establishment, it has always been committed to multi-stakeholder’s dialogue at national and supra-national level.

The Association has always participated and actively contributed to European and international decision-making processes, as most recently during public consultations on the Tobacco Products Directive and Europe's Beating Cancer Plan.

For this reason, it is with great interest that ANAFE intends to submit its views regarding the Draft Amendment of the Tobacco and Smoking Products Order for regulation of e-cigarette flavours, notified by the Netherlands to the European Commission on the 17th of March 2022, under the reference 2022/508/NL.

This Draft Amendment effectively bans the use of flavouring additives in e-liquids by presenting an exhaustive list of 16 flavouring additives that are allowed.

First of all, it is important to highlight that ANAFE fully supports harm reduction objective. Therefore, the Association would like to point out the possible negative and unintended consequences of the measures proposed, which could ultimately go against the general principles and objectives of EU sectoral provisions.

In extreme summary and in general terms, ANAFE considers the proposed measures to be neither proportionate nor effective in achieving the intended public health objectives and call on the European Commission to consider the proportionality of the proposed ban on flavorings and to encourage national authorities to adopt measures that are appropriate to the objective pursued and based on thorough scientific evidence.

2. Considerations regarding the principle of harm reduction and the potential of e-cigs

As it is now well known, e-cigarettes and, in general, new generation products, are completely different from traditional cigarettes, in consideration of the distinctive scientific and technological principle of operation and use. As a result of many recognitions by the international scientific community, the so-called principle of harm reduction, according to which new generation products are not only characterized by less significant effects on human health, but also assume a decisive role in the cessation of the use of traditional tobacco and in the fight against smoking, can be considered as acquired.

In this regard, there are many examples of successful policies (first and foremost the one adopted in the UK) which, by promoting and ensuring greater information in favor of consumers and constant in-depth and technical-scientific updates on new generation products (in some cases also aimed at encouraging smokers to purchase these products), have led to extraordinary results in the fight against traditional smoking, demonstrating that these products do not represent a first step towards nicotine addiction,

neither do they constitute a replacement product for traditional cigarettes. On the contrary, they are tools capable of bringing about significant changes in traditional smokers toward cessation.

The Dutch authorities, however, in their explanatory memorandum, selectively consider only a few sources that refer to the harm effects of e-cigarettes. It is therefore unclear why they did not consider the many independent, publicly funded studies that highlighted the harm-reducing potential of e-cigarettes. These include, amongst others: a report commissioned by Public Health England, which found that using e-cigarettes is 95% less harmful than smoking combustible cigarettes and a study financed by the prestigious Institut Pasteur confirming that vaping is significantly less carcinogenic than smoking and constitutes an acceptable replacement for traditional tobacco. In addition, other sources pointing at the harm reduction potential in vaping can be found in studies by the Royal College of Physicians or published in the British Medical Journal. Overall, e-cigarette reduced the risk of cancer for smokers.

In addition, regarding young people, the Dutch proposal assumes that e-cigs can be a tool to bring young people closer to smoking. About that, Yale School of Public Health's above-mentioned study 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"*.

In conclusion, it is useful to remind that the European Commission presented its Beating Cancer Plan 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 and could help meet the Beating Cancer Plan's goals - bearing in mind that 91% of smokers cannot or do not want to quit smoking, at least in the short term. Public health policy should exploit the harm reduction potential offered by e-cigarettes.

3. Considerations on flavourings in e-cigs

One element that has contributed to making e-cigarettes a valuable tool in the fight against smoking by changing consumption habits is **flavourings**. As confirmed by many studies and analyses, traditional tobacco smokers choose new generation products only if they are sufficiently satisfying and, among the principal elements that determine the level of satisfaction, is the supply of flavourings. In this regard, it is worth mentioning 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."*

The University of Memphis study also states that flavourings are fundamental in the process of quitting tobacco and how the ban on their sale has increased the number of smokers.

There are also studies that show the correlation between aromas other than that of tobacco and smoking cessation; in particular we refer to the study conducted by Prof. Farsalinos, according to which former smokers prefer e-cig with liquids flavored with sweet or fruit. In general, we would like to emphasize how the attractiveness of consumers to e-cigarettes also develops starting from flavours. Consequently, the attractiveness of flavours must not be considered a danger itself, but must be evaluated as a factor that allows adult smokers to switch from certainly harmful products such as traditional cigarettes to new products (such as e-cig), technologically advanced, controlled by health authorities and which according to many studies imply fewer risks to human health.

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.

Before going any further, however, and in order to be able to contribute constructively to the European institutional dialogue, ANAFE would like to make it clear that the offer of liquid inhalation products (with or without characteristic flavourings) is to be understood as aimed exclusively at an adult smoking public.

In fact, as defined by European legislation on the subject and also set out in the Declaration drawn up by the Association and promoted by LIAF (Italian Anti-Smoking League) and MOIGE (Italian Parents Movement), it is necessary to pursue the protection of minors and non-smokers, disincentivising them both from tobacco consumption and from the use of any other product with and without combustion. With this in mind, ANAFE is therefore committed to combating the sale of e-cigarettes and inhalation liquids, with and without nicotine, to minors, also by promoting through its retailers' awareness of the health risks for minors associated with their consumption.

This explanation is, in general, necessary when talking about new generation products and becomes even more valuable when referring specifically to flavourings, in view of the widespread misjudgement about their potential attractiveness to young people and non-smokers.

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"*.

Moreover, regarding 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"*.

4. Potential risks from the Dutch proposal

The RIVM (the Dutch National Institute for Public Health and the Environment), on which work the Dutch proposal 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, Esigbond, 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. The report found out 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.

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 actually 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. ANAFE strongly argues against it, and notes that its consequences are not proportional to the public health goals that the government intends to reach.

3. Conclusions

Therefore, in considering the statements made above, ANAFE believes the proposed flavour ban is not proportionate to the objective pursued, as the measure fails to be appropriate, or in any case a suitable mean to attain the objective with a reasonable connection between the aim and the measure.

Moreover, the ban will lead to a rise in black market activity and restrict (legal) free trade between Member States, moving European legislation away from the objective of harmonisation. Specifically, ANAFE believes that the ban on e-cigarette products with particular flavor profiles will consist in a violation of EU provision, being a quantitative restriction as defined by Article 34 of the TFEU (Treaty on the Functioning of the EU). This would create a difference in treatment and access to the market in different countries. 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;

In addition, the Tobacco and Smoking Products Act already fully regulates the market and prevents adolescents under 18 years old from buying such products. On this point, it is not clear why Eurobarometer data also take into account a sample aged between 15 and 24, as both in Italy and the other EU countries, only 18-year-olds are allowed to buy e-cigs.

In conclusion, ANAFE considers that the scientific basis on which the Dutch flavour ban is built does not take into account the full picture, but it 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 prove that vaping is significantly less harmful than smoking and indicate that a flavour ban is likely to discourage smokers from abandoning combustible tobacco, ANAFE does not consider the draft amendment to comply with the eligibility criteria to achieve the goal prosecuted by the government (public health protection).