

WE **W**ILLEM **A**LEXANDER,
BY THE GRACE OF GOD,
KING OF THE NETHERLANDS,
PRINCE OF ORANGE-NASSAU,
ETC. ETC. ETC.

Decree of the State Secretary for Health,
Welfare and Sport of regulating e-
cigarette flavors

On

On the recommendation of the State Secretary for Health, Welfare and Sport, of...,
reference;

Having regard to Article 2(1) and (2), and Article 3b(1) of the Tobacco and Tobacco
Products Act;

Having heard the Advisory Division of the Council of State of the Netherlands
(opinion of xxx, No xxx, Council of State);
In view of the further report of the State Secretary for Health, Welfare and Sport of
xxx, xxx);

Have approved and understood:

Article I

The Tobacco and Tobacco Products Decree shall be amended as follows:

A

Article 1.1 shall be amended as follows:

1. The following definition shall be inserted in alphabetical order: *Common entry gate*: a shared European portal for the provision of data and documents on tobacco products or related products;

B

Article 2.4 shall be amended as follows:

1. The marking '1' shall be placed in front of the text.

2. Four paragraphs shall be added, reading:

2. It is prohibited to use other flavoring additives as ingredients in liquids containing nicotine and nicotine-free liquids referred to in the first paragraph and in components of electronic vaping products other than those designated by ministerial regulation.

3. The additives designated pursuant to the second paragraph may be subject to a maximum number and a maximum quantity by ministerial regulation.
4. By ministerial regulation, research methods shall be appointed as exclusively decisive in determining whether the requirements laid down in the second paragraph have been met.
5. It is also prohibited to place on the market liquids containing nicotine and nicotinefree liquids and other components of electronic vaping products where unauthorised additives or additives that exceed the maximum quantity were specified on the packaging unit or outer packaging or in the package leaflet or in the CEGS.

Article II

This Decree shall enter into force on 1 January 2022.

We order and command that this Decree and the associated Explanatory Memorandum be published in the Government Gazette.

The State Secretary of Health, Welfare and Sports,

Paul Blokhuis

Explanatory Memorandum

I. General section

1. Rationale

In the National Prevention Agreement¹ (hereinafter: Prevention Agreement), measures have been agreed with civil society organisations to achieve a smoke-free generation by 2040. To achieve these objectives, it has been decided that by 2020 more children must grow up in a smoke-free and tobacco-free environment. According to the signatories of the Prevention Agreement, a smoke-free and tobacco-free environment also means that children will not come into contact with novel tobacco products and electronic cigarettes (hereinafter referred to as e-cigarettes), with and without nicotine. By using these products, children can become addicted to nicotine and, in addition, they will be exposed to harmful substances. There is also increasing scientific evidence that young people are more likely to start smoking tobacco as a result of using these products than young people who do not use them. For these reasons, it has been decided that there is no room for such products in a smoke-free generation and a number of measures have been included in the Prevention Agreement to discourage the use of e-cigarettes. For example, on 1 July 2020, the smoking ban was extended to include a ban on vaping e-cigarettes, with and without nicotine. In all places where a smoking ban is in effect, the restriction also applies to e-cigarettes. This includes cafes, restaurants and public buildings. In addition, as with tobacco products, a display ban will apply to e-cigarettes, requiring them to be hidden from view in supermarkets (from 1 July 2020) and other sales points (from 1 January 2021). Neutral packaging for electronic vaping products will also be introduced in 2022. New insights into the harmfulness, addictiveness and attractiveness of these products for young people have led the government to supplement these measures by further discouraging the use of e-cigarettes and reducing their attractiveness to young people in particular. The progress letter for the Prevention Agreement of 22 June 2020² therefore announced a ban on all flavors other than tobacco. With this Order in Council, the Tobacco and Tobacco Products Decree (hereinafter: the Decree) includes the option to no longer allow additives that create flavors other than tobacco flavor in liquids containing nicotine and nicotine-free liquids for, and other components of e-cigarettes.

2. Introduction

2.1 Attractiveness of e-cigarettes

Since their introduction to the Western markets in 2004, e-cigarettes have been gaining popularity in the United States and Europe. Currently, there is a wide variety of models and flavors available and the number of providers of e-cigarettes has increased significantly in recent years. In the Netherlands, e-cigarettes are for sale through the internet, in kiosks, specialist tobacco stores and e-cigarette stores. E-cigarettes are available in many shapes and sizes, both as a disposable product without nicotine for single use (nicotine-free e-cigarettes³) and in variants that may contain nicotinecontaining liquid (e-cigarettes⁴).

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¹ *Parliamentary Papers II* 2018/19, 32793, no. 339, p. 13 and see also: www.rijksoverheid.nl, search term: nationaal preventieakkoord (national prevention agreement).

² *Parliamentary Papers II* 2019/2020, 32793, no. 484.

³ Definition in Article 1 Tobacco and Tobacco Act: *nicotine-free electronic cigarettes*: a disposable product with a reservoir that contains a nicotine-free liquid and which can only be used for the consumption of nicotine-free vaping through a mouthpiece.

⁴ Definition in Article 1 Tobacco and Tobacco Products Act: *electronic cigarette*: a product which can be used for the consumption of nicotine-containing vapor through a mouthpiece, or a component of that product, including a cartridge, a reservoir and the device without cartridge or reservoir; ⁵ S. Troelstra, E. Croes, J. Bommelé, M. Willemsen, 'Factsheet elektronische sigaretten' [Electronic cigarettes factsheet], *Trimbos institute, division: National Expertise Centre for Tobacco Control*, April 2020.

The liquids for e-cigarettes are available both with and without nicotine. These liquids are sold separately in bottles to refill the e-cigarettes, but for some e-cigarettes specific refills are available that contain the liquid and that can be clicked into an e-cigarette like a kind of cartridge.

2.2 Harmfulness of e-cigarettes

In the summer of 2019, there was unrest surrounding the use of e-cigarettes, after e-cigarette users in the United States suffered serious lung problems and dozens of them died. The condition was named EVALI (electronic cigarette, or vaping, product use-associated lung injury). Research has shown that most EVALI patients used a liquid containing THC, the active ingredient of cannabis. There appears to be a strong relationship between EVALI and vitamin E acetate, an excipient found in some e-liquids containing THC.⁵ Although there are no known cases of EVALI in the Netherlands, a survey among Dutch lung physicians revealed a number of cases of people who developed serious lung problems after using e-cigarettes.⁵

In response to the concern about the harmfulness of e-cigarettes, at the request of the State Secretary of Health, Welfare and Sport, the Trimbos Institute's National Expertise Centre for Tobacco Control has re-assessed the current scientific knowledge on e-cigarettes. On the harmfulness of e-cigarettes, the Trimbos Institute has concluded that e-cigarettes do not contain many of the toxic combustion products of tobacco, but that harmful substances, such as nicotine and propylene glycol, as well as (traces of) toxic and carcinogenic substances, are released in the vapour of the e-cigarettes. Research conducted by the RIVM in 2015 shows that e-cigarettes are harmful to users.⁶ This research showed that inhalation can lead to irritation and damage to the respiratory tract, palpitations and a higher risk of cancer. The exact long-term harmfulness of using e-cigarettes is still unknown. The Trimbos Institute has concluded, based on the precautionary principle, that Dutch public health would benefit most from discouraging the use of e-cigarettes.⁷

E-cigarettes have been marketed by producers as a less harmful alternative to smoking regular tobacco cigarettes. It is not known exactly how much less harmful e-cigarettes are. According to the available scientific literature, e-cigarettes only seem to be less harmful than tobacco cigarettes if users completely switch to vaping. However, in the Netherlands, 72% of e-cigarette users had not switched completely by 2018. These were dual users who also used tobacco cigarettes in addition to e-cigarettes. This results in little or no health gain and there are even signs that dual use could be potentially more harmful than using only tobacco cigarettes or e-cigarettes.⁸

The Netherlands Association of Physicians for Pulmonary Diseases and Tuberculosis (hereinafter: NVALT) is concerned about the harmfulness of e-cigarettes and considers the product, along with ordinary cigarettes, to be a danger to public health. The doctors point to the addictive effect of e-cigarettes and to the fact that vaping cause inflammation of the respiratory mucosa and compromise the immune system. The NVALT is therefore of the opinion that the use of e-cigarettes among young people should be discouraged and thus reduced.⁹

2.3 E-cigarette use among young people

⁵ Ditto.

⁶ W.F. Visser et al., 'De gezondheidsrisico's van het gebruik van e-sigaretten' [The health risks associated with the use of e-cigarettes], *RIVM* 2015.

⁷ Ditto footnotes 4 and 5.

⁸ M.L. Goniewicz, D.M Smith, K.C Edwards et al., 'Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes.', *JAMA Network Open* 14 December 2018.

⁹ www.nvalt.nl, search terms: "belangrijke documenten" [key documents], "NVALT-standpunt" [NVALT position] and "e-sigaret" [e-cigarette]. See also: https://www.nvalt.nl/vereniging/belangrijke-documenten/_/E-sigaret/NVALT%20standpunt%20omtrent%20de%20e-sigaret.pdf.

In the Netherlands, e-cigarettes are mainly used by adults who smoke, have smoked and/or want to quit and young people. In 2018, 3.1 percent of Dutch adults had used e-cigarettes at least once and 4.3 percent of Dutch adults were former (occasional) e-cigarette users.¹⁰ Research conducted among young people in 2019 shows that a quarter of young people aged 12 to 16 have used an e-cigarette at least once. Although this percentage has fallen from 34% in 2015 to 25% in 2019, it remains a very worrying percentage. It is also striking that in 2019 more schoolchildren aged 12 to 16 have used e-cigarettes at least once (25%) than ordinary cigarettes (17%).¹¹ The government is concerned about the large number of young people who are using e-cigarettes, not only because of the harmfulness of the product, but also because research has shown that young people become addicted to nicotine faster than adults. Most e-cigarettes contain nicotine, and nicotine exposure during adolescence can be harmful to the developing brain, which continues to develop until about the age of 25. Exposure to nicotine during adolescence can affect learning, memory and attention and may increase the risk of future addiction to other drugs.¹²

In the United States, the use of e-cigarettes has increased enormously in recent years. Since 2014, e-cigarettes have been the most widely used tobacco product among young people. The popularity of e-cigarettes in the form of USB flash drives and other similar devices has probably contributed to the increase in use among young people; these devices can be used discreetly, they could have a high nicotine content and are available in flavors that appeal to young people.¹³ Between 2011 and 2018, the use of e-cigarettes among U.S. high school students increased from 1.5% to 20.8%.¹⁴ The Food and Drug Administration Commissioner and the US Surgeon General identified the use of e-cigarettes among US youth in 2018 as an epidemic.

The Surgeon General's Advisory called for aggressive steps to reduce the use of e-cigarettes among young people, including the decision to introduce a ban on sweet flavors in cartridges.¹⁵

In addition to the fact that young people may become addicted to nicotine and exposed to harmful substances through the use of e-cigarettes, young people who use e-cigarettes are more likely to smoke tobacco cigarettes and vice versa. It is difficult to determine whether young people started smoking because of e-cigarettes or whether common underlying factors increase the risk of vaping and smoking. However, recent insights increasingly suggest that e-cigarettes may be a stepping stone to tobacco smoking.¹⁶ Research has identified several factors that could cause this stepping stone:

¹⁰ S. Troelstra, E. Croes, J. Bommel , M. Willemsen, 'Factsheet elektronische sigaretten' [Electronic cigarettes factsheet], *Trimbos institute, division: National Expertise Centre for Tobacco Control*, April 2020.

¹¹ M. Rombouts, S. van Dorsselaer, T. Scheffers - van Schayck, et al, 'Jeugd en riskant gedrag 2019' [Youth and risky behaviour 2019]. Key data from the Peilstation research among school students', *Trimbos Institute* 2020.

¹² K.A. Cullen, A.S. Gentzke, M.D. Sawdey et al., 'e-Cigarette Use Among Youth in the United States, 2019', *JAMA* 3 December 2019, Volume 322, Number 21.

¹³ Ditto.

¹⁴ A.S. Gentzke, M. Creamer, K.A. Cullen et al., 'Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018', *Morbidity and Mortality Weekly Report* 15 February 2019, Volume 68, Number 6.

¹⁵ S. Caccamo, 'FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint', *U.S. Food & Drug Administration* 2 January 2020. See also: www.fda.gov, search terms: "press announcements", "enforcement policy unauthorised flavored cartridge-based e-cigarettes".

¹⁶ S. Troelstra, E. Croes, J. Bommel , M. Willemsen, 'Factsheet elektronische sigaretten' [Electronic cigarettes factsheet], *Trimbos institute, division: National Expertise Centre for Tobacco Control*, April 2020.

- E-cigarette use is associated with an increase in positive attitudes towards smoking, willingness to smoke and a decrease in the perception that smoking is bad for health.
- The hand-mouth movements, puffing, inhalation and exhalation show similarities in vaping and smoking. These habits make it easier to make the switch to tobacco cigarettes.
- Young people can develop a nicotine addiction through the use of ecigarettes that contain nicotine. The earlier young people are exposed to nicotine, the more likely they are to become addicted and the less likely they will be to quit the habit.¹⁷

It was therefore decided in the Prevention Agreement that a smoke-free and tobaccofree environment also means that children must not come into contact with novel types of tobacco products and e-cigarettes, with and without nicotine.¹⁸ The government wants to further discourage the use of e-cigarettes through new insights into the harmfulness of e-cigarettes and indications that it may be a stepping stone product.

3. Making e-cigarettes less attractive

3.1 Liquids for e-cigarettes and generating different flavors

In recent years, the number of flavors of liquids for e-cigarettes has increased enormously. RIVM has done extensive research into the liquids and the different flavors that are available. By 2017, almost 20,000 different liquids had been registered for the Dutch market and could be classified into 245 different flavors. RIVM has divided these flavors into categories. Examples of these categories are different candy flavors, different categories of fruit flavors, desserts, alcoholic beverages, coffee and tea, menthol/mint and tobacco.²⁰

In the desserts category, flavors¹⁹ such as apple pie, cheese cake and milkshake are available for sale on the market. Candy flavors include, for example, bubble gum, wine gum, marshmallows and sour mats. There are also liquids for sale on the Dutch market with a taste derived from an alcoholic beverage. These include drinks such as piña colada or mojito, but rum and whiskey flavors are also available for e-cigarette liquids. The RIVM researchers concluded on the basis of their analysis in 2017 that more than half of the liquids studied could be labelled as sweet and only 16% of the liquids could be classified as a tobacco flavor.²⁰

To create a flavor, several flavorings are added as an additive to e-cigarette liquids. The RIVM concluded this from a chemical-analytical examination of flavorings in certain liquids²¹, as well as from an analysis of the data entered into the EU-Common Entry Gate system (hereinafter: EU-CEG). This shows that on average ten flavorings are added per liquid to create a certain flavor.²² The EU-CEG is the European registration system in which producers must provide information about their products and when they want to market their product in a European member state. This information

¹⁷ S. Soneji, J.L. Barrington-Trimis, T.A. Wills, A.M. Leventhal, J.B. Unger, L.A. Gibson, et al., 'Association between initial use of e-cigarettes and subsequent cigarette smoking among adolescents and young adults: a systematic review and meta-analysis', *JAMA Paediatrics* 2017, Volume 171 p. 788–97.

¹⁸ *Parliamentary Papers II* 2018/19, 32793, no. 339, p. 13 and see also: www.rijksoverheid.nl, search term: nationaal preventieakkoord (national prevention agreement).

¹⁹ A. Havermans, E.J.Z. Krüseemann, J. Pennings, et al. '20 000 e-liquids and 250 unique flavor descriptions: an overview of the Dutch market based on information from manufacturers', *Tobacco Control* 2019.

²⁰ Ditto.

²¹ E.J.Z. Krüseemann, J.A. Pennings, J.W.J.M. Cremers, F. Bakker, S. Boesveldt, R. Talhout 'GC-MS analysis of e-cigarette refill solutions: A comparison of flavoring composition between flavor categories' *J. Pharm Biomed Anal.* June 2020.

²² E.J.Z. Krüseemann, A. Havermans, J.A. Pennings, K. de Graaf, S. Boesveldt, R. Talhout 'Comprehensive overview of common e-liquid ingredients and how they can be used to predict an e-liquid's flavor category', *Tobacco Control* February 2020.

includes the ingredients and therefore also the flavorings in the liquids. It is not yet well known whether most flavorings are safe to inhale. The flavorings added to the liquids are substances that are also widely used in food, e.g. the flavoring agent diacetyl, which gives a buttery taste. Diacetyl has been used in food for a long time, but it has been shown that inhalation of larger quantities can cause serious lung disease (*bronchiolitis obliterans*).²³

3.2 Attractiveness of flavors

In 2018, RIVM carried out research into the attractiveness of e-cigarettes. This research showed that the wide range of flavors for liquids that can be vaped in e-cigarettes makes the use of e-cigarettes particularly attractive. The sweet and fruity flavors, which account for a large share of the market, are particularly popular among young people.²⁴ A major research of young American e-cigarette users found that 98% of young people, 95% of students and 71% of young adults did not use a tobacco flavor when using an e-cigarette for the first time. Fruit and candy flavors were particularly popular.²⁵ In addition to providing flavor, flavorings can mask the bitter taste of nicotine, making the e-liquid more attractive.

People also mistakenly believe that sweet flavors such as candy and fruit would be less harmful.²⁶ Based on the scientific research on e-cigarettes, the Trimbos Institute concluded that regulating flavored e-cigarettes could reduce the attractiveness of e-cigarettes.

4. Broad outline of the proposal

4.1 Ban on attractive flavors

Directive 2014/40/EU²⁷ (hereinafter: Tobacco Products Directive) prohibits the marketing of cigarettes and fine-cut tobacco with characteristic flavorings (in short, a distinct aroma or taste other than that of tobacco²⁸). As a result of this European ban on characteristic flavorings in fine-cut tobacco and cigarettes, menthol-flavored cigarettes, for example, will no longer be permitted in the Netherlands as of 20 May 2020.²⁹ When the Tobacco Products Directive was drawn up, Member States were given scope to regulate flavors for liquids from e-cigarettes nationally. This is set out in more detail in Chapter 5 of this Explanatory Memorandum. Although the government envisages a ban on characteristic flavorings for liquids containing nicotine and nicotine-free liquids, for reasons of implementation technology it has not been decided to follow the definition of characteristic flavorings as intended for tobacco cigarettes. If a ban on characteristic flavorings were to be introduced, monitoring of the ban on each liquid would have to determine whether the liquid has a tobacco flavor or not. Observing and describing flavors and aromas can only be done by people. The same aroma or taste can differ in intensity for different people, and can be described in different ways. For this reason, it must be done by a group of people trained to assess the intensity of flavors and

²³ RIVM, 'Flavorings in tobacco and related products', June 2018.

²⁴ RIVM, 'E-cigarette attractiveness for smokers and non-smokers', March 2018.

²⁵ M.B. Harrell, S.R. Weaver, A. Loukas, et al. 'Flavored e-cigarette use: Characterizing youth, young adult, and adult users', *Elsevier - Preventive Medicine Reports* 5 March 2017, Volume 5, p. 33-40.

²⁶ K.A.G.J. Romijnders, L. van Osch, H. de Vries, R. Talhout, 'Perceptions and reasons regarding e-cigarette use among users and non-users: A narrative literature review', *International Journal of Environmental Research and Public Health* 1 June 2018, volume 15, number 6.

²⁷ 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 relating to the production, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJEU 2014, L 127), Article 7(1).

²⁸ Definition Article 1 of the Tobacco and Tobacco Products Regulations: *distinctive aroma*: a clearly perceptible aroma or taste other than that of tobacco that is the result of an additive or combination of additives, including, but not limited to, fruit, spices, seasoning, alcohol, candy, menthol, or vanilla, which can be perceived before or during consumption of tobacco products;

²⁹ See Articles 2.5 and 7.3(2) of the Tobacco and Tobacco Products Regulations, read in conjunction with Article 7 of the Tobacco Products Directive.

aromas, also known as a 'sensory expert panel'.³⁰ Using and retaining a sensory expert panel is costly and very labour-intensive. Furthermore, it is not clear to industry whether their product should or should not be on the market when an enforcement panel determines whether the ban is complied with. In the government's view, therefore, it is not desirable to always have to use such a panel when monitoring the ban. That is why we have opted for the alternative outlined below.

4.2 Restrictive list of designated additives

In order to allow the regulation of non-tobacco flavors in e-cigarette liquids, only additives that are relatively more common in tobacco-flavored liquids than in attractive, sweet flavors are allowed.

In this way, the government very likely expects that it will no longer be allowed to market the sweet, attractive flavors. A ministerial regulation will establish a restrictive list of flavoring additives permitted as ingredients in liquids and other components of e-cigarettes.

By allowing only certain flavoring additives as ingredients, compliance can already be monitored on the basis of the declared ingredients. Furthermore, in case of doubt as to whether the product complies with the regulations, it can be determined on the basis of chemical analysis whether unauthorised additives are present in the liquids. By also prohibiting the use of flavoring additives which are not authorised as ingredients for other components of electronic vaping products, the addition of unauthorised flavoring additives through, for example, cartridges, a loose mouthpiece or other components of the e-cigarette will be prevented. Such detailed regulations are unambiguous for the producer. After all, on the basis of the list of authorised flavoring additives, it is immediately clear which products may and which may not be marketed in the Netherlands, whereas with a sensory panel it is only really clear on the basis of a statement by such a panel as to whether or not something is classified as tobacco flavor.

In order to compile the list, it will be examined which flavoring additives were present in liquids registered for the Dutch market on 1 June 2020, the moment prior to the proclamation of the ban on flavors other than tobacco flavor. This will be done on the basis of data provided by producers themselves in the EU CEG. RIVM will be requested to draw up a list of all flavorings that are relatively more common in tobacco flavors than in other flavors. This list will be used to determine which additives will still be allowed to create tobacco flavoring. It will also be considered how other countries have regulated the number of flavors available for the liquids of e-cigarettes. On the basis of the above-mentioned sources, it will also be assessed whether the setting of a maximum number of additives and maximum limits of the additives (or some of the additives) is necessary to prevent the additives designated by ministerial regulation from creating a taste other than tobacco flavor. A ministerial regulation will explain how this will be monitored.

The list of permitted additives covers all liquids and components of e-cigarettes intended for use in e-cigarettes and which determine their taste. This includes liquids for refills or pre-filled cartridges, as well as pre-filled e-cigarettes, and single-use e-cigarettes. The list does not cover preservatives, acids or other additives added to ingredients of electronic vaping products which do not have a flavoring motive but do have a flavoring effect. The ban will therefore not cover such additives. The government is aware that such additives may have a flavoring effect, but sees no need at present to regulate these ingredients as well. Due to the technical and detailed nature of these regulations for liquids and other components of e-cigarettes, the government will monitor whether and to what extent the restrictive list drawn up by ministerial regulation, as well as the investigation methods, are sufficient once the regulations enter into force.

4.4 No more mention of flavorings on the packaging

³⁰ RIVM (2018), 'Flavorings in tobacco and related products'. See: www.rivm.nl/www, search terms: factsheet smaakstoffen tabaks- en aanverwante producten [tobacco and related products flavors factsheet].

Not only has the enormous increase in the available supply of liquids in recent years been a matter of concern for the government, but also the marketing of these liquids.

The liquids are not only marketed under the name of the flavor, but special names are also given to the flavors or brand variants of the liquids which may be particularly attractive to young people. Examples include the addition of the word 'unicorn', such as 'unicorn milk' or 'unicorn strawberry', but also terms such as 'bad boy fuel', 'chillin', 'happy' or 'party' are part of the name of the e-liquid's taste. Word jokes are also made in the name of taste that are consistent with the language used on social media, such as 'OMgin' for a liquid that tastes like gin and 'have anise day' for a liquid with an anise flavor. This is often accompanied by eye-catching packaging with lots of colour and different symbols.

The Prevention Agreement stipulates that neutral packaging for electronic vaping products will be introduced in 2022. In addition to this, with this order in council the government is restricting the flavors of liquids for e-cigarettes in order to make the products less attractive to young people. This will also greatly reduce the possibility of using the name of the flavor as a marketing tool, thereby reducing the attractiveness of the product. After all, the listing of flavorings on packaging for liquids without them actually being contained in the liquid suggests that these flavorings are contained in the liquids for e-cigarettes. This constitutes a misleading commercial practice within the meaning of the Unfair Commercial Practices Act³¹. More specifically, it concerns Article 6:193c of the Dutch Civil Code. The consumer is encouraged to purchase the liquid in question because it is distinguished from other liquids by its ingredient listing and composition. As a result, consumers are not given fair, but misleading information.

A commercial practice is misleading if it provides factually incorrect or misleading information which, although factually correct, may or may not be 'misleading' to the consumer because of its overall presentation.³² EU Court of Justice³³ (hereinafter: ECJ EU) jurisprudence has clarified that a commercial practice is to be regarded as misleading "where (a) it involves false information or is likely to deceive the average consumer and (b) it is of such a nature that it could lead the consumer to make a transactional decision that he/she would not have taken otherwise". Elements a and b apply cumulatively.³⁴ Article 6:193c(1) of the Dutch Civil Code provides in subparagraphs a to g a number of elements which make a commercial practice misleading, if the information in this respect is incorrect or misleading. One of these elements concerns the main characteristics of the product, such as its availability, benefits, risks, design composition, accessories, possibilities of use, quantity, geographical or commercial origin (subparagraph b). The geographical or commercial origin of a product or composition may include the situation where furniture that does not contain leather is labelled as 'textile leather'.³⁵

In fact, under food law³⁶, the ECJ ruled³⁷ in 2015 that if the list of ingredients is correct and complete, the public can still be misled by the rest of the packaging. The Court thereby gave a general rule on misleading: "*in a situation where the labelling of a food and the manner in which it has been applied, taken as a whole, give the impression that it contains an ingredient which it does not in fact contain, such labelling may therefore*

³¹ Law adapting Books 3 and 6 of the Dutch Civil Code and other laws to the Directive on unfair business-to-consumer commercial practices in the internal market, Bulletin of Acts and Decrees 2008, 391.

³² *Parliamentary Papers II* 2006/2007, 30928, no. 3, p. 15.

³³ ECJ EU 19 December 2013, C-281/12.

³⁴ See also B.B. Duivenvoorde, 'Note under Court of Justice 19 December 2013, C.281/12 (Trento Sviluppo)', *TvC*2014/4, p. 192-196.

³⁵ Guideline (SWD(2016)163), Paragraph 3.3.1.

³⁶ Tobacco is explicitly excluded from the definition of food in Article 2 of Regulation 178/2002.

³⁷ ECJ EU:4 June 2015, ECLI:EU:D:2015:361, Recitals: 36, 40, 41, 43.

mislead the purchaser with regard to the characteristics of that food." The Court held in that case that account must be taken of: words and images, their position, size and font, colour, language, syntax and punctuation of the various elements on the packaging.

In other words, the listing of flavorings on packaging for liquids for e-cigarettes, even if they are not actually contained in the liquid, means that consumers are not being informed fairly or are being misled. Article 20(4)(b)(ii) of the Tobacco Products Directive does not change this. On the basis of this article, e-cigarette packaging may contain information on nicotine content and aromatic and flavoring substances. However, this article should not be interpreted as meaning that the prohibition on misleading consumers contained in consumer law no longer applies. If an ingredient appears in the name of the product or is usually associated with that name by the consumer (as in the case of 'unicorn strawberry') and/or is emphasised or depicted prominently on the labelling in words, pictures or graphics, it is also misleading if this product does not subsequently constitute an ingredient of the liquid. This form of deception is not permitted and justifies, *inter alia*, a right to compensation, termination of the sales contract and the right to a refund. The Consumer & Market Authority (ACM) monitors compliance with the Unfair Commercial Practices Act. The government therefore assumes that once this Decree comes into force, packaging of liquids and other components of e-cigarettes will not contain any information that is misleading to consumers.

Enforcement is expected to be more efficient and effective and it is expected to improve clarity by also banning products where the unauthorised flavoring additives are declared on the packaging or where the unauthorised flavoring additives are declared in the EUCEG. Pursuant to Article 4.6(1) of the Decree and Article 4.6(1), (2) and (4) of the regulation, electronic vaping products may only be placed on the market if e-cigarettes and refill packs with and without nicotine, refill packs without nicotine and cartridges without nicotine have been delivered to the EU CEG, including, *inter alia*, a list of all ingredients contained in the product.³⁸ By also not allowing unauthorised additives to be declared in the EU CEG, enforcement possibilities are created even before e-cigarettes are placed on the market to prevent unauthorised additives from being placed on the market. By also prohibiting such additives from being listed on the packaging, a monitoring system will be put in place which will make it possible to prevent unauthorised additives from remaining on the market.

The draft Decree therefore includes, in Article 2.4(5), the prohibition of mentioning on the packaging unit, outer packaging or in the package leaflet of liquids containing nicotine and nicotine-free liquids, and other components of electronic vaping products, additives that have not been designated in the restrictive list that is yet to be drawn up. These additives may also not be declared in the EU CEC on the basis of this fifth paragraph.

4.5 E-cigarettes as an aid to stop smoking.

E-cigarettes can be an aid to stop smoking tobacco for a small group of smokers. If a smoker wants to live a healthier life, the advice is to stop smoking altogether and to use a proven effective method. The Multidisciplinary Directive on Tobacco Addiction and Support to Quit Smoking in the healthcare sector³⁹ states that the most effective way to stop smoking is through the use of stop-smoking coaching in combination with the use of nicotine substitutes. Based on the Directive, the use of e-cigarettes is not a first choice, but should not be discouraged. However, the intention is for people to reduce nicotine levels and therefore also to stop using e-cigarettes in the short term. The Trimbos Institute has concluded, on the basis of the scientific research on harmfulness, that the use of e-cigarettes should be restricted to the group of smokers who really

³⁸ See Article 4.6(1) and (2), read in conjunction with Article 20 of the Tobacco Products Directive.

³⁹ National Expertise Centre for Tobacco Control, 'Treatment of Tobacco Addiction and Support to Quit Smoking', *Trimbos Institute* revision 2016.

cannot quit smoking with the proven effective aids.⁴⁰ Therefore, the government has opted to regulate the attractive flavors and not to impose a total ban on e-cigarettes in order to keep e-cigarettes available to those people.

5. Change in an international context

5.1 Worldwide

There are several countries that, like the Netherlands, want to discourage the attractiveness of e-cigarettes by banning flavors in liquids for e-cigarettes. Within Europe, Hungary and Finland have issued similar bans and a number of other European member states are in the process of doing so. Denmark has regulations in preparation. The federal government in the United States has also decided to ban sweet flavorings in liquids in cartridges. A ban on flavored liquids has already been imposed in San Francisco in the United States. There are also a few countries around the world that have banned e-cigarettes altogether. This includes countries that have not yet allowed it, but also countries, such as India, that initially allowed the product, but later banned it because of concerns about its harmfulness.

5.2 Relationship to higher duty

In the view of the government, regulation of flavors for liquids for and other parts of the e-cigarette is in line with, inter alia, the Tobacco Products Directive, rulings of the European Court of Justice (hereinafter: Court of Justice), the Treaty on the Functioning of the European Union (hereinafter: TFEU) and the European Convention on Human Rights (hereinafter: ECHR).

5.3 Tobacco Products Directive and free movement of goods

5.3.1 Harmonisation level

The Tobacco Products Directive aims to approximate the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products or related products. This is in order to improve the functioning of the Internal Market for tobacco products or related products. This is based on a high level of public health protection, especially for young people⁴¹ The Tobacco Products Directive does not provide for total harmonisation, allowing Member States to set their own rules on a number of issues.⁴³

Recitals 47 and 48, read in conjunction with Recital 55 of the Tobacco Products Directive, indicates that Member States should be free to maintain or introduce, as a general rule, rules applicable to *all* products marketed in that Member State. These recitals indicate that the Tobacco Products Directive does not harmonise all aspects of these products in respect of, inter alia, e-cigarettes and refill packs. The responsibility for establishing rules on these products, such as rules on flavors, remains with the Member States. With regards the authorisation of specific flavors for e-cigarettes, Member States are made aware of their potential appeal to young people and non-smokers. Member States may lay down further rules on the attractiveness of such products. The Netherlands is therefore free, within its own jurisdiction, to prohibit liquids and other components of e-cigarettes from containing certain flavors. The Tobacco Products Directive even encourages this.⁴² For example, some Member States (Hungary and Finland) have already made use of this option and Denmark is preparing legislation. This order in council is therefore consistent with the Tobacco Products Directive, provided that it is compatible with the Treaty on the Functioning of the European Union (hereinafter: TFEU) and does not jeopardise the full application of the

⁴⁰ S. Troelstra, E. Croes, J. Bommel , M. Willemsen, 'Factsheet electronic cigarettes', *Trimbos Institute, part: National Expertise Centre for Tobacco Control*, April 2020.

⁴¹ See, inter alia, Recitals 8 and 21 of the Tobacco Products Directive ⁴³ See the scope of application of the Tobacco Products Directive in Article 1.

⁴² See Recitals 47 and 48 of the Tobacco Products Directive.

Tobacco Products Directive.⁴³ The latter means that this proposal must not, in any event, promote tobacco consumption or give rise to a tobacco product or a product resembling a tobacco product. This is not the case with the regulation of flavors for e-cigarettes. In view of the TFEU, the free movement of goods is of particular importance, and Article 24 of the Tobacco Products Directive is also relevant for this purpose.

5.3.2 Article 24(3) of the Tobacco Products Directive

Article 24(3) of the Tobacco Products Directive allows Member States to ban a particular category of tobacco or related products on grounds relating to the specific situation in that Member State, provided that:

- 1) this is justified by the need to protect public health, taking into account the high level of protection of human health established by this Directive, and
- 2) it has been assessed whether or not those rules are justified, necessary and proportionate to their aim and whether or not they constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

Taking into account principles such as proportionality and the importance of protecting public health, Member States have the option to impose requirements on the additives of the liquids and other components used for e-cigarettes. In this context, the Netherlands has opted to ban certain additives. As a result, e-cigarettes are not banned in their entirety, as is the case in other Member States. However, individually attractive and distinctive flavors are banned. Certain liquids containing nicotine and nicotine-free liquids are therefore no longer permitted. An important reason for making these far-reaching demands is to protect the health of young people.

5.3.3 Justification on the grounds of public health protection

Because of the harmful effects of inhaling chemicals in e-cigarette liquids and the addictive effect of nicotine-containing e-cigarettes (see Chapter 2 of this Explanatory Memorandum), reducing the attractiveness of e-cigarettes may result in health benefits. As already highlighted in Chapter 2, the wide choice of flavors that can be used for e-cigarettes, as well as the many different designs and distinctive taste names that have emerged on the market, make the use of e-cigarettes particularly attractive.⁴⁴ In addition, the highly addictive nature of nicotine carries the risk that e-cigarette users, including many young people, will switch to traditional cigarettes. Some health experts are already calling e-cigarettes a stepping stone product that opens the door to smoking.⁴⁷ For these reasons, regulating flavorings for e-cigarettes is justified by the need to protect public health.

Article 24(3) of the Tobacco Products Directive is a *lex specialis* of the free movement of goods within the meaning of Article 34 of the TFEU. Article 34 of the TFEU - like Article 24 of the Tobacco Products Directive - also lays down the condition that (1) the regulation of available flavors for e-cigarettes must be justified on grounds of the protection of health and life of humans, and (2) the measure must be proportionate and must not constitute discrimination or a disguised restriction on trade between Member States. Therefore, for the sake of completeness, Article 34 of the TFEU is also discussed.

⁴³ See Recital 55 of the Tobacco Products Directive.

⁴⁴ K.A. Romijnders, E.J.Z. Krüsemann, S. Boesveldt, K. de Graaf, H. de Vries, R. Talhout 'E-liquid flavor preferences and individual factors related to vaping: A survey among Dutch never-users, smokers, dual users, and exclusive vapers', *International journal of environmental research and public health* 2019. ⁴⁷ Ditto footnote 17.

5.4. Article 34 of the TFEU: free movement of goods

The ban on flavors for e-cigarettes could be considered a quantitative restriction on imports or a measure that has an equivalent effect within the meaning of Article 34 of the TFEU. However, Article 36 of the TFEU allows Member States to introduce such a restriction if a number of conditions⁴⁵ are met. The measure must:

1. respond to overriding reasons relating to the public interest;
2. be suitable for securing the attainment of the objective pursued;
3. not go any further than necessary;
4. be known and predictable, and 5. be applied without discrimination.

In the government's view, regulating the number of flavors available for e-cigarettes, if at all, is justified by an overriding reason of public interest. Namely: the protection of public health, as already addressed in §5.3.3. Article 36 of the TFEU explicitly refers to the protection of health as a possible justification. ECJ jurisprudence shows that Member States have wide policy freedom in the field of public health and in determining the level of protection.⁴⁶ Member States may set their own level of protection. The Dutch government strives for a high level of protection and aims to achieve a smoke-free generation by 2040 in which young people also do not encounter e-cigarettes. The present proposal to regulate the number of flavors available for e-cigarettes is an appropriate means of ensuring that this objective is achieved, as regulating the number of flavors available for e-cigarettes means that only those cigarettes that generate a tobacco flavor can still be marketed. Tobacco taste is also generally perceived as less attractive by e-cigarette users. The many sweet and fruity flavors, as mentioned in §2.3 and §3.2 of this Explanatory Memorandum, which make the use of e-cigarettes attractive will no longer be possible. Therefore, the government sees regulating the number of flavors available for e-cigarettes as an appropriate means to reduce the attractiveness of e-cigarettes. This is mainly due to the explicit choice (see Chapter 4 of this Explanatory Memorandum) not to ban flavors other than tobacco flavor, because otherwise, when monitoring the ban on each liquid, a sensory expert panel must determine whether the liquid has a tobacco flavor or not. In addition, enforcement on the basis of a ruling by such a panel does not provide clarity for the business community. Compliance with the regulations can already be monitored on the basis of the ingredients declared, by allowing only certain flavoring additives as ingredients and prohibiting other flavoring additives from appearing on the packaging or from being notified to the EU CEG. This detailed regulation is unambiguous for both the producer and for enforcement purposes, and is therefore considered by the government as an appropriate means.

The Government also considers the measure to be proportionate, since the restrictive list still to be drawn up by ministerial regulation concerns only authorised flavoring additives. The list will not be used to prescribe all the ingredients of liquids and other components of e-cigarettes. The measure therefore does not go beyond what is necessary, even if the packaging of e-cigarettes complies with the current requirements that will still be introduced.⁵⁰ Neutral packaging does not in itself affect the wide range of sweet and fruity flavors. The ministerial regulation will henceforth include a clearance arrangement with a reasonable term in order to be able to sell existing stocks.

The requirement of recognisability and predictability is also met with this proposal to amend the Tobacco and Tobacco Products Decree and the subsequent amendment of the Tobacco and Tobacco Products Regulations. After all, both changes will be offered for internet consultation and will be published in good time. In addition, the ministerial regulation, which specifically prescribes which additives are still permitted in liquids

⁴⁵ ECJ 30 November 1995, No C-55/94, ECLI:EU:C:1995:411 (*Gebhard*); ECJ 4 July 2000, No C424/97, ECLI:EU:C:2000:357, (*Haim*); ECJ 1 February 2001, No C-108/96, ECLI:EU:C:2001:67 (*Mac Quen et al*).

⁴⁶ ECJ 13 July 2004, C-262/02, ECLI:EU:C:2004:432 (*Commission t. France*), Recital: 33. ⁵⁰ *Parliamentary Papers II* 2018/19, 32793, no. 339, p. 13 and see also: www.rijksoverheid.nl, search term: nationaal preventieakkoord (national prevention agreement).

and other components of e-cigarettes, will include a transitional clearance arrangement.

Finally, the further packaging requirements will apply to all e-cigarettes that are or will be marketed in the Netherlands, thereby ensuring that the measure is applied without discrimination. On the basis of the above, the Government considers this measure to be in accordance with Article 24(3) of the Tobacco Products Directive in particular, and the European rules relating to the free movement of goods in general.

5.4 Property right

By prohibiting the addition of certain additives to liquids and other components of e-cigarettes that generate an attractive and distinctive taste, certain types of liquids - being related products - now made available on the market will be banned. These far-reaching requirements serve to protect public health. This degree of protection should be weighed against the right to property.

Article 1, First Protocol to the European Convention on Human Rights (hereinafter: ECHR) lays down the principle of undisturbed enjoyment of property, protection against deprivation of property and the possibility of regulating property. This article prescribes that interference by the public authorities and thus restricting the right of ownership is only justified if (1) this is provided for by law, (2) it is in the public interest and (3) it is proportionate. According to established case law, property right is not an absolute right either.⁵¹ The right of ownership must be considered in relation to its social function.⁵² The use of property rights may be restricted, provided that the restrictions imposed genuinely meet the general interest objectives pursued by the European Union and, having regard to the objective pursued, are not to be regarded as a disproportionate and unacceptable interference affecting the very essence of the guaranteed right.⁵³

Applying these criteria to the present proposal results first of all in the finding that the requirement that the measure must be provided for by law is met by the present proposal. This means that the law is precise, predictable and accessible. This amending act creates in Article 2.4 of the Decree a basis for regulating the ingredients of liquids for and other components of e-cigarettes. The list to be drawn up by ministerial regulation will be exhaustive in nature and will determine which additives are still permitted. It is immediately clear which products may and which may not be marketed in the Netherlands on the basis of this list of authorised flavoring additives. The proposal will be consulted through the Internet. In addition, should the proposal become part of the Tobacco and Tobacco Products Decree, it will be published in the Bulletin of Acts and Decrees in good time, including a transitional provision with a clearance arrangement, so that people can prepare for it and the new rules are foreseeable and accessible.

⁵¹ See, inter alia, the judgment of the ECJ of:

- 30 January 2019, *Planta Tabak*, C-220/17, EU:C:2019:76, point 94;
- 15 January 2013, *Križan et al*, C-416/10, EU:C:2013:8, point 113;
- 9 March 2010, *ERG et al*, C-379/08 and C-380/08, *Jurispr.* page I-2007, point 80;
- 12 May 2005, *Regione autonoma Friuli-Venezia Giulia*, C-347/03, EU:C:2005:285, points 119-122, and
- 13 December 1994, *SMW Winzersekt*, C-306/93, point 22.

⁵² Ditto.

⁵³ Ditto.

The amendments to the Tobacco and Tobacco Products Regulations required for this purpose will also be consulted through the Internet and published in the Government Gazette at the same time as this Amendment Decree.

As mentioned in §5.3.3, the regulation of flavors for e-cigarettes is also important for the protection of public health. Reducing the attractiveness of e-cigarettes - in which flavors play a large part - can bring health gains. Restricting the available flavors experienced in the consumption of e-cigarettes and the resulting restriction on the right of ownership

therefore serves a legitimate purpose and is in line with the public interest. Especially if this measure is seen in conjunction with the other measures of the Prevention Agreement.

Moreover, according to the settled case law of the ECJ, the threshold of deprivation of property is only exceeded if the owner is permanently excluded by the actual or indirect effects of a measure from any relevant or useful means of exercising and disposing of his property.⁴⁷ Since it does not prohibit the sale or use of fluids for e-cigarettes and e-cigarettes themselves, nor does it regulate all possible ingredients, but rather regulates the ingredients that can be added to such products as flavoring additives, the Government believes that the proposed amendment is proportionate and meets the requirements of subsidiarity. The ministerial regulation will also include a clearance arrangement with a reasonable term in order to be able to sell existing stocks. Because the many flavors available for e-cigarettes are a large part of marketing, these regulations make the presentation of the product subject to requirements. This limits the ability of producers to promote such harmful products and it protects public health. Given the importance of the flavors in the attractiveness of the product as mentioned above (especially among young people), the government sees no other option but to reduce the attractiveness, even if that results in further requirements on the packaging of e-cigarettes.⁴⁸ Furthermore, failure to regulate the many distinctive and attractive flavors available for e-cigarettes would undermine the overall tobacco control policy. After all, there is no point in continuing to give room within tobacco control policy to products which in themselves can cause nicotine addiction and open the door to smoking.

5.5 Freedom of expression

The proposed rules are also assessed in the light of Article 10 of the ECHR, which enshrines the right to freedom of expression. The regulation of flavors for e-cigarettes may violate freedom of expression; after all, it restricts the free choice about the ingredient use of these products and the way in which they are consumed, but also the choice to include markings in the form of taste names and taste indications on packaging (see also §4.4). It is clear from Article 10 of the ECHR that conditions and restrictions may be imposed on freedom of expression, subject to a number of conditions.

A condition is that the measure must be provided for by law. Compliance with this requirement has already been addressed in §5.4.

Furthermore, the regulation of flavors for e-cigarettes, as already justified in chapter 2, is in the interest of public health, which is referred to in Article 10(2) of the ECHR. As highlighted in Chapter 2 and §5.3.3, e-cigarettes contain many toxic substances and research by the RIVM, inter alia, has concluded that e-cigarettes are harmful to users. Since nicotine can also be released in the vapour of e-cigarettes, consuming e-cigarettes with nicotine also has a highly addictive effect. The government is also concerned about the large number of young people that use e-cigarettes. By regulating flavors for e-cigarettes, the attractiveness of e-cigarettes is reduced and the ability to differentiate the product from other tobacco and related products is reduced. This also reduces the possibility of advertising these products. Use is discouraged and awareness of the harmfulness is increased. This will improve health.

Therefore, the requirements imposed on the ingredients for liquids containing nicotine and nicotine-free liquid and other components of e-cigarettes under this amending act are not disproportionate in the light of the protection of public health. In view of the overriding importance of the protection of public health, these measures fall within the discretion of national states. The measures are also necessary in a democratic society, because the legitimate objective of achieving a smoke-free generation by 2040 where no young person starts smoking, the prevention of second-hand smoke in general, and for those who already smoke, is more likely to succeed if the attractiveness of e-

⁴⁷ Ditto.

⁴⁸ *Parliamentary Papers II* 2018/19, 32793, no. 339, p. 13 and see also: www.rijksoverheid.nl, search term: nationaal preventieakkoord (national prevention agreement).

cigarettes is reduced. The government therefore considers this interference with the freedom of expression to be justified and in accordance with Article 10 ECHR.

5.6 Technical notification

As is known, the requirements for the ingredients of liquids for e-cigarettes are – not included in this Decree, but are included in a ministerial regulation. A draft of this regulation will be notified to the European Commission in compliance with Article 5(1) of Directive (EU) 2015/1535. The development of the technical notification will be dealt with in the Explanatory Memorandum to the regulation.

6. Consequences for implementation and enforcement

6.1 Business effects

Regulating flavors for liquids for e-cigarettes means that sellers can offer a more limited range of liquids for sale. For producers for the Dutch market it means that they will only be able to place a limited number of products on the Dutch market, or that they will have to adapt their products on the basis of the restrictive list. The associated business effects for producers, importers and retailers will be included in the ministerial regulation detailing the regulation of additives for liquids for e-cigarettes. It is expected that the regulation of flavors will discourage the use of e-cigarettes. This will logically lead to negative effects for companies that are active in this sector. However, the Government considers that this is justified in the context of public health, particularly that of young people. The ministerial regulation will include a clearance arrangement with a reasonable term in order to be able to sell existing stocks.

6.2 Implementation and enforcement

The supervision of these regulations and their enforcement will be carried out by the NVWA. The Amendment Decree has therefore been submitted to the NVWA for an assessment of the enforceability, feasibility and resistance to fraud (HUF test) of the draft Decree.

The NVWA has concluded that the proposed amendment is enforceable and practicable, taking into account the recommendations made.

6.3 Defining flavoring additives

The purpose of the proposed regulation of flavoring additives is to prevent flavors (other than tobacco flavors) in liquids for e-cigarettes and its components. In the absence of a more precise definition of what flavoring additives are, enforcement may give rise to uncertainty as to whether certain additives can be considered as such. In particular, these are additives which, according to the producer or importer, are added as preservatives, for example, but which also determine the taste. The NVWA has indicated that enforcement would serve to include - a definition of what a flavoring additive is or to clarify this explicitly in the Explanatory Memorandum. The NVWA thereby suggested that the prohibition concerns both flavoring additives and additives that are added to the liquid for another reason, but which (also) have flavor determining effects in the liquid itself. It should also be clarified whether acids (to influence pH) are seen as a flavoring additive. The Explanatory Memorandum is supplemented in response to this observation (see §4.2). Additives such as preservatives and acids that also have a flavor are not classified as prohibited. For the present, the government is refraining from defining flavoring additives. Every ingredient, including preservatives and acids, will have a taste or neutralising effect in a certain sense, which will also have an effect on the taste. For reasons of clarity and proportionality, the Government does not wish to add such substances to the restrictive list to be drawn up by ministerial regulation. The list still to be drawn up is exhaustive in nature: all flavoring additives that are not on the list are prohibited. There will always be borderline cases - substances that are included and that generate a flavor - but which are not included for the purpose of generating a flavor. Such substances are not banned. Because the majority of flavoring additives are easily traceable and the clarity of the list is guaranteed if it is not extended to all possible additives, the government maintains that the list refers to designated *flavoring*

additives. Whether the list is sufficient will have to be considered. Future developments may make it necessary to revise the list on this point.

6.4 Flavoring additives in loose mouthpieces and cartridges

The NVWA also notes that it must be prevented that flavored loose mouthpieces, cartridges or other parts of e-cigarettes, for example, could circumvent the ban on flavors. It is recommended to stress in the Explanatory Memorandum to the draft Decree that flavoring additives are also considered to be flavoring ingredients and vice versa. The NVWA suggests adding in the Explanatory Memorandum that flavoring additives added to, for example, cartridges or a loose mouthpiece, separate of the liquid, because of the definition of 'ingredient' in the law (tobacco, an additive, and all substances or elements present in a finished tobacco product or related product, including paper, filters, inks, capsules and sticks), are also not permitted. This provides greater clarity in implementation and enforcement. The government endorses this observation of the NVWA and has implemented it by adding in Article 2.4(2) that it is also not permitted to add other flavoring ingredients in other parts of e-cigarettes with and without nicotine.

6.5 Additional enforcement instruments

The designation of flavoring additives which may be used exclusively leaves no room for multiple interpretations by producers and importers as to whether or not a flavoring additive is permitted. However, when an unauthorised flavoring additive is added to the liquid, its enforcement becomes relatively complex. The proposed establishment of the ban will have to demonstrate that the flavoring additive in question is actually present in the liquid (that the additive has been used). For this purpose, the liquids must be sampled and examined in the laboratory. A research method would then have to be developed and implemented for each unauthorised flavoring additive. This will lead to high costs given the likely large number of unauthorised flavoring additives. Enforcement is expected to be more efficient and effective by also banning products on which these unauthorised flavoring additives have been declared on the packaging or on which these unauthorised flavoring additives have been declared in the EU-CEG system. This suggestion is included in Article 2.4(5) of the draft Decree.

6.6 Capacity

Finally, the NVWA notes the following. The concrete requirements regarding the regulation of flavors for e-cigarettes must still be elaborated at the level of a ministerial regulation. The required capacity for both the NVWA and the RIVM, which carries out the laboratory analyses for the NVWA, will depend on, inter alia, the requirements and designated research methods laid down therein. The HUF test of the ministerial regulation will indicate the enforceability and feasibility of the concrete requirements. The present regulation of available flavors for e-cigarettes is not part of the National Prevention Agreement. Therefore, the claimed and already allocated capacity for the implementation and monitoring of the measures contained in the agreement does not provide for the capacity needed to monitor the regulation of the flavors of e-cigarettes. In this context, it is noted that it is not yet possible to estimate the capacity of the supervision required for this purpose. This will be discussed in more detail during the elaboration of the concrete requirements in the ministerial regulation referred to above. In the event of further agreements on the required capacity which depends on the concrete requirements in the ministerial regulation yet to be established, it will be examined whether and to what extent the preparations for these new tasks will still be practically feasible in 2021.

7. Consequences for regulatory burden

This order in council has no regulatory burden for citizens. The consequences of this Decree for producers, importers and retailers in terms of regulatory burden will be assessed when the ministerial regulation is drawn up. The regulation of flavors for liquids for e-cigarettes will only then become a reality. It is only then that it is possible to determine the actual regulatory burden costs. However, producers, importers and suppliers of e-cigarettes will need to take note of the principles and of this Explanatory Memorandum.

The regulatory burden costs are listed in the tables below. Retailers of electronic vaping products consist for a large part of retailers with a small proportion of electronic vaping products in their range of tobacco products, such as supermarkets and petrol stations. Another part concerns a small number of retailers with a large proportion of electronic vaping products in their range of tobacco products; these will mainly be specialist stores. The number of retailers that sell electronic vaping products in the range is unknown. The retailers in the diagram below are therefore the retailers of specialist stores.

The table below is based on the notification costs for producers and importers of e-cigarettes and the sales points that have these products on offer. The number of suppliers of electronic vaping products is estimated at 1600 sales points. The number of producers and importers active on the Dutch market is estimated at 360.

One-time action	Who	Time in hours	Cost per hour	Q	Total
Taking note of the new regulations	Producers and importers of electronic vaping products	1	€ 45.00	360	€ 16,200.00
Taking note of the new regulation	Retailers of electronic vaping products	1	€ 45.00	1600	€ 72,000.00

The time needed for producers, importers and retailers to become acquainted with this order in council is estimated at 1 hour. The standard is set at € 45.00 per hour. The rounded-off amount of € 45 is no more than a pragmatic approach to what the required time could cost.

The bill has been submitted to the Regulatory Burden Review Advisory Board (ATR). The municipal executive has established that the above paragraph provides an adequate picture of the consequences of the regulatory burden. The municipal executive has therefore decided to dispose of the request for advice on an official basis and to refrain from issuing a formal opinion.

8. Advice and consultation

Via <https://www.internetconsultatie.nl> from ... to ... everyone was given the opportunity to comment on the bill and the accompanying Explanatory Memorandum.

PM report on the internet consultation

9. Entry into force

The planned date of entry into force is 1 January 2022.

II. Article by article

Article I *Part A*

Article I(A) amends Article 1 of the Tobacco and Tobacco Products Decree (hereinafter: Decree). The amendment concerns the inclusion of the definition of common entry gate. At present, this concept is included in Article 1 of the Tobacco and Tobacco Products Regulations (hereinafter: Regulation), but in view of the new Article 2.4(5) of the Decree, the concept is also necessary at the level of the Decree. It should be noted that this is not intended to change the substance.

Part B

Article I(B) adapts Article 2.4 of the Decree by adding four paragraphs. Pursuant to Article 2.4(1) and (2), requirements may be imposed by ministerial regulation on the ingredients of liquids containing nicotine and nicotine-free liquids (hereinafter: liquids) for e-cigarettes and other components of electronic vaping products. These requirements mean that only the flavoring additives designated by ministerial regulation may still be used as ingredients for liquids. In addition, it is not permitted for undesignated flavoring additives to be added as an ingredient through other parts of e-cigarettes such as mouthpieces, cartridges or fillers. Since this concerns components of e-cigarettes with and without nicotine, the second paragraph is based on the concept of electronic vaping products. This includes the components of e-cigarettes with and without nicotine.⁴⁹ This will prevent the list of designated additives to be drawn up by ministerial regulation from being circumvented with, for example, flavored loose mouthpieces.

The list to be drawn up by ministerial regulation is exhaustive in nature. Flavoring additives not designated by ministerial regulation are therefore prohibited. In general, this means that only liquids and other components of electronic vaping products can be placed on the market that generate a tobacco flavor in the liquid and in the components, but also at the time of consumption.

The third paragraph also prescribes that the maximum number of additives to be combined and maximum quantity may be determined for the designated additives. The rules to be specified by ministerial regulation under Paragraphs 2 and 3 prohibit most of the distinctive and attractive flavors currently available for liquids for e-cigarettes.

Paragraph 4 requires that ministerial regulations designate research methods by means of which it can be checked whether the products in question contain only the authorised additives, or whether there are more. The restrictive list of designated additives, which can be linked to maximum permitted levels, forms the basis for this. An explicit decision has been made not to draw up a list of banned substances, because developments in industry would then have to be kept under constant review. Any new additive that is applied and can create a taste other than tobacco must then be added to the list. The additional details of the research methods will be discussed when the ministerial regulation is drawn up.

The choice to regulate this by ministerial regulation lies in the knowledge that these regulations will be of a very detailed nature. There is also a chance that other, more efficient research methods may become available in the future. In view of the detailed nature of the requirements still to be drawn up and in order to be able to respond decisively to possible new market and research developments, it is reasonable to regulate research methods and to designate specifically authorised additives by ministerial regulation.

Paragraph 5 prescribes that it is also prohibited to mention on the packaging unit, outer packaging or in the package leaflet of liquids containing nicotine and nicotine-free liquid and other components of electronic vaping products, additives which have not been designated in the restrictive list to be drawn up. These additives may also not be declared in the EU CEC system on the basis of this fifth paragraph.

Article II

⁴⁹ Definition of electronic vaping products (Article 1 of the Act): electronic cigarette, refill pack, non-nicotine electronic cigarettes, non-nicotine refill pack and non-nicotine cartridge.

This article contains the entry into force provision. On that basis, the amended Articles 1.1 and 2.4 will enter into force as of 1 January 2022, simultaneously with the ministerial regulation. Nevertheless, the ministerial regulation, which specifically prescribes which additives are still permitted in the liquids, will include a transitional provision with a clearance arrangement. This clearance arrangement will include a period of time that is reasonable for selling stocks of liquids already produced.

The State Secretary of Health, Welfare and Sports,

Paul Blokhuis