EXPLANATORY MEMORANDUM

I. General section

1. Explanation of the need for the draft legislation and justification of its main principles

Act No 110/1997 on foodstuffs and tobacco products and amending certain related acts, as amended (hereinafter the 'Foodstuffs Act'), is the basic legislation governing the obligations of businesses placing electronic cigarettes, refills and herbal products intended for smoking on the market. § 19(4) of the Foodstuffs Act authorises the Ministry of Health to stipulate further requirements for e-cigarettes, refill containers for them and herbal products intended for smoking.

The implementing legislation for § 19(4)(a) and (b) of the Foodstuffs Act is Decree No 37/2017 on electronic cigarettes, refill containers and herbal products intended for smoking (hereinafter 'Decree No 37/2017'). Decree No 37/2017 implemented 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 (hereinafter 'Directive 2014/40/EU') into the national legal code, as well as the following:

- Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes;
- Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers;
- Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing the format for the submission and making available of information on tobacco products, as the submission and making available of information on herbal products is carried out in the format for the submission and making available of information on tobacco products (see Recital 5 and information available on the European Commission website: Uploading and downloading data – European Commission (europa.eu)).

Although Directive 2014/40/EU and implementing decisions issued on the basis thereof only apply to electronic cigarettes and refill containers containing nicotine, most requirements of this legislation were already also applied in the past to nicotine-free electronic cigarettes and refill containers (see the definitions of electronic cigarettes and electronic cigarette refill containers in Act No 180/2016) and thus went beyond the scope of Directive 2014/40/EU. The Czech Republic was thus among the first EU Member States to apply the provisions of Directive 2014/40/EU. A number of EU Member States followed this approach of the Czech Republic over the following years. Although these requirements, which go beyond the scope of the Directive, are capable of creating restrictions on the free movement of goods as defined by Article 34 of the Treaty on the Functioning of the European Union, they are justified by the need to ensure a high level of protection of human health, in particular for young people and other vulnerable persons.

As part of the surveillance activities carried out by regional public health authorities since 2017, several problematic aspects have been detected concerning unclear requirements transposed from Directive 2014/40/EU, which the amendment to the decree now removes. These include, for example, accurate stipulation of how electronic cigarettes and refill containers are to be secured against use by children, introduction of a requirement for health warnings for electronic cigarettes and refill containers that do not contain nicotine, clarification of access to nicotine salt content, introduction of requirements for the notification of market information for herbal products intended for smoking, etc.

At the same time, at its 13th meeting held on 5 March 2024, the Senate Health Committee adopted Resolution No 60 on the issue of the use of flavoured and sweet electronic cigarettes among children, in which, in point III, it requests the Ministry of Health to immediately and effectively amend Decree No 37/2017 with provisions regulating the use of so-called confectionery flavours that are particularly attractive to minors, such as gummy bear or cotton candy flavours, and on provisions regulating the graphic design of packaging, namely elements directly or indirectly targeted at minors.

Similarly, at its 35th meeting on 24 April 2024 the Health Committee of the Chamber of Deputies of the Parliament of the Czech Republic adopted Resolution 134. requesting the Czech Government to ask the Ministry of Health to immediately and effectively amend Decree No 37/2017 with provisions regulating the use of so-called confectionery flavours that are particularly attractive to minors.

Following the above information, the Ministry of Health proceeded to amend Decree No 37/2017, in which the Chamber of Commerce of the Czech Republic, whose members include entities involved in the production and marketing of products related to tobacco products, also participated in order to reduce the impact on the business sector.

2. Assessment of compliance of the draft legislation with the Act which it is intended to implement

The submitted Draft Decree is issued on the basis of the authorisation contained in § 19(4)(a) and (b) of the Foodstuffs Act, pursuant to which the Ministry of Health shall lay down by decree:

- requirements for the composition, appearance, quality and characteristics of electronic cigarettes and their refill containers;
- labelling requirements, including prohibited elements and features of herbal products intended for smoking, electronic cigarettes and their refill containers;
- the method, deadlines and scope of the notification obligation for herbal products for smoking, electronic cigarettes and their refill containers;
- the scope of the data required for registration and the manner in which it is to be carried out.

The Draft Decree is in full compliance with the Foodstuffs Act.

3. Assessment of compliance of the draft legislation with European Union legislation, European Union case law, and the general principles of European Union law

The draft amendment to the Decree is compatible with the following legal acts of the European Union:

- Article 34 et seq. of the Treaty on the Functioning of the European Union (hereinafter 'TFEU'), concerning the free movement of goods;
- Articles 20 to 22 and Article 24(1) of 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, as amended;
- Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes;
- Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers;
- Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products.

The Draft Decree is indirectly related to the following European Union legislation in particular:

- Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, as amended;
- Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that may be added to foods, including food supplements;
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, as amended;
- Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC, as amended;
- Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, as amended;
- Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods;

- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended (hereinafter the 'CLP Regulation');
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;
- Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, as amended;
- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in relation to food safety.

While the proposed Draft Decree constitutes a restriction on the free movement of goods (since the requirements of Directive 2014/40/EU only apply to products containing nicotine, whereas the Food Act and Decree No 37/2017 also regulate nicotine-free products), it does not create unjustified restrictions on the free movement of goods as defined by Article 34 TFEU, since the restrictions imposed are justified and proportionate (pursuing legitimate public health objectives) and therefore permissible. In accordance with Article 36 TFEU, the free movement of goods may be restricted for reasons such as the protection of public health and safety, provided that the restrictions are non-discriminatory, necessary to achieve a legitimate objective and proportionate in relation to the intended purpose.

The Draft Decree regulates the requirements for composition, appearance, quality, characteristics, labelling, including prohibited elements and features, the manner, time limit and scope of the notification obligation and the scope of the data required for registration and the manner of its implementation. However, current regulation has proven to be unclear in many respects. The new measures set out in the Draft Decree are proportionate and do not restrict the free movement of goods more than is necessary to achieve the objectives: banning confectionery flavours targeted at children, retaining a variety of flavours to encourage smokers of conventional cigarettes to switch to e-cigarettes with e-liquids, removing ambiguities of a legislative and technical nature in connection with application practice, and requiring the provision of resealable or non-resealable packaging to secure electronic cigarettes and their refill containers to prevent use by children.

On the basis of the above, the draft Decree complies with Article 34 TFEU, as it does not interfere with the free movement of goods through disproportionate or discriminatory measures. At the same time, it meets the requirements of Article 36 TFEU, as it pursues the legitimate objective of protecting public health and safety, while the measures are non-discriminatory and proportionate.

Hence, the Draft Decree does not constitute a disproportionate barrier to trade within the EU and is consistent with the principles of market regulation under EU law. The draft complies both with EU law and the general principles of EU law. EU case law does not regulate this area.

4. Assessment of the existing legal situation and justification of the need to change it

The current Decree No 37/2017 is a partial transposition of Directive 2014/40/EU, which aims to improve the functioning of the EU internal market for tobacco and related products, in particular electronic cigarettes, refill containers and herbal products intended for smoking, based on ensuring a high level of human health protection, especially for young people, while complying with the Union's obligations under the WHO Framework Convention on Tobacco Control.

Decree No 37/2017 regulates requirements for electronic cigarettes and refill containers, both containing nicotine and nicotine-free, as well as for disposable and refillable electronic cigarettes and requirements for herbal products for smoking (hereinafter 'products related to tobacco products').

E-liquids may contain only substances that, in heated or unheated form, do not pose a risk to human health and nicotine, which they may contain a maximum of 20 mg/ml. E-liquids must not contain vitamins or other ingredients that give the impression that the e-liquid is beneficial to health or that it presents a reduced health risk; caffeine, taurine or other additives and stimulants that are associated with energy and vitality; ingredients whose properties cause discolouration of emissions; and ingredients that have carcinogenic, mutagenic or toxic to reproduction properties in unburnt form. There are no other restrictions on the composition of e-liquids.

Not only chemical substances and mixtures that make these products taste appealing by suppressing the unpleasant taste of nicotine have begun to be added to e-liquids, but also newly emerging substances and mixtures that in the future, following the performance of studies, have the potential to be classified as addictive, psychomodulatory or toxic to health. Nicotine salts are also present in e-liquids, the amount of which is not regulated by the current legislation. The packaging itself of tobacco-related products is often very attractive in appearance not only to adults, but also to children and young people, who are generally unaware of the impact of products on their health and mental development, not only in the present but above all in the future[1].

Electronic cigarettes were placed on the market by manufacturers as a less harmful alternative for smokers. Even though current scientific knowledge maintains that the view of this being a 'healthier' version of smoking in comparison with tobacco products[2, , 3,, 4, 5] cannot be accepted without reservation, as the long-term effects of the use of electronic cigarettes are not known, due to the high number of persons in the Czech Republic using combustible tobacco products, the Czech Government believes there is a need to motivate smokers to switch to electronic cigarettes containing e-liquids by offering various flavours and thus reduce the risks arising from the use of combustible tobacco products.

An Australian study[6] concluded that, given the extreme harmfulness of smoking, smokers who have been unable to quit by other means and who quickly and completely switch to suitable

electronic cigarettes may benefit, although uncertainty about the effects of electronic cigarettes on serious health problems must be taken into account. However, the overall balance of the risks and benefits of using electronic cigarettes is not entirely, clear even for smokers.

Directive 2014/40/EU aims at approximating laws, regulations and administrative provisions in fields such as the placing on the market of tobacco-related products, while providing the basis for ensuring a high level of protection of human health, in particular for young people. This fundamental requirement is also emphasised in several paragraphs of the preamble to the Directive:

- Recital 36 of the preamble: A high level of public health protection should be taken into account when regulating these products. At the same time, Member States are to be able to take measures if electronic cigarettes and their refill containers pose an unforeseen risk to human health. Such measures may include a ban on placing certain electronic cigarettes or refill containers on the market or a ban on placing certain types of electronic cigarettes or refill containers on the market.
- Recital 53 of the preamble: Member States should, under certain conditions, retain the power to impose further requirements in certain respects in order to protect public health.
- Pursuant to Recital 55 of the preamble, a Member State should be able to introduce national legislation for all products placed on its national market relating to aspects not regulated by this Directive.

Based on the above, national legislation has been introduced with the aim of reducing the visual and sensory appeal of products harmful to children's health, while at the same time preserving as much as possible the existing appeal and range of flavours in e-cigarette refills for smokers of combustible products. The national legislation also aims to ensure that consumers are better informed about the composition of products and the amount of addictive substance, and that certain requirements that have led to confusion and unnecessary activity are better defined in the business environment and in the supervisory sphere.

5. Expected economic and financial impact of the proposed legislation on the national budget, other public budgets, the business environment in the Czech Republic, social impacts, including impacts on families and specific population groups, in particular socially disadvantaged persons, persons with disabilities and ethnic minorities, and environmental impacts

The draft legislation is intended to reduce the visual and sensory attractiveness of demonstrably harmful products to children, while maintaining products sufficiently attractive to smokers of combustible products so that they are more motivated to make a full transition to the use of electronic cigarettes with e-liquid. At the same time, the legislation includes measures that are formally technical in nature for a clearer definition of the legal framework. Representatives of the business milieu took part in drawing up the entire draft (see information in Part 1 and information below), so no significant financial impacts on business entities are expected.

Excise duties have been levied on herbal products intended for smoking, electronic cigarettes and their refill containers, as well as other products that are not regulated as addictive products, from 2024 onwards. However, the proposed legislation is not expected to have a negative financial impact on the state budget, or if so, only a minimal one. Its exact amount cannot be quantified at present. Although manufacturers and importers of electronic cigarettes and refills submit sales information to the Czech Republic (this obligation does not apply to herbal products intended for smoking), the reported data cannot be effectively verified, as the notifying entities are often located not only outside the Czech Republic but also outside the European Union.

The Decree will have a minimal impact on the industry concerned, or on operators engaged in the manufacture and placing on the market of electronic cigarettes, their refill containers and herbal products intended for smoking. Impacts on these subjects are expected to be both negative and positive. Among the impacts that can be characterised as negative are include stricter requirements for packaging labelling, as these make products visually appealing. On the contrary, a clearer legal framework for emerging products, such as nicotine salt products, can be identified as a positive effect on economic operators.

In order to ensure the objective of the amended legislation while eliminating any negative impact on economic operators, the Chamber of Commerce of the Czech Republic was involved in the amendment, and the association ‘Komora elektronického kouření’ [‘Chamber of Electronic Smoking’], Org ID No: 01782401, associating sellers of electronic cigarettes and related accessories, concerning a proposal on how to define confectionery flavours in e-liquids. The association said that it is aware of the problem of the use of electronic cigarettes by minors and proposed solutions (information from the Ministry of Health on the proposed solutions is provided in brackets):

1) reducing the availability of nicotine products to persons under the age of 18;

   (This proposal is not sufficient to ensure a reduction in the number of people addicted to nicotine, as to reduce this number it is essential that the products are not attractive to people under the age of approximately 25[7].)

2) introduction of the licensed sale of nicotine products;

   (Young people currently obtain products through other channels[8] – social networks, friends. Furthermore, studies suggest that even nicotine-free products are not without risks. Heated glycerol with propylene glycol[9] alone, i.e. substances which generally make up more than 90% of e-liquid, already poses a risk. Furthermore, herbal products intended for smoking may not contain nicotine, but they are burned. They therefore present a similar risk as combustible tobacco products. In other words, this proposal cannot be considered effective either.)

3) timely transposition of Directive 2006/66/EU;

   (Directive 2006/66/EU was repealed by Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and

repealing Directive 2006/66/EC. The Regulation is directly applicable legislation without the need for its transposition.)

4) the definition of a specific list of authorised or prohibited substances is not possible as not all products, flavourings, variants can be covered.

(A specific overview of authorised CAS substances in e-liquids has already been introduced by more than 5 countries in the European Union. A third of the countries of the European Union only permit tobacco or menthol flavours.)

In the association's opinion, the only solution is to focus on the name and appearance of the product itself. As per the proposal of the Chamber of Commerce of the Czech Republic, this was implemented in the Draft Decree.

6. Assessment of whether the draft legislation constitutes state aid

The draft does not constitute state aid.

7. Assessment of impact on the rights and obligations of natural persons and corporate entities

The draft implementing decree does not create new rights and obligations, these are laid down by the Foodstuffs Act or directly applicable legal standards of the European Union, and the draft implementing decree only specifies the obligations. Persons notifying products through the EU Common Entry Gate (hereinafter 'EU-CEG') will now report data that will enable more effective enforcement of legal requirements and at the same time remove the burden from inspected entities in surveillance activities.

8. Assessment of whether the draft legislation contains a provision which by its nature would constitute a technical regulation under the legislation governing technical requirements for products and information on compliance with the notification obligation under this legislation

This Decree is a technical regulation as defined by Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services and will be notified in accordance with the requirements of that Directive. The Draft Decree will be sent for technical notification after the settlement of the interdepartmental consultation procedure.

9. Assessment of the impacts of the proposed policy in relation to the prohibition of discrimination and in relation to gender equality

The draft legislation contains no provisions that would infringe or otherwise affect the principles of non-discrimination, nor does it affect gender equality in any way.

10. Assessment of the impacts of the proposed policy in relation to the protection of privacy and personal information

The draft has no impact on privacy and does not create any new way of processing personal data.

11. Assessment of corruption risks

The proposed legislation does not introduce any provisions that would pose a risk of corruption. Corruption risks are assumed only in the context of the legislative process, where, similarly to the adoption of Directive 2014/40/EU[10, 11], it is highly likely that the industry will seek to influence the government representatives of the Czech Republic.

12. Assessment of impact on state security or defence

The draft amendment of the decree has no implications for the security or defence of the state.

13. Impact assessment on digitally friendly legislation

Given the nature of the proposed amendment, this is not a decree with an impact on the digital agenda, so the principles for creating digitally friendly legislation could not be taken into account.

14. Assessment of the impact on families

The Draft Decree does not foresee any negative social impacts, including on families and impacts on specific groups of the population, in particular the socially vulnerable, persons with disabilities and national minorities. More precisely, only positive effects, as products that are harmful to health will be less attractive, better secured against tampering by children, and non-compliant products will be more effectively withdrawn from the market. In other words, these individuals, as potential users of harmful products, will be less tempted to use them.

15. Evaluation of territorial impacts, including impacts on local self-governing units

The draft legislation does not create provisions affecting local and regional authorities.

II. Special part

Re: Article I

Re: § 2 Definitions

The shorthand expression ‘portal’ for the Common Entry Gate for the submission of information (EU-CEG) is being introduced in order to simplify and clarify the requirements of the Decree.

The definition of a retail seller is amended to include any seller placing herbal products intended for smoking or electronic cigarettes or refills for them on the market. The definition of a retail seller is thus harmonised with the definition of a retail seller of tobacco products set out in the Foodstuffs Act.

The decree newly defines the term ‘characteristic flavour’ in order to comply with Resolution No 60 of the Senate Committee on Health and Resolution No 134 of the Committee on Health of the Chamber of Deputies of the Parliament of the Czech Republic. The committees asked the Ministry of Health of the Czech Republic to amend the Decree with provisions regulating the use of so-called confectionery flavours attractive primarily to minors, but also to non-smokers. The characteristic flavour is now defined as a clearly recognisable smell or taste of coffee, tea, tobacco, mint and other plants, including their fruit, flowers, seeds, leaves and extracts thereof, or a combination thereof. The aim is to establish a framework of acceptable flavours that are traditional or natural in character and are not primarily aimed at attracting children.

Re: § 3 General requirements for electronic cigarettes and refill containers

§ 3 regulates general requirements for electronic cigarettes and their refill cartridges, or e-liquids.

§ 3(1) is supplemented by Subparagraph (d) which specifies precisely what can be considered as security measures to prevent use by children. The requirement to secure electronic cigarettes and their refill containers is a transposition provision of Article 20(3)(e) of Directive 2014/40/EU. At the same time, Article 20(1) of this legislation provides that electronic cigarettes and refill containers may be placed on the market only if they comply not only with the Directive but also with all other relevant Union legislation. E-liquids are a chemical mixture (Commission Implementing Decision (EU) 2015/2186 provides for the classification of both individual components and the whole chemical mixture when notifying refills), which as such are regulated by directly applicable REACH and CLP Regulations. Nicotine is a toxic substance and, taking into account possible health and safety risks, including those for persons for whom the product is not intended, whether or not it contains nicotine, an electronic cigarette and its refill container must comply with certain safety and quality requirements. Both the e-liquid in an electronic cigarette and an electronic cigarette refill container in separate packaging can pose a health risk if the product is handled by children or other vulnerable persons. The CLP Regulation directly specifies requirements for resealable and non-resealable packaging, and for child-resistant seals. Products not secured against opening by children cause an annual increase in the number of poisonings, especially in children under 3 years of age, who are attracted by the attractive packaging and, in

particular, by the aroma of the product[12]. In the Czech Republic, the Toxicological Information Centre is monitoring a similar trend, stating that e-liquids represent a new method of suicide – see the press release from leading experts at the General University Hospital[13]. Given the risks that electronic cigarettes and refill containers pose, in particular to young children and other vulnerable persons, and taking into account the requirements of Article 20(3)(e) of Directive 2014/40/EU, the requirements laid down in the CLP Regulation for the seals of only certain chemical substances and mixtures are stipulated for all electronic cigarettes and refill containers, not only for products that meet the classification requirements laid down in the CLP Regulation. Although this requirement may create restrictions on the free movement of persons and goods, it can be considered necessary to achieve the objective of protecting public health, in particular that of children and other vulnerable persons, and is therefore justified and proportionate. According to the National Survey on Tobacco and Alcohol Use in the Czech Republic, conducted annually by the National Institute of Public Health, 13.9% of people use electronic cigarettes, according to the most recent survey for 2024. The most users are from the age group 15-44 (25.3% - i.e. 290 366 people from the age group 15-24; 19.9% - i.e. 544 076 people from the age group 25-44), i.e. almost 850 000 people from the age group 15-44. (The numbers of persons in individual age groups and in individual years were provided by the Czech Statistical Office.) These are therefore people in the youngest age group, or people of reproductive age who have children and often leave their electronic cigarettes and refills in places that are easily accessible to their small children. The Draft Decree maintains a variety of flavours, the aromas of which are attractive to these young children, leading to accidental use not only by children but also by animals, both abroad and in the Czech Republic – see the Annual Reports of the Toxicological Information Centre (https://www.tis-cz.cz/index.php/informace-o-stredisku/vyrocni-zpravy-tis), but also other information provided by the Centre. In the context of preserving different flavours, it is necessary to ensure that products are adequately child-resistant, as products often contain nicotine or nicotine salt, which can and do cause acute poisoning, especially in small children. Currently, openings for filling electronic cigarettes are often secured with only a silicone stopper, which is attached with a silicone strap. However, the silicone stopper can be easily removed and after it has been opened and filled several times, the slipperiness of the edges of the filling opening and the silicone stopper increases, leading to the risk of leakage of liquid. Such protection cannot be regarded as sufficiently child-resistant. Indeed, such devices have been assessed as hazardous by another EU Member State (Safety Gate: the EU rapid alert system for dangerous non-food products). The Draft Decree thus introduces a clear definition for determining whether or not a product is child-resistant.

This section adds a new paragraph implementing the requirements of ČSN EN 17648 regarding the ingredients of e-liquids – see Annexes 1 and 2 of the amended Draft Decree. ČSN EN 17648 lays down general principles and requirements concerning ingredients used in electronic cigarettes and refill containers in order to ensure an adequate level of safety. At the same time, it provides guidance for regulators. The standard provides state-of-the-art guidelines for ensuring the safety of consumers using electronic cigarettes or their refill containers. The standard is from January 2023, which is a few years later than Directive 2014/40/EU. It thus provides much more recent knowledge. Therefore, parts thereof are being incorporated into national legislation.

The provision in Paragraph (5) specifies that e-liquids may contain either nicotine or nicotine salt. This means that the e-liquids must not contain nicotine and nicotine salt at the same time. (In addition, such e-liquids are generally always assigned a category 1 or 2 acute toxicity hazard class and category under the CLP Regulation and may not be sold to consumers pursuant to other national legislation (§ 44a of Act No 258/2000).) E-liquid can therefore contain nicotine, nicotine salt, or be nicotine-free. Nicotine salt, like nicotine, is a substance posing a risk to human health and in order to ensure a high level of human protection, it is therefore undesirable for there to be several such substances in an e-liquid. Nicotine salt can be added to products as a separate substance, but it can also be formed by mixing individual components, by combining nicotine and acid. The Draft Decree allows products to contain only one nicotine salt, or nicotine. The content of multiple nicotine salts in an e-liquid is not allowed. A similar approach is taken to nicotine, in which only nicotine, i.e. CAS 54-11-5, is allowed in e-liquids, not its analogues or derivatives, such as 6-methylnicotine. These nicotine derivatives or analogues are not nicotine, but substances which pose a risk to human health as defined by § 3(5) of the amended Draft Decree. In the case of defining nicotine as substance CAS 54-11-5, this is only clarifying information, because since 2016 Article 2(19) of Directive 2014/40/EU has been reported in the so-called comparative table as it is implemented in Annex 1 to Act No 467/2009. – i.e. nicotine (ISO) CAS 54-11-5; in the CLP Regulation index number 614-001-00-4; EC number 200-193-3. This is specified for reasons of public health protection, as various analogues and derivatives of nicotine have not been studied in terms of their effects on the human body. For example, nornicotine (has different CAS numbers depending on whether it is a racemic mixture or different enantiomers) is probably less effective than nicotine, but at the same time studies suggest that it may have neurotoxic effects. However, its exact impact on the human brain and body is not yet fully clarified. The requirement that e-liquids contain, in addition to nicotine, only substances not presenting a risk to human health in heated or unheated form is a transposition requirement (Article 20(3)(e) of Directive 2014/40/EU). Pursuant to Part 4 of the Annex to Commission Implementing Decision (EU) 2015/2186, the components of e-liquids may only be ingredients used in the food industry and identified by a FEMA number, an E number in accordance with Regulation (EC) No 1333/2008, an FL number in accordance with Regulation (EC) No 1334/2008 or, where applicable, a European Community number. Ingredients identified with a CAS number are chemical substances for which, in accordance with the principles of REACH, adverse effects on human health or the environment are also assessed in the context of safety assessments (Title I, Chapter 1, Article 1(3) and Article 14(3)(a) of the REACH Regulation). The European Chemicals Agency (ECHA) website publishes information on the evaluation of chemical substances. For substances posing a risk to human health, the appropriate health hazard class is indicated in accordance with the REACH Regulation. Substances identified by a health hazard class are not allowed to be used as ingredients of refill containers pursuant to Article 20(3)(e) of Directive 2014/40/EU. Only nicotine (CAS 54-11-5) or its salts are permitted.

Pursuant to point 18 of the preamble to Directive 2014/40/EU states that certain additives are used to create the impression that tobacco products have health benefits, present reduced health risks or increase mental alertness and physical performance. These additives, as well as additives that increase addictiveness and toxicity, are to be prohibited in order to ensure a high level of protection of human health. Those requirements are laid down in Articles 7(6) and 20(3)(c) of Directive 2014/40/EU respectively, which prohibit the additives referred to in

Article 7(6) of that directive in e-liquids. § 3 expands or further specifies the list of substances that electronic cigarettes and their refill containers must not contain in order not to create the impression of a harmless product or even one that is beneficial to health. Ingredients are generally not specifically listed in order to maintain the objective of the legal standard and Directive 2014/40/EU in the future when, on the basis of future scientific knowledge, ingredients that not classified as problematic based on the current level of scientific knowledge may be classified as problematic as defined by Article 7(6) of Directive 2014/40/EU. Ingredients that are considered to create the impression that an e-liquid is beneficial to health or that it poses a reduced health risk are also, for example, medicinal substances pursuant to § 2(4)(a) of Act No 378/2007, the Pharmaceuticals Act, mineral substances pursuant to Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and certain other substances to foods, or novel ingredients pursuant to Commission Implementing Regulation (EU) 2017/2470 establishing a Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. Similarly, in order to ensure a high level of public health protection, the use of cannabinoids and their derivatives is prohibited, as their inhalation cannot be considered safe.

The addition of sugars and sweeteners or other ingredients that create or contribute to the creation of a sweet smell or flavour, such as vanilla, is prohibited, unless these are products with a characteristic flavour as defined in § 2. According to a statement by the Czech Chamber of Commerce and the Chamber of Electronic Vaping, sugars, sweeteners and other ingredients that create or contribute to the creation of a sweet aroma or flavour are present in 95% of e-liquids, as they suppress the bitter taste of nicotine. Restricting their use in products with a characteristic flavour other than that defined in § 2 should prevent the marketing of confectionery-flavoured e-liquids.

The content of substances from which psychomodulatory substances, classified psychoactive substances or addictive substances are produced by heating is also prohibited under the Addictive Substances Act. The reason for this is to prevent the use of substances which, although they do not have psychoactive properties in the form in which they are sold, produce other substances when heated that are on the list of controlled substances, among other things because of their psychoactive properties. An example based on current scientific and technical knowledge is the substance THCA (tetrahydrocannabinolic acid), which when heated converts to tetrahydrocannabinol, a substance scheduled in the list of addictive substances. The new legislation is therefore also being introduced in order to prevent the circumvention of control measures in a way that is based on new scientific evidence. At the same time, the requirement of ČSN EN 17648 regarding the ingredients of e-liquids, concerning the prohibition of the content of mineral or vegetable oils and fats, which products are not allowed to contain, either as a diluent or in any other function, is implemented. Products containing MCT oils in e-liquids have previously been reported in the Safety Gate RAPEX system under number 446/20. The inhalation of oil components, in particular vitamin E, was the cause of several dozens of deaths in the United States in 2020.

The amount of nicotine that e-liquids may contain is specified in the case of nicotine salt content, which may be added to e-liquids as such, or which may occur in the e-liquid only after the individual components are combined.

Pursuant to Article 20(3)(a) of Directive 2014/40/EU, Member States shall ensure that the content of disposable electronic cigarettes, disposable cartridges, refill containers or tanks does not exceed a volume of 2 ml. Although it follows from the definition of an electronic cigarette in the Foodstuffs Act that all of its tanks or cartridges may not exceed the volume stipulated by the Decree, this requirement is not completely obvious for manufacturers and persons placing products on the market and various electronic cigarettes with multiple cartridges or tanks with a total volume exceeding 2 ml are placed on the market. The new provision regarding the capacity requirement for a tank or cartridge clarifies the intention of the requirement of the Directive. At the same time, 2 ml of e-liquid provides even heavy smokers of traditional cigarettes with a sufficient number of puffs, as in terms of the number of puffs, a 2 ml cartridge can be considered equivalent to 2-4 packs of traditional cigarettes. (A conventional cigarette allows for 10-15 puffs, with some sources citing up to 20 puffs, meaning that a smoker of conventional cigarettes gets 200-400 puffs from one pack of cigarettes. A 2 ml volume of e-liquid provides approximately 600-800 puffs.)

The draft amendment applies the provision that the shape, appearance, unit and outer packaging of products shall not cause them to resemble a food, cosmetic product or toy. This requirement transposes the intention of Article 13(1)(d) of Directive 2014/40/EU and implements the provisions of Article 6(1) of Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety. This provision stipulates that products shall not resemble anything other than e-cigarettes and their refill containers.

In relation to information about electronic cigarettes with functions for receiving text messages, call alerts, playing games and music, lighting functions, etc., available on foreign markets, a provision prohibiting electronic cigarettes from enabling functions other than the use of vapours containing nicotine or other vapours applies. For instance, this could pertain to the above-mentioned playback of games and music, various lighting functions, text message and Bluetooth alerts regarding low e-liquid, etc., because these functions increase attractiveness primarily for people in the youngest age group and are completely unnecessary in terms of use.

<u>Re: § 4</u> Additional requirements for refillable electronic cigarettes and their refill containers

The requirements applicable in the current version of the Decree only to e-cigarettes containing nicotine are now also applicable to nicotine-free products, as e-cigarette devices intended only for nicotine-free e-liquids also allow the use of liquids containing nicotine without any restrictions, effectively violating the requirements of Directive 2014/40/EU. From a technical perspective it is the same product, which makes it possible to use both liquids which contain nicotine and liquids which are nicotine-free.

Electronic cigarettes and their refill containers are considered by the Government of the Czech Republic as products that can reduce the risks caused by smoking conventional cigarettes. -A conventional cigarette allows one to take 10 to 15 puffs from a single cigarette, with some sources citing up to 20 puffs. The volume of a 2ml tank provides a minimum of 600, but also up to 800 puffs. This means that 2 ml of e-liquid provides approximately the

same number of puffs as 2–-4 packs of cigarettes. The Government of the Czech Republic requires refillable electronic cigarettes to be able to contain up to three tanks or cartridges. Therefore, it is stipulated that a refillable electronic cigarette may contain up to three tanks or containers in total. However, these cartridges or tanks, which are or may be part of an electronic cigarette, must not exceed a total volume of 2 ml. Otherwise, there would be a conflict with Directive 2014/40/EU. An electronic cigarette is defined as a product including a cartridge or a tank (Article 2(16) of Directive 2014/40/EU). If they contain more than 2 ml of cartridges or tanks, then these would, from a technical point of view, be part of an electronic cigarette and, from a legal point of view, would fall under the definition of an electronic cigarette. The de facto volume of the cartridges or tanks of an e-cigarette would thus be more than 2 ml, which would be contrary to Article 20(3)(a) of Directive 2014/40/EU. At the same time, electronic cigarettes containing or capable of containing multiple tanks or cartridges must not allow the simultaneous use of the content of different tanks or cartridges. If that were to happen, such liquid content, among other things, would not be notified pursuant to § 6(1)(a) of the Decree. A refillable electronic cigarette may therefore contain up to three tanks or cartridges with a total volume of up to 2 ml, and at any given time it must allow the use of only one tank or cartridge.

<u>Re: § 5</u> Labelling of electronic cigarettes and their refill containers

As regards Paragraph (1)(a), it is specified that the information required to appear on unit packets and outside packaging pursuant to § 12h(2) of Act No 110/1997 must be indelibly printed directly on the packaging and cannot be supplemented by means of stickers, even if they are non-removable, even if this is information that appears on the packaging and is merely translated into Czech. The presentation of this mandatory information has historically been derived from the presentation of the health warning pursuant to Article 8(3) of Directive 2014/40/EU, which cannot also be presented on the packaging in the form of stickers. In particular, the requirement is an important aspect for consumers themselves in preventing the placing on the market of counterfeit products or products that do not meet requirements as to the composition or characteristics of the product. This provision was amended in order to increase consumer protection, as the possibility of relabelling significantly increases the risk of non-compliant products being placed on the market (e.g. by relabelling information on the composition, the product itself, the UFI code, health warnings, etc.), the use of multiple labels, or the import or distribution of products by persons who are not registered as importers or distributors of products. This is not an obstacle to the free movement of goods within the EU, as Article 8(3) of Directive 2014/40/EU requires Member States to ensure that health warnings on unit packets and outside packaging are printed indelibly. The health warnings must be in the official language of the Member State (Article 8(1) of Directive 2014/40/EU), i.e. the packaging with the health warning must always be printed in the Czech language. In this context, the cost of providing or printing all other information in Czech directly on the unit and outer packaging is minimal.

The provisions of Paragraph (2) are supplemented with the fact that ingredients listed pursuant to § 12h(2)(b) of the Foodstuffs Act must appear on the packaging under the same name as that used in the notification of all ingredients in EU-CEG in accordance with the procedure pursuant to § 6(1)(a). The ingredients of e-liquids are chemical substances that may

have various names. The use of different names on the packaging and in the EU-CEG not only greatly prolongs the inspection activities of supervisory authorities, but at the same time makes it difficult for consumers to verify on the website of the Ministry of Health (https://mzd.gov.cz/vyrobky-oznameni-eu-ceg/) the notification of the ingredients contained in the liquid. Pursuant to Article 6(2)(a) of Commission Implementing Decision (EU) 2015/2183, the Commission does not, in principle, consider ingredients used in quantities exceeding 0.1% of the final liquid composition to be business secrets. Therefore, ingredients contained in e-liquid in quantities of 0.1% and less do not have to be listed on the packaging pursuant to § 12h(2)(b) of the Foodstuffs Act for reasons of business secrets, provided that they are not ingredients causing allergies or intolerances as defined by Article 9(1)(c) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council.

The method of reporting data pursuant to § 12h(2)(c) and (d) of the Foodstuffs Act was not sufficiently specified. This not only creates legal uncertainty and leads to different practice, but especially the consumer cannot compare products in terms of the amount of nicotine contained and supplied. In addition to the compulsory indication of the nicotine content of the product, it is therefore necessary to indicate the amount of nicotine in mg per ml of e-liquid. Currently, the amount of nicotine in the product is often reported as a percentage, which visually evokes a low amount. In addition, it is difficult for users to compare the amount of nicotine in different products if the amount of nicotine is stated on one product in mg per ml and on the other in percent. Percentage expressions can also be weight-based and volume-based, which are always different numbers. For the same reasons, the method of providing mandatory information pursuant to § 12h(2)(d) of the Act is also clarified and the term ‘dose’ is specified. If the liquid filling contains nicotine salt, then the required information shall be provided in nicotine equivalent.

The amendment introduces mandatory health warnings on the packaging of all electronic cigarettes (i.e. products that can be used for vapour consumption; not on the packaging of individual components of electronic cigarettes, such as the mouthpiece, cable, tank or cartridge without refill, etc.) and refills, i.e. also on the packaging of nicotine-free products and on the packaging of electronic cigarettes without e-liquid. The reason for this is that the use of the products mimics smoking behaviour and the available studies do not indicate that their use would be without a negative impact on health[14, 15].

The newly added text in Paragraph (7) is the text contained in the original text of the decree in Paragraph (3) and transposes Article 8(2) of Directive 2014/40/EU.

The new Paragraph (8) implements the requirement of other national legislation on the obligation to label products related to tobacco products with tobacco stickers and at the same time transposes the requirement of Article 8(3) of Directive 2014/40/EU.

The introductory part of Paragraph (9) is reworded slightly in order not to reduce the scope of the prohibition referred to in Article 20(4)(b)(ii) of Directive 2014/40/EC, the requirement of which has been transposed. In order to reduce the visual attractiveness of products, especially for persons under the age of 18, additional labelling requirements are added, according to which the labelling must not contain any element or feature reminiscent of a foodstuff, cosmetic product or toy. To the selected newly added subparagraphs:

- Re Subparagraph (e): Elements or features associated with illegal or dangerous substances are not permitted, such as products referring to the narcotics trade (e.g. the product name ‘Pablo’ available on the market, which, in conjunction with its graphic design, clearly refers to the drug lord Pablo Escobar). Similarly, for example, product designation ‘Dope’. Elements or features referring to life-threatening (e.g. radioactive) substances or behaviour, such as presently with the designation ‘Fatality’, are also not permitted.
- Re Subparagraph (g): Elements or features reminiscent of vulgar terms that may be particularly attractive to minors (e.g. product designations ‘Kurwa’ or ‘Bitch’ that are available on the market) are not acceptable.
- Re Subparagraph (h): This provision prohibits, for example, cartoon or animated images of animals, most commonly monkeys, pandas and others, comics depictions of clowns and other characters, science fiction images, i.e. cartoon images of aliens or depictions of various fantasy characters, depictions referring to popular children's or fairy tale characters (e.g. depictions of Minions or SpongeBob), characters from culture attractive to minors (e.g. Spiderman or the Squid Game series), depictions of sports (e.g. acrobatic sports, wingsuits, etc.), computer game motifs (e.g. Angry Birds) and modern technology motifs (e.g. elements referring to virtual reality). The provisions of (not only) this Subparagraph apply to all elements and features.

It is specified that the flavour of the product may be labelled only in the form of a text that is followed by the word ‘flavour’ and that is not contrary to legal standards.

The addition of information on the impermissibility of an element or feature indicating economic advantages is merely a clarification, as the original wording of the decree already referred to the terms ‘element’ and ‘feature’, which, however, were not expressed in the paragraph in question.

It is added that a prohibited element or feature includes the name of the subtype. The flavour of a product or the name of a subtype of a product may only be marked with text, which may not, however, be contrary to this Decree. The non-exhaustive list of prohibited elements and features, which can also be text, also applies to the foreign-language name, or its equivalent in the Czech language. This requirement can be considered transposition of Article 20(4)(b)(ii) or of Article 13(3) of Directive 2014/40/EU, as prohibited elements or features include texts. The word ‘texts’ in this part of the Directive is not defined as text in an official language of a Member State, but as any text (e.g. Article 2(32) and (33) refer generally to health warning texts, while Article 12(2) specifies further the requirements for the text of a health warning in relation to the official languages of the Member States). The requirement for a non-exhaustive list of prohibited elements and features is set out in Article 13(3) of Directive 2014/40/EU, which states that elements and features *may include but are not limited to*. The application of this Article to electronic cigarettes and refill containers is referred to in Article 20(4)(b)(ii) of Directive 2014/40/EU.

Since the product is not always traceable in the EU-CEG system, a new obligation is introduced to indicate the identification number under which the product is notified in the EU-CEG directly on the unit and outer packaging for clear identification of the product not only during state health surveillance, but also as auxiliary information for consumers and retailers

themselves, so that they can verify the notification of the product and the notification of its composition themselves on the website of the Ministry of Health, which publishes this information on the basis of the authorisation in the Foodstuffs Act.

It introduces the use of a warning in the form of a graphic symbol that cannot be easily overlooked, as is the case with the text, namely ‘Product not intended for persons under the age of 18’, the obligation to provide a warning of the risks of use of the product by pregnant and lactating women, and the mandatory wording of the text pursuant to § 12h(2)(f) of the Foodstuffs Act.

Conditions for the possible use of a barcode or QR code on packaging are added. Both a barcode and a QR code enable automatic identification when selling products to consumers, among other things. It is acceptable to display one or the other code on the packaging, provided that it does not represent an image, logo, text, etc. In order to prevent codes from being used as a visually appealing element or a carrier of misleading information, the manner in which they are displayed on the product is regulated. The barcode allows the country of origin, manufacturer, and other information about the product to be determined. Similar or more detailed information can be provided via a QR code. In order to prevent misleading information being made about products by means of a QR code, e.g. the use of prohibited elements and features in the QR code references, only a QR code referring to information available by barcode or to information whose inclusion is mandatory on/for products is permitted. However, the information communicated by means of a barcode or a QR code does not replace information that, pursuant to applicable legislation, is mandatory on products, packaging of products, leaflets (e.g. pursuant to § 12h(2) and (3) of the Foodstuffs Act), since such information would not be available to all persons without distinction at the moment the consumer is making a purchase decision.

<u>Re § 6</u> The notification process when placing electronic cigarettes and their refill containers on the market

In Paragraphs (1) and (3) (originally Paragraph (2)), the term ‘common electronic gateway for submitting information’ is replaced by the shortcut ‘portal’. (In this Explanatory Memorandum, the better known abbreviation EU-CEG is used.)

Paragraph (1)(c) is supplemented in connection with the possibility of e-liquid containing nicotine salt.

The requirements referred to in Paragraph (1)(e) and (g) are specified in relation to the requirement of § 12a(1)(a) and § 3(1)(b) of the Foodstuffs Act and the fact that, under Czech law, only a sole trader may be a producer, importer or distributor, and not a natural person as such.

A new Paragraph (2) adds information that is not mandatory under the Annex to Commission Implementing Decision (EU) 2015/2183, but whose notification is made possible by the EU-CEG. A new obligation to report the following has also been introduced:

- Name and contact details of the corporate entity or sole trader established in the Czech Republic that is responsible for placing the product on the market in the Czech Republic, or contact details of the authorised representative defined in the Market Surveillance

Regulation (2019/1020) and in the General product safety regulation (2023/988) if the entity responsible for placing the product on the market in the Czech Republic is not established in the Czech Republic. The required information shall be provided in the product notification as an ‘affiliate company’ in accordance with the procedure set out in Section 2.2 of the Annex to Commission Implementing Decision (EU) 2015/2183.

  - This information is required by the draft legislation in order to enforce the law more effectively in the case of non-compliant products, as the persons inspected often fail to provide proof of the product's origin, which ultimately means that it is impossible to trace where non-compliant products come from and their withdrawal from the market is ineffective, taking place at the end of the commercial chain rather than at the beginning. The requirement that non-compliant products must not be available on the market should also be in the interests of the industry itself, which complies with the applicable legal standards, as it is precisely non-compliant products that cast a bad light on the entire industry.

- In the case of e-liquids, a safety data sheet drawn up in accordance with directly applicable European Union legislation regulating chemical substances (REACH Regulation), i.e. in Czech, as the products are placed on the market in the Czech Republic where the official language is Czech;

  - E-liquids often contain nicotine salt or the maximum permitted amount of nicotine, which makes these mixtures dangerous. The safety data sheet contains much important information about the mixture (hazard information, information on safe storage and handling of the mixture, toxicological data, etc.). However, inspected entities are not obliged to have the safety data sheet with them and the subsequent request for a safety data sheet unnecessarily prolongs the supervisory activity and renders it inflexible and ineffective. Thus, a safety data sheet stored directly in the EU-CEG also entails a lower administrative burden for both parties, i.e. also for the inspected entity. The safety data sheet can be uploaded to the EU-CEG as an attachment in the ‘Product details’ section in ‘Market research files’ or in ‘Market studies summary files’ (i.e. right next to the words ‘CLP Classification (as a mixture)’, as these sections allow multiple attachments to be uploaded.

- Date of withdrawal of the electronic cigarette or refill container from the market if the information pursuant to § 12h(4)(b) of the Foodstuffs Act, i.e. market information, has not been notified;

  - At present, more than 100 000 products have been notified in the Czech Republic, which however does not mean that all notified products are available on the Czech market. Submitters often give notification of products ahead of time, even if the products are not placed on the market. In order to reduce the amount of information being submitted and thus increase the clarity of notified products, it is now required, in accordance with Article 2(1) of Commission Implementing Decision (EU) 2015/2183, to specify the date of withdrawal of the product from the market, at the latest on the date on which market information is to be notified through the EU-CEG, unless market information is notified in the required manner.

The amended draft newly refers in Paragraph (4) (originally Paragraph 3) to legislation specifying the method of assigning identification numbers to notified products. This is only clarification information, as it originally did not refer to the specific number of the legislation.

Paragraphs (5), (6) (formerly 4 and 5) and (7) specify the deadlines for the submission of information pursuant to Paragraphs (1) and (2) of the Decree or § 12h(4) and (5) of the Foodstuffs Act. The new information required pursuant to Paragraph (2) must be submitted via the EU-CEG prior to placing on the market (i.e. the 6-month requirement does not apply). Information on products for which a substantial change has occurred pursuant to § 12h(5) of the Foodstuffs Act must be notified via the EU-CEG in the same time frame as for new products. This requirement is a transposition provision of Directive 2014/40/EU (the last sentence of the first paragraph in Article 20(2)).

Re § 8 Notification of information on the electronic cigarette and refill container market

The amendment proposal specifies that market information shall be reported via the EU CEG portal-, i.e. the same channel used to report information about the products themselves.

The information pursuant to Paragraph (1)(a) shall be provided in the EU-CEG in the manner published for several years on the website of the Ministry of Health (Information on the market for electronic cigarettes and refill containers – Ministry of Health), i.e. by creating a new year and entering a specific figure in the 'Annual sales data' section.

In connection with the possible content of nicotine salts in e-liquids, the provisions of this section are supplemented in this context.

Re § 9 Labelling of herbal smoking products

It is specified that the mandatory information stipulated by law must be indelibly printed directly on the unit and outer packaging, i.e. it cannot be added by means of stickers, even if they are indelible, even if the information is already stated on the packaging and only translated into Czech. The presentation of this mandatory information has historically been derived from the presentation of the health warning provided for in Article 8(3) of Directive 2014/40/EU, which states that self-adhesive labels may only be used to provide health warnings on tobacco products sold in pouches. In particular, the requirement is an important aspect for consumers themselves in preventing the placing on the market of counterfeit products or products that do not meet requirements as to the composition or characteristics of the product.

In Paragraph (2), as in the case of the packaging of electronic cigarettes and refill containers, the impermissibility of downplaying the health warning is added.

As in the case of electronic cigarettes and their refill containers, the transposition requirement of Article 8(3) of Directive 2014/40/EU is added to Paragraph (3), as other national legislation now requires that only packaging marked with tobacco stickers be placed on the market.

For those health warnings, the requirements currently in force for electronic cigarettes and refill containers are added, i.e. that they must appear on the two largest surfaces and parallel

to the main text in the area reserved for that warning, that is to say, they must be parallel to the name and, where applicable, the name of the product subtype. This requirement is a transposition of Article 21(2) of Directive 2014/40/EU.

Herbal products intended for smoking are used similarly to tobacco products, electronic cigarettes and their refill containers. Hence similar requirements to those applicable to electronic cigarettes and refill containers are being added as regards their labelling. That is, that their unit packets, any outside packaging and the labelling of the herbal product intended for smoking as such must not contain any element or feature resembling a food, cosmetic product or toy, suggesting increased biodegradability of the product or other environmental benefits, referring to an aroma, smell or flavour other than the plants, herbs or fruits that are the basis of the product. The labelling also must not contain any element or feature referring to the absence of additives or flavourings. This is a clarification of the transposition of Article 21(4) of Directive 2014/40/EU.

As with electronic cigarettes and refill containers, the fact that in addition to those already mentioned, the name of the subtype may also be an element or feature, and that these must not suggest any economic advantages. The non-exhaustive list of prohibited elements and features, which include text, also applies to names in foreign languages or their equivalents in Czech. The requirement for a non-exhaustive list of prohibited elements and features is set out in Article 13(3) of Directive 2014/40/EU, which states that elements and features *may include but are not limited to*. The application of this Article to herbal products intended for smoking is referred to in Article 21(4) of Directive 2014/40/EU.

The last paragraph allows marking the unit and outside packaging of the product with a barcode or a QR code. Neither the barcode or nor the QR code may resemble anything other than a barcode or QR code. The reason for this is the same as for electronic cigarettes and their refill containers. As with electronic cigarettes and their refill containers, herbal products intended for smoking may only display a QR code that links to information available via a barcode or to information that is mandatory to display on or with the products and does not contain prohibited elements or features, as otherwise this would be in breach of Directive 2014/40/EU. However, the information communicated by means of a barcode or a QR code does not replace information that, pursuant to applicable legislation, is mandatory on products, packaging of products (e.g. pursuant to § 12h(2) of the Foodstuffs Act), since such information would not be available to all persons without distinction at the moment the consumer is making a purchase decision.

<u>Re § 10</u> Method of implementation of the notification obligation for the placing on the market of herbal products for smoking

Throughout the paragraph, the shortcut ‘EU portal’ is introduced for the term ‘electronic gateway for the submission of information (EU-CEG)’ and the legislation of the implementing decision regulating the common format for the submission and disclosure of information is specified by stating the number of the legislation. Although this legislation has the following in its title: ‘... on tobacco products’, it was created with the intent for it to also apply to herbal products intended for smoking (see Recital 5 of the preamble and the translated reference tables for tobacco products available on the European Commission’s

website (Recording and downloading of data - European Commission), which explicitly states that one type of product(s) are herbal smoking products).

In Paragraph (1)(a), the specification of the natural person who must be an entrepreneur is added, as in the national legal environment it is not possible for a natural person alone to be a manufacturer, importer, distributor.

The newly added Paragraph (2) specifies the information that the submitter is required to notify in addition to the mandatory information under Commission Implementing Decision 2015/2186. This is similar information to that for electronic cigarettes and their refill containers. In the case of herbal products intended for smoking, information about the person responsible for placing the product on the market in the Czech Republic must also be reported, the manufacturing process must also be described, and a safety data sheet must also be submitted via EU-CEG (as with nicotine pouches (Nicotine pouches without tobacco content – decree, notification via EU-CEG – Ministry of Health) in the 'Technical files' section), the nicotine content in emissions must be reported if nicotine or nicotine salt is contained in the product, and data on sales volumes or the date of withdrawal of the herbal product intended for smoking from the market must be reported annually. This new required information must be notified before the product is placed on the market, i.e. it must be submitted no later than 2 months before the placing on the market – see added Paragraph (5) (formerly Paragraph (4)).

In Paragraph (4) (originally 3) reference is made to a regulation specifying the method of assigning identification numbers to notified products. This is only clarification information, as it originally did not refer to the specific number of the legislation.

Re § 10a Availability of Czech technical standards

The amendment to the Decree now refers to Czech technical standards, which is why a provision has been added that regulates their publication on the website of the Czech Standardization Agency.

Re Article II Transitional provisions

The provisions of Paragraphs (1) and (2) allow submitters, for products related to tobacco products that have already been notified in the EU-CEG prior to the effective date of the amended regulation, to be able to add the newly required information through the EU-CEG, without postponing the date for placing the products on the market, which depends on the date of notification of the products through the EU-CEG.

Pursuant to Paragraph (3), products related to tobacco products that comply with the requirements laid down in the Decree applicable until the effective date of the amended legislation and that have been manufactured or placed on the market and labelled before the effective date of the amended legislation may be offered for sale and sold no more than 7 months after the effective date of the amended legislation. This period for the sale of remaining stock is standard in the context of similar regulations and is of sufficient duration.

It ensures a reasonable balance between the protection of public health and the needs of the market.

<u>Re Article III</u> Technical regulation

Given that this is technical legislation, it needs to be notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for providing information in the field of technical regulations and of rules on Information Society services.

<u>Re Article IV</u> Effective date

This Decree enters into effect on the first day of the calendar month following the date of its promulgation. The legislation's date of entry into effect is set as the earliest possible date in order to ensure a high level of protection of human health at an early stage, in particular for children, but also for the users of the products themselves, who should be sufficiently informed about the products they use. At the same time, this will reduce the administrative burden on the supervised entities, as the data needed to evaluate the compliance of the products with the legal standards will no longer need to be sought from their suppliers.

<u>Annex 1</u> Ingredients that may not be used in the manufacture of e-liquids

Annex 1 lists the ingredients which may not be used in e-liquids due to their toxicity. These ingredients may only be present as impurities. The list of ingredients is identical to those listed in Annex A of standard ČSN EN 17648. The ingredients listed in this standard are accompanied by synonyms, EC numbers and FEMA numbers. They are therefore not additional ingredients, but merely a clarification of the requirement laid down in ČSN EN 17648.

<u>Annex 2</u> Maximum permitted quantities of selected ingredients in e-liquids

Annex 2 lists the ingredients that may be used in e-liquids if their quantity does not exceed the declared concentration. The list of components, including their permissible concentrations, is identical to the data specified in Annex B of standard ČSN EN 17648.

The substance safrole, CAS 94-59-7, has been removed from the annex as opposed to ČSN EN 17648, as it is listed in Regulation No 273/2004 as a Category I substance and its use is therefore prohibited pursuant to § 3(6)(h) of this Decree.

<u>Annex 3</u>

Contains one prohibitory graphic sign 'Product not intended for persons under 18 years of age.'.

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Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10980913/. [cited 2024-04-24].

[3] Obertova N., Navratil T., Zak I., Zakharov S. *Acute exposures to e-cigarettes and heat-not-burn products reported to the Czech Toxicological Information Centre over a 7-year period (2012-2018).* Online. 3. 2. 2020.
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