EXPLANATORY REPORT

Name: Decree on Psychomodulatory Substances

I. General part

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

Act No 321/2024 amending Act No 167/1998 on addictive substances and amending certain other acts, as amended, and other related acts (the 'Amendment to the Addictive Substances Act' or 'Act') introduced legislation for two new categories of psychoactive substances, known as scheduled psychoactive substances and psychomodulatory substances.

The new legislation laid down the conditions for the handling of the two categories of psychoactive substances. This adjustment enables the effective regulation of the supply of psychoactive substances that are not monitored on the UN or EU level and effective monitoring in this area in order to minimise risks to public health, without the need for these substances to be included in the schedule of addictive substances, i.e. narcotics and psychotropic substances associated with criminal consequences.

Scheduled psychoactive substances are defined as substances which are assumed to be psychoactive, but whose potential risk to the health is unknown. Following their inclusion in the list of scheduled psychoactive substances set out in the Government Regulation, the substances in this category are prohibited from being traded, produced, imported or exported, except for the purpose of research, while the handling of these substances by natural persons for personal use will not be subject to penalties. The Act lays down the procedure for assessing the risks of these substances and their possible subsequent inclusion in the schedule of addictive substances or psychomodulatory substances or retention of a substance on the list of scheduled psychoactive substances or removal from any list of psychoactive substances.

Psychomodulatory substances (hereinafter also referred to as 'PMS') are defined as new psychoactive substances and other substances with psychoactive effect that do not pose a serious risk to public health or a risk of serious social impacts on individuals and society. For that reason, their informed use constitutes an acceptable risk for an adult in terms of addiction and other health and social impacts, so statutory regulation allows them to be placed on the market under strict conditions.

The proposed legislation stipulates that the importation, production, distribution, placing on the market and other forms of handling of PMS are subject to a handling permit.

The amendment to the Addictive Substances Act in § 33e to 33g lays down the conditions for the production, composition, packaging and labelling of psychomodulatory substances and for their subsequent placing on the market. On the basis of the enabling provisions of the law, the implementing legislation lays down technical requirements for the composition, appearance, quality and characteristics of psychomodulatory substances, including the

maximum permitted amount of active substances in unit packets, maximum permitted concentrations of active substance, prohibited elements and features in the placing on the market of psychomodulatory substances and limits for chemical and microbiological contamination, as well as the manner of display and detailed definition of the information on the packaging of PMS and the form of the consumer information notice, the safety warning on the danger of use by minors and the health warning.

Under § 33f(1) of the Act, the manufacturer of psychomodulatory substances is obliged to comply with the requirements of good manufacturing practice, which are set out in Part Three of this Decree.

Furthermore, under § 33h of the Act, a person handling psychomodulatory substances must keep records of the handling of psychomodulatory substances, and the manner of keeping such records and the model form for reporting are also to be specified in the implementing legislation, which in this case is the new Decree on evidence and documentation of addictive substances and preparations.

The Draft Decree is a follow-up to the new legislation on the regulation of psychoactive substances whose harmfulness to the health and society is low, and are not controlled by the UN International Conventions on the Control of Narcotic Drugs and Psychotropic Substances of 1961 and 1971 nor by EU law under Council Framework Decision 2004/757/JHA nor Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of drug and repealing Council Decision 2005/387/JHA.

This legislation introduces rational and modern regulation of psychoactive substances, the control of which is not regulated transnationally or for which transnational regulations and European law allow it. A new category of psychoactive substances, known as psychomodulatory substances, has been introduced into the Addictive Substances Act as a special category of psychoactive substances, in which their handling and placing on the market is subject to strict conditions laid down in the Act. These conditions concern the content and concentration of active substances and the quantity of psychomodulatory substances in the unit packet, in which psychomodulatory substances may only be placed on the market in ‘unit packets’ (i.e. in the smallest possible package for placing on the market). In addition, the labelling of psychomodulatory substances is regulated and must contain all relevant information, including the amount of active substance, recommended dosage, health and safety warnings. Psychomodulatory substances are also not allowed to contain excessive amounts of chemical and microbial agents that could harm consumers’ health. It also establishes strict conditions for the production of psychomodulatory substances and products made from them.

The Act provides that the strict conditions in § 33e(2) and (4) and § 33f(1) and (8) must be specified by implementing legislation. It also provides that the implementing legislations in question means a decree of the Ministry of Health drawn up in cooperation with the Government Office as per § 44c(7). In view of the above, it is not possible to specify the conditions by any other means than legislative means, i.e. by adopting a decree.

2. Assessment of compliance of the draft legislation with the Act, for the implementation of which it is being proposed

This Decree is proposed on the basis of the authorisation to implement in § 33e(2) and (4) and §33f(1) and (8) pursuant to § 44c(7) of Act No 167/1998 on addictive substances and amending certain other acts. The Draft Decree is in full compliance with the Addictive Substances Act, as amended, including the regulation of psychomodulatory substances.

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

The submitted Draft Decree is directly related to the following European Union legislation:

- Articles 34 and 36 of the Treaty on the Functioning of the European Union (hereinafter 'TFEU').
- Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of a drug and repealing Council Decision 2005/387/JHA;
- Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 amending Regulation (EC) No 1920/2006 as regards information exchange on, early warning and risk assessment of new psychoactive substances.

The Draft Decree does not constitute an unjustified restriction on the free movement of goods within the meaning of Article 34 TFEU, as it pursues the legitimate objectives of protecting public health, public safety and crime prevention. 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 does not provide for any restrictions that would favour domestic producers over producers from other EU Member States. The requirements for composition, appearance, quality, labelling, package size, etc. apply equally to all manufacturers and distributors, regardless of their origin. As such, the measure does not lead to undue discrimination against imports or trade within the EU single market. The free availability of PMS without sufficient regulation could pose a serious threat to public health, especially to children, but also to adults, as without any regulation or quality control, PMS would enter the market with moulds, pesticides, bacteria, etc., thereby endangering public health.

For that reason, the Draft Decree introduces technical requirements on composition, appearance, quality, packaging size, labelling and hygiene standards of production, thereby minimising the risk of contamination of PMS during production, transport, storage, uncontrolled use and uninformed consumers about what they are using. At the same time, the Decree ensures control over the production process and provides for compulsory registration of the persons involved in the production and distribution of PMS, which is in line with the interests of public health and the prevention of crime, i.e. the uncontrolled spread and misuse of these substances. The measures established by the Decree are proportionate and do not restrict the free movement of goods any more than is necessary to achieve these objectives.

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

As such, the Decree does not constitute a disproportionate barrier to trade within the EU and complies with the principles of market regulation laid down in EU law.

The Draft Decree has an indirect relationship primarily to the following European Union legislation:

- 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;
- 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 matters of food safety, as amended;
- 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;
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, as amended;
- Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council, as amended;
- 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;
- 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, 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;

- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast), as amended.

The proposal complies with EU law as well as with the general principles of EU law. EU jurisprudence does not regulate this area.

4. Expected economic and financial impact of the proposed legislation on the national budget, other public budgets, the business environment in the Czech Republic, social impact, including impact on families and specific population groups, in particular socially disadvantaged persons, persons with disabilities and ethnic minorities, impacts on the protection of children's rights, environmental impacts and impacts on the rights and obligations of natural persons and legal entities.

The Draft Decree in question specifies the obligations in relation to business operators, so no economic and financial impact on the national budget or other public budgets is expected.

The proposed legislation will have an impact on economic operators who will deal with psychomodulatory substances on the basis of permits issued by the Ministry of Health, since it lays down strict conditions for the labelling of psychomodulatory substances intended to be placed on the market and strict conditions for compliance with good manufacturing practice so as to ensure that the products in question will not be harmful to consumers' health. Given that this market is unregulated for the time being, an increase in product quality and safety and a positive selection of the business environment for this purpose can be expected. The new regulation can be expected to have an overall positive impact on the business environment.

This regulation is not expected to have any new significant negative financial impacts on health insurance companies or the social security system. A de facto market for psychomodulatory substances already exists at present, even in an unregulated form. As such, the regulated supply of these substances cannot be expected to increase the negative impacts on expenditures for public health as compared to the current situation. On the contrary, stricter quality requirements and limited accessibility for minors in the short and long term may lead to lower costs for the health and social system.

Greater safety of psychomodulatory substances, clear labelling rules for these products and clear rules for the supply of these substances will have a positive impact on consumer protection, i.e. the inhabitants of the Czech Republic in general, but especially on specific vulnerable groups of the population. Socially disadvantaged persons, members of minority groups and persons with mental health disorders are among the most vulnerable groups of persons, both in terms of risky use of psychoactive substances and in terms of the consequences associated with it. Use, especially risky use, can also have a disruptive impact, in particular on the family environment, healthy development and social inclusion for young people. The strict conditions for the placing on the market, including the conditions and limits for the content and characteristics of psychomodulatory substances and their labelling, specified in greater detail in this Draft Decree, aim to limit the negative health and social impacts for these vulnerable groups.

Positive impacts on the environment are expected. Since the Draft will introduce legal regulation of the production of these products, it will also allow waste management to be conducted according to statutory rules as opposed to an unregulated market.

5. Assessment as to whether the Draft Government Regulation constitutes state aid

The Draft Government Regulation does not constitute state aid.

6. Assessment of the impacts of the proposed solution in relation to the prohibition of discrimination and in relation to gender equality

The proposed legislation is not a provision that infringes or otherwise affects the principles of non-discrimination, nor does it affect gender equality in any way.

7. Assessment of the impact of the proposed solution in relation to the protection of privacy and personal information

The Decree regulates the processing of personal data of persons working in the production facility, employees responsible for record keeping, purchasers and suppliers of psychomodulatory substances. Personal data is processed for the purposes of ensuring good manufacturing practice, verifying the medical fitness of employees and keeping documentation of manufacturing processes.

Specific purposes for the processing of personal data under the Decree:

1. Verifying the medical fitness of employees working in contact with psychomodulatory substances (PMS) to prevent their possible contamination with pathogenic microorganisms (§ 13(3)).

2. Registration of employees and responsible persons in the production process and documentation management (§ 17).

The Decree builds on occupational health services under Act No 373/2011 on specific health services, and on the obligation of employers to keep documentation on employees' medical fitness. It is also related to the PMS production records under § 17, which include personal data of responsible employees, their signatures and time data on production processes.

The processing of personal data is necessary for the fulfilment of the legal requirements for the protection of occupational health and safety in work with PMS. The legal basis is based on compliance with a legal obligation (Article 6(1)(c) GDPR) and the processing of a special category of data is allowed on important grounds of public interest in the field of public health (Article 9(2)(i) GDPR).

Categories of personal data processed

- Employees of production facilities – identification data, job classification, medical fitness.

- Persons responsible for documentation management – name, signature, position.
- Customers and suppliers – identification data and contact information.

The processing is proportionate because it is limited to the data necessary for health protection and the management of production processes.

8. Assessment of corruption risks

The proposed legislation does not create provisions that would be subject to corruption risk.

9. Assessment of impact on state security or defence

The draft legislation does not have any impact on state security or defence.

10. Assessment of the impact on families

The Draft Decree has an indirect impact on families because it aims, among other things, to minimise the risks associated with the use of psychomodulatory substances, which will have a positive impact on public health and the protection of children and adolescents. Specifically, the Draft Decree contains safety and health warnings highlighting the dangers of the use of psychomodulatory substances by persons under the age of 18. Restricting minors' access to these substances and their regulation can contribute to the prevention of health risks in children and adolescents.

11. Assessment of the impact on the performance of the State Statistical Service

The draft legislation contains no provisions that would have an impact on the State Statistical Service.

12. Assessment of compliance with the principles for creating digitally friendly legislation

In accordance with Government Resolution No 870 of 9 December 2019, an evaluation of the compliance of the Draft Decree with the principles for the creation of digitally-friendly legislation was also carried out. The Draft Decree in question does not affect this area and is therefore consistent with these principles.

13. Evaluation of the impact on local and regional authorities

The draft legislation will have no impact on local and regional authorities.

14. Justification for not performing a regulatory impact assessment (RIA)

The draft implementing decree only contains provisions of a technical nature, so on the basis of the General Principles for Regulatory Impact Assessment point 5, sub-point 5.7, it was decided that a regulatory impact assessment would not be prepared.

This Decree was 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 the provision of information in the field of technical regulations and of rules on Information Society services.

II. Specific part

Re § 1

§ 1 defines the areas of regulation of the Decree in connection with the enabling provision of § 44c(7) to implement § 33e(2) and (4) and § 33f(1) and (8) of the Addictive Substances Act. This specifically pertains to:

- the manner in which the particulars on the unit packet and the outer packaging of the psychomodulatory substances shall be indicated,
- the manner in which the consumer information message, warning of the danger of use of the product by minors and the health warning is displayed,
- technical requirements for the composition, appearance, quality and characteristics of psychomodulatory substances, including the maximum permitted amount of active substances in unit packets, maximum permitted concentrations of active substance, prohibited elements and features in the placing on the market of psychomodulatory substances and requirements for maximum permissible chemical and microbiological contamination.
- Requirements of Good Manufacturing Practice (GMP) for manufacturers of psychomodulatory substances

Re § 2

This provision defines terms used in the text of the Decree.

These include in particular the terms ‘active substance’, ‘safety warning of the danger of use of the product by minors’ and ‘health warning’, which are referred to in § 33d(1) of the Addictive Substances Act.

Furthermore, the term ‘distribution with a view to placing on the market’ is intended to distinguish the distribution of a raw psychomodulatory substance from a psychomodulatory substance packed in a unit packet which is already intended to be placed on the market.

In addition, the legislative abbreviations ‘consumer information’, ‘production facility’, ‘production equipment’, ‘establishment’, ‘operational hygiene’, ‘personal hygiene’, ‘individual dose’ and ‘good manufacturing practice’ are introduced to clarify the text.

The concept of ‘verification of quality’ is introduced, in particular, in the light of the obligation laid down in § 33f(2) of the Act.

The term ‘product intended for placing on the market’ clarifies the definition of a psychomodulatory substance pursuant to § 2(1)(l) of the Act, in which a psychomodulatory

substance means psychoactive substances [...] and products thereof, but the products must be precisely defined for the purposes of this Decree.

The term ‘single dose’ is introduced in order to clarify the possibility of adjusting the dose of a psychomodulatory substance within the framework of this Decree.

Re § 3

Requirements for the quality and composition of psychomodulatory substances established on the basis of authorisation pursuant to § 33f(8) of the Addictive Substances Act.

The requirements for the ingredients contained in the product are laid down. Psychomodulatory substances may contain, in addition to active substances and constituents naturally occurring in the psychomodulatory substance, only constituents which do not pose a risk to human health at the concentration used, provided that the psychomodulatory substance is used in accordance with the information message to the consumer and in accordance with the instructions for use. The list of active substances for each psychomodulatory substance is set out in Annex 1 to the Decree. On the basis of the authorisation, Annex 1 also sets out the maximum concentration and the maximum quantity of psychomodulatory substance and active substances contained in the unit packet. This is because the amount of active psychoactive substances is limited to a level that constitutes an acceptable level of risk of adverse effects for the adult consumer at the recommended (normal) dosage. The usual or most frequent use of psychomodulatory substances will be *per os* use, i.e. by mouth and through the gastrointestinal tract. For this reason, the application of food legislation with reference to the possibility of using additives can be considered justified if they comply with the requirements set out in Part B of Annex 2 to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. Additives include sweeteners, binders and other substances that are necessary in the production of the psychomodulatory substances for technological reasons. The use of sugars is also enabled according to the definitions contained in Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, as amended. Oils and fats are also considered to be ingredients that do not pose a risk to human health, which may only be contained in a product intended for placing on the market if the addition increases the safety of the product intended for placing on the market or if it is technically necessary in accordance with § 21(2) of this Decree. Oils or fats could pose health risks when using a psychomodulatory substance by inhalation, for this reason it is prohibited in § 8(4)(d) that the instructions for use contain instructions that would instruct the consumer to inhale a non-burning aerosol if the psychomodulatory substance contains oils or fats. Any admixtures or impurities may only be present in ‘technologically unavoidable’ amounts, i.e. as a natural part of the PMS in PMS of natural origin or as a result of the given technological process of production. The list of chemical and microbiological indicators and their permitted values for contaminants significant to the health are set out in Annex 3 to the Decree. A list of

ingredients which may not be added separately to a psychomodulatory substance, where the restriction in question is based on statutory authorisation, is also provided, namely substances contaminating chemicals and micro-organisms as defined by § 33f(6)(h) of the Act. These are restrictions in addition to those set out in § 33f(6)(e) to (f) of the Act.

Furthermore, the provision in question provides for a restriction in relation to the values of the active substance in the unit packet of the psychomodulatory substance, Annex 1 to which sets out the values which must not be exceeded in the product intended to be placed on the market.

Re § 4

The psychomodulatory substance contained in the unit packet shall be allowed to be divided into several doses of the same composition. For example, a unit packet may thus contain smaller packages containing PMS in powder form, but it must be ensured that the individual packages are of the same composition.

For reasons of normal use *per os*, the packaging requirements for the psychomodulatory substance and its individual doses, in so far as the psychomodulatory substance contains them, also refer to food legislation (Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food, Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, and Decree No 38/2001 on hygiene requirements for products intended to come into contact with food and meals). At the same time, it is not allowed to use edible packaging or packaging impregnated with any substance, such as addictive substances, sugars, sweeteners, vitamins; the list is demonstrative in nature.

Re § 5

The requirements for the appearance and properties of a psychomodulatory substance are established on the basis of the authorisation pursuant to § 33e(2) and (4) and § 33f(8) of the Addictive Substances Act.

A psychomodulatory substance is a psychoactive substance and must meet safety and quality requirements in view of the possible health risks, including risks to persons for whom the product is not intended. a psychomodulatory substance may pose a health risk if handled by children and it is therefore necessary to ensure that these products are secured to prevent handling by children by means of an appropriate child-resistant closure and opening mechanism, e.g. pursuant to ČSN EN ISO 8317 and ČSN EN 862.

Under § 33e(1) of the Addictive Substances Act, the packaging of a unit packet and any outer packaging must be labelled with the words ‘Psychomodulatory substance’ and other particulars must be provided in accordance with § 33e(1) of the Act. The Decree lays down additional labelling requirements for the unit packet and the outer packaging. In order to protect PMS from loss or theft, outer packaging containing more than one unit packet of psychomodulatory substance shall indicate the number of unit packets contained in the outer packaging. In addition, for inspection purposes, the manufacturer shall indicate on the packaging of the unit packet the number of individual doses if the unit packet contains individual doses. The individual dose of the psychomodulatory substance is defined at the same time.

Re § 6

A psychomodulatory substance may be labelled with a brand name chosen by the manufacturer or distributor, whereby the brand name must fill only one line. Furthermore, a barcode or QR code may be provided, but mandatory information may not be provided solely by means of a barcode or QR code due to its availability to all persons, regardless of their technological capabilities.

Re § 7

Section 7 is laid down on the basis of the authorisation in § 33e(2) of the Addictive Substances Act and technically specifies in greater detail the method of labelling psychomodulatory substances in such a way that persons placing the psychomodulatory substances on the market cannot circumvent the obligations concerning packaging labelling. This provision establishes the obligation to define mass or volume data in relation to the form of PMS. The net quantity of a psychomodulatory substance means the actual quantity of a psychomodulatory substance without ingredients added to a product intended for placing on the market. The concentration of the active substances in the psychomodulatory substance must be given as a percentage by weight using the symbol '%' and may be given in a range which includes the actual value of the concentration of the active substance and which does not exceed one third of the average of this range (e.g. 8.5-11.5% for an expected concentration of approx. 10%, 16.7-23.3% for an expected concentration of approx. 20%, etc.).

Furthermore, the provision states that the composition must be indicated on the packaging in descending order to indicate which ingredients are present in the greatest quantities.

Re § 8

This provision of the implementing decree further specifies the form of the consumer information notice and information on the recommended dosage pursuant to § 33e(1)(l) and (m) of the Act.

The information to the consumer consists of the heading 'Consumer information', the text of the information notice itself, which is listed for each psychomodulatory substance in Annex 4 to the Decree, information on the recommended dosage and instructions for use in accordance with Act No 634/1992 on consumer protection, as amended, where necessary given the nature of the product.

The information on the recommended dosage means information on the value of the recommended single dose of the psychomodulatory substance and the recommended daily dose of the psychomodulatory substance, in mg or g for substances which are powdery, solid or semi-solid in consistency or in ml for liquids. If the value of the recommended dose exceeds 1,000 mg, it shall be indicated in g. The recommended dosage may be given in units of tablespoon, teaspoon or number of drops, in which the Decree provides for conversion from units of volume. The recommended dosage may also be given in the number of individual doses of the psychomodulatory substance if the unit packet contains individual doses. However, the recommended dosage may not exceed the maximum values specified in Annex 5 to the Decree. The purpose of this measure is to protect consumers from the excessive use or consumption of psychomodulatory substances in consideration of their psychoactivity.

The instructions for use may not contain instructions that would lead the consumer to smoke the product, i.e. inhale an aerosol produced by combustion, to use it transdermally, i.e. via absorption through intact skin, or to violate the integrity of the skin or mucous membranes, e.g. use by parenteral injection. The purpose of this provision is to protect the health from the negative effects of inhaling smoke produced by combustion and from the significant risks of injection outside a medical setting. It will also not be possible to direct consumers to inhale products containing qualities of oily substances which exceed the limit due to the risk of aspiration lipoid pneumonia, or to use the product transdermally, so as to avoid confusion with products regulated as cosmetics or pharmaceuticals. The instructions for use also have to contain instructions for the storage and safe-keeping of the psychomodulatory substance.

Re § 9

§ 9 ensures that the instructions for use and the information on the recommended dosage do not conflict with the information for the consumer on the packaging. The aim is to avoid ambiguities or misleading interpretations that could lead to improper use of psychomodulatory substances. This requirement contributes to consumer protection, ensures uniformity and consistency of information and minimises the risk of incorrect dosing.

Re § 10

The consumer information referred to in § 8(1) or the packaging of the psychomodulatory substance may not contain any additional text or graphic element which in any way supplements, modifies, comments on, paraphrases or refers to the consumer information. The consumer information referred to in Article 8(1) may be provided directly on the packaging of the product, on an adhesive (meaning a sticker or decal), peel-off, laminated or sandwich label, or may be included in the packaging in another way, as the surface area of the packaging itself may be too small to provide all of the mandatory information. However, information on the recommended dosage must always be provided on the packaging itself.

Re § 11

This section of the Decree elaborates on the obligation to indicate the batch designation on the packaging of the psychomodulatory substance, which is an obligation under § 33e(1)(i) of the Act. This obligation is conceived similarly as for foodstuffs.

Re § 12

This section of the Decree provides in greater detail for the obligation to include a safety warning on the packaging of a psychomodulatory substance about the danger of use of the product by minors, health warnings and information on the possible presence of allergens pursuant to § 33e(1)(o) and (p) of the Draft Act.

The safety warning consists of a graphic sign specified in greater detail in Annex 6 to the Implementing Decree and the text ‘Not for persons under the age of 18’ and ‘Keep out of the reach of children.’. The purpose of the safety warning is to prevent accidental and unintended consumption by children and adolescents and to warn consumers to store and dispose of the psychomodulatory substance so as to prevent unintended consumption.

The health warning consists of the text ‘The use of this product may be hazardous to your health. Observe the information for consumers.’ In order to warn the consumer that the use of the product in question, and in particular use in violation of the instructions for use, poses

a risk to the health, in particular in relation to the psychoactive properties of psychomodulatory substances.

No additional text or graphic element may appear on the packaging that comments on, paraphrases or makes reference to the safety or health warning in any way;

Where any ingredients or excipients are used in the manufacture of psychomodulatory substances which may cause allergies or intolerances in some persons, which may in some cases endanger the health of the persons concerned, and are still present in the final product, this information on their presence must be provided on the unit packet and on the outer packaging as referred to in Article 9(1)(c) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

Re § 13

§ 13 sets out the requirements for how the health warnings will appear on the packaging (size and type of lettering, location on the packaging). The main text referred to in point (c) is the text containing the name, form and subtype of the product in question.

Re § 14

§ 9 of the Decree contains a list of symbols and elements that are not allowed to appear in the labelling and appearance of psychomodulatory substances, e.g. promotional elements of consumption, information giving the impression of benefit to health, mental and physical fitness, or that the product is environmentally friendly. Furthermore, it is not allowed to provide any information suggesting economic benefits or to encourage a mode of use that increases the risks of the psychomodulatory substance in question. Elements and features suggesting a connection with illegal substances, promoting socially undesirable behaviour, suggesting an increased possibility of achieving personal or social achievements, increasing the attractiveness of the product to minors (i.e. elements from youth culture such as popular heroes or animal figures, including comic or fairy-tale depictions, highlighting flavours or aromas particularly attractive to minors, etc.) are prohibited.

The prohibition on the display of such information shall apply to all forms of expression, i.e. text, words, symbols, names, trade names, figurative or other signs, with the exception of information on flavour, which may be given in text form.

In view of the possible doubts as to whether or not a psychomodulatory substance intended for oral use resembles a foodstuff, a provision is included which regulates in greater detail the appearance of an individual dose of a psychomodulatory substance semi-solid or solid, so that its shape is neutral and corresponds to simple spatial geometrical formations. The appearance of PMS of liquid consistency is not regulated, because the volume of all liquid PMS in the unit packet is not allowed to exceed 10 ml, which is a very low volume.

Re § 15

In § 33f(2), the Act lays down an obligation for the manufacturer or distributor of psychomodulatory substances to verify that a batch of PMS meets the requirements for the maximum concentration of active substances and the maximum permissible chemical and microbiological contamination before it is placed on the market. § 10 of this Decree lays down the technical requirements for verifying the quality of the batch, where these technical requirements are provided for in Annex 8 to this Decree.

Re § 16

The provisions in question summarise the areas under good manufacturing practice, which is based on the authorising provisions in § 33f(1) of the Act, where these areas are described in greater detail in the following provisions of the Implementing Decree.

Requirements for employees are not directly specified, as these are regulated in general labour law legislation, such as Title II of Act No 262/2006, the Labour Code, as amended. In the course of its activities, the manufacturer must enter into employment relationships with a number of competent and trained employees so as to comply with good manufacturing practice and at the same time ensure the required quality of the resulting psychomodulatory substance.

Re § 17

The provision in question lays down the minimum requirements for a system designed to ensure that a manufacturer manufactures a psychomodulatory substance that meets the quality requirements. Given the different types of operations and processes, it does not precisely specify what the quality management system should look like, but it allows for flexibility in setting up the system to meet the minimum requirements and internal control mechanisms.

Re § 18

This provision specifies in greater detail the requirements for ensuring operational and personal hygiene laid down in general legislation, such as §§ 104 and 106 of the Labour Code. The manufacturer is obliged to ensure compliance with the principles of operational and personal hygiene in order to minimise the risk of contamination of psychomodulatory substances. Since the use of psychomodulatory substances will be similar to that of food, obligations similar to those for food have been introduced in relation to the personal hygiene of persons who come into contact with PMS during the production thereof.

Re § 19

This provision lays down the requirements for production premises, i.e., the part of the manufacturer’s premises in which the production of psychomodulatory substances or products intended to be placed on the market takes place. Due to the similarity with food and to minimise the contamination of psychomodulatory substances, a level of conditions similar to those in food production was set in relation to materials, structures, surfaces of parts of the production facility. Emphasis is placed on ensuring the simplicity of cleaning and disinfection of entire production areas.

Re § 20

This provision lays down the requirements for production equipment and the manner in which it is installed. The conditions are set so as to minimise the risk of contamination of psychomodulatory substances through production facilities.

Re § 21

This provision lays down certain requirements for production processes and technologies.

This is a restriction of extraction solvents in the extraction of the active substance PMS only within the range of extraction solvents used in the production of foodstuffs as defined in Decree No. 253/2018, on requirements for extraction solvents used in the production of foodstuffs, as amended. The reason for this is to ensure the protection of the user against the use of PMS contaminated with an extraction agent, the health of which is not assured.

Furthermore, in the case of the manufacture of psychomodulatory substances intended for oral use, only the ingredients listed in § 3(3) of this Decree may be used.

Furthermore, the provision provides that the ingredients referred to in § 3(3)(a) of this Decree may not be added to psychomodulatory substances by the manufacturer indefinitely, but the manufacturer may only do so if the addition of such a substance increases the safety of the psychomodulatory substance or if it would not be possible to manufacture a technologically psychomodulatory substance without adding such a component.

Re § 22

This provision contains requirements for the maintenance of documentation demonstrating compliance with the conditions of good manufacturing practice set by the manufacturer, the quantity of psychomodulatory substance produced or processed and the disposal of waste generated during production.

At the same time, there is a requirement to establish an internal system of controlled documentation, which will ensure that production processes are properly documented and make it clear which specific persons will be engaged in specific activities in connection with documentation.

Furthermore, there is a condition of retaining the documentation for at least 5 years after the document was created or since the last record in it, and at the same time there are conditions for storing the documentation. This is to enable the Czech Agriculture and Food Inspection Authority to check individual production activities retrospectively.

The requirements for the content of the documentation are set so as to make it clear which manufacturer is involved, in which premises or production premises the production processes and related activities were carried out, what batches were involved in the activities, what was the source raw material, under what conditions the batch was produced, whether there was any extraordinary event that could affect the production, when the production took place, confirmation that a check for compliance with good manufacturing practice was carried out. If production waste is generated, it is necessary to document when it was generated, to what extent and when it was disposed of.

Re § 23

This provision lays down the minimum requirements for packaging material that can be used to store PMS or to package PMS in a unit packet. In principle, the material used is the choice

of the manufacturer, but it may not be a source of contamination. Related to this is also the requirement to properly store the packaging and ensure the integrity and cleanliness of the packaging.

Furthermore, the provision lays down a requirement for the proper procedure of persons who package psychomodulatory substances to avoid contaminating the psychomodulatory substance during packaging.

Re § 24

The provision in question lays down a requirement for the storage of psychomodulatory substances during manufacture and psychomodulatory substances already packed in a unit packet.

In the case of a PMS which is the raw material for production, it should only be stored in clean production areas to minimise the risk of contamination.

Products from psychomodulatory substances that are already in the form of unit packets may be stored outside the production premises (but within the manufacturer's establishment). However, it should be ensured that at least the minimum requirements for storage conditions are ensured, in which the conditions in question are monitored and documented.

Re § 25

The provision in question relates to waste arising from the manufacture of psychomodulatory substances. These wastes must be sorted according to the nature of the waste, stored and properly labelled. Waste is to be classified in accordance with Decree No 8/2021 on the Waste Catalogue and on assessment of properties of waste (Waste Catalogue). The storage of waste in the production area must be limited to the time necessary.

The concentration of waste must comply with the technical requirements pursuant to Act No 541/2020 on waste, as amended, and Decree No 273/2021 on the details of waste management, as amended. The waste must be concentrated outside the production site but within the manufacturer's premises where the waste was generated.

The provision also stipulates that the manufacturer must set up waste management instructions as part of the internal quality control system, in which the instructions must be part of the operating rules for manufacturing operations.

The provision also lays down the condition of ensuring the disposal of the production waste according to the type and nature of the waste and the condition of ensuring documentation on the implementation of the disposal of the waste.

Re § 26

§ 26 provides for a transitional period for holders of permits for the disposal of psychomodulatory substances to sell psychomodulatory substances that were manufactured before the entry into force of this Decree. Likewise, a transitional period applies to the resale to the holder of a licence for the handling of psychomodulatory substances of products intended to be placed on the market which were manufactured or placed on the market before the entry into force of this Decree.

Re § 27

Given that this is a technical regulation, since it sets out the technical specifications of products to be placed on the EU market, it should be sent for notification in accordance with 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 (the 'Directive').

Re § 28

The effective date of the Decree is proposed in view of the expected duration of the legislative process and in accordance with § 9(2) of Act No 222/2016 Coll. on the Collection of Laws and International Treaties and on the Creation of Legal Regulations promulgated in the Collection of Laws and International Treaties, as amended, dated 1 July 2025.

Annex 1

This contains limits for the maximum quantity of psychomodulatory substance in a unit packet, the list of active substances and their maximum quantity in a unit packet and the maximum concentration of active substances in the psychomodulatory substance.

The above data are provided for psychomodulatory substances currently listed in the List of Psychomodulatory Substances, which constitutes an annex to the Government Regulation on the List of Psychomodulatory Substances:

- Kratom,
- Kratom extract,
- Cannabis containing no more than 1% of substances from the tetrahydrocannabinol group
- Cannabis extract and tincture containing not more than 1% of substances belonging to the tetrahydrocannabinol group.

Whenever the Government Regulation on the List of Psychomodulatory Substances is extended to include a new substance, it will be necessary to amend Annex 1 with information on the newly added psychomodulatory substance.

Transitional provisions introduced by Act No 321/2024 Art. II enables the Government to decide, in justified cases, within one year from the date of entry into force of this Act, to include a new psychoactive substance in the list of psychomodulatory substances. In the case of this procedure, § 33i(2) of the Addictive Substances Act shall apply mutatis mutandis and § 33i(1) of Act No 167/1998, in the version in force from the date of entry into force of this Act, shall not apply. A rapid evaluation of the substances proposed for inclusion in the List of Psychomodulatory Substances is therefore sufficient.

The set maximum amount and minimum concentration of active substances should then be seen in the context of Annex 5 and its justification, i.e. the setting of the maximum permitted single dose and the maximum permitted daily dose of the active substance.

Annex 2

It contains the names, forms and sub-types of psychomodulatory substances that may be placed on the market and the corresponding characteristic appearance and characteristics. Data are provided for psychomodulatory substances currently included in the List of

Psychomodulatory Substances annexed to the Government Regulation on the List of Psychomodulatory Substances.

Whenever the Government Regulation on the List of Psychomodulatory Substances is extended to include a new substance, it will be necessary to amend Annex 2 with information on the newly added psychomodulatory substance.

Annex 3

This Annex lays down the chemical and microbiological requirements for psychomodulatory substances. It contains chemical parameters, i.e. contaminants and toxicologically relevant substances, and microbiological parameters and their acceptable values.

They have been selected with regard to their health risks from occasional exposure in adults and are also used in food surveillance as indicators of health safety with regard to chemical and microbial contamination.

Annex 4

It contains the text of a consumer information notice for each psychomodulatory substance included in the List of Psychomodulatory Substances annexed to the Government Regulation on the List of Psychomodulatory Substances (see Annex 1 above).

Whenever the Annex to the Government Regulation on the List of Psychomodulatory Substances is extended to include a new substance, Annex 4 will need to be amended with information on the newly added psychomodulatory substance.

The text of the information notice shall include a warning that the product has psychoactive effects, is not a food or food supplement and is not a medicinal product. It is also recommended to consult a physician if the user is not sure that this product is suitable for him or her.

In addition, the text for each psychomodulatory substance (or group of psychomodulatory substances) indicates the effects of the substance and a warning of the adverse effects of the substance resulting from its psychoactivity and a recommendation not to use it immediately before and for a period of less than 8 hours before activities in which attention is required (e.g. driving a motor vehicle). There is a warning that the product is not intended for children and a recommendation not to use the product in conjunction with other psychoactive substances or medicines, during pregnancy or breastfeeding, during mental illness or in disorders of the function of the kidneys, liver, heart and blood vessels, taking possible side effects into account (e.g. considering the limited capacity for metabolising the substance). Furthermore, recommendations not to exceed the recommended daily dose and to store the product out of reach of children are specified.

Annex 5

This Annex contains the maximum permitted single doses and the maximum permitted daily doses of the active substance for the recommended single and daily dose values for each psychomodulatory substance. The doses shown in the table are for the recommended oral doses. Oral use is defined as a use that involves swallowing a substance in which absorption mainly takes place in the inner parts of the digestive tract, i.e. not exclusively or nearly exclusively in the oral cavity. For uses other than oral uses, the maximum permitted single and daily doses are reduced to 30 % of the value of the oral doses shown in the table. This

coefficient is based on the fact that the bioavailability of the different routes of administration for most psychoactive substances is highest for intravenous (=100%) and intramuscular (≈ 100%) injections, lower for other parenteral administrations (≈ 40-50%) such as intranasal sublingual or inhalation, and lowest (≈ 10-25%) for oral use (1-8).

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As regards kratom, the main active substances are the indole alkaloids mitragynine and 7-hydroxymitragynine (1, 2). Mitragynine accounts for up to two thirds of the alkaloid content. 7-hydroxymitragynine accounts for about 1-2 % of the alkaloid content and is also produced by the metabolism of mitragynine in the body. Mitragynine and 7-hydroxymitragynine act as partial μ-opioid receptor (MOR) agonists, with 7-hydroxymitragynine being about 9 times more effective than mitragynine. The activation of the μ-opioid receptor is considered responsible for most of the pharmacological effects of kratom. Kratom alkaloids are non-traditional MOR agonists in the sense that they activate MOR coupled with a G-protein but not the beta-arrestin pathway. This results in much less respiratory depression or physical dependence. Kratom alkaloids also act as antagonists at the kappa- and delta-opioid receptors, but with less intensity. Mitragynine also binds to alpha1- and alpha2-adrenergic receptors, 5-HT1A and 5-HT2A serotonin receptor sub-types, as well as the dopamine receptor D1. The binding to these receptors appears to have a stimulating, sympathomimetic effect that in small doses outweighs the sedation caused by the association with MOR (1).

Although the active substances mitragynin and 7-hydroxymitragynin are μ-opioid receptor agonists, side effects such as respiratory depression, coma, pulmonary oedema and direct death have not been observed. The greatest risks are use in combination with alcohol, other psychoactive substances, as well as undesirable interactions with other medicines, primarily because kratom reduces the activity of liver enzymes responsible for the metabolism of exogenous substances, including pharmaceuticals and drugs (2-4). In addition, possible cardiotoxicity is attributed to kratom due to the inhibition of the calcium channels. The most common manifestations are tachycardia and hypertension. Some *in vitro* studies have found

that mitragynine causes QT interval prolongation[1] and therefore there is an increased risk of malignant ventricular tachycardia (known as torsades de pointes) (5). However, recent studies in long-term kratom users have found that QTc interval prolongation occurs, but not above the cut-off level (6, 7).

In general, kratom is considered a relatively safe natural drug, acute toxicity is very low. Deaths in rats were only observed at a dose of 200 mg/kg body weight in the administration of kratom alkaloid extract (8).

A number of studies show that the most common dose of kratom plant material (ground leaves) is in the range of 2-6 grams, which is influenced by both the type of kratom and the intent of the user, depending on whether he/she wants a slightly stimulating (lower dose) or rather relaxing (higher dose) effect (9). These data are consistent with the data on use in the Czech Republic (10-12). Alkaloids are absorbed from the gastrointestinal system when kratom powder is taken, depending on the individual state of the intoxicated subject (on an empty stomach, after a meal). The initial effect is most often observed after 5-10 minutes after taking and lasts no more than 6 hours. In the animal study, mitragynine only has a low oral bioavailability of 3% (13). A 2015 study of 10 male volunteers (14) reported a elimination half-life of 3.5 h and a 2018 study of 2.5 h (15). On the basis of the above-mentioned data, the maximum recommended single dose and the maximum recommended daily dose of active substances for the psychomodulatory substances Kratom and Kratom extract were selected after consultation between representatives of the Government Office, the Ministry of Health, the National Institute of Public Health, the Ministry of Agriculture and the Czech Agriculture and Food Inspection Authority, although the data were not revised by the State Health Institute due to the lack of established toxicological data.

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With regard to cannabis of up to 1% THC and extracts thereof, the content of the tetrahydrocannabinol group of substances in these products is such that the psychoactive effect of THC is none or very low depending on the dose. In addition, cannabidiol (CBD), which is regularly present in relatively high concentrations in these extracts, mixtures or solutions, inhibits the action of substances from the tetrahydrocannabinol group on CB1 receptors. The National Institute of Public Health based its determinations of the maximum permitted single dose and the maximum permitted daily dose of active substances of cannabis substances containing no more than 1% of substances from the group of tetrahydrocannabinols and Cannabis extract and tincture containing no more than 1% of substances from the group of tetrahydrocannabinols on the scientific opinion of the European Food Safety Authority (EFSA), which specifies the LOAEL (Lowest Observed Adverse Effect Level) and other toxicological points used to determine the required values. The evaluation took into account in particular the pharmacological and toxicological properties of the substance, as well as the degree and nature of psychoactivity of the substance, which also corresponds to the established maximum recommended single dose and the maximum recommended daily dose of active substances for the substance cannabis up to 1% THC and extracts thereof.

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Annex 6

This specifies the form of the graphic safety warning sign, which has the character of a prohibition sign, i.e. it is circular in shape with a white background and a circle with a red reinforced edge, a red diagonal stripe across the text indicating prohibition of use by children and minors.

Annex 7

This Annex lays down technical requirements for verifying the quality of a batch of psychomodulatory substances as defined by § 33f(2) of the Act.