Explanatory memorandum

Draft Government Regulation on the list of psychomodulatory substances

1. General part

1. Description of the content of the draft legislation, stating the reasons for its submission and a summary of the basic principles and the most important changes it introduces compared to the current legislation

With the entry into force of Act No 321/2024 amending Act No 167/1998 on addictive substances and amending certain other acts (hereinafter the 'Act'), it will be possible from 1 January 2025, subject to compliance with the conditions laid down in the Act, to schedule substances in the group of scheduled psychoactive and psychomodulatory substances. This will allow the evaluation of these substances, ensure their limited availability, and thus protect health, in particular of the sensitive child population, while preventing the criminalisation of the possession of these substances by individuals. The scheduling of substances is therefore primarily aimed at protecting children and preventing the occurrence of intoxication, especially in young people.

2. Assessment of the existing legal situation

New psychoactive substances complying with the definition of psychomodulatory substance in accordance with § 2(l) of Act No 167/1998 on addictive substances and amending certain other acts, as amended from 1 January 2025 (hereinafter the 'Act'), and in accordance with § 33i(2) of the Act, which shall apply mutatis mutandis, may be included in the annex to the Government Decree or in the list of psychomodulatory substances in the first year following the effective date of the Act on the basis of Article II(1) of Act No 321/2024. The Ministry of Health proposes to the Government to schedule the new psychoactive substance in cooperation with the National Health Institute and the Office of the Government of the Czech Republic, and the proposal includes a rapid evaluation of the newly scheduled psychoactive substances.

The four newly scheduled substances (kratom, kratom extract, hemp up to 1% THC and hemp extract and tincture up to 1 % THC) fulfil the condition laid down in the Act, because they do not pose a serious risk to public health or a risk of serious social impacts on individuals and society on the basis of the existing scientific knowledge, and for this reason it is possible to place the substances in question on the market under the conditions laid down by the Act and implementing legislation.

3. Evaluation of the compliance of the draft legislation with the constitutional order and other components of the legal order of the Czech Republic

The proposed draft Government Regulation respects the scope and limits of the legal authorisation pursuant to Act No 167/1998

4. Evaluation of the compliance of the draft legislation with the obligations arising for the Czech Republic from its membership of the European Union

The draft Government Regulation is compatible with the following European Union legislation:

Articles 34 and 36 of the Treaty on the Functioning of the European Union (hereinafter 'TFEU').

The present draft is compatible with Articles 34 and 36 TFEU, '), as under Article 36 TFEU, the free movement of goods may be restricted for reasons such as the protection of public health, public security, or the prevention of crime, provided that such restrictions are not manifestly discriminatory, are proportionate (necessary to achieve a legitimate objective), and are implemented in a way that does not infringe the principle of proportionality. The scheduling of four new substances (kratom, kratom extract, hemp up to 1% THC, and hemp extract and tincture up to 1% THC) in the annex to the Government Regulation is based on the need to regulate access to these substances, the free and unregulated availability of which would seriously endanger the health of the population, especially children and adolescents, and could potentially increase the use of these substances with the risk of addiction, where the unrestricted expansion of the availability of these substances on the market would result in negative social impacts. The protection of public health is recognised as a legitimate reason under Article 36 TFEU to restrict the free market, provided that it is ensured that the measures do not discriminate against products from other EU Member States and that they comply with the principle of proportionality.

The scheduling of substances in the list of psychomodulatory substances was based on expert knowledge and the current level of understanding and risk assessment. The scheduling of the substances is therefore compatible with Article 34 TFEU, since that measure pursues a legitimate objective of protecting public health, does not give rise to unjustified discrimination and is proportionate to the risks posed by those substances. Consequently, the scheduling of these substances does not lead to an unjustified interference with the free movement of goods.

In the economic and business circulation, the European Union, as a lex specialis to the free movement of goods under Article 34 et seq. TFEU, will also apply the rules of other EU regulations, such as regulations

1. concerning food:

• • Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, as amended;

• • Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, as amended;

2. concerning medicinal products:

• Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended;

3. concerning tobacco products:

• 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;

4. concerning cosmetic products:

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

In order to expedite the legislative process concerning the protection of public health, an exemption from the interdepartmental consultation procedure and regulatory impact assessment (RIA) was granted on 20 December 2024.

5. Assessment of compliance of the draft legislation with international treaties binding on the Czech Republic.

The proposed draft Government Regulation is also in line with the international treaties by which the Czech Republic is bound.

6. Assessment of whether the draft legislation contains a provision which, by its nature, would be a technical regulation under the legislation

regulating technical requirements for products

Given that this is a technical regulation, 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 (hereinafter the 'Directive').

7. Information on compliance with the notification obligation under this legislation (in relation to non/included provisions, which by their nature would be a technical regulation under the legislation regulating technical requirements for products)

The draft Government Regulation will be announced after the Government approves the draft.

8. Information on the consultation of the European Central Bank on draft legislation and the outcome of the consultation if the draft legislation is subject to such consultation

Draft government regulations are not subject to consultation with the European Central Bank.

9. Expected economic and financial impact of the draft legislation on the state budget and other public budgets

Impacts on the state budget can be presumed, as the inclusion of the substances in question in the list of psychomodulation substances introduces a regime for these substances where a handling authorisation issued by the Ministry of Health is required for their production, distribution and marketing, while an administrative fee is to be paid depending on the type of activity. At the same time, in connection with the expansion of the list of psychomodulatory substances, a higher burden on control authorities and thus higher expenditure from the state budget can be expected, but these will be covered by the approved budget of Chapter 335 for 2025 et seq. However, since it is not possible to estimate the number of entities that will be interested in engaging in the new regulated sales of the substances in question, it is also not possible to estimate the impact on the state budget.

10. Expected impact of the draft legislation on the rights and obligations of natural and legal persons

The rights and obligations of natural persons and corporate entities arise from Act No. 167/1998; the present draft Government Regulation does not establish any new rights or obligations.

11. Expected impact of the draft legislation on the business environment of the Czech Republic

Impacts on the business environment can be expected, as in connection with the scheduling of the substances in the list of psychomodulatory substances, entities wishing to handle the substances will need to adapt to the new legislation, i.e. they will have to obtain authorisation to handle psychomodulatory substances, they will have to ensure that the products comply with the requirements of the law and implementing legislation, they will have to keep records of the handling of the substances and submit annual reports to the Ministry of Health. Otherwise, they will have to cease their activities.

12. Projected social impact of the draft legislation, including the impact on specific groups of the population, in particular the socially vulnerable, persons with disabilities and national minorities

The amendment will have a positive impact on the reduced availability of the substances to persons under the age of 18 and will ensure the quality of the products sold, thus ensuring greater protection of vulnerable groups against the use of the substances in question.

The inclusion of the substances in question in the list of psychomodulatory substances creates an obligation for manufacturers, distributors, and sellers to ensure the required quality of the substance supplied, including consumer information, health warnings, and warnings against use by children, which should increase consumer protection, in particular against the negative effects of excessive quantities of active substances.

13. Expected impact of the draft legislation on equality between men and women, where the draft legislation regulates or affects the status of natural persons

The proposed legislation contains no provisions that could result in discrimination.

14. Expected environmental impact of the draft legislation

The proposed Government Regulation has no negative impact on the environment.

15. Expected impact of the draft legislation on the protection of children's rights

The amendment will have a positive impact on the reduced availability of the substances to persons under 18 years of age.

16. Expected impact of the draft legislation on national security or defence

The draft amendments have no impact on the security or defence of the state.

17. Expected impact of the draft legislation in relation to the protection of privacy and personal data

The proposed legislation does not concern the protection of privacy or personal data.

18. Assessment of whether the draft legislation constitutes State aid

The draft Government Regulation does not constitute State aid.

19. Assessment of corruption risks of the draft legislation

The draft legislation is not expected to create or increase corruption risks.

20. Justification for a possible proposal for the Chamber of Deputies to give its consent to the draft legislation at first reading (if proposed)

Not proposed.

21. Justification for any proposal that the proposed legislation should enter into force earlier than the beginning of the 15th day following the date of its publication (if proposed)

Not proposed.

22. Justification for derogations in the procedure for discussing draft legislation (if proposed and different from previous ones) (if proposed, may be covered by previous chapters)

There are no derogations in the legislative procedure.

11. Special part

Justification of the individual provisions of the draft legislation; the justification contains an explanation of

their purpose and necessity, a description of the legal rules contained therein and the rights and obligations arising therefrom [within the meaning of § 20(2)(i) of Act No 222/2016]

Regarding the entire Government Regulation

Re § 2

Given that this is a technical regulation, 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 (hereinafter the 'Directive').

Re § 3

The date of entry into force is determined, in accordance with § 9(2) of Act No 222/2016 on the Collection of Laws and International Treaties and on the creation of legislation promulgated in the Collection of Laws and International Treaties (the Act on the Collection of Laws and International Treaties), as amended, as of 1 July 2025.

Re the Annex

Kratom (Mitragyna speciosa) is scheduled in the Annex to the Government Decree. The substance in question is currently on the Czech market, in a grey area, where it is sold as a collector's item, most often in the form of powder from the crushed leaves of the Mitragyna speciosa plant. There was an extensive discussion at the political level regarding this substance, addressing whether to schedule the substance in the list of addictive substances, wherein the handling of the substance by a natural person for personal use also constituted an unlawful act by the given natural person. In view of the fact that kratom is often used by students to improve their academic achievements and to prevent the criminalisation of the persons concerned, the Czech Republic finally decided, on the basis of a parliamentary proposal, to create a new system of regulation for kratom and similar substances that, under current scientific knowledge, do not pose a serious risk to public health or a risk of serious social impacts on individuals and society.

Kratom is a common name for Mitragyna speciosa Korth, a tree native to Southeast Asia. The native population has used kratom leaves for centuries as an herbal remedy to treat various health problems, especially pain and to reduce withdrawal symptoms in opioid addiction. Another reason to consume it is to increase energy and reduce fatigue, especially for manual workers. Lower doses have stimulating effects, while higher doses have opioid-like effects. Kratom is taken almost exclusively orally, usually by chewing leaves, ingesting leaf powder, or drinking kratom tea or suspensions of finely ground leaves. More than 40 alkaloids have been identified in kratom, but biological effects have only been studied in some of them: mitragynine, 7-hydroxymitragynine, corynantheidine, and speciociliatine.1 In general, kratom is considered a relatively safe natural drug, with acute toxicity being very low. Even though deaths in rats were only observed at a dose of 200 mg/kg kratom alkaloid extract.2, kratom has been placed on the Drugs of Concern list by the United States Drug Enforcement Administration (DEA). The Expert Group on Drug Addiction of the World Health Organization assessed kratom during its 44th session and concluded that kratom should be included in the watch list, but did not recommend the inclusion of kratom in the lists of narcotic drugs or psychotropic substances. At the same time, a document of the Drug Addiction Expert Group entitled 'Pre-Review Report Kratom (Mitragyna speciosa), mitragynine, and 7-hydroxymitragynine' contains information on the toxicity and potential for addiction associated with the use of kratom, with detailed references to this material[1].

Reports on kratom indicate a frequent occurrence of kratom in schools, even at the primary level, where it is used in combination with sweetened beverages such as juices or so-called energy drinks. Medical

facilities also report an increasing number of intoxications related to kratom use. Data from the Toxicology Information Centre indicate the need for regulation of kratom, especially a strict ban on consumption by children and adolescents. At the same time, the quantities of kratom imported into the Czech Republic are increasing, with reports from the Customs Administration showing that since 2021, when the monthly average was around 2.6 tonnes, imports increased to a monthly average of 33.5 tonnes in 2024.

It is clear from these data that there is a substance on the market in the Czech Republic that needs to be regulated to prevent sale to persons under 18 years of age and to ensure a low level of active substances, which are potentially dangerous at higher concentrations, for persons over 18 years of age. The content of active substances, substances dangerous to human health, and the maximum possible amount in a unit packet shall be laid down in other implementing legislation to Act No 167/1998, which shall be adopted following the entry into force of the Government Regulation in question.

The substance **Kratom extrakt** is being scheduled in the Annex to the Government Decree. It is a preparation made from kratom. The specific authorised forms of the product are laid down in another implementing legislation to Act No 167/1998, which will be adopted following the entry into force of the Government Regulation in question. In other respects, reference can be made to the justification given for 'Kratom'.

The substance **Cannabis up to 1% THC** (Cannabis containing no more than 1% of substances belonging to the tetrahydrocannabinol group) is being scheduled in the Annex to the Government Decree. It is the flowering or fruiting top of a cannabis plant (Cannabis) or the aerial part of a cannabis plant, which includes a top containing the sum of substances of the tetrahydrocannabinol group and their acids up to a maximum of 1% of the content of the substance, intended for human consumption or for processing for human consumption, excluding the source material for processing into food or cosmetics.

After the entry into force of Act No 366/2021, by which the term 'industrial hemp' has been introduced into Czech law and that has been defined by § 2(1)(g) of Act No 167/1998 as 'hemp from the industrial hemp plant' and at the same time § 5(5) of Act No 167/1998 was amended to read 'A licence to handle industrial hemp plants or industrial hemp, in particular for industrial, food, cosmetic, technical or horticultural purposes, is not required'. With this legislative change, the market for inflorescences of industrial hemp plants for personal use has expanded significantly. In view of the huge expansion and the fact that the criminal justice authorities did not see the conduct in question as a social danger reaching the level of a crime, an essentially unregulated market for products that have psychoactive properties has arisen. Due to the fact that a group of Members of Parliament proposed a law to introduce strict regulation of psychoactive substances with low health hazards and low social impacts on individuals and society, the legislation in question was evaluated as a suitable vehicle for the regulation of low-potency cannabis intended for human use.

It should be noted that these are products that are offered for human consumption and are also produced and manufactured for this purpose, and therefore do not fall under the treatment defined in § 5(5) of Act No 167/1998. Hemp with a content of substances from the tetrahydrocannabinol group of up to 1% is, if it is not intended for human use, considered to be industrial hemp, which can be handled without a licence to handle addictive substances and preparations and identically without a licence to handle psychomodulatory substances. Given the similarity mentioned above, it is necessary to keep documentation from the beginning of cultivation on the purpose of handling industrial hemp plants in order to distinguish whether the treatment will be directed to the area of addictive substances or to the area of psychomodulatory substances. It should be noted that cannabis containing up to 1% of substances from the tetrahydrocannabinol group cannot be used in food for direct consumption, and therefore such cannabis will always be considered psychomodulatory substances.

Cannabis extract and tincture up to 1% THC (Cannabis extract and tincture containing not more than 1% of substances of the tetrahydrocannabinol group) is included in the Annex to the Government Decree. It is an extract or tincture obtained from cannabis with up to 1% THC, containing a total of substances from the tetrahydrocannabinol group and their acids at a level of 1% of the substance content, intended for

human consumption or for processing for human consumption, excluding the source material for processing into food or cosmetics, and preparations thereof.

After the entry into force of Act No 366/2021, which introduced into Czech law an exception to the definition of addictive substance set out in § 2(1)(a) of Act No 167/1998, as amended, 'For the purposes of this Act, addictive substances shall mean narcotic substances and psychotropic substances of natural or synthetic origin that have psychoactive effects and are simultaneously listed in one of Annexes 1 to 7 to the Government Regulation on the list of addictive substances, **with the exception of the substance hemp extract and tincture containing at most**

1% of substances belonging to the tetrahydrocannabinol group and meeting the safety requirement of the General Product Safety Act', where for the substance cannabis extract and tincture under the above conditions, it is not required to meet the conditions required by Act No 167/1998 for addictive substances. Similarly, an exemption has been introduced from the concept of a preparation, which has been redefined as 'a solution or mixture in any physical state containing an addictive substance or an addictive substance and a scheduled substance of category 1 or a medicinal product containing a scheduled substance of category 1, **with the exception of a solution or mixture containing the substance hemp extract and tincture containing not more than 1% of substances belonging to the tetrahydrocannabinol group; the solution or mixture must contain the substance hemp extract and tincture in such a quantity that this substance can not be misused or easily or economically extracted from the solution or mixture. Such a solution or mixture must meet the safety condition laid down in the General Product Safety Act**'. The substance or preparation containing the substance in question is intended for further processing into substances that are not addictive substances and not for use by an individual. However, following that legislative amendment, products appeared on the market in the Czech Republic that contained information that they were intended for collecting purposes, industrial processing, or consumption, but did not meet the conditions laid down for foodstuffs or medicinal products. This has created an unregulated market that is a source of products potentially hazardous to health, both for single and long-term use. With regard to the fact that these are not addictive substances in terms of Act No 167/1998 and at the same time the products in question fall into a grey area, there is no control that would protect consumers from any negative impacts on their health. For these reasons, it is proposed the substance in question to be scheduled in the list of psychomodulatory substances in order to ensure the protection of children and adolescents from the free use of the substance in question, while at the same time ensuring the standardisation of products with regard to the maximum levels of active substances.

[1] unedited--advance-copy-44th-ecdd-review-report_kratom.pdf (who.int).