I.

Explanatory memorandum

Draft Government Regulation amending Government Regulation No 458/2013 on the list of starting substances and excipients and their annual quantitative limits, Government Regulation No 463/2013 on lists of addictive substances and Government Regulation No 11/2025 on the list of scheduled psychoactive substances

I. 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, and assessment of the current legal situation.

The draft Government Regulation amending Government Regulation No 458/2013 on the list of starting substances and excipients and their annual quantitative limits, Government Regulation No 463/2013 on lists of addictive substances, and Government Regulation No 11/2025 on the list of scheduled psychoactive substances includes HHC in the list of addictive substances, specifically in Annex 4, Psychotropic Substances; this substance is simultaneously removed from the list of scheduled psychotropic substances. Furthermore, GBL is removed from the list of starting substances and excipients, as it is already included on the list of psychotropic substances. The rescheduling of HHC is based on a decision by the United Nations Commission on Narcotic Drugs. At its 68th session in March 2025, the Commission on Narcotic Drugs added Hexahydrocannabinol (HHC) to Schedule II of the 1971 Convention on Psychotropic Substances. The change in scheduling takes effect six months (180 days) after the official notification by the Secretary-General of the United Nations. The amendment to the scheduling was notified to all party states on 9 June 2025 and will take effect on 6 December 2025. For this reason, it is necessary to transfer HHC to the list of addictive substances as soon as possible. The Ministry of Health did not propose this rescheduling in the previous amendment to Government Regulation No 463/2013 and No 11/2025 because the Anti-Drug Policy Department of the Office of the Government of the Czech Republic was negotiating at the international level regarding the possibility of keeping HHC on the current list of scheduled psychoactive substances. However,

these negotiations were unsuccessful, which is why the Ministry of Health is now submitting this proposal in order to fulfil the Czech Republic's international obligations.

2. Assessment of compliance of the draft legislation with the Act it is to implement, including compliance with the statutory authorisation to issue the legislation and compliance with the constitutional order the Czech Republic.

Pursuant to § 44c(1)(d) in conjunction with § 44(2)(d) of the Addictive Substances Act, a substance that is scheduled as a prohibited substance pursuant to international conventions can be included in Annex 4 to the Government Regulation.

3. Assessment of compliance of the draft legislation with the Czech Republic's obligations that follow from its membership in the European Union and assessment of the draft legislation's compliance with international treaties by which the Czech Republic is bound.

The draft Government Regulation is consistent with the Convention on Psychotropic Substances of 1971 and European regulations.

The present draft is in accordance with Article 34 et seq. of the Treaty on the Functioning of the European Union (hereinafter '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 (i.e., necessary to achieve a legitimate objective), and are implemented in a way that does not violate the principle of proportionality. The scheduling of three THC derivatives and plants of the Mitragyna genus (Annex to Government Regulation No 11/2025) and the rescheduling of HHC (from Government Regulation No 11/2025 to Regulation No 463/2013) is based on the need to regulate access to addictive substances whose free availability would seriously endanger the health of the population, cause an increase in the use of addictive substances with a risk of dependence, the spread of these dangerous substances on the market or their production, which would ultimately lead to 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 new substances in the list of scheduled addictive substances was based on the expertise and recommendations of European and international organizations, for example the European Union Drugs Agency (EUDA), and does not restrict trade in other substances that do not have addictive potential. The scheduling of new substances in the Annex to Government Regulation No 11/2025 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.

It is proposed to transfer HHC from the List of Scheduled Psychoactive Substances to the List of Addictive Substances, as the category of scheduled psychoactive substances by definition [new psychoactive substances as defined in Article 1(4) of Council Framework Decision 2004/757/JHA laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking ('the Council Framework Decision'), where the

definition reads as follows: ‘a substance in pure form or in a preparation that is not covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances but may pose health or social risks similar to those posed by the substances covered by those Conventions’] cannot contain any substance listed in any of the international conventions on narcotic drugs and psychotropic substances. Pursuant to Act No 167/1998 on addictive substances and amending certain other acts, as amended, substances scheduled in the list of scheduled psychoactive substances are temporarily included in the list pending sufficient evidence of their final risk assessment, on the basis of which these substances are transferred to the list of addictive substances or the list of psychomodulatory substances or completely removed from the lists. The legislator has set a two-year time limit for this assessment, which may be extended if there is insufficient data to make a decision. However, the explanatory memorandum for Act No 321/2024 clearly states that the reason for removing a substance from the list of scheduled psychoactive substances is its international classification on one of the international schedules, whether at the EU or UN level. The WHO has carried out a risk assessment of HHC and proposed its inclusion in the list of psychotropic substances. It was precisely this situation that the legislator clearly anticipated as a reason for transferring the substance from the list of Scheduled Psychoactive Substances to the list of Addictive Substances. For reasons of compliance with international obligations, it is not sufficient to retain HHC in the category of Scheduled Psychoactive Substances. In addition to the above definition of a new psychoactive substance, it is also the case that, in terms of the definition of a drug, the Council Framework Decision mirrors Government Regulation No 463/2013 on lists of addictive substances, as amended, which follows from § 44c of Act No 167/1998, as amended, and not Government Regulation No 11/2025 on lists of scheduled psychoactive substances, which mirrors the definition of a new psychoactive substance. This inconsistency with the European legal framework could not only create conditions for initiating proceedings against the Czech Republic for inconsistency with European legislation, but could also lead to differences in international cooperation in the assessment of crimes and subsequent extradition of offenders.

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

The draft legislation will not have an impact on the state budget or on other public budgets.

5. Justification of any potential draft that the proposed legislation come into effect on a date other than 1 January or 1 July of the calendar year.

The reason for determining the effective date pursuant to § 9(3) of the Act on the Collection of Laws and International Treaties is the fulfilment of international obligations arising from the 1971 United Nations Convention on Psychotropic Substances.

6. 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 that legislation.

The draft legislation does not need to be notified pursuant to 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 standards and regulations, and of rules on Information Society services.

7. Expected impact of the draft legislation, in particular.

7.1 Impact on the rights and obligations of natural and legal persons.

The draft legislation has no impact on the environment.

7.2 Impact on the business environment of the Czech Republic.

The proposed transfer of the substance hexahydrocannabinol (HHC) from the list of scheduled psychoactive substances to the list of addictive substances does not have a direct impact on the legal business environment, as this substance can no longer be legally handled outside the scope of research purposes. However, the transfer strengthens the legal regime, in particular in the area of criminal liability, thereby enhancing legal certainty and enforcement in cases of illegal production, distribution, and further handling of the substance. From the perspective of the business environment, this measure contributes to curbing the illegal market and protecting legally operating entities from unfair competition.

7.3 Assessment of whether the draft legislation constitutes State aid.

The proposed legislation does not establish public support.

7.4 Social impact, including impact on specific groups of the population, in particular the socially vulnerable, persons with disabilities and national minorities.

The draft legislation has no impact on the environment.

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

The draft legislation has no impact on the environment.

7.6 Environmental impact.

The draft legislation has no impact on this area.

7.7 Impact on the protection of children’s rights.

The draft legislation has no impact on the environment.

7.8 Impact on national security or defence.

The draft legislation has no impact on this area.

7.9 Impact relating to the protection of privacy and personal data.

The proposed legislation does not concern privacy.

8.10 Impact on local and regional authorities.

The draft legislation has no impact on this area.

8.11 Impact in the area of digitally friendly legislation.

Given the nature of the draft 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.

8.12 Impact on families.

The draft legislation has no impact on the environment.

8. Assessment of corruption risks associated with the draft legislation.

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

9. Information under the Lobbying Regulation Act

The submitters are not aware of any lobbying having taken place during the preparation of the proposal.

II. Special part

Re: Part One (Amendment to the Government Decree on the list of starting substances and excipients and their annual quantitative limits)

Re: Article I

Re: Annex table

Re: gamma-butyrolactone (GBL)

GBL is already included in the list of psychotropic substances and should therefore be removed from the list of starting substances and excipients, where it was originally included.

Re: Part One (Amendment to the Government Regulation on lists of addictive substances)

Re: Article II

Re: Annex 4 table and Re: Part Three, Article IV, Annex table

Re: hexahydrocannabinol (HHC)

At its 68th session in March 2025, the United Nations Commission on Narcotic Drugs added HHC (II) and carisoprodol (IV) to Schedules II and IV of the 1971 Convention. The change in scheduling shall take effect six months (180 days) after the official notification by the Secretary-General of the United Nations. The amendment to the scheduling in the list was notified to all party states on 9 June 2025 and shall enter into force on 6 December 2025. However, HHC is on the list of Scheduled Psychoactive Substances in the Czech Republic, where it is subject to a certain oversight regimen for the duration of the review, which is still ongoing. The list of

scheduled psychoactive substances is based on the definition of new psychoactive substances stated in Council Framework Decision 2004/757/JHA laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as amended, and is therefore not adequate for listing under the 1961 and 1971 Conventions. This should correspond to the scheduling among psychotropic substances according to the lists in Government Regulation No 463/2013 on lists of addictive substances, either in Annex 4 or 5. Given that it is currently unclear whether HHC has therapeutic potential, it is proposed that it be included in Annex 4.

HHC was included as a psychotropic substance in Schedule II of the 1971 Convention because of its structural similarity to THC, the psychoactive effects of one of its stereoisomers, which willingly binds to cannabinoid receptors in the brain, leading to changes in mood, perception and behaviour. There have been cases of disturbances of consciousness, aggressiveness, nausea, and mood swings among users. Its safe use is complicated by a lack of toxicological data; there are no reliable data on the acute or chronic toxicity of HHC. Cases of severe intoxication have been reported in the Czech Republic, including among young people, and for this reason HHC has been temporarily classified as a psychotropic substance in Annex 4. The concentration of HHC in some products reached tens of percent, and several children were poisoned due to foods sold containing HHC (gummy bears, biscuits). For the reasons stated above, the Ministry of Health proposes its rescheduling in Annex 4 psychotropic substances.

Since HHC acts on the same receptors as THC, it may have similar analgesic or anxiolytic effects. There is a lack of clinical studies and no verified research confirming the safe therapeutic profile of HHC. The risks outweigh the benefits, and experts currently agree that HHC should not be used as a medicine due to its unclear toxicity.

Re: Part Three (Amendment to the Government Decree on the list of scheduled psychoactive substances)

Re: Article IV

Re: Annex table

EDMB-4en-PINACA is an indazole-based synthetic cannabinoid structurally related to internationally controlled MDMB-4en-PINACA (Annex II to the 1971 UN Convention on Psychotropic Substances). This substance was detected in samples in Italy, France, Denmark, and Turkey. This substance was also detected in cannabis samples in the Czech Republic during inspections carried out by the Czech Agriculture and Food Inspection Authority (CAFIA).

No information is available on the pharmacology and toxicology of EDMB-4en-PINACA. Given its chemical structure and similarity to MDMB-4en-PINACA, EDMB-4en-PINACA is expected to act as a cannabinoid receptor agonist.

France reported adverse effects following consumption of EDMB-4en-PINACA by smoking. In one case, a user reported unusual effects with CBD, including a relatively strong feeling of euphoria, loss of balance, insomnia, and headaches.

Given its similarity to the already scheduled cannabinoid MDMB-4en-PINACA and its presumed similar effects on the human body, this substance is proposed for inclusion among Scheduled

Psychoactive Substances, which will enable its effects and possible toxicity to the human body to be determined and ensure that the substance is not available for consumption until its effects are known and possible intoxication is prevented.

ADB-5en-HEXINACA (also known as ADMB-5en-HEXINACA) is a synthetic indazole-based cannabinoid that is structurally similar to the internationally controlled ADB-BUTINACA (ADMB-BUTINACA) (Schedule II of the 1971 Convention on Psychotropic Substances).

ADB-5en-HEXINACA is also a higher homologue of ADB-4en-PINACA (ADMB-4en-PINACA), which was formally notified in March 2021.

There is limited information on the toxicology and pharmacology of ADB-5en-HEXINACA.

ADB-5en-HEXINACA has been found to be an in vitro agonist of cannabinoid receptors and acts as a highly potent agonist.

In a test, ADB-5en-HEXINACA showed comparable efficacy compared to ADMB-HEXINACA at the CB1 receptor and more than 3 times higher efficacy at CB2. The cannabinoid ADB-5en-HEXINACA has been identified in Denmark and the Czech Republic in CAFIA samples.

Given its similarity to already classified cannabinoids and its presumed similar effects on the human body, this substance is proposed for inclusion in the list of Scheduled Psychoactive Substances.

ADB-3en-BUTINACA is a synthetic cannabinoid based on indazole, which is the lower homologue of ADB-4en-PINACA and ADB-5en-HEXINACA, and is also very similar to the cannabinoid ADB-BUTINACA, included in List No 4 of psychotropic substances under Government Regulation No 463/2013 on lists of addictive substances. Although no pharmacological or toxicological information is available for this substance, its structural similarity to ADB-BUTINACA suggests significant activity on cannabinoid receptors, with the double bond at the end of the carbon side chain sometimes exhibiting higher activity towards cannabinoid receptors than the original aliphatic chain. Given its similarity to already scheduled cannabinoids and its presumed similar effects on the human body, this cannabinoid is also proposed for inclusion in the list of Scheduled Psychoactive Substances, as in the previous two cases.

Plants of the genus Mitragyna (with an exception)

Given the appearance on the market of new species of the Mitragyna plant, which are not regulated by any legislation and whose composition is unknown, as is the content of active substances (especially opioids) and their safe consumption cannot be guaranteed, it is proposed that plants of the Mitragyna genus be included in the list of classified psychoactive substances, with the exception of the Mitragyna Speciosa plant, the marketing of which is already regulated by law.

Re: Article III and V (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 (hereinafter the ‘Directive’).

Article 6(7) of the Directive permits exceptions, to postpone the adoption of a draft by 3 months for urgent reasons (hereinafter the ‘urgent technical notification procedure’).

This derogation may be used where, for reasons of urgency brought about by serious and unforeseeable circumstances relating to the protection of public health or safety, the protection of animals or plants and, in the case of rules on services, also public order, in particular the protection of young people, a Member State is obliged to prepare technical regulations within a very short period of time in order to issue and implement them without delay and without any consultation being possible. The reasons for inclusion of substances are mainly protecting public health, preventing the occurrence of intoxication, in particular in young people, preventing the further development of the grey area of these substances even before some of them penetrate the Czech market, and avoiding the establishment of the Czech Republic as a high-source country for other EU Member States.

In the light of the above, it is necessary to make use of the urgent technical notification procedure provided for in Article 6(7) of Directive 2015/1535, since a standard notification procedure would lead to a disproportionate delay and thus to a potential risk of intoxication and a threat to public health.

Re: Part Four (Effective date of the provisions)

Re: Article VI

The effective date is stipulated in accordance with § 9(3) 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, on the first day after its promulgation in the Collection of Laws. The reason for stipulating the effective date pursuant to § 9(3) of the Act on the Collection of Laws and International Treaties is the urgent public interest in protecting public health from the risk of intoxication caused by substances that are newly proposed for scheduling iin the List of Scheduled Psychoactive Substances.