JUSTIFICATION

I. GENERAL PART

Explanation of the need for the draft legislation, justification of its main principles, assessment of the current legal situation, and justification of the need to change it

Act No 167/1998 on addictive substances and on amendments to certain other acts (hereinafter the ‘Act’) empowers the government in Section 44c(1) and (2) to publish a list of narcotic drugs and psychotropic substances. This provision is implemented by Government Regulation No 463/2013 on lists of addictive substances, as amended (hereinafter the 'Government Regulation').

The Government Regulation divides the list of addictive substances into narcotic drugs and psychotropic substances into 7 groups according to the system of classification used in the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances of 1971 and the Protocol amending the Single Convention on Narcotic Drugs of 1961. This division has proven to be satisfactory in practice and can reliably provide for different control regimes for these substances, while meeting the need for availability of medicines containing addictive substances.

The most stringent measures from the point of view of the law are subject to narcotic drugs listed in Annex 3 and psychotropic substances listed in Annex 4 to the Government Regulation. The Act permits the use of these substances and products containing them only for restricted research and scientific purposes, and very restricted therapeutic purposes identified in a handling permit issued by the Ministry of Health. Hence, the Act does not permit their routine therapeutic use and persons intending to handle these substances must have a handling permit for these activities and follow strict record-keeping and storage rules when handling these substances. This measure also affects most entities that are not legally required to have a handling permit for activities with other groups of addictive substances, e.g. health care providers or veterinarians. For this group of substances there is no real reason for individuals to acquire them.

Another group are narcotic drugs listed in Annex 1 and psychotropic substances listed in Annex 5 of the Government Regulation. For this group of substances, the law permits their therapeutic, scientific, teaching, veterinary or other purposes of use based on a permit for treatment, but subject to strict conditions of keeping written records and storage. Some entities, such as providers of health services or pharmaceutical care, or veterinarians, are exempted by the Act from the requirement to have a handling permit for activities involving these substances or products containing them. Medicinal products containing these addictive substances may be dispensed to individuals only based on a prescription with a blue stripe.

The last group are narcotic drugs listed in Annex 2 and psychotropic substances listed in Annexes 6 and 7 to the Government Regulation. For this group of addictive substances, the Act exempts some entities from the requirement for a handling permit for activities involving these substances and from the stringent record-keeping and storage requirements. Individuals may acquire products containing these substances based on a prescription.

As a result, the amendment to the annexes to the Government Regulation leads to regime changes in the legal handling of the addictive substances in question, affecting, for example, the authorisation to handle these substances, record keeping, storage and the regime for the dispensing of these addictive substances. In addition to the legal treatment, the amendments to the annexes of the Government Regulation also have an impact on criminal

law, where illegal handling of these substances may be qualified as a misdemeanour or a criminal offence.

Given that the drug market, not only in the Czech Republic, but also in the entire European Union, is constantly being flooded by new synthetic drugs synthesised in order to avoid chemical structures that are controlled as narcotic or psychotropic substances, it is necessary to confront these tendencies.

At its 65th regular session, the UN Commission on Narcotic Drugs decided to place three new psychoactive substances under international control. Following WHO recommendations, the substances brorphine, metonitazene and eutylene were added to the relevant schedules of the 1961 Single Convention on Narcotic Drugs as amended by the 1972 Protocol and the 1971 Convention on Psychotropic Substances. Since metonitazene and eutylon are already on the list of addictive substances in the Czech Republic, it remains to include brorphine among the narcotic substances. The substance brorphine is proposed for inclusion in Annex 3 in view of the fact that it has no therapeutic use in the Czech Republic.

At its 45th session, the WHO Expert Committee on Drug Dependence considered nine substances and decided to recommend that seven of them be added to the list and that the remaining two continue to be monitored. Of these seven substances, four are already included in the list of addictive substances in the Czech Republic and the remaining three (ADB-BUTINACA, protonitazene and etonitazepine) are proposed for inclusion in the list of addictive substances in the Czech Republic in accordance with the proposal of the European Commission, which has prepared a unified EU position on new psychoactive substances that should be placed under international control within the framework of the UN Conventions.

Based on the request of the NPC SKPV of the Police of the Czech Republic and the Ministry of Defence, it was recommended to include HHC (hexahydrocannabinol) and THCP (tetrahydrocannabinol) in the list of addictive substances. As these substances may occur naturally in very low concentrations in industrial hemp, an exception has been made for these substances when they are present in the industrial hemp plant, industrial hemp, hemp extract and tincture and industrial hemp preparation in quantities of less than 0,3 %.

On the basis of the request of the State Health Institute and the General Directorate of Customs and due to the rapid spread of the substance kratom into the free trade in the Czech Republic, especially due to its prevalence among the immature population, it is proposed to include the substance kratom (crushed dried leaves of the plant Mitragyna speciosa) and the main substances with psychoactive effect contained in kratom (mitragynine, 7-hydroxymitragynine) to the list of psychotropic substances at least until the regulation of kratom is legislated in such a way that it is not available to the juvenile population.

In view of the above, the Ministry of Health, Inspectorate of Narcotic Drugs and Psychotropic Substances proposes an amendment to the above-mentioned Government Regulation to include six new psychoactive substances and to include a product from the Mitragyna speciosa plant with the trade name kratom.

Table 1 provides an overview of the three newly classified synthetic opioids included in Annex 3, indicating the chemical group and the proposed target Annex of the Government Regulation.

Table 1 – Overview of the three newly classified synthetic opioids in Annex 3

Number	Name	Group	Annex No
1	Brorphine	Synthetic opioids	3
2	Etonitazepyne	Synthetic opioids	3
3	Protonitazene	Synthetic opioids	3

Table 2 provides an overview of the six newly classified substances included in Annex 4, indicating the characteristic group and a proposal for a target annex to the Government Regulation.

Table 2 – Overview of the six newly classified substances in Annex 4

Number	Name	Group	Annex No
1	ADB-BUTINACA	Cannabinoids	4
2	Hexahydrocannabinol (HHC)	Cannabinoids	4
3	7-hydroxymitragyne	Indole alkaloids	4
4	Kratom	Plants containing psychoactive substances	4
5	Mitragynine	Indole alkaloids	4
6	Tetrahydrocannabiphorole (THCP)	Cannabinoids	4

Given the fact that this is a technical regulation, the draft Government Regulation will be notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 on the procedure for the provision of information in the field of technical regulations and of rules on information society services.

Assessment of compliance of the proposed legislation with the Act it is to implement, including compliance with the statutory authorisation to issue the legislation

The proposed amendment to the Government Regulation is entirely in accordance with the Act as well as with the power contained in Section 44c(1) and (2) of the Act for the implementation of which it is proposed.

Assessment of compliance of the draft legislation with European Union legislation, European Union case law and the general principles of European Union law and international conventions

The draft amendment to the Government Regulation is compatible with the following international conventions:

- The UN Single Convention on Narcotic Drugs of 1961,
- The UN Convention on Psychotropic Substances of 1971,

and the following legal acts of the European Union:

- Article 34 et seq. of the Treaty on the Functioning of the European Union;

- Council Decision 1999/615/JHA of 13 September 1999 defining 4-MTA as a new synthetic drug which is to be made subject to control measures and criminal sanctions;

- Council Decision 2002/188/JHA of 28 February 2002 on control measures and criminal sanctions in relation to the new synthetic drug PMMA;

- Council Decision 2003/847/JHA of 27 November 2003 on control measures and criminal sanctions in relation to the new synthetic drugs 2C-I, 2C-T-2, 2C-T-7 and TMA-2;

- Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal offences and sanctions in the field of drug trafficking;

- Council Decision 2005/387/JHA of 10 May 2005 on the exchange of information, risk assessment and control of new psychoactive substances;

- Council Decision 2008/206/JHA of 3 March 2008 on the definition of 1-benzylpiperazine (BZP) as a new psychoactive substance to be subject to control measures and criminal provisions;

- Council Decision 2010/759/EU of 2 December 2010 on submitting 4-methylmethcathinone (mephedrone) to control measures;

- Implementing Decisions Council Implementing Decision (EU) 2015/1873 of 8 October 2015 subjecting 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4′-DMAR) and 1-cyclohexyl-4-(1,2-diphenylethyl)-piperazine (MT-45) to control measures;;

- Council Implementing Decision (EU) 2015/1874 of 8 October 2015 concerning the submission of 4-methamphetamine to control measures;

- Council Implementing Decision (EU) 2015/1875 of 8 October 2015 concerning the submission of 4-iodine-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25I-NBOMe), 3,4-dichloro-N-[[1-(dimethylamine)cyclohexyl]methyl]benzamide (AH-7921), 3,4-methylendioxypyro-Valerone (MDPV) and 2-(3-methoxyphenyl)-2-(ethylamino)cyklohexanone (methoxetamine) to control measures;

- Council Implementing Decision (EU) 2015/1876 of 8 October 2015 concerning the submission of 5-(2-aminopropyl)indole to control measures;

- Council Implementing Decision (EU) 2016/1070 of 27 June 2016 on subjecting 1-phenyl-2-(pyrrolidine-1-yl)pentane-1-one (α-pyrrolidinovalerophenone, α-PVP) to control measures;

- Council Implementing Decision (EU) 2017/369 of 27 February 2017 concerning the submission of methyl-2-{[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]amino}-3,3-dimethylbutanoate (MDMB-CHMICA) to control measures;

- Council Implementing Decision (EU) 2017/1774 of 25 September 2017 concerning the submission of the substance N-(1-phenethylpiperidine-4-yl)-N-phenyllacrylamamide (acrylic-phentanyl) to control measures;

- 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;

- Council Implementing Decision (EU) 2017/2170 of 15 November 2017 concerning the submission of N-phenyl-N-[1-(2-phenylethyl)piperidine-4-yl]furan-2-carboxamide (furanylfentanyl) to control measures;

- Council Implementing Decision (EU) 2018/748 of 14 May 2018 concerning the submission of the new psychoactive substance 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carbox-amide (CUMYL-4CN-BINACA) to control measures;

- Council Implementing Decision (EU) 2018/747 of 14 May 2018 concerning the submission of the new psychoactive substance N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmet-hyl)-1H-indazole-3-carboxamide (ADB-CHMINACA) to control measures; and

- Council Implementing Decision (EU) 2018/1463 of 28 September 2018 concerning the submission of new psychoactive substances N-phenyl-N-[1-(2-phenylethyl)piperidine-4-yl]cyclopropane carbox-amide (cycloropylphentanyl) and 2-methoxy-N-phenyl-N-[1-(2-phenylethyl)piperidine-4-yl]acetamide (methoxyacetylfentanyl) to control measures;

- Commission Delegated Directive (EU) 2019/369 of 13 December 2018 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of new psychoactive substances in the definition of a drug;

- Commission Delegated Directive (EU) 2020/1687 of 2 September 2020 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of a new psychoactive substance N, N-diethyl-2-[[4-(1-methylethoxy)phenyl] methyl] -5-nitro-lH-benzimidazole-l-ethanamine (isotonitazene) in the definition of addictive substance;

- reference to Commission Delegated Directive (EU) 2021/802 of 12 March 2021 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of new psychoactive substances methyl 3,3-dimethyl-2-{[1-(pent-4-en-1-yl)-1H-indazole-3-carbonyl]amino} butanoate (MDMB-4en-PINACA) and methyl-2-{[1-(4-fluoro-butyl) -1H-indole-3-carbonyl] amino}-3,3-dimethylbutanoate (4F-MDMB-BICA) in the definition of a drug;

- Commission Delegated Directive (EU) 2022/1326 of 18 March 2022 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of new psychoactive substances in the definition of drug (inclusion of 3-MMC and 3-CMC).

The proposed legislation is, according to the grounds of the proposal, a technical regulation within the meaning of 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. For this reason, the draft Government Regulation is to undergo a notification process in accordance with this EU legislation.

In order to speed up the legislative process with regard to the protection of public health, the Legislative Council of the Government has been asked to grant an exemption from conducting a Regulatory Impact Assessment (RIA) on the draft Government Regulation amending Regulation No. 463/2013 Coll., on lists of addictive substances, as amended.

In letter ref. No 9947/2023-UVCR of 28 February 2023 from the Chairman of the Legislative Council of the Government, it was decided, in accordance with Article 76(2) of the Government's Legislative Rules, to grant an exemption from the requirement to draw up a regulatory impact assessment (RIA).

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

The proposed amendment to the Government Regulation may have an impact on businesses involved in the sale of HHC and kratom, often referred to as the sale of collectibles, even though the instructions and information provided by sellers make it clear that they are to be used for consumption. In view of the significant prevalence of these substances in the immature population, and the associated significant risk to public health, the applicant has prioritised the health risks arising from the easy availability of the above substances over the potential impact on operators involved in the sale of HHC and kratom.

Given its nature, the present draft amendment to the Government regulation has no negative social impact and has no impact on specific population groups.

The present draft amendment to the Government Regulation has no adverse environmental impact.

Assessment of the current situation and impacts of the proposed solution in relation to the prohibition of discrimination

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

Assessment of the impact of the proposed solution in relation to the protection of privacy and personal data

The proposed legislation does not affect Act No 110/2019 on the processing of personal data.

Assessment of corruption risks

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

Assessment of impact on State security or defence

The draft legislation has no impact on State security or defence.

Impact assessment on digitally friendly legislation

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

Assessment of the impact on families

With regard to the subject matter of the proposed legislation, no impact is seen in this area.

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

The proposed legislation does not foresee any territorial impacts or impacts on local self-governing units.

II. SPECIAL PART

Re: Article I
Re: Point 1

Commission Delegated Directive (EU) 2022/1326 of 18 March 2022 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of new psychoactive substances in the definition of a drug is added to the list of transposed EU legislation.

Re: Point 2

The substance **Brorphine** is included in Annex 3 to the Government Regulation in alphabetical order following the decision of the 65th Ordinary Session of the United Nations Commission on Narcotic Drugs, when the Commission decided to include Brorphine among the new psychoactive substances to be placed under international control under the UN Conventions.

Re: Point 3

The substance **Etonitazepine** is included in Annex 3 to the Government Regulation in alphabetical order on the basis of the European Commission's proposal for a common EU position on new psychoactive substances to be placed under international control under the UN Conventions.

Re: Point 4

The substance **Protonitazene** is included in Annex 3 to the Government Regulation in alphabetical order on the basis of the European Commission's proposal for a common EU position on new psychoactive substances to be placed under international control under the UN Conventions.

Re: Point 6

The substance **ADB-BUTINACA** is included in Annex 4 to the Government Regulation in alphabetical order on the basis of the European Commission's proposal for a common EU position on new psychoactive substances to be placed under international control under the UN Conventions.

Re: Point 7

The substance **Hexahydrocannabinol (HHC)** is included in Annex 4 to the Government Regulation in alphabetical order based on the proposal of the NPC of the Police of the Czech Republic, the Ministry of Defence and the Ministry of Health and belongs to the group of cannabinoids. There are laboratory studies that report that HHC generally has similar effects to THC, the main psychoactive substance in cannabis. The pharmacological and behavioural effects of HHC have not been studied in humans, although recent unofficial reports from consumers suggest that its effects may be similar to those of cannabis. The occurrence of the substance has so far been reported in Italy and Denmark. Based on information from CAFIA, HHC has been detected in food in the Czech Republic, especially in confectionery via so-called HHC mats, internet and retail shops. Products with HHC content higher than 50% are also available on the market. Data from the Toxicological Information Centre indicate the need to regulate the trade in these products, in particular a strict ban on consumption by children and adolescents.

Re: Points 5 and 8

The substances **7-hydroxymitragynine and mitragynine** are included on the basis of the request of the State Institute of Health and the General Directorate of Customs as active substances of kratom (crushed dried leaves of Mitragyna speciosa) and due to the rapid spread of kratom into free sale in the Czech Republic, especially due to its occurrence in the immature population. As part of kratom, they are found in most EU countries and in the Czech Republic the import of kratom reaches tons per month. Healthcare facilities are reporting an increasing number of intoxications related to kratom use.

Re: Point 9

The substance kratom (crushed dried leaves of the plant Mitragyna speciosa) is included on the basis of the request of the State Institute of Health and the General Directorate of Customs due to its rapid spread to free sale in the Czech Republic and easy availability to the immature population. It is found in most EU countries and in the Czech Republic the import of kratom reaches tons per month. Healthcare facilities are reporting 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. The inclusion of kratom and its active ingredients in the list of psychotropic substances is necessary at least until the regulation of kratom is legislated in such a way that it is not available to the underage population.

Re: Point 10

The substance **Tetrahydrocannabinol (THCP)** is included in Annex 4 to the Government Regulation in alphabetical order on the basis of the proposal of the NPC of the Police of the Czech Republic, the Ministry of Defence and the Ministry of Health and belongs to the group of cannabinoids. This is a relatively new psychoactive substance that is found in the cannabis plant, but in very small quantities. With the advent of extraction methods for

concentrating active ingredients, this substance has been newly captured in the market. It is similar in effect to THC, but has a much higher potency and could be more dangerous than THC if widespread. No cases of fatal intoxication have been recorded in the Czech Republic in connection with this substance.

Re Article II

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.