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.

Based on the request of the National Anti-Drug Centre of the Bureau of Criminal Police and Investigation Service of the Police of the Czech Republic and the Ministry of Defence, inclusion of HHC (hexahydrocannabinol) and THCP (tetrahydrocannabiphorol) on the schedule of addictive substances had already been requested in 2022. 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 an industrial hemp plant, industrial hemp, hemp extract and tincture and industrial hemp preparation in quantities of less than 0.3 %.

The main problem currently lies in the sale of 'edibles', i.e. foods containing a psychoactive substance, in this case HHC, HHC-acetate, HHC-O or THCP. They are sold in the form of gummy bears, chocolate, cookies, beverages, etc. The effect of cannabinoids commences 30 minutes to 1 hour from ingestion; this delayed effect results in cases of intoxication. The user takes, for example, a gummy bear containing HHC and does not notice any effects, so he/she takes another in 10 minutes and then another, leading to an overdose. HHC is almost absent in natural cannabis varieties (up to 0.1% content), hence it is produced semi-synthetically from cannabidiol (CBD) or via hydrogenation of tetrahydrocannabinol (THC) and this concentrated form is then sold either sprayed on industrial hemp buds or added to the aforementioned edibles. Concentrates being sold thus have HHC content as high as 50-70 %. From June 2022 to 4 February 2024, the toxicological information centre recorded 170 cases of intoxication, mainly in children and adolescents.

The situation in terms of excessive use of HHC and its derivatives deteriorated significantly in late 2023 and early 2024. In January 2024 alone, eight cases of HHC[1] overdose of children and adolescents already occurred in the Karlovy Vary Region, with at least one child being hospitalised in the Karlovy Vary hospital's intensive care unit. In Plzeň, eleven children were treated in connection with HHC over the past quarter-year[2]. However, overdoses do not only involve children, one adult woman even had to be connected to pulmonary ventilation, and last weekend three adults ended up in intensive care units. Children and adolescents use these substances mainly in the form of gummy bears[3], which are sold under the designation of 'collector's items' and can also be purchased through vending machines[4]. Emergency services have also already been called due intoxicated primary school pupils[5]. The negative health effects of HHC are associated with its interaction with the endocannabinoid system in the body, which affects a variety of physiological processes,

[1] https://karlovarsky.denik.cz/zpravy_region/hhc-otravy-dospeli-karlovarsky-kraj.html.

[2] https://radiozurnal.rozhlas.cz/latka-hhc-deti-mohou-mit-priznaky-snizeneho-vedomi-az-bezvedomi-popisuje-9167230?consent=CP1E6gAP1E6gAD3ACBCSAmEsAP_gAEPgAATIJVwQQAAwAKAAsACAAFQALgAZAA6ACAAFAAKgAWgAyABoADmAIgAigBHACSAEwAJwAVQAtgBfgDCAMUAgACEgEQARQAjoBOAE6AL4AaQA4gB3ADxAH6AQgAkwBOACegFIAKyAWYAuoBgQDTgG0APkAjUBHQCaQE2gJ0AVIAtQBbgC8wGMgMkAZcA0oBqYDugHfgQHAhcBGYCVYIXQIoAFAAWABUAC4AIAAZAA0ACIAEcAJgAVQAtgBiAD8AISARABEgCOAE4AMsAZoA7gB-gEIAIsAXUA2gCbQFSALUAW4AvMBggDJAGpgQuAAAAA.YAAAAAAAAAAA&szncIid=Vj8ya2dmZ2Bnbmdlb25jZWNiY2dkYWJgKiJrZ2BhZmVlY25nY3huZmcqIjNrZ2FmYWRnYGFmbnhlbmEqNWsXb2YXYmRjZGMUFRNhFWVgYG9jZG8XYGViFWRhb2VgYA&utm_source=www.seznam.cz&utm_medium=sekce-z-internetu.

[3] https://ct24.ceskatelevize.cz/clanek/domaci/ministerstvo-zdravotnictvi-se-stavi-proti-hhc-reaguje-na-otravy-mladistvych-i-deti-345701.

[4] https://www.denik.cz/krimi/drogy-hcc-intoxikace-deti-skoly-nemocnice-karlovy-vary-sokolov-cheb.html.

[5] https://archiv.hn.cz/c1-67291590-pripadu-otrav-hhc-v-karlovarskem-kraji-pribyva-zachranka-musela-o-vikendu-zasahovat-sedmkrat.

including pain, mood and appetite. Like THC, HHC binds to cannabinoid receptors in the brain and body, which can lead to changes in perception, mood, and behaviour. Patients with intoxicated with HHC experience disturbances in consciousness, mood swings, aggression or nausea.

Based on the above, it is clear that not only is there a danger to public health of children and adolescents, but this danger has already occurred and continues to occur. In order for these substances to not reach children and adolescents and avoid further cases of intoxication, it is necessary to strictly regulate these substances. The fastest and most effective solution is the inclusion of these substances on the schedule of addictive substances, at least until the amendment of the Act on Addictive Substances and related acts, which will newly regulate so-called psychomodulatory substances; legislation will regulate the ability to prohibit certain substances for children under the age of 18, but will continue to make them accessible to the adult population under strict conditions.

Table 1 provides an overview of the three newly classified substances included in Annex 4, indicating the characteristic group and a proposal for a target annex to the Government Regulation.

Table 1 — Overview of the three new substances included in Annex 4

Number	Name	Group	Annex No
1	Hexahydrocannabinol (HHC)	Cannabinoids	4
2	Hexahydrocannabinol-O-acetate (HHC-acetate, HHC-O)	Cannabinoids	4
3	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 decision Council Implementing Decision (EU) 2015/1873 of 8 October 2015 on subjecting 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazole-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, on 7 February 2024 during a Cabinet meeting, the Deputy Prime Minister and the Minister of Health were granted an oral derogation from the implementation of the Regulatory Impact Assessment (RIA) and the comment procedure on the draft government regulation amending Regulation No 463/2013 on schedules of addictive substances, as amended.

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 present amendment of the government regulation may have an impact on business entities engaged in the sale of goods containing hexahydrocannabinol (HHC), hexahydrocannabinol-O-acetate (HHC-acetate, HHC-O) and tetrahydrocannabiforol (THCP). Such goods are often marketed under the designation of collector's items, although from instructions and information from sellers it is obvious they are for consumption, cf. the decision of the Regional Court in Plzeň of 30 June 2023, ref. No 55 A 4/2023-32. In view of the significant presence of these substances among the juvenile population and the associated significant risk to public health, the proposer gave priority to the health risks arising from the easy availability of the aforementioned substances over potential impacts on economic operators engaged in the sale of products containing the aforementioned substances.

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

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. HHC currently has no medical or industrial use. The pharmacological and behavioural effects of HHC in humans have not yet been studied, although recent unofficial reports from consumers suggest that its effects may be similar to those of cannabis. The HHC was first identified in Europe in May 2022 by the Danish police. It was already present in 70 % of EU Member States during the eight-month period between May and December 2022. 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: Point 2

Hexahydrocannabinol-O-acetate (HHC-acetate, HHC-O) is included in Annex 4 to the Government Decree in alphabetical order on the basis of the finding that this substance is also present in so-called ‘edibles’ and thus poses a threat to children and adolescents.

It is a semi-synthetic cannabinoid derivative that has been on the market since around 2022.

It is believed to be produced via a multi-stage process from cannabidiol obtained from cannabis. The legal status of hexahydrocannabinol and derivatives such as HHC-O varies between countries, leading to

large-scale sales in some jurisdictions in Europe and the U.S. and thus they also reach us, but many European countries already strictly regulate these substances, such as Belgium, Denmark, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Austria, Poland, Finland, Iceland.

Re: Point 3

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.

Re: Article III

This Government Decree comes into effect on the day following the date of its promulgation.

It is not possible to stipulate an effective date for the draft in accordance with the expected § 3(3) of Act No 309/1999, because the draft legislation is based on the current need to quickly add new substances to the schedule of narcotics and psychotropic substances, where these present a significant risk to public health and the health of persons on both the national and European level.