J U S T I F I C A T I O N

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 amending certain other acts (hereinafter the ‘Act’) empowers the government in § 44c(1) and (2) to declare a schedule of narcotic 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.

On the initiative of the National Drug Centre, the Institute of Forensic Science and the Customs Technical Laboratory, a meeting of the Working Group of the Early Warning System for New Synthetic Drugs – Early Warning System (EWS), coordinated by the National Monitoring Centre for Drugs and Addiction of the Department of Drug Policy of the Government Office, was held on 26 January 2024 in order to assess the proposal of these authorities to include 146 new psychoactive substances on the schedules of narcotic drugs and psychotropic substances pursuant to Government Regulation No 463/2013 on schedules of addictive substances. Substances that, with the exception of two substances, have no therapeutic, research or industrial use were selected for inclusion. One of the substances used is thiafentanil (A-3080, Thianil), an opioid analgesic that is an analogue of fentanyl. Thiafentanil is used in veterinary medicine for animal anaesthesia. The Ministry of Health records imports of thiafentanil into the Czech Republic. According to the Institute for State Control of Veterinary Biologicals and Medicines, the inclusion of thiafentanil in the schedule of narcotic drugs and psychotropic substances should not pose any problem. The second of these substances is gamma-butyrolactone (GBL), which is a liquid used in industry as a cleaning agent and solvent. GBL has long been abused as a drug due to its euphoric effects; however, recently, cases of abuse have become more frequent. GBL is metabolised after ingestion in the digestive tract to gamma-hydroxybutyric acid (GHB, gamma-butyrate), a psychotropic substance included in Annex 5 to Government Regulation No 463/2013. Overdose can cause irrational behaviour, coma, and, in extreme cases, death. Due to the hazardous effects of GBL, the health risks outweighed the possibility of the substance being freely sold. The National Anti-Drug Centre negotiated with the companies using GBL in their activities, and it was agreed that the entities concerned were able to cope with certain restrictions resulting from the classification of GBL as a psychotropic substance.

The substances Hexahydrocannabinol, Hexahydrocannabinol-O-acetate and Tetrahydrocannabiphorol, which were included in the schedule of addictive substances by Government Regulation No 52/2024, as well as the substances Hexahydrocannabiphorol, Hexahydrocannabihexol, Hexahydrocannabioctyl, Hexahydrocannabutol, Tetrahydrocannabihexol, Tetrahydrocannabioctyl and Tetrahydrocannabutol, which were included in the schedule of addictive substances by Government Regulation No 176/2024, will be removed from the schedule of addictive substances by these Government Regulations on 1 January 2025. This solution was adopted due to the discussion of the amendment to Act No 167/1998 on addictive substances, as amended, and other related acts (hereinafter the ‘amendment to the Act’), which newly regulates the issuance of two additional schedules, namely the list of scheduled psychoactive substances and the schedule of psychomodulatory substances, which are intended, inter alia, to serve as a more adequate instrument for regulating some of these substances. This amendment to the Act was approved by the Senate

at its 29th session as Senate Press 316 on 9. 10. 2024 and subsequently on 17. 10. 2024 was signed by the president of the Czech Republic. On 7. 11. 2024 this amendment to the Act was promulgated in the Collection of Laws, will take effect on ....., however, preparatory work is still being carried out on the implementing legislation for this amendment to the Act and the consultation procedure is expected to not start until the beginning of December 2024, and these substances cannot be transferred to the new schedules as of ..... For this reason, it is necessary to re-include these substances in the schedule of addictive substances, so as to avoid the undesirable consequence that these substances will again be unregulated, as this fact has caused a threat to the health of children and adolescents in the past. On the basis of the above, it is proposed to re-include this group of substances in the schedule of addictive substances, with the proviso that once the Government Regulation on Psychomodulatory Substances and the Government Regulation on Scheduled Psychoactive Substances are ready to be issued, these substances will be reclassified into the appropriate schedules based on a risk assessment. Representatives of the Ministry of Health were consulted on this procedure at the EWS, along with representatives of the State Health Institute, the State Agricultural and Food Inspection Authority, and the Office of the Government of the Czech Republic.

Table 1 provides an overview of the 18 newly scheduled substances in Annex 3 and thiafentanil in Annex 1, indicating the characteristic group and proposing a target annex to the Government Decree.

Table 1 – Overview of 18 newly scheduled substances in Annex 3 and thiafentanil in Annex 1.

Number	Name	Group	Annex No
1	2’-Fluoro-2-fluoro-3-methylfentanyl	opioids	3
2	2F-viminol	opioids	3
3	4-(Trifluoromethyl) U-47700	opioids	3
4	AP-238	opioids	3
5	Desmethylmoramide	opioids	3
6	Dipyanone	opioids	3
7	Ethylene oxynitazene	opioids	3
8	Etomethazene	opioids	3
9	Etonitazepipne	opioids	3
10	Furanyl UF-17	opioids	3
11	Isobutyrfentanyl	opioids	3
12	Carbonyl bromadol	opioids	3
13	Metonitazepyne	opioids	3
14	N-desethyl etonitazene	opioids	3
15	N-desethyl isotonitazene	opioids	3
16	Nortilidine	opioids	3

Number	Name	Group	Annex No
17	O-AMKD	opioids	3
18	Protonitazepyne	opioids	3
19	Thiafentanil	opioids	1

Table 2 provides an overview of 123 new substances scheduled in Annex 4 with an indication of the characteristic group and a proposal for a target annex to the Government Regulation.

Table 2 — Overview of the 123 new substances scheduled in Annex 4

Number	Name	Group	Annex No
1	5-Methylthiopropamine	arylalkylamines	4
2	BOH-PHP	arylalkylamines	4
3	M-ALPHA-HCMA	arylalkylamines	4
4	Mephedrene	arylalkylamines	4
5	2-Fluoro-deschloro-N-ethylketamine	arylcyclohexylamines	4
6	3-Cl-PCP	arylcyclohexylamines	4
7	3F-PCP	arylcyclohexylamines	4
8	3-Me-PCP	arylcyclohexylamines	4
9	3-Me-PCPy	arylcyclohexylamines	4
10	Deoxymethoxetamine	arylcyclohexylamines	4
11	Fluorexetamine	arylcyclohexylamines	4
12	Hydroxetamine	arylcyclohexylamines	4
13	Methoxisopropamine	arylcyclohexylamines	4
14	4'-Chlordeschloralprazolam	benzodiazepines	4
15	Bretazenil	benzodiazepines	4
16	Desalkylgidazepam	benzodiazepines	4
17	Deschloroctizolam	benzodiazepines	4
18	Flubrotizolam	benzodiazepines	4
19	Fluetizolam	benzodiazepines	4
20	6-BR-DMPEA	phenethylamines	4
21	N-pyrrolidinyl-3,4-DMA	phenethylamines	4
22	PEAP	phenethylamines	4

Number	Name	Group	Annex No
23	2-(4-methylpiperazine-1-yl)-1-phenylpropan-1-one	cathinones	4
24	2-MEB	cathinones	4
25	2'-Me-PVP	cathinones	4
26	2-Methyl-α-PHiP	cathinones	4
27	3,4-Pr-PipVP	cathinones	4
28	3F-NEB	cathinones	4
29	3F-N-ethylhexedrone	cathinones	4
30	3F-α-PHP	cathinones	4
31	3-Chlorocathinone	cathinones	4
32	3'-Me-PVP	cathinones	4
33	3-Methyl-N-propyl-cathinone	cathinones	4
34	4’-Methylhexedrone	cathinones	4
35	4-Cl-3-MMC	cathinones	4
36	4F-3-methyl-α-PHP	cathinones	4
37	4F-3-methyl-α-PVP	cathinones	4
38	MDPEP	cathinones	4
39	MDPHiP	cathinones	4
40	N,N-Diethylpentylone	cathinones	4
41	N-butylbutylone	cathinones	4
42	N-cyclohexyl butylone	cathinones	4
43	N-cyclohexyl methylone	cathinones	4
44	N-ethylheptylone	cathinones	4
45	N-ethylhexylone	cathinones	4
46	N-sec-butyl-pentedrone	cathinones	4
47	α-D2PV	cathinones	4
48	α-PCYP	cathinones	4
49	3-Chlorfenmetrazine	other	4
50	3-Methoxyphenmetrazine	other	4
51	4Br-MAR	other	4
52	4Cl-MAR	other	4
53	4-Fluorfenibut	other	4
54	Dichlormethqualone	other	4

Number	Name	Group	Annex No
55	Ephinazone	other	4
56	Fenozolone	other	4
57	Iso-(meta-methyl-propcathinone)	other	4
58	Iso-3-CMC	other	4
59	Iso-3-MMC	other	4
60	N-ethyl zolpidem	other	4
61	Nitromethaqualone	other	4
62	Pagoclone	other	4
63	Rilmazafone	other	4
64	3,4-CFP	piperazines	4
65	4F-MBZP	piperazines	4
66	pBPP	piperazines	4
67	4,4-Dimethyl-1-phenyl-1-pyrrolidin-1-yl-pentan-3-one	piperidines and pyrrolidines	4
68	Methyl 2-phenyl-2-(pyrrolidin-1-yl)acetate	piperidines and pyrrolidines	4
69	3,5-ADB-4en-PFUPPYCA	synthetic cannabinoids	4
70	4en-PDMB-4en-PINACA	synthetic cannabinoids	4
71	4F-ABINACA	synthetic cannabinoids	4
72	5,3-AB-CHMFUPPYCA	synthetic cannabinoids	4
73	5,3-ADB-4en-PFUPPYCA	synthetic cannabinoids	4
74	5B-AKB48	synthetic cannabinoids	4
75	5F-BZO-POXIZID	synthetic cannabinoids	4
76	5F-EDMB-PICA	synthetic cannabinoids	4
77	5F-EMB-PICA	synthetic cannabinoids	4
78	ABO-4en-PINACA	synthetic cannabinoids	4
79	ADB-4en-P-5Br-INACA	synthetic cannabinoids	4
80	ADB-4en-PINACA	synthetic cannabinoids	4
81	ADB-5Br-INACA	synthetic cannabinoids	4
82	ADB-B-5Br-INACA	synthetic cannabinoids	4
83	ADB-BUTINACA	synthetic cannabinoids	4
84	ADB-D-5Br-INACA	synthetic cannabinoids	4

Number	Name	Group	Annex No
85	ADB-FUBHQUCA	synthetic cannabinoids	4
86	ADB-FUBIACA	synthetic cannabinoids	4
87	ADB-HEXINACA	synthetic cannabinoids	4
88	ADB-IACA	synthetic cannabinoids	4
89	ADB-P-5Br-INACA	synthetic cannabinoids	4
90	ADMB-3TMS-PRINACA	synthetic cannabinoids	4
91	ADMB-INACA	synthetic cannabinoids	4
92	A-FUBIACA	synthetic cannabinoids	4
93	A-PBITMO	synthetic cannabinoids	4
94	A-PONASA	synthetic cannabinoids	4
95	BENZYL-4CN-BINACA	synthetic cannabinoids	4
96	BZO-4en-POXIZID	synthetic cannabinoids	4
97	BZO-POXIZID	synthetic cannabinoids	4
98	CUMYL-1Cl-CHSINACA	synthetic cannabinoids	4
99	CUMYL-3TMS-PRINACA	synthetic cannabinoids	4
100	Cumyl-BC-HpMeGaClone-221	synthetic cannabinoids	4
101	Cumyl-CB-MeGaClone	synthetic cannabinoids	4
102	CUMYL-CBMICA	synthetic cannabinoids	4
103	CUMYL-CBMINACA	synthetic cannabinoids	4
104	CUMYL-CHSINACA	synthetic cannabinoids	4
105	CUMYL-INACA	synthetic cannabinoids	4
106	CUMYL-NBMICA	synthetic cannabinoids	4
107	CUMYL-NBMINACA	synthetic cannabinoids	4
108	CUMYL-TsINACA	synthetic cannabinoids	4
109	EDMB-PINACA	synthetic cannabinoids	4
110	FUBIAT	synthetic cannabinoids	4
111	CH-FUBBMPDORA	synthetic cannabinoids	4
112	CH-FUBIACA	synthetic cannabinoids	4
113	CH-IACA	synthetic cannabinoids	4
114	CHM-MDA-19 (BZO-CHMOXIZID)	synthetic cannabinoids	4
115	CHM-MDMB-CHMINACA	synthetic cannabinoids	4
116	CH-PIACA	synthetic cannabinoids	4

Number	Name	Group	Annex No
117	MDMB-5Br-INACA	synthetic cannabinoids	4
118	MDMB-7Br-INACA	synthetic cannabinoids	4
119	MDMB-BINACA	synthetic cannabinoids	4
120	MDMB-CHMINACA	synthetic cannabinoids	4
121	MDMB-INACA	synthetic cannabinoids	4
122	NMDMSB	synthetic cannabinoids	4
123	PTI-3	synthetic cannabinoids	4

Table 3 lists a newly scheduled substance in Annex 6, indicating the characteristic group and the draft target annex to the Government Decree.

Table 3 – The substance newly scheduled in Annex 6

Number	Name	Group	Annex No
1	Gammabutyrolactone, GBL	other	6

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

Pursuant to § 44c(1)(d) in conjunction with § 44(2)(d) of the Addictive Substances Act, only the following may be included in Annex 3 to the Government Regulation:

1. narcotic drugs included in Schedule I pursuant to the Convention on Narcotic Drugs or

2. other narcotic drugs for which it is necessary to ensure that substances and preparations containing such additional narcotic drugs are used only for limited research, scientific and very limited therapeutic purposes as defined in the authorisation, by reason of the extent of their misuse or because they pose an immediate or indirect threat to health.

Pursuant to § 44c(1)(d) in conjunction with § 44(2)(d) of the Addictive Substances Act, only the following may be included in Annex 4 to the Government Regulation:

1. psychotropic substances included in Schedule I under the Convention on Psychotropic Substances; or

2. other psychotropic substances for which it is necessary to ensure that substances and preparations containing such additional psychotropic substances are used only for limited

research, scientific and very limited therapeutic purposes as defined in the authorisation, by reason of the extent of their misuse or because they pose an immediate or indirect threat to health.

The 143 newly scheduled substances (19 narcotic drugs and 124 psychotropic substances) fulfil the condition set out in point 2. The above substances are potential psychoactive substances and may pose an immediate threat to the health of children and adolescents. In order to prevent these substances from reaching children and young people and thus preventing further risks to health, it is necessary to strictly control these substances. For this reason, the draft amendment of the Government Decree is fully in line with the Act as well as with the above-mentioned empowerment, the implementation of which is being 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.

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

- Article 34 et seq. TFEU;
- 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 penalties;
- 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 concerning control measures and criminal sanctions in respect of 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 acts and penalties in the field of illicit drug trafficking;
- 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;

- Council Implementing Decision (EU) 2015/1873 of 8 October 2015 concerning the submission of 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 on subjecting 4-iodo-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25I-NBOMe), 3,4-dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]benzamide (AH-7921), 3,4-methylenedioxypyrovalerone (MDPV) and 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone (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 on subjecting N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl) 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;

- 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) 2018/1463 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 the new psychoactive substance N,N-diethyl-2-[4-(1-methylethoxy)fenyl]methyl]-5-nitro-1H-benzimidazole-1- ethanamine (isotonitazene) in the definition of the drug;

- 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 the 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-fluorobutyl)-1H-indole-3-carbonyl]amino}-3,3-dimethylbutanoate (4F-MDMB-BICA) in the definition of ‘drug’; and

- 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.

Substances that are subject to control measures under European Union regulations and have been included in the list of addictive substances, i.e., in Government Regulation No 463/2013, remain on the schedule of addictive substances even after the replacement of the entire Annex 3 and Annex 4; they are all still included in the new Annexes 3 and 4.

The present proposal 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 infringe the principle of proportionality. The inclusion of 143 new substances in Annexes 3 and 4 to Government Regulation No 463/2013 is based on the need to regulate access to addictive substances, the free availability of which would seriously endanger the health of the population, cause an increase in the use of addictive substances with a risk of addiction, the spread of these dangerous substances on the market or their production, which would 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 inclusion of new substances in the schedule of addictive substances was based on the expertise and recommendations of European and international organizations, e.g. the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), and does not restrict trade in other substances that do not have addictive potential. The inclusion of substances in Annexes 3 and 4 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 inclusion of those substances does not lead to an unjustified interference with the free movement of goods.

In order to expedite the legislative process concerning the protection of public health, a letter from the Minister of Justice and the President of the Legislative Council of the Government, ref. 62859/2024-UVCR of 25. 10. 2024, granted a derogation from the regulatory impact assessment (RIA) and shortened the comment procedure on the draft Government Regulation amending Regulation No 463/2013 on schedules of addictive substances, as amended, to 10 working days.

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 only a small impact on business entities, as the proposed substances, apart from gamma-butyrolactone, have not yet been established on the Czech market. Such goods are often marketed under the designation of collectors' items. In view of the potential risk to public health, the submitter has prioritised the health risks arising from the easy availability of the substances mentioned above, as opposed to possible impacts on economic operators, which in this case will be small.

Gammabutyrolactone is used as a solvent and therefore it is proposed to include it in the less stringent Annex 6 of psychotropic substances. Its inclusion in the list of psychotropic substances will have some impact on the producers and end-users of this substance in the Czech Republic. According to the NPC Police of the Czech Republic, however, there has recently been a strong trend of increasing abuse of this substance as a drug, leading to moderate to severe intoxications. Operators who use this substance in their activities will need to obtain a handling permit from the Ministry of Health and further comply with the obligations under the Addictive Substances Act. However, the administrative burden is not significant in this case.

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 concern the protection of privacy or 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 negative impacts are identified 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 **thiafentanil (A-3080, Thianil)** is being included in alphabetical order on the basis of a decision of the EWS Working Group in Annex 1 to the Government Decree. As a veterinary medicinal product, the substance is commonly found in EU countries. It is rarely used in the Czech Republic, and no case of abuse has yet been recorded. In terms of health risks, it is a highly potent opioid used in veterinary medicine for animal anaesthesia, usually

in combination with other anaesthetics such as ketamine, xylazine or medetomidine to reduce the prevalence of side effects. Since it is more than 1000 times more potent than morphine, there is a risk of fatal intoxication if handled improperly, and it is therefore necessary to have this substance under control.

Re: Point 2 Opioids group (all substances in this group are classified in Annex 3 to the Government Decree):

The substance **2'-Fluoro-2-fluoro-3-methylfentanyl** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. In Europe, it is a controlled substance in Finland and Sweden. In terms of health risks, the substance has similar effects to 3-methylfentanyl and 4-fluorofentanyl. The presence of this substance in the Czech Republic has not been confirmed.

The substance **2F-viminol** is being included in alphabetical order based on a decision by the EWS Working Group. The presence of the substance has hitherto been reported in Germany and Sweden. The substance is controlled in Europe in Sweden, Lithuania, and Latvia. 2F-viminol is significantly more active than viminol, which has similar pharmacological properties to morphine. The presence of this substance in the Czech Republic has not been confirmed.

The substance **4-(Trifluoromethyl) U-47700** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is controlled in Europe in Italy and Lithuania. The substance is structurally similar to the internationally controlled opioid U-47700. Based on this similarity to U-47700 and other opioids, 4-trifluoromethyl) U-47700 is expected to act as an opioid agonist and have analgesic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **AP-238** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in France, Germany and Slovenia. The substance is controlled in Europe in Italy and Lithuania. Limited information is available on the pharmacology and toxicology of this substance. In a molecular modelling study of a set of piperazine and other derivatives, investigating the main factors that modulated their affinity for the μ-opioid receptor, AP-238 was reported to have a similar affinity for the μ-opioid receptor as morphine, but with analgesic activity 4 times higher. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Desmethylmoramid** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is controlled in Europe in Italy and Lithuania. Limited information is available on the pharmacology and toxicology of desmethylmoramide. Based on its chemical structure and chemical similarity to racemoramide (racemic mixture of the active enantiomer dextromoramide and the inactive enantiomer levomoramide), desmethylmoramide is expected

to act as an opioid agonist and to have analgesic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Dipyanone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Germany and Slovenia. The substance is controlled in Europe in Italy and Lithuania. Limited information is available on the pharmacology and toxicology of dipyanone. Based on its chemical structure and chemical similarity to dipipanone, methadone and phenadoxone, dipyanone is expected to act as an opioid agonist and to have analgesic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Ethyleneoxynitazene** is being inlcuded in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Estonia. The substance is controlled in Europe in Denmark, France and Great Britain. Ethyleneoxynitazene is a cyclic analogue of the internationally controlled substance etonitazene. Based on its chemical structure and similarity to etonitazene and isotonitazene, ethyleneoxynitazene is expected to have analgesic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Etometazene** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hiterto been reported in eight EU countries. The substance is controlled in Europe in Denmark and France. Etometazene is structurally related to the internationally controlled opioid etonitazene. Despite limited information on the pharmacology and toxicology of etometazene, based on its chemical structure and similarity to etazene and etonitazene, etometazene is expected to have analgesic effects that are likely to be much greater than those of morphine. According to unconfirmed reports from the U.S. National Drug Early Warning System (NDEWS), etometazene may be up to twice as potent as fentanyl. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Etonitazepipne** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in five EU countries. The substance is controlled in Europe in Bulgaria, Denmark, Finland, France, Italy, Lithuania, and Great Britain. Based on its chemical structure and similarity to clonitazene, etonitazene and isotonitazene, etonitazepipne is expected to have analgesic effects. Recent in vivo data indicate that etonitazepipne (N-piperidinyl etonitazene) is slightly less potent than etonitazene but more potent than fentanyl. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Furanyl UF-17** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Belgium, Finland, Germany and the United Kingdom. The substance is controlled in Europe in Lithuania. No information is available on the pharmacology and toxicology of this substance. Based on its chemical structure, the substance is expected to be an opioid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Isobutyrfentanyl** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Italy. The substance is controlled in Europe in Lithuania and Norway. Based on its chemical structure and similarity to fentanyl and butyrfentanyl, this substance is expected to have opioid narcotic analgesic effects.

Isobutyrfentanyl was evaluated for antinociceptive activity in mice and was found to be 1.3 times more potent than morphine in this test, but about 50 times less potent than fentanyl. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Carbonyl bromadol** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of carbonyl bromadol. Based on its chemical structure and similarity to bromadol, this substance is expected to have analgesic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Metonitazepine** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Lithuania, Germany, Slovenia and Sweden. The substance is controlled in Europe in Denmark and France. Limited information is available on the pharmacology and toxicology of metonitazepine. Based on its chemical structure and similarity to clonitazene, metonitazene, etonitazene and isotonitazene, metonitazepine is expected to have analgesic effects. Recent in vitro activity and efficacy studies have found that metonitazepine is an active opioid with an efficacy approximately twice that of fentanyl. In the Czech Republic, the presence of this substance has not been confirmed.

The substance **N-desethyl etonitazene** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Estonia, Lithuania and Sweden. The substance is controlled in Europe in Denmark, France and Great Britain. Limited information is available on the pharmacology and toxicology of N-desethyl etonitazene. Based on its chemical structure and similarity to etonitazene and other 2-benzimidazole opiates, N-desethyl etonitazene is expected to have analgesic effects. A pharmacological study demonstrates that N-desethyl etonitazene is an active μ opioid agonist with efficacy similar to etonitazene and approximately 10 times more potent than fentanyl. The presence of this substance in the Czech Republic has not been confirmed.

The substance **N-desethyl isotonitazene** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Estonia and Portugal. The substance is controlled in Europe in Denmark, France, and Great Britain. Limited information is available on the pharmacology and toxicology of N-desethyl isotonitazene. Based on its chemical structure and similarity to etonitazene, isotonitazene, and other 2-benzimidazole opioids, it is expected to have analgesic effects. An in vitro pharmacological study by Vandeputte et al. concludes that N-desethyl isotonitazen has a very

high potency, exceeding that of isotonitazene and comparable to etonitazene. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Nortilidine** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Poland. The substance is controlled in Europe in Italy, Lithuania and Norway. Nortilidine is listed as the active metabolite of tilidine. Nortilidine is reported to easily cross the blood-brain barrier and bind to the mu-opioid receptor as a potent agonist. In a systematic study of the agonistic and antagonistic effects of tilidine and nortilidine, it was found that nortilidine is a selective MOP receptor agonist exhibiting efficacy about 100 times greater than that of the original tilidine molecule. In the Czech Republic, the presence of this substance has not been confirmed.

The substance **O-AMKD** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of O-AMKD. Based on its chemical structure and similarity to ketobemidone, O-AMKD is expected to have opioid narcotic analgesic effects. In the Czech Republic, the presence of this substance has not been confirmed.

The substance **Protonitazepine** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Ireland, Latvia, Germany and Slovenia. The substance is controlled in Europe in Denmark, France and Great Britain. Limited information is available on the pharmacology and toxicology of protonitazepine. Based on its chemical structure and similarity to clonitazene, metonitazene, etonitazene, and isotonitazene, protonitazepine is expected to have analgesic effects. Recent in vitro studies examining activity and potency have found that protonitazepine is an active opioid with a potency approximately 25 times greater than that of fentanyl. The presence of this substance in the Czech Republic has not been confirmed.

Re: point 3: The groups of arylalkylamines, arylcyclohexylamines, benzodiazepines, phenethylamines, cathinones, piperazines, piperidines, pyrrolidines, synthetic cannabinoids, and others (all substances from these groups are being included in Annex 4 to the Government Regulation):

Arylalkylamines

The substance **5-Methylthiopropamine** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Hungary. No information is available on the pharmacology and toxicology of 5-methylthiopropamine. Based on its structural similarity to amphetamine and arylalkylamines such as methylthienylpropamine (MPA) and thiopropamine, 5-methylthiopropamine is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **BOH-PHP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Estonia, Germany and Slovenia. The substance is controlled in Europe in Italy, Lithuania and Norway. Limited information is available on the pharmacology and toxicology of BOH-PHP. BOH-PHP has been identified as the main metabolite (dihydro-α-pyrrolidinohexiophenone; dihydro-α-PHP; M1) α-PHP in human urine, which is formed by the reduction of the keto group in α-PHP with hydrogen. Based on its structural similarity to α-PHP, the substance is expected to have stimulatory effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **M-ALPHA-HCMA** is included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of M-ALPHA-HCMA. Based on its chemical structure and its similarity to MDMA and M-ALPHA, the substance can be expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Mephedren** is included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 15 EU countries. The substance is controlled in Europe in Italy, Lithuania and Norway. Based on its structural similarity to methamphetamine and arylalkylamines such as methylthienylpropamine and thiopropamine, which are known to have stimulating effects, mephedrene is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

Arylcyclohexylamines

The substance **2-Fluoro-deschloro-N-ethylketamine** is included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Finland, Germany, Spain and Sweden. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of 2-fluoro-deschlor-N-ethylketamine. Based on its chemical structure and similarity to ketamine, 2-fluoro-deschlor-N-ethylketamine is expected to have dissociative effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3-Cl-PCP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in seven EU countries. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of 3-Cl-PCP. Based on its structural similarity to other arylcyclohexylamines with known dissociative effects, such as PCP, 3-Cl-PCP is expected to have dissociative effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3F-PCP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Belgium,

Slovenia and Sweden. The substance is controlled in Europe in Italy and Lithuania. Limited information is available on the pharmacology and toxicology of 3F-PCP. Based on its structural similarity to PCP, with known dissociative effects, 3F-PCP can be expected to have dissociative effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3-Me-PCP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in nine EU countries. The substance is controlled in Europe in Italy and Lithuania. 3-Me-PCP is a 3-methyl derivative of PCP, also known as phencyclidine, which is listed in Schedule II of the 1971 United Nations Single Convention on Psychotropic Substances. Based on the structural similarity to PCP, which has known dissociative effects, 3-Me-PCP can be expected to have dissociative effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3-Me-PCPy** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in six EU countries. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of 3-Me-PCPy. Based on its structural similarity to other arylcyclohexylamines with known dissociative effects, such as PCP, 3-Me-PCPy is expected to have dissociative effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Deoxymethoxetamin** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 15 EU countries. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of deoxymethoxetamine. Based on its structural similarity to other arylcyclohexylamines with known dissociative effects, such as methoxetamine, deoxymethoxetamine is expected to have dissociative effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Fluorexetamine** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in six EU countries. It is not a controlled substance in Europe. Fluorexetamine, also known as FXE and 3-fluoro-deschlor-N-ethylketamine, is structurally related to the dissociative anaesthetic ketamine. No information is available on the pharmacology and toxicology of fluorexetamine. Based on its chemical structure and similarity to ketamine, fluorexetamine is expected to have dissociative effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Hydroxetamine** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 10 EU countries. The substance is controlled in Europe in Lithuania. Hydroxetamine, also known as HXE, is structurally related to internationally controlled methoxetamine. Limited information is available on the pharmacology and toxicology of hydroxetamine. Based on its chemical

structure and its similarity to methoxetamine and ketamine, hydroxetamine is expected to have dissociative effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Methoxisopropamine** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 13 EU countries. The substance is controlled in Europe in Italy and Lithuania. Methoxisopropamine (MXiPr) is a higher homologue of the internationally controlled substance methoxetamine (MXE). No information is available on the pharmacology and toxicology of methoxisopropamine. Based on its structural similarity to other arylcyclohexylamines with known dissociative effects, such as methoxetamine, metoxisopropamine is expected to have dissociative effects. The presence of this substance in the Czech Republic has not been confirmed.

Benzodiazepines

The substance **4'-Chlordeschloralprazolam** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Ireland. The substance is controlled in Europe in Lithuania. 4'-Chlordeschloroalprazolam is a structural isomer of the internationally controlled triazolobenzodiazepine alprazolam. No information is available on the pharmacology and toxicology of 4'-chlordeschloroalprazolam. Based on structural similarity with other benzodiazepines, such as alprazolam, 4'-chlordeschloroalprazolam is expected to have sedative-hypnotic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Bretazenil** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Denmark, Germany and Sweden. The substance is controlled in Europe in Lithuania. Bretazenil was developed in the late 1980s as an anti-anxiety drug. A partial benzodiazepine agonist is reported to have ten times the benzodiazepine receptor activity of diazepam and a different pharmacological profile. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Desalkylgidazepam** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 11 EU countries. It is not a controlled substance in Europe. Limited information is available on the pharmacology and toxicology of desalkylgidazepam. Based on the structural similarity with other benzodiazepines such as phenazepam and flubromazepam, desalkylgidazepam is expected to have sedative hypnotic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Deschlorclotizolam** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Romania and Sweden. The substance is controlled in Europe in Lithuania. No information is available

on the pharmacology and toxicology of deschloroclotisam. Based on its chemical structure and chemical similarity to brotizolam and etizolam, the substance is expected to have sedative-hypnotic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Flubrotizolam** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 10 EU countries. It is not a controlled substance in Europe.

Limited information is available on the pharmacology and toxicology of flubrotizolam. Based on the structural similarity with other thienodiazepines, such as brotizolam, flubrotizolam is expected to have sedative-hypnotic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Fluetizolam** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Belgium, Finland, Italy and Sweden. It is not a controlled substance in Europe. Limited information is available on the pharmacology and toxicology of fluetizolam. Based on the structural similarity with other thienodiazepines, such as etizolam, fluetizolam is expected to have sedative-hypnotic effects. The presence of this substance in the Czech Republic has not been confirmed.

Phenethylamines

The substance **6-BR-DMPEA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in nine EU countries. The substance is controlled in Europe in Lithuania. 6-BR-DMPEA is a full agonist of the 5-HT2A receptor with an efficacy of 97% compared to LSD, but its efficacy is significantly lower than that of LSD. The presence of this substance in the Czech Republic has not been confirmed.

The substance **N-pyrrolidinyl-3,4-DMA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Finland and Ireland. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of N-pyrrolidinyl-3,4-DMA. Based on its chemical structure and chemical similarity to DMA, N-pyrrolidinyl-3,4-DMA is expected to have stimulating effects. In the Czech Republic, the presence of this substance has not been confirmed.

The substance **PEAP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Sweden. The substance is controlled in Europe in Italy and Lithuania. PEA (phenylethylaminopentane), a substituted phenethylamine, is a higher homologue of the internationally controlled substance methamphetamine. No information is available on the pharmacology and toxicology of PEAP. Based on its chemical structure and chemical similarity to methamphetamine and

PPAP, PEAP is expected to have stimulating effects. In the Czech Republic, the presence of this substance has not been confirmed.

Cathinones

The substance **2-(4-Methylpiperazine-1-yl)-1-phenylpropan-1-one** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Finland. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of 2-(4-methylpiperazin-1-yl)-1-phenylpropan-1-one. Based on its chemical structure and chemical similarity to cathinone, α-piperidinobutiophenone (α-PipBP) and piperazine, methoxypiperamide, 2-(4-methylpiperazine-1-yl)-1-phenylpropan-1-one is expected to have stimulating effects. In the Czech Republic, the presence of this substance has not been confirmed.

The substance **2-MEB** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Sweden. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of 2-methylethylbuphedrone. Based on its structural similarity to cathinones such as 4-methylethcathinone and N-ethylhexedrone, with known stimulating effects, 2-methylethylbuphedrone is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **2'-Me-PVP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Sweden. The substance is controlled in Europe in Lithuania. 2'-Me-PVP is a 2-methyl derivative of the internationally controlled cathinone α-pyrrolidinovalerophenone (α-PVP). Based on its chemical structure and its similarity to α-PVP and α-PHP, 2'-Me-PVP is expected to have stimulant effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **2-Methyl-α-PHiP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Spain and Sweden. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of 2-methyl-α-PHiP. Based on its chemical structure and its chemical similarity to cathinone α-PHiP (α-PiHP and α-pyrrolidinoisohexanophenone), 2-methyl-α-PHiP is expected to have stimulant effects. In the Czech Republic, the presence of this substance has not been confirmed.

The substance **3,4-Pr-PipVP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Sweden. The substance is controlled in Europe in Lithuania. 2'-Me-PVP is a 2-methyl derivative of the internationally controlled cathinone α-pyrrolidinovalerophenone (α-PVP). Based on its chemical structure and its similarity to α-PVP and α-PHP, 2'-Me-PVP is expected to have stimulant effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3F-NEB** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Sweden. The substance is controlled in Europe in Lithuania. No information is available on the pharmacology and toxicology of 3F-NEB. Based on its chemical structure and its chemical similarity to 4-MEC and N-ethylhexedrone, 3F-NEB is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3F-N-ethylhexedrone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Slovenia and Sweden. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of 3F-N-ethylhexedrone. Based on its chemical structure and its similarity to N-ethylhexedrone, 3F-N-ethylhexedrone is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3F-α-PHP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Sweden. The substance is controlled in Europe in Lithuania and Norway. No information is available on the pharmacology and toxicology of 3F-α-PHP. Based on its structural similarity to other cathinones with known stimulating effects, such as α-PVP, the substance is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3-Chlorocathinone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Hungary, Germany and Poland. The substance is controlled in Europe in Italy and Lithuania. 3-Chlorcathinone is a 3-chloro derivative of the internationally controlled substance cathinone. Limited information is available on the pharmacology and toxicology of 3-chlorocathinone. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3'-Me-PVP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Sweden. It is not a controlled substance in Europe. Information on the pharmacology and toxicology of 3'-Me-PVP is limited. Based on its chemical structure and its chemical similarity to α-PVP, 3'-Me-PVP is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3-Methyl-N-propyl-cathinone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Hungary and Sweden. The substance is controlled in Europe in Lithuania. No information is available on the pharmacology and toxicology of 3-methyl-N-propyl-cathinone. Based on its chemical structure and its chemical similarity to mephedrone and 4-MEC, 3-methyl-N-propyl-cathinone is expected to have stimulating effects. Occurrence of this substance in the Czech Republic has not been confirmed.

The substance **4'-Methylhexedrone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Poland. The substance is controlled in Europe in Lithuania. No information is available on the pharmacology and toxicology of this substance. Based on its chemical structure, which contains the cathinone backbone, 4'-methylhexedrone can have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **4-Cl-3-MMC** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Sweden. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of 4-Cl-3-MMC. Based on its chemical structure and its chemical similarity to 3-MMC and 4-CMC, 4-Cl-3-MMC is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **4F-3-methyl-α-PHP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Sweden. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of 4F-3-methyl-α-PHP. Based on its structural similarity to other cathinones with known stimulating effects, such as α-PHP, the substance is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **4F-3-methyl-α-PVP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 13 EU countries. The substance is controlled in Europe in Lithuania and Norway. No information is available on the pharmacology and toxicology of 4F-3-methyl-α-PVP. Based on its structural similarity to other cathinones with known stimulating effects, such as α-PVP, the substance is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **MDPEP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in nine EU countries. The substance is controlled in Europe in Lithuania and the United Kingdom. No information is available on the pharmacology and toxicology of MDPEP. Based on its structural similarity to other cathinones with known stimulating effects, such as MDPV, MDPEP may also have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **MDPHiP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Sweden. The substance is controlled in Europe in Italy, Lithuania, and Sweden. No information is available on the pharmacology and toxicology of MDPHiP. Based on its structural similarity to cathinones such as MDPV and α-PVP, which are known for their stimulating effects,

MDPHiP is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **N,N-diethylpentylone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Slovenia and Spain. The substance is controlled in Europe in Italy, Lithuania and Norway. Limited information is available on the pharmacology and toxicology of N,N-diethylpentylone. Based on its structural similarity to other cathinones with known stimulating effects, such as pentylone and dipentylone, N,N-dipentylone is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **N-butyl butylone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in the Netherlands, Slovenia and Spain. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of N-butyl butylone. Based on its chemical structure and chemical similarity to butylone and N-ethylhexylone, N-butyl butylone is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **N-cyclohexyl butylone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Finland and Spain. It is not a controlled substance in Europe. Limited information is available on the pharmacology and toxicology of N-cyclohexyl butylone. Based on its chemical structure and chemical similarity to butylone, N-cyclohexyl butylone is expected to have stimulating effects. Studies suggest that the substance is likely to exhibit similar effects to other stimulants such as MDMA, MDPV, MDPBP, and that N-cyclohexyl butylone may have a slightly higher risk of abuse than MDMA. The presence of this substance in the Czech Republic has not been confirmed.

The substance **N-cyclohexyl methylone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 10 EU countries. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of N-cyclohexyl methylone. Based on its chemical structure and its chemical similarity to methylone and MDPV, N-cyclohexyl methylone is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **N-ethyl heptylone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Hungary and Sweden. The substance is controlled in Europe in Lithuania and Norway. No information is available on the pharmacology and toxicology of N-ethyl heptylone. Based on its structural similarity to other cathinones with known stimulating effects, such as ethylone, N-ethyl heptylone is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **N-ethyl hexylone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Poland. The substance is controlled in Europe in Lithuania. No information is available on the pharmacology and toxicology of this substance. Based on its chemical structure, which contains the cathinone main chain, N-ethyl hexylon can have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **N-sec-butyl-pentedrone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in five EU countries. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of N-sec-butyl-pentedrone. Based on its chemical structure and its chemical similarity to pentedrone, N-sec-butyl-pentedrone is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **α-D2PV (α-Pyrrolidino-2-phenylacetophenone)** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 13 EU countries. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of α-D2PV. Based on its structural similarity to other cathinones with known stimulating effects, such as α-PVP and α-PHP, α-D2PV is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **α-PCYP (α-Pyrrolidinocyclohexylphenone)** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 13 EU countries. The substance is controlled in Europe in Lithuania, Germany and Norway. Limited information is available on the pharmacology and toxicology of α-pyrrolidinocyclohexylphenone. The study indicated that there is a potential relationship between efficacy and the nature of the α-substituent, with larger substituents providing greater potency. The presence of this substance in the Czech Republic has not been confirmed.

Other

The substance **3-Chlorphenmetrazine** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in nine EU countries. The substance is controlled in Europe in Lithuania. Limited information is available on the pharmacology and toxicology of 3-chlorophenmetrazine. Based on its chemical structure and chemical similarity to phenmetrazine, 3-chlorophenmetrazine is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **3-Methoxyphenmetrazine** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Finland. The substance is controlled in Europe in Italy, Lithuania and Norway. Limited

information is available on the pharmacology and toxicology of this substance. Based on its chemical structure and similarity to phenmetrazine, the substance is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **4Br-MAR (Para-bromo-4-methylaminorex)** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Italy, Germany, Slovenia, and Sweden. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of 4Br-MAR. Based on its chemical structure and chemical similarity to 4-methylaminorex and para-methyl-4-methylaminorex (4,4'-DMAR), 4Br-MAR is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **4Cl-MAR (Para-chloro-4-methylaminorex)** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Estonia, Italy, Slovenia and Sweden. The substance is controlled in Europe in Italy and Lithuania. No information on the pharmacology and toxicology of 4Cl-MAR is available. Based on its chemical structure and its chemical similarity to 4-methylaminorex and para-methyl-4-methylaminorex (4,4'-DMAR), 4Cl-MAR is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **4-Fluorophenibut** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Finland, Germany and Sweden. The substance is controlled in Europe in Lithuania. Limited information is available on the pharmacology and toxicology of this substance. 4-Fluorfenibut is structurally related to the naturally occurring mammalian neurotransmitter GABA and the substance baclofen. Based on its chemical structure, the substance is expected to have anxiolytic or sedative hypnotic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Dichloromethaqualone (SL-164)** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Denmark, Germany and Sweden. The substance is controlled in Europe in Lithuania. Limited information is available on the pharmacology and toxicology of this substance. Limited information is available on the pharmacology and toxicology of SL-164. SL-164 is structurally related to metaqualone, which has been sold in the past as a hypnotic for the short-term treatment of insomnia and is reported to exhibit sedative, hypnotic, anticonvulsant, and anxiolytic properties through action on the GABA-A receptor. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Ephinazone** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is controlled in Europe in Lithuania. Limited information is available on the pharmacology and toxicology of ephinazone. Based on its chemical structure and its

similarity to methaqualone, ephinazone is expected to have anxiolytic or sedative-hypnotic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Phenozolone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Denmark and Germany. It is not a controlled substance in Europe. The pharmacology and toxicology of phenozolone in humans has not been fully described. However, animal studies have revealed that phenozolone acts as a mild psychostimulant that inhibits the re-uptake of dopamine, norepinephrine and serotonin. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Iso-(meta-methyl-propcathinone)** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Hungary and Sweden. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of iso-(meta-methyl-propcathinone). Based on the chemical structure and chemical similarity with 4-methylmethcathinone (mephedrone; 4-MMC) and 4-methylethcathinone (4-MEC), it is expected that iso-(meta-methyl-propcathinone) will have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Iso-3-CMC** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in five EU countries. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of iso-3-CMC. Based on its chemical structure and its chemical similarity to 3-CMC and 4-CMC, iso-3-CMC is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Iso-3-MMC** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in five EU countries. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of iso-3-MMC. Based on its chemical structure and chemical similarity to 3-MMC and 4-MMC, iso-3-MMC is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **N-ethyl zolpidem** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. It is not a controlled substance in Europe. No information is available on the pharmacology and toxicology of N-ethyl zolpidem. Based on its structural similarity to zolpidem and other ‘Z-drugs’ such as zopiclone and zaleplon, N-ethyl zolpidem is expected to have sedative-hypnotic effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Nitromethaqualone** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is controlled in Europe in Lithuania and Norway. Limited

information is available on the pharmacology and toxicology of nitromethaqualone. It is structurally related to methaqualone, which has been sold in the past as a hypnotic agent for the short-term treatment of insomnia and is reported to exhibit sedative, hypnotic, anticonvulsant, and anxiolytic properties through action on the GABA-A receptor. The hypnotic properties of nitromethaqualone for psychiatric disorders were investigated in a 1965 study. Nitromethaqualone has been described as a more potent hypnotic than methaqualone and mecloqualone, with a single therapeutic dose reported as 15 mg, compared to 150 mg for methaqualone or mecloqualone. An overdose of nitromethaqualone, when taken with alcohol, is said to cause toxic hallucinosis. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Pagoclone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in six EU countries. The substance is controlled in Europe in Lithuania. Limited information is available on the pharmacology and toxicology of this substance.

(+)-Pagoclone is an anxiolytic non-benzodiazepine that has similar effects to benzodiazepines but a different chemical structure. Like zopiclone, it belongs to the cyclopyrrolone group. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Rilmazafone** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Denmark, Germany, Austria and Sweden. The substance is not controlled in Europe. Rilmazafone is reported to be a short-acting hypnotic with a half-life of 10 hours and a benzodiazepine precursor. The selectivity of rilmazafone for benzodiazepine receptor 1 (BZ1) is not considered high. The presence of this substance in the Czech Republic has not been confirmed.

Piperazines

The substance **3,4-CFP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in five EU countries. The substance is controlled in Europe in Lithuania and Poland. There is little information available on the pharmacology and toxicology of this substance. Based on its chemical structure and its similarity to mCPP, the substance is expected to be a psychostimulant. Occurrence of this substance in the Czech Republic has not been confirmed.

The substance **4F-MBZP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Austria and Sweden. The substance is not controlled in Europe. Limited information is available on the pharmacology and toxicology of 4F-MBZP. Based on its chemical structure and its chemical similarity to BZP and MBZP, 4F-MBZP is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **pBPP** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Poland. The substance is controlled in Europe in Lithuania.

There is little information available on the pharmacology and toxicology of this substance. Based on its chemical structure, the substance is expected to be a psychostimulant. The presence of this substance in the Czech Republic has not been confirmed.

Piperidines and pyrrolidines

The substance **4,4-Dimethyl-1-phenyl-1-pyrrolidin-1-yl-pentan-3-one** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in the UK. The substance is controlled in Europe in Italy, Lithuania and Norway. No information is available on the pharmacology and toxicology of 4,4-dimethyl-1-phenyl-1-pyrrolidin-1-yl-pentan-3-one. Based on its structural similarity to other pyrrolidines, such as methyl-2-phenyl-2-(pyrrolidine-1-yl)acetate, and piperidines with known stimulating effects, such as methylphenidate and ethylphenidate, 4,4-dimethyl-1-phenyl-1-pyrrolidin-1-yl-pentan-3-one may have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

The substance **methyl 2-phenyl-2-(pyrrolidin-1-yl)acetate** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in France and Sweden. The substance is controlled in Europe in Lithuania and Norway. No information is available on the pharmacology and toxicology of methyl-2-phenyl-2-(pyrrolidine-1-yl) acetate. Based on its structural similarity to other piperidines and pyrrolidines with known stimulating effects, such as methylphenidate, the substance is expected to have stimulating effects. The presence of this substance in the Czech Republic has not been confirmed.

Synthetic cannabinoids

The substance **3,5-ADB-4en-PFUPPYCA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in five EU countries. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of 3,5-ADB-4en-PFUPPYCA. Based on its structural similarity to other cannabinoids, 3,5-ADB-4en-PFUPPYCA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **4en-PDMB-4en-PINACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in five EU countries. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of 4en-PDMB-4en-PINACA. Based on its structural similarity to other synthetic cannabinoids, such as MDMB-4en-PINACA, 4en-PDMB-4en-PINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **4F-ABINACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 13 EU countries.

The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of 4F-ABINACA. Based on its structural similarity to other synthetic cannabinoids, such as 5F-AKB48 (5F-APINACA), 4F-ABINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **5,3-AB-CHMFUPPYCA** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is not controlled in Europe. Limited information is available on the pharmacology and toxicology of 5,3-AB-CHMFUPPYCA. Based on its structural similarity to other cannabinoids, such as 5F-AB-FUPPYCA (5F-5,3-AB-PFUPPYCA) and 5F-3,5-AB-PFUPPYCA, 5,3-AB-CHMFUPPYCA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **5,3-ADB-4en-PFUPPYCA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in France. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of 5,3-ADB-4en-PFUPPYCA. Based on its structural similarity to other cannabinoids, 5,3-ADB-4en-PFUPPYCA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **5B-AKB48** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Slovenia. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of 5B-AKB48. Based on its structural similarity to other synthetic cannabinoids, such as 5F-AKB48 (5F-APINACA), 5B-AKB48 is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **5F-BZO-POXIZID (MDA-19 5-fluoropentyl analogue)** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in nine EU countries. The substance is controlled in Europe in Denmark. After China introduced generic legislation controlling synthetic cannabinoids with seven potential basic structures in 2021, the MDA-19 5-fluoropentyl analogue appeared along with other synthetic cannabinoids derived from MDA-19, apparently driven by manufacturers' efforts to circumvent the aforementioned Chinese legislation. Based on the structural similarity of this analogue with other cannabinoids, this substance is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **5F-EDMB-PICA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 15 EU countries. The substance is controlled in Europe in Italy, Lithuania and Norway. Based on its structural similarity to other synthetic cannabinoids, such as 5F-EDMB-PINACA and 5F-MDMB-PICA, it is expected to act as a cannabinoid receptor agonist. 5F-EDMB-PICA is a

CB1 receptor agonist with efficacy of 130% compared to JWH-018. The presence of this substance in the Czech Republic has not been confirmed.

The substance **5F-EMB-PICA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 12 EU countries. The substance is controlled in Europe in Italy, Lithuania, and Norway. Based on its structural similarity to other synthetic cannabinoids, such as 5F-MDMB-PINACA and 5F-MDMB-PICA, it is expected to act as a cannabinoid receptor agonist. 5F-EMB-PICA is a CB1 receptor agonist with efficacy of 117% compared to JWH-018. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ABO-4en-PINACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in France. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of ABO-4en-PINACA. Based on its structural similarity to other synthetic cannabinoids, ABO-4en-PINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-4en-P-5Br-INACA** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of ADB-4en-P-5Br-INACA. Based on its structural similarity to other synthetic cannabinoids, such as ADB-CHMINACA and ADB-FUBINACA, ADB-4en-P-5Br-INACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-4en-PINACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 14 EU countries. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of ADB-4en-PINACA. Based on its structural similarity to other synthetic cannabinoids, such as MDMB-4en-PINACA, ADB-4en-PINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-5Br-INACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 15 EU countries. The substance is controlled in Europe in Denmark. No information is available on the pharmacology and toxicology of ADB-5Br-INACA. Based on its structural similarity to other synthetic cannabinoids such as ADB-FUBINACA, ADB-5Br-INACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-B-5Br-INACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 15 EU countries. The substance is not controlled in Europe. No information is available on the

pharmacology and toxicology of ADB-B-5Br-INACA. Based on its structural similarity to other synthetic cannabinoids such as ADB-CHMINACA and ADB-FUBINACA, ADB-B-5Br-INACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-BUTINACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 22 EU countries. The substance is controlled in Europe in five EU countries. The activity of ADB-BUTINACA on the CB1 receptor was characterised, indicating that this substance is a CB1 receptor agonist with an efficacy of 290% compared to JWH-018. ADB-BUTINACA was detected in a herbal smoking mixture at concentrations between 8.1 mg and 8.4 mg per gram of plant material, along with 24.2 mg/g of tobacco. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-D-5Br-INACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 7 EU countries. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of ADB-D-5Br-INACA. The length of the alkyl chain between three and six carbon atoms is considered sufficient to bind with high affinity to the CB1 and CB2 receptors, and an increase in the length of the alkyl chain above this boundary is associated with a decrease in binding at both receptors. However, it cannot be ruled out that ADB-D-5Br-INACA may act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-FUBHQUCA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Turkey. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of ADB-FUBHQUCA. Based on its structural similarity to other synthetic cannabinoids such as ADB-FUBINACA, ADB-FUBHQUCA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-FUBIACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 12 EU countries. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of ADB-FUBIACA. Based on its structural similarity to other synthetic cannabinoids such as ADB-FUBINACA, ADB-FUBIACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-HEXINACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in nine EU countries. The substance is controlled in Europe in Lithuania. No information is available on the pharmacology and toxicology of ADB-HEXINACA. Based on its structural similarity to other synthetic cannabinoids, such as ADB-CHMINACA, ADB-HEXINACA is expected to

act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-IACA** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Hungary. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of ADB-IACA. Based on its structural similarity to other synthetic cannabinoids such as ADB-FUBINACA, ADB-IACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADB-P-5Br-INACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in nine EU countries. The substance is controlled in Europe in Denmark. No information is available on the pharmacology and toxicology of ADB-P-5Br-INACA. Based on its structural similarity to other synthetic cannabinoids, such as ADB-CHMINACA and ADB-FUBINACA, ADB-P-5Br-INACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADMB-3TMS-PRINACA** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of ADMB-3TMS-PRINACA. Based on its structural similarity to other synthetic cannabinoids such as ADB-FUBINACA, ADMB-3TMS-PRINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **ADMB-INACA (ADB-INACA)** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in six EU countries. The substance is not controlled in Europe. Limited information is available on the pharmacology and toxicology of ADMB-INACA. Based on its structural similarity to other synthetic cannabinoids, such as ADB-FUBINACA, ADMB-INACA is expected to act as a cannabinoid receptor agonist. ADMB-INACA has also been identified as a metabolite of the synthetic cannabinoids ADB-PINACA and 5F-ADB-PINACA. The presence of this substance in the Czech Republic has not been confirmed.

The substance **A-FUBIACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Hungary, Portugal, Greece and Spain. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of A-FUBIACA. Based on its structural similarity to other synthetic cannabinoids such as ADB-FUBINACA and JWH-018, A-FUBIACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **A-PBITMO** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The

substance is not controlled in Europe. No information is available on the pharmacology and toxicology of A-PBITMO. Based on its structural similarity to other synthetic cannabinoids, such as the adamantoyl derivative JWH-018 (AB-001) and the benzimidazole analogue AM-2201, A-PBITMO is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **A-PONASA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Bulgaria, Germany and Sweden. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of A-PONASA. However, based on its structural similarity to other synthetic cannabinoids, A-PONASA can be expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **BENZYL-4CN-BINACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Lithuania, Germany, Poland and Sweden. The substance is controlled in Europe in Lithuania and Sweden. No information is available on the pharmacology and toxicology of BENZYL-4CN-BINACA. Based on its structural similarity to other synthetic cannabinoids, such as CUMYL-4CN-BINACA, it is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **BZO-4en-POXIZID (MDA-19 4en-pentyl analogue)** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in 11 EU countries. The substance is not controlled in Europe. The activity of the MDA-19 4en-pentyl analogue at CB1 and CB2 receptors was experimentally characterised, showing that this substance is a complete agonist of both CB1 and CB2. Compared to JWH-018, it shows lower efficacy. The presence of this substance in the Czech Republic has not been confirmed.

The substance **BZO-POXIZID (MDA-19 pentyl analogue)** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in five EU countries. The substance is controlled in Europe in France. The activity of the MDA-19 pentyl analogue on CB1 and CB2 receptors was experimentally characterised, showing that this substance is a complete agonist of both CB1 and CB2. Similar to the MDA-19 4en-pentyl analogue, it exhibits lower efficacy compared to JWH-018. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CUMYL-1Cl-CHSINACA** is being included in alphabetical order by decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Hungary. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of CUMYL-1Cl-CHSINACA. Based on the structural similarity with other synthetic cannabinoids such as CUMYL-4CN-BINACA and CUMYL-PEGACLONE, CUMYL-1Cl-CHSINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CUMYL-3TMS-PRINACA** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Hungary, Germany and Sweden. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of CUMYL-3TMS-PRINACA. Based on its structural similarity to other synthetic cannabinoids, such as CUMYL-4CN-BINACA, CUMYL-3TMS-PRINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Cumyl-BC-HpMeGaClone-221** is being included in alphabetical order by decision of the EWS Working Group. The presence of the substance has hitherto been reported in Hungary, Germany and Sweden. The substance is controlled in Europe in Italy, Lithuania and Norway. No information is available on the pharmacology and toxicology of Cumyl-BC-HpMeGaClone-221. Based on its structural similarity to other synthetic cannabinoids, such as CUMYL-PeGACLONE, which is reported to bind to human cannabinoid receptors hCB1 and hCB2 and acts as a complete and potent agonist at CB1 receptors, Cumyl-BC-HpMeGaClone-221 is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **Cumyl-CB-MeGaClone** is being included in alphabetical order based on a decision of the EWS Working Group. The presence of the substance has hitherto been reported in six EU countries. The substance is controlled in Europe in Denmark, Lithuania, and Norway. No information is available on the pharmacology and toxicology of Cumyl-CB-MeGaClone. Based on its structural similarity to other synthetic cannabinoids, such as Cumyl-CH-MeGaClone and CUMYL-PeGACLONE, it is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CUMYL-CBMICA** is being inlcuded in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in 10 EU countries. The substance is controlled in Europe in Lithuania and Norway. No information is available on the pharmacology and toxicology of CUMYL-CBMICA. Based on its structural similarity to other synthetic cannabinoids, it is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CUMYL-CBMINACA** is being included in alphabetical order based on the decision of the EWS Working Group. The presence of the substance has hitherto been reported in Germany and Sweden. The substance is controlled in Europe in Italy, Lithuania and Norway. No information is available on the pharmacology and toxicology of CUMYL-CBMINACA. Based on its structural similarity to other synthetic cannabinoids, it is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CUMYL-CHSINACA** is being included in alphabetical order based on a decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Hungary. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of CUMYL-CHSINACA. Based on its structural similarity to other synthetic cannabinoids such as CUMYL-4CN-BINACA and CUMYL-PEGACLONE, CUMYL-CHSINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CUMYL-INACA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in Hungary and Germany. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of CUMYL-INACA. Based on its structural similarity to other synthetic cannabinoids, such as CUMYL-4CN-BINACA, CUMYL-INACA is expected to act as a cannabinoid receptor agonist. A study showed that CUMYL-INACA is a metabolite of CUMYL-4CN-BINACA (N-dealkylated metabolite). The presence of this substance in the Czech Republic has not been confirmed.

The substance **CUMYL-NBMICA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in the Netherlands. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of CUMYL-NBMICA. Based on its structural similarity to other synthetic cannabinoids, CUMYL-NBMICA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CUMYL-NBMINACA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in nine EU countries. The substance is controlled in Europe in Lithuania. No information is available on the pharmacology and toxicology of CUMYL-NBMINACA. Based on its structural similarity to other synthetic cannabinoids, CUMYL-NBMINACA is expected to act as a cannabinoid receptor agonist.

The presence of this substance in the Czech Republic has not been confirmed.

The substance **CUMYL-TsINACA** is being included in alphabetical order based on a decision of the EWS Working Group. The presence of the substance has hitherto been reported in Hungary and Germany. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of CUMYL-TsINACA. Based on its structural similarity to other synthetic cannabinoids such as CUMYL-4CN-BINACA and CUMYL-PEGACLONE, CUMYL-TsINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **EDMB-PINACA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in 14 EU countries. The substance is controlled in Europe in Denmark, Italy and Lithuania. No information is available on the pharmacology and toxicology of EDMB-

PINACA. Based on its structural similarity to other synthetic cannabinoids such as MDMB-4en-PINACA, EDMB-PINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **FUBIAT** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of FUBIAT. Based on its structural similarity to other synthetic cannabinoids such as ADB-FUBINACA, FUBIAT is expected to act as a cannabinoid receptor agonist. It is reported that FUBIAT could potentially be a metabolite of ADB-FUBIACA (ADB-FUBIATA). The presence of this substance in the Czech Republic has not been confirmed.

The substance **CH-FUBBMPDORA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hiterto been reported in eight EU countries. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of CH-FUBBMPDORA. Based on its structural similarity to other synthetic cannabinoids such as URB-597, CH-FUBBMPDORA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CH-FUBIACA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in Bulgaria and Spain. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of CH-FUBIACA. Based on its structural similarity to other synthetic cannabinoids such as JWH-018 and MDA 19, CH-FUBIACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CH-IACA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of CH-IACA. Based on its structural similarity to other synthetic cannabinoids such as JWH-018 and MDA 19 (BZO-HEXOXIZID), CH-IACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CHM-MDA-19 (BZO-CHMOXIZID)** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in the Netherlands, Hungary and Romania. The substance is not controlled in Europe. According to one study, replacing the aliphatic chain with cyclohexylmethyl in CHM-MDA-19 ‘led to a large increase in both CB1 and CB2 functional activity’ and was ‘the most effective of the series in terms of CB2 functional activity’. The activity of CHM-MDA-19 at CB1 and CB2 receptors has been experimentally characterised, showing that this substance is a complete agonist of both CB1 and CB2. CHM-MDA-19

showed greater efficacy at the CB2 receptor than JWH-018. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CHM-MDMB-CHMINACA** is being included in alphabetical order based on a decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Germany. The substance is controlled in Europe in Italy and Lithuania. No information is available on the pharmacology and toxicology of CHM-MDMB-CHMINACA. Based on its structural similarity to other synthetic cannabinoids such as MDMB-CHMICA, ADB-CHMINACA, and AB-CHMINACA, CHM-MDMB-CHMINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **CH-PIACA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in 15 EU countries. The substance is controlled in Europe in Denmark. No information is available on the pharmacology and toxicology of CH-PIACA. Based on its structural similarity to other synthetic cannabinoids such as JWH-018 and MDA 19, CH-PIACA is expected to act as a cannabinoid receptor agonist.

The presence of this substance in the Czech Republic has not been confirmed.

The substance **MDMB-5Br-INACA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in seven EU countries. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of MDMB-5Br-INACA. Based on its structural similarity to other synthetic cannabinoids, such as MDMB-4en-PINACA, MDMB-5Br-INACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **MDMB-7Br-INACA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in Bulgaria, Germany and Spain. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of MDMB-7Br-INACA. Based on its structural similarity to other synthetic cannabinoids such as MDMB-4en-PINACA, MDMB-7Br-INACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **MDMB-BINACA** is being included in alphabetical order based on a decision of the EWS Working Group. The presence of the substance has hitherto been reported in 15 EU countries. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of MDMB-BINACA. Based on its structural similarity to other synthetic cannabinoids, such as 4F-MDMB-BINACA, MDMB-BINACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **MDMB-CHMINACA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in seven EU countries. The substance is controlled in Europe in Lithuania. Little information is available on the pharmacology of this cannabinoid receptor agonist. Indole and indazole synthetic cannabinoid receptor agonists were synthesised and evaluated for cannabimimetic activity in vitro and in vivo using a fluorometric membrane potential test. All compounds studied, including (S)-MDMB-CHMINACA, activated the CB1 and CB2 receptors, exhibit greater efficacy than either delta-9-THC or CP 55 940 for the activation of G protein-coupled inwardly rectifying potassium channels (GIRK) mediated by the CB1 receptor. Most of the compounds studied, including (S)-MDMB-CHMINACA, had a similar maximum effect as CP 55 940 on CB1 and CB2 receptors, suggesting that these substances are also highly effective agonists. (S)-MDMB-CHMINACA showed a preference for CB1 receptors over CB2 receptors. The presence of this substance in the Czech Republic has not been confirmed.

The substance **MDMB-INACA** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in 12 EU countries. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of MDMB-INACA. Based on its structural similarity to other synthetic cannabinoids, such as MDMB-4en-PINACA, MDMB-INACA is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

The substance **NMDMSB** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The presence of the substance has hitherto been reported in Hungary, Germany and Spain. The substance is not controlled in Europe. No information is available on the pharmacology and toxicology of NMDMSB. Based on its structural similarity to other synthetic cannabinoids such as QMPSB and 2F-QMPSB, NMDMSB is expected to act as a cannabinoid receptor agonist.

The presence of this substance in the Czech Republic has not been confirmed.

The substance **PTI-3** is being included in alphabetical order on the basis of a decision of the EWS Working Group. The occurrence of the substance has hitherto been reported in Hungary. The substance is controlled in Europe in Italy, Lithuania and Norway. No information on PTI-3 pharmacology and toxicology is available. Based on its structural similarity to other synthetic cannabinoids, such as PTI-1 and PTI-2, it is expected to act as a cannabinoid receptor agonist. The presence of this substance in the Czech Republic has not been confirmed.

Re: point 4:

The substance **gammabutyrolactone (GBL)** is being included in alphabetical order in Annex 6 Psychotropic substances based on a decision of the EWS Working Group. The substance is controlled in Europe in Belgium, Denmark, Finland, France, Italy, the Netherlands, Germany, Norway, Poland, Spain, Sweden and the United Kingdom. In the Czech Republic, it is

currently included among precursor and excipient substances, which allows for the inspection of distributors, and sales are limited to sole traders and corporate entities. Despite this regulation, GBL escapes to illegal channels due to its easy accessibility (solvent, cleaning agent). It is therefore necessary to implement stricter control of this substance due to intoxications, which are quite common. After oral ingestion, GBL is in the body metabolised to GHB. At low doses there is a euphoric effect while at higher doses there is a sedative effect. Sedation can have fatal consequences, especially when GBL/GHB is combined with alcohol or other addictive substances.

Re: Article II

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 ('the Directive').

Article 6(7) of the Directive permits exceptions to postpone the adoption of a draft by 3 months in cases of imperative grounds of urgency (hereinafter the 'urgent technical notification procedure').

This derogation may be used where, for imperative 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, public policy, 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 the health of the population, preventing the occurrence of intoxication in particular in young people, preventing the further development of the grey zone 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. The consequences of delay in the regulation of substances, as demonstrated by the HHC case, clearly demonstrate that delays can lead to significant negative impacts. Health, public safety and drug experts were consulted on the proposed measure, with a majority consensus supporting the need for the immediate inclusion of these substances in the list of addictive substances. This step is necessary to prevent the escalation of the problem and to protect the population, especially children. The use of an urgent technical notification procedure is justified and necessary for the rapid adoption of measures to protect public health and prevent health consequences associated with the use of newly identified hazardous substances.

Re: Article III

The effective date is stipulated 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, on ....., with the exception of Article I(4), for which the effective date is postponed by 3 months, as the newly included substance GBL is currently used in industry. Corporate entities working with this substance must submit an application for a permit to handle this substance and adapt the premises where the substance is located and where it is worked with so that everything corresponds to the legal regime laid down in Act No 167/1998 on addictive substances and amending certain other acts, as amended. Based on the above, a time frame of 3 months is established, which the Ministry of Health considers sufficient to adapt to the newly established regulation of GBL handling.