

DRAFT

GOVERNMENT REGULATION

of ... 2025,

amending Government Regulation No 463/2013 on the schedules of addictive substances, as amended, and Government Regulation No 11/2025 on the list of scheduled psychoactive substances

Pursuant to § 44c(1) to (3) and for the implementation of § 33k(6)(b) of Act No 167/1998 on addictive substances and on amendments to certain other acts, as amended by Act No 273/2013, Act No 366/2021 and Act No 321/2024, the Government hereby orders the following:

PART ONE

Amendment to the Government Regulation on the schedules of addictive substances

Article I

Government Regulation No 463/2013 on the schedules of addictive substances, as amended by Government Regulation No 243/2015, Government Regulation No 46/2017, Government Regulation No 30/2018, Government Regulation No 242/2018, Government Regulation No 184/2021, Government Regulation No 159/2022, Government Regulation No 228/2023, Government Regulation No 52/2024, Government Regulation No 176/2024 and Government Regulation No 419/2024, is amended as follows:

1. In the table in Annex 3, a new row is inserted above the row with the entry 'Acetylbenzylfentanyl' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Acetoxynitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '[4-[[1-[2-(diethylamino)ethyl]-5-nitrobenzimidazol-2-yl]methyl]phenyl] acetate' in the column headed 'IUPAC chemical name'.
2. In the table in Annex 3, a new row is inserted above the row with the entry 'Brorphine' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Bronitazene' in the column headed 'International Non-proprietary

- Name (INN) in Czech/generic name' and the entry '2-[2-[(4-bromophenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine' in the column headed 'IUPAC chemical name'.
3. In the table in Annex 3, a new row is inserted above the row with the entry 'Desomorphine' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Desnitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '1-diethylaminoethyl-2-benzyl-benzimidazole' in the column headed 'IUPAC chemical name'.
 4. In the table in Annex 3, a new row is inserted above the row with the entry 'Dipyanone' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Dimethoxynitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the entry 'Dimetonitazene' in the column headed 'Other international non-proprietary name or generic name' and the entry '2-[2-[(3,4-dimethoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine' in the column headed 'IUPAC chemical name'.
 5. In the table in Annex 3, a new row is inserted below the row with the entry 'Ethyleneoxynitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Ethylthionitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-[2-[(4-ethylsulfanylphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine' in the column headed 'IUPAC chemical name'.
 6. In the table in Annex 3, a new row is inserted below the row with the entry 'Ethylthionitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Etodesnitazepine' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the entry 'etodesnitazene pyrrolidine analogue' in the column headed 'Other international non-proprietary name or generic name' and the entry '2-[(4-ethoxyphenyl)methyl]-1-(2-pyrrolidin-1-ylethyl)-benzimidazole' in the column headed 'IUPAC chemical name'.
 7. In the table in Annex 3, a new row is inserted below the row with the entry 'Etodesnitazepine' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Etoetonitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-[2-[[4-(2-ethoxyethoxy)phenyl]methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine' in the column headed 'IUPAC chemical name'.
 8. In the table in Annex 3, a new row is inserted above the row with the entry 'Fluonitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Fluetonitazepyne' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-[[4-(2-fluorethoxy)phenyl]methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)benzimidazole' in the column headed 'IUPAC chemical name'.
 9. In the table in Annex 3, a new row is inserted above the row with the entry 'Isotonitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Isotodesnitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-[2-[(4-propan-2-yloxyphenyl)methyl]benzimidazol-1-yl]-N,N-diethylethanamine' in the column headed 'IUPAC chemical name'.

10. In the table in Annex 3, a new row is inserted below the row with the entry 'Isotonitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Isotonitazepyne' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-[4-(2-propoxy)benzyl]-5-nitro-1-[2-(pyrrolidin-1-yl)ethyl]-1H-benzimidazole' in the column headed 'IUPAC chemical name'.
11. In the table in Annex 3, a new row is inserted above the row with the entry 'Carbonyl bromadol' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Isotonitazepipne' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-[4-(2-propoxy)benzyl]-5-nitro-1-[2-(piperidin-1-yl)ethyl]-1H-benzimidazole' in the column headed 'IUPAC chemical name'.
12. In the table in Annex 3, a new row is inserted above the row with the entry '3,4-methylenedioxy-U-47700' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Methylenedioxynitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-(2-((1,3-benzodioxol-5-yl)methyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine' in the column headed 'IUPAC chemical name'.
13. In the table in Annex 3, a new row is inserted below the row with the entry '3-methylcrotonylfentanyl' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Methylnitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the entry 'menitazene' in the column headed 'Other international non-proprietary name or generic name' and the entry '2-[2-[(4-methylphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine' in the column headed 'IUPAC chemical name'.
14. In the table in Annex 3, a new row is inserted above the row with the entry 'Metodesnitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Methylthionitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-[2-[(4-methylsulfanylphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine' in the column headed 'IUPAC chemical name'.
15. In the table in Annex 3, a new row is inserted above the row with the entry 'Metonitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Metodesnitazepyne' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-(4-methoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole' in the column headed 'IUPAC chemical name'.
16. In the table in Annex 3, a new row is inserted below the row with the entry 'Metonitazepyne' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Metonitazepipne' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-(4-methoxybenzyl)-5-nitro-1-(2-(piperidin-1-yl)ethyl)-1H-benzimidazole' in the column headed 'IUPAC chemical name'.
17. In the table in Annex 3, a new row is inserted below the row with the entry 'N-methyl U-47931E' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'N,N-dimethylamino etonitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-

- [2-[(4-ethoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-dimethylethanamine' in the column headed 'IUPAC chemical name'.
18. In the table in Annex 3, a new row is inserted above the row with the entry 'Nortilidine' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Nitazene' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-(2-benzyl-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethanamine' in the column headed 'IUPAC chemical name'.
 19. In the table in Annex 3, a new row is inserted above the row with the entry 'Cannabis resin' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Protonitazepipne' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '2-[(4-propoxyphenyl)methyl]5-nitro-1-(2-piperidin-1-ylethyl)benzimidazole' in the column headed 'IUPAC chemical name'.
 20. In the table in Annex 3, a new row is inserted above the row with the entry 'Tetrahydrofuranfentanyl' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Spirochlorphine' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the entry 'R6890' in the column headed 'Other international non-proprietary name or generic name' and the entry '8-[1-(4-chlorophenyl)ethyl]-1-phenyl-1,3,8-triazaspiro[4.5]decan-4-one' in the column headed 'IUPAC chemical name'.
 21. In the table in Annex 4, a new row is inserted above the row with the entry 'ADB-FUBINACA' in the column headed 'Other international non-proprietary name or generic name', the new row containing the entry 'ADB-BUTINACA' in the column headed 'Other international non-proprietary name or generic name' and the entry 'N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1H-indazole-3-carboxamide' in the column headed 'IUPAC chemical name'.
 22. In the table in Annex 5, a new row is inserted above the row with the entry 'Secobarbital' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name', the new row containing the entry 'Psilocybin for medical use' in the column headed 'International Non-proprietary Name (INN) in Czech/generic name' and the entry '[3-[2-(dimethylamino)ethyl]-1H-indol-4-yl] dihydrogen-phosphate' in the column headed 'IUPAC chemical name' and the sentence 'Active substance pursuant to Act No 378/2007 on pharmaceuticals and on amendments to certain related acts (the Pharmaceuticals Act)' in the column headed 'Note'.
 23. In Annex 6, the words 'gamma-butyrolactone' are replaced by the sentence 'With the exception of preparations containing GBL, from which GBL cannot be obtained in an economically feasible manner and whose oral or other administration is precluded for health or taste reasons.'
 24. In the table in Annex 7, a new row is inserted above the row with the entry 'Ketamine' in the column headed 'International Non-proprietary Name (INN) in Czech', the new row containing the entry 'Carisoprodol' in the column headed 'International Non-proprietary Name (INN) in Czech' and the entry '(RS)-2-[[[(aminocarbonyl)oxy]methyl]-2-methylpentyl isopropylcarbamate' in the column headed 'IUPAC chemical name'.

PART TWO

Amendment to the Government Regulation on the list of scheduled psychoactive substances

Article II

Government Regulation No 11/2025 on the list of scheduled psychoactive substances is amended as follows:

1. In the table in the Annex, the words ‘quantities below 0.3%’ are replaced by the words ‘inevitably occurring natural trace amounts’.
2. In the table in the Annex, the row with the entry ‘ADB-BUTINACA’ in the column headed ‘International Non-proprietary Name (INN) in Czech’ is deleted.
3. In the table in the Annex, a new row is inserted below the row with the entry ‘FUBIAT’ in the column headed ‘International Non-proprietary Name (INN) in Czech’, the new row containing the entry ‘10-hydroxy-HHC’ in the column headed ‘International Non-proprietary Name (INN) in Czech’ and the entry ‘(6aR,10R,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,10,10a-hexahydro-6H-dibenzo[b,d]pyran-1,10-diol’ in the column headed ‘IUPAC chemical name’.
4. In the table in the Annex, a new row is inserted above the row with the entry ‘CH-FUBBMPDORA’ in the column headed ‘International Non-proprietary Name (INN) in Czech’, the new row containing the entry ‘10-hydroxy-THC’ in the column headed ‘International Non-proprietary Name (INN) in Czech’ and the entry ‘(6aR,10R,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,10,10a-tetrahydro-benzo[c]chromene-1,10-diol’ in the column headed ‘IUPAC chemical name’.
5. In the table in the Annex, a new row is inserted below the row with the entry ‘MDMB-INACA’ in the column headed ‘International Non-proprietary Name (INN) in Czech’, the new row containing the entry ‘MDMB-PINACA’ in the column headed ‘International Non-proprietary Name (INN) in Czech’ and the entry ‘methyl 3,3-dimethyl-2-[(1-pentyl-1H-indazole-3-carbonyl)amino]butanoate’ in the column headed ‘IUPAC chemical name’.
6. In the table in the Annex, a new row is inserted above the row with the entry ‘NMDMSB’ in the column headed ‘International Non-proprietary Name (INN) in Czech’, the new row containing the entry ‘Muscimol’ in the column headed ‘International Non-proprietary Name (INN) in Czech’, the entry ‘5-(aminomethyl)-3(2H)-isoxazolone’ in the column headed ‘IUPAC chemical name’ and the sentence ‘With the exception of unprocessed mushrooms, in which muscimol occurs naturally.’ in the column headed ‘Note’.

PART THREE

TECHNICAL REGULATION

Article III

This Regulation was notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

PART FOUR
EFFECTIVE DATE

Article IV

This Regulation shall come into effect on the day following the date of its promulgation, except for the provisions of Article I, point 22, which shall come into effect on.....

Prime Minister:

Deputy Prime Minister and Minister of Health: