

Message 001

Communication from the Commission - TRIS/(2025) 3066

Directive (EU) 2015/1535

Notification: 2025/0647/CZ

Notification of a draft text from a Member State

Notification – Notification – Notifizierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késésekét - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx il-perijodi ta' dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20253066.EN

1. MSG 001 IND 2025 0647 CZ EN 24-10-2025 CZ NOTIF

2. Czechia

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4. 2025/0647/CZ - C00C - CHEMICALS

5. Draft Government Regulation 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

6. The draft Government Regulation proposes to include extremely hazardous benzimidazole opioids in the schedule of prohibited substances and to reclassify the substance ADB-BUTINACA from the schedule of psychoactive substances in Government Regulation No 11/2025 to the schedule of addictive substances.

7.

8. The draft Government Regulation includes psilocybin for medical use in the schedule of psychotropic substances in Annex 5 to Government Regulation No 463/2013 on the schedules of addictive substances. In addition, benzimidazole opioids are included in the schedule of prohibited substances, specifically in Annex 3 to Government Regulation No 463/2013. Benzimidazole opioids (nitazene derivatives) are extremely hazardous to human health. Even very small doses can cause a fatal overdose. Their use outside strictly controlled laboratory or clinical conditions poses a high risk to human health. Furthermore, spirochlorphine is included in the schedule of narcotic substances in Annex 3. Spirochlorphine is a synthetic opioid, an analogue of buprenorphine, showing 2 to 5 times higher potency than fentanyl, which makes it an exceptionally high-risk substance, and fatal intoxications with this substance have been reported in the Czech Republic. At the same time, it is proposed to reclassify the substance ADB-BUTINACA from the list of scheduled psychoactive substances in Government Regulation No 11/2025 to the schedule of addictive substances, specifically in Annex 4 to Government Regulation No 463/2013, as it is listed in Schedule II of the 1971 Convention on Psychotropic Substances. It is also proposed to include the substance carisoprodol in the schedule of addictive substances, specifically in Annex 7 to Government Regulation No 463/2013, as it is listed in Schedule IV of the 1971 Convention on Psychotropic Substances.

For the substance gabapentinolactone, which is currently in the schedule of psychotropic substances in Annex 6 to Government Regulation No 463/2013, it is proposed to add a note for preparations containing this substance in order to allow the use of, for example, graffiti cleaners.

The substances 10-hydroxy-THC, 10-hydroxy-HHC and muscimol are newly added to the list of Scheduled Psychoactive Substances.

In addition, the notes relating to substances HHC, THCP, THCH, THC-H6 and THCB; THC-C4 are being amended.

Keywords:

Psychoactive substances, psychotropic substances, addictive substances, medical use of addictive substances

Government Regulation No 463/2013 has been uploaded to the TRIS database, as amended effective from 1 April 2025, 2024/0645/CZ.

Act No 167/1998 has been uploaded to the TRIS database, as amended effective from 1 July 2025, 2024/0093/CZ

Act No 167/1998 has been uploaded to the TRIS database, as amended effective from 1 January 2026, 2024/0093/CZ

Government Regulation No 11/2025 has been uploaded to the TRIS database, as amended effective from 17 January 2025, 2024/0691/CZ

9. Due to the promulgation in the Collection of Laws of Act No 270/2025, amending Act No 40/2009, the Criminal Code, as amended, and Act No 141/1961, the Code of Criminal Procedure, as amended, which newly introduces psilocybin for medical use, it is proposed to amend Government Regulation No 463/2013 on the schedules of addictive substances, namely to include psilocybin for medical use in the schedule of psychotropic substances in Annex 5.

The substances 10-hydroxy-THC, 10-hydroxy-HHC and muscimol, which have been newly added to the list of Scheduled Psychoactive Substances, have not yet been studied in detail; however, due to their wide availability and sale in online stores, it is necessary to determine their toxicity, dependence potential and possible therapeutic use and, for the duration of this assessment, to restrict their availability to scientific purposes only in order to prevent adverse impacts on public health. It is also proposed to include the substance MDMB-PINACA in this list, as a series of intoxications with this substance has been recorded in the Czech Republic over the past month, mainly among adolescents. In addition, the notes relating to substances HHC, THCP, THCH, THC-H6 and THCB; THC-C4 are being amended.

10. References to basic texts: 2024/0691/CZ, 2024/0645/CZ, 2025/0093/CZ

The basic texts were forwarded with an earlier notification:

2024/0691/CZ

2024/0645/CZ

2025/0093/CZ

11. Yes

12. The draft Government Regulation includes the new synthetic cannabinoid MDMB-PINACA in the list of scheduled psychoactive substances in Government Regulation No 11/2025. This responds to the fact that, over the past 30 days, cases of intoxication in the Czech Republic have required the hospitalisation of nine persons aged 13 to 17. Furthermore, it is proposed to include benzimidazole opioids in the schedule of psychotropic substances in Government Regulation No 463/2013. Since 2019, nitazene opioids have been increasingly spreading as narcotics in North America, West Africa, and Europe. Since the end of 2018, a number of designer analogues of nitazene have begun to appear on illegal markets around the world. Benzimidazole opioids (nitazene derivatives) are extremely hazardous to human health. Even very small doses can cause a fatal overdose. Their use outside strictly controlled laboratory or clinical conditions poses a high risk to human health. It is essential that the draft Government Regulation come into effect as soon as possible in order to minimise the serious threat to public health, in particular to children and adolescents.

13. No

14. No

15. Yes

16.

TBT aspects: No

SPS aspects: No

European Commission

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