

Message 001

Communication from the Commission - TRIS/(2026) 0522

Directive (EU) 2015/1535

Notification: 2026/0084/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 - Atidējimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħ 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: 20260522.EN

1. MSG 001 IND 2026 0084 CZ EN 19-02-2026 CZ NOTIF

2. Czechia

3A. Úřad pro technickou normalizaci, metrologii a státní zkušebnictví

Biskupský dvůr 1148/5

110 00 Praha 1

tel: 221 802 216

e-mail: eu9834@unmz.gov.cz

3B. Ministerstvo zdravotnictví

Palackého náměstí 375/4

128 00 Praha 2 – Nové Město

tel.: 224 971 111

podatelna@mzd.gov.cz

4. 2026/0084/CZ - C00C - CHEMICALS

5. Draft government regulation amending Government Regulation No 458/2013, Government Regulation

No 463/2013, as amended, and Government Regulation No 11/2025, as amended by Government Regulation No 534/2025.

6. The draft governs the legal regime for other substances with psychoactive effects, thereby responding to the emergence of new synthetic drugs, in particular THC derivatives.

7.

8. Draft Government Regulation amending Government Regulation No 458/2013 on the list of starting materials and adjuvants and their annual quantitative limits, Government Regulation No 463/2013 on lists of addictive substances and Government Regulation No 11/2025 on the list of scheduled psychoactive substances, as amended by Government Regulation No 534/2025

The aim of the draft is to respond to the emergence of new synthetic drugs, in particular THC derivatives, and to regulate the legal regime of other substances with psychoactive effects. Under Government Regulation No 458/2013, it is proposed to remove the substance gamma-butyrolactone from the list of initial materials and adjuvants and their annual quantity limits, as this substance has previously been moved to the list of addictive substances. Under Regulation No 11/2025, it is proposed to remove HHC from the list of scheduled psychoactive substances and to include it in Annex 4 of psychotropic substances under Regulation No 463/2013. It is also proposed to place ADB-3en-BUTINACA, ADB-5en-HEXINACA, EDMB-4en-PINACA and plants of the *Mitragyna* genus on the list of scheduled psychoactive substances in Regulation No 11/2025 due to their psychoactive effects, risks of abuse and the need for their adequate regulation.

Keywords: psychomodulatory substances, addictive substances

The following basic texts have been entered into TRIS:

Government Regulation No 11/2025 on the list of scheduled psychoactive substances. effective from 16 December 2025

Act No 167/1998 on addictive substances and amending certain other acts, as amended effective 1 January 2026

Act No 272/2013 on drug precursors, effective from 1 July 2025

Government Order No 458/2013 on the list of starting materials and adjuvants and their annual quantitative limits, effective 18 May 2021

and Government Regulation No 463/2013, on lists of addictive substances, effective from 1 January 2026

We also refer to the previous notification:

2025/0647/CZ

2015/0412/CZ

and 2015/0268/CZ

9. The draft adds HHC to the list of addictive substances, namely to Annex 4 of psychotropic substances, while removing it from the list of scheduled psychotropic substances. Furthermore, GBL is removed from the list of starting materials and adjuvants, as it is already included in the list of psychotropic substances.

The reclassification of HHC is based on a decision by the United Nations Commission on Narcotic Drugs. At its 68th session in March 2025, the Commission on Narcotic Drugs added Hexahydrocannabinol (HHC) to

the Schedule of the 1971 Convention.

The change in scheduling shall take effect six months (180 days) after the official notification by the Secretary-General of the United Nations. The amendment to the scheduling in the list was notified to all party states on 9 June 2025 and shall enter into force on 6 December 2025. For this reason, it is necessary to transfer the substance HHC to the list of addictive substances as soon as possible.

The Ministry of Health did not propose this reclassification in the previous amendment to Government Regulation No 463/2013 and No 11/2025, because the Anti-Drug Policy Department of the Office of the Government of the Czech Republic negotiated at the international level regarding the possibility of keeping HHC on the current list of classified psychoactive substances. However, these negotiations have not been successful and it is therefore submitting this proposal in order to comply with the international obligations of the Czech Republic.

10. Reference(s) to basic text(s): 2025/0647/CZ, 2015/0268/CZ, 2015/0412/CZ

The basic texts were forwarded with an earlier notification:

2025/0647/CZ

2015/0268/CZ

2015/0412/CZ

11. Yes

12. It is proposed to include hexahydrocannabinol (HHC) as a psychotropic substance in Annex 4 to Government Regulation No 463/2013, following its inclusion in Schedule II of the Convention on Psychotropic Substances of 1971 by decision of the UN Commission on Narcotic Drugs. At the same time, it is proposed to extend the list of classified psychoactive substances to include the new synthetic cannabinoids EDMB-4en-PINACA, ADB-5en-HEXINACA and ADB-3en-BUTINACA, which are structurally related to already regulated substances and which, based on available data and structural similarity, can be expected to have a strong effect on cannabinoid receptors and pose a risk of intoxication. These substances have already been identified on the illegal market in several European Union countries, including the Czech Republic. Furthermore, it is proposed to include plants of the genus *Mitragyna* on the list of scheduled psychoactive substances, with the exception of the species *Mitragyna speciosa*, as new, legally unregulated species with unknown composition and content of active substances, for which safe consumption cannot be guaranteed, appear on the market.

The aim of the proposed regulation is to reduce the risk of a serious threat to public health and to ensure the preventive protection of the population, in particular children and adolescents. 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

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu