



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Notification Number : 2023/0230/CZ (Czechia)

Lists of addictive substances

Date received : 10/05/2023

End of Standstill : Not applicable (closed)

Message

Zpráva 001

Zpráva od Komise - TRIS/(2023) 01305

směrnice (EU) 2015/1535

Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notifica -
Pieteikums - Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie - Notificação - Hlásenie-Obvestilo -
Ilmoitus - Anmälan - Нотификация : 2023/0230/CZ - Notificare.

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία
έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu -
Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie
otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist
- Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 202301305.CS)

1. MSG 001 IND 2023 0230 CZ CS 10-05-2023 CZ NOTIF

2. CZ

3A. Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
Biskupský dvůr 1148/5
110 00 Praha 1
tel: 221 802 212
e-mail: eu9834@unmz.cz

3B. Ministerstvo zdravotnictví České republiky,
Palackého náměstí 4,
128 01 Praha 2

4. 2023/0230/CZ - C00C

5. Draft Government Regulation amending Government Regulation No 463/2013 on the lists of addictive substances, as amended

6. Psychotropic substances included in Schedule I under the Convention on Psychotropic Substances and Other Psychotropic or Narcotic Substances or their analogues included in the list due to abuse or possible danger to the health of the inhabitants of the Czech Republic.

7. -

8. The Draft Regulation introduces new substances in Annexes 3 and 4.



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Annex 3 to Government Regulation No 463/2013 on the lists of addictive substances, as amended, is proposed to be extended to include 3 other addictive substances. Specifically bupropion, etonitazepine and protonitazene.

Annex 4 to Government Regulation No 463/2013 on the lists of addictive substances, as amended, is proposed to be extended to include 6 other addictive substances. Specifically ADB-BUTINACA, hexahydrocannabinol (HHC), 7-hydroxymitragynine, kratom, mitragynine and tetrahydrocannabinol (THC).

As a result, the amendment to the Annexes to the Government Regulation leads to regime changes in the legal treatment of the substances concerned, which affect, for example, permits to handle these substances, record keeping, storage as well as the regime of dispensing of these addictive substances. In addition to the above, the amendments to the Annex to the Government Regulation also impacts criminal law as illegal handling of these substances may be classified as a misdemeanour or criminal offence.

Keywords:

new synthetic drugs,
psychotropic substances,
addictive substances,
control regime of narcotic drugs or psychotropic substances.

reference to:

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;

9. Bupropion is listed on the basis of a decision of the UN Narcotic Drugs Commission, with the Commission deciding to include bupropion as a new psychoactive substance that should be placed under international control under the UN Conventions. The substances ADB-BUTINACA, protonitazene and etonitazepine are proposed to be included in the list of addictive substances in the Czech Republic in accordance with the proposal of the European Commission, which prepared a unified EU position on new psychoactive substances. The substance kratom (crushed dried leaves of the *Mitragyna speciosa*) and its main psychoactive components (mitragynine, 7-hydroxymitragynine) as well as the substances hexahydrocannabinol (HHC) and tetrahydrocannabinol (THC) are proposed to be included in the list of addictive substances due to their rapid expansion into free sale in the Czech Republic, mainly among juvenile populations. For HHC and THC, an authorised limit of up to 0.3 % is proposed so as not to restrict trade in technical hemp and preparations thereof.

10. reference(s) to basic text(s): - Government Regulation No 463/2013 on the lists of addictive substances, as amended - Act No 167/1998 on addictive substances and on amendments to certain other acts, as amended.

The basic texts were forwarded within an earlier notification: 2022/314/CZ

11. Yes

12. Medical facilities report an increasing number of intoxications associated with the use of kratom. The data of the Toxicology Information Centre demonstrates the need to regulate kratom, in particular by introducing a strict ban on its consumption by children and adolescents. The inclusion of kratom and its active ingredients on the list of psychotropic substances is necessary at least until the regulation of kratom has been resolved in such a way that the substance is not available to the juvenile population. Furthermore, the data of the Toxicology Information Centre demonstrates the need to regulate trade in products containing hexahydrocannabinol (HHC), in particular a strict ban on its consumption by children and adolescents.

Tetrahydrocannabinol (THC) is a relatively new psychoactive substance found in very small amounts in the cannabis plant. With the advent of extraction methods for the concentration of active substances, this substance was newly found on the market. Its effect is similar to THC, but it has much higher efficiency and could be more dangerous than THC when spread.

The substances bupropion, ADB-BUTINACA, protonitazene and etonitazepine are proposed to be included in the list of addictive substances in the Czech Republic in accordance with the obligations for the Czech Republic under the UN



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Conventions.

13. No

14. No

15. Yes

16. TBT aspect

NO - The Draft has no significant impact on international trade.

SPS aspect

NO - The Draft has no significant impact on international trade.

No - The Draft is not a sanitary or phytosanitary measure

Evropská komise

Kontaktní bod směrnice (EU) 2015/1535

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