Message 001

Communication from the Commission - TRIS/(2025) 0975

Directive (EU) 2015/1535

Notification: 2025/0191/CZ

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – 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 késéseket - 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: 20250975.EN

1. MSG 001 IND 2025 0191 CZ EN 02-04-2025 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.cz

3B. Ministerstvo zdravotnictví České republiky,
Palackého náměstí 4,
128 01 Praha 2
tel.: 224971111
e-mail: mzcr@mzcr.cz

4. 2025/0191/CZ - C00C - CHEMICALS

5. Draft Decree on psychomodulatory substances

6. The Decree lays down the technical requirements for the composition, appearance, quality, and properties of psychomodulatory substances, including the maximum permitted quantity of psychomodulatory substance in a unit packet and the maximum permitted quantity of active substances in a unit packet

7.

8. In §§ 33e to 33g, Act No 167/1998 on addictive substances and amending certain other acts (hereinafter the ‘Act’) lays down the conditions for the production, composition, packaging, and labelling of psychomodulatory substances and for their subsequent placing on the market. On the basis of the authorising provisions under the Act, the present Decree lays down the technical requirements for the composition, appearance, quality, and properties of psychomodulatory substances, including the maximum permitted quantity of psychomodulatory substances in a unit packet, the maximum permitted quantity of active substances in a unit packet, the maximum permitted concentrations of active substances, the prohibited elements and features when placing psychomodulatory substances on the market, and the limits for chemical and microbiological contamination. It also lays down the manner of indicating and the detailed specification of the information on the packaging of psychomodulatory substances, the format of the consumer information notice, the safety warning concerning the risks of use of the product by minors, and the health warning. Pursuant to § 33f(1) of the Act, the manufacturer of psychomodulatory substances is required to comply with the requirements of good manufacturing practice, as laid down in Part Three of the Decree.

keywords: psychomodulatory substances, manufacturer, good manufacturing practice
references to:
Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, as amended
Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

The basic act is Act No 167/1998 on addictive substances and amending certain other acts; reference is made to Notification 2025/0093/CZ.

9. The amendment to the Addictive Substances Act, in §§ 33e to 33g lays down the conditions for the

production, composition, packaging, and labelling of psychomodulatory substances and for their subsequent placing on the market. On the basis of the authorising provisions under the Act, the present Decree lays down the technical requirements for the composition, appearance, quality, and properties of psychomodulatory substances, including the maximum permitted quantity of psychomodulatory substances in a unit packet, the maximum permitted quantity of active substances in a unit packet, the maximum permitted concentrations of active substances, the prohibited elements and features when placing psychomodulatory substances on the market, and the limits for chemical and microbiological contamination. It also lays down the manner of indicating and the detailed specification of the information on the packaging of PMS, the format of the consumer information notice, the safety warning concerning the risks of use of the product by minors, and the health warning.
The draft Decree builds upon the new legislation on psychoactive substances with a low degree of health and social harm, which, at the same time, are neither controlled by the UN international conventions on the control of narcotic drugs and psychotropic substances of 1961 and 1971, nor by EU law under Council Framework Decision 2004/757/JHA or 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 drug and repealing Council Decision 2005/387/JHA.
The legislation introduced a rational and modern framework for the regulation of psychoactive substances whose control is not governed at the supranational level, or for which this is permitted under supranational regulations and European law.

10. Reference(s) to basic text(s): 2025/0093/CZ

The basic texts were forwarded with an earlier notification:
2025/0093/CZ

11. No

12.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

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European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu