Message 001

Communication from the Commission - TRIS/(2026) 1590

Directive (EU) 2015/1535

Notification: 2026/0299/PL

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: 20261590.EN

1. MSG 001 IND 2026 0299 PL EN 15-06-2026 PL NOTIF

2. Poland

3A. Ministerstwo Rozwoju i Technologii, Departament Obrotu Towarami Wrażliwymi i Bezpieczeństwa Technicznego,
Plac Trzech Krzyży 3/5, 00-507 Warszawa, e-mail: notyfikacjaPL@mrit.gov.pl

3B. Ministerstwo Zdrowia
Departament Prawny
ul. Miodowa 15,
00-952 Warszawa
e-mail: kancelaria@mz.gov.pl lub dep-pr@mz.gov.pl

4. 2026/0299/PL - C00P - PHARMACEUTICAL AND COSMETICS

5. Regulation of the Minister for Health amending the Regulation on the list of psychotropic substances, narcotic drugs and new psychoactive substances.

6. Psychotropic substances, narcotic drugs, new psychoactive substances, including medicinal products

containing substances that affect the central nervous system.

7.

8. On the basis of the decision of the Commission on Narcotic Drugs, amendments have been made to Annex No. 1 — List of Psychotropic Substances (P), Annex 2 — List of Narcotic Drugs (N). These amendments concern:
1) the reassignment from group I-P to group II-P of the psychotropic substance HHC;
2) the addition to group IV-P of the substance CARISOPRODOL;
3) the addition to group I-N of the following substances: PROTONITAZENE, PROTONITAZEPINE, METONITAZEPINE, ETONITAZEPINE, N-DESETYLISOTONITAZENE.
Pursuant to Commission Delegated Directive (EU) 2025/2062 of 14 October 2025, amendments have been made to transfer the reassign 2-MMC and NEP from the list of new psychoactive substances to group II-P of psychotropic substances.
Following the recommendations of the Working Group on the Assessment of Risks to Human Health or Life Associated with the Use of New Psychoactive Substances, amendments have been made to Annex 3 – the list of new psychoactive substances (NPS). These changes involve adding the following substances to the above list: delta-9-THCP-O and delta-8-THCP. In addition, the Regulation adds abbreviated names for tetrahydrocannabinols and clarifies the description of the general formula of groups I-NPS and II-NPS.

9. The substances delta-9-THCP-O and delta-8-THCP, which are the subject of this Regulation, not only pose a risk to human health and life, but also pose a high risk of poisoning, including fatal poisoning, and lead to the development of addictions. The aim of the draft Regulation is to allow for an effective protection of society against new psychoactive substances and the effects of the use thereof.

9a. The proposed measure is appropriate because it addresses the real risks associated with the illicit trafficking of new psychoactive substances, which can lead to poisoning, deaths and the development of addiction. The solutions adopted are directly linked to the objective of protecting public health, since they update the lists of substances on the basis of international decisions and the results of the evaluation of the national expert team. The public objective is pursued in a consistent and systematic manner, as the changes are uniform in nature, based on the ongoing identification of risks and the adaptation of regulations to the current state of knowledge.

9b. The scope of the restriction for the internal market is limited to the marketing of substances assessed as posing a risk to the health of society. The existing regulations proved insufficient to fully protect public health, which is why it was necessary to update the lists and clarify the regulations. The chosen measure was assessed as the least restrictive, as it is limited to introducing the necessary regulatory changes.

9c. The imposed restrictions are proportionate to the importance of the protected public interest, which is the protection of human life and health. The authorities, following the recommendation of the expert group, assessed the degree of interference in the functioning of the internal market and considered that the need to

address realistic risks outweighed the restriction of the freedom of trade. Failure to achieve the public objective would be more harmful than the potential severity of the restriction, as it would maintain the risk of poisoning, deaths and the spread of addictions.

10. References to basic texts:

11. Yes

12. Protection of public health.
The Regulation has been drafted in response to the urgent need to contain the practice of placing substances on the market which affect the central nervous system and are dangerous to human life and health. Reducing the risks created by new psychoactive substances, which are increasingly highly toxic, is a serious public health challenge. If the use of a given substance is not prohibited, it may lead to the misleading impression, especially among young people, that it is harmless. This Regulation responds to the rapid development of the market for new psychoactive substances, which pose a high risk of poisoning, including fatal poisoning, and the development of addiction.

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