

Message 001

Communication from the Commission - TRIS/(2025) 0715

Directive (EU) 2015/1535

Notification: 2025/0140/DE

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 - Nezahtuje 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 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: 20250715.EN

1. MSG 001 IND 2025 0140 DE EN 13-03-2025 DE NOTIF

2. Germany

3A. Bundesministerium für Wirtschaft und Klimaschutz, Referat E B 3, 11019 Berlin, Tel.: 0049-30-2014-6392, E-Mail: infonorm@bmwk.bund.de

3B. Bundesministerium für Gesundheit, Referat 122, 53107 Bonn

4. 2025/0140/DE - C00C - CHEMICALS

5. Twenty-fifth Ordinance amending Annexes to the Narcotic Drugs Act

6. The Federal Republic of Germany intends to place three new psychoactive substances under the Narcotic Drugs Act (Betäubungsmittelgesetz, BtMG). Etomethazene, fluoro-etonitazene and fluoro-etonitazepyne are to be included in Annex II to the BtMG.

7.

8. Three new psychoactive substances (NPS), etomethazene, fluoro-etonitazene and fluoro-etonitazepyne, which are associated with severe intoxication and deaths due to misuse for the purposes of recreational abuse in Germany, have been identified on the drug market. The effects of these three compounds are considered to be comparable to fentanyl and other opioids.

The aim of this Ordinance is to include these three NPSs in Annex II of the BtMG on the basis of § 1(4) of the BtMG. This is intended to address the public health threat arising from the emergence and spread of ever new chemical variants of psychoactive substances by curtailing, as quickly as possible, the further spread and abuse of these harmful substances in order to protect the health of individuals and the population.

9. Etomethazene, fluoro-etonitazene and fluoro-etonitazepyne are three synthetic opioids reported for the first time via the European Early Warning System in 2023 and 2024, respectively. They are associated with severe intoxication and deaths due to misuse as recreational substances in several federal states and neighbouring European countries.

The European Early Warning System has already registered first-time reports of fluoro-etonitazene in DE, fluoro-etonitazepyne in four countries (IT, DE, AT, SI), and etomethazene in eight countries (SE, FI, SI, DK, EE, DE, PL, FR).

Etomethazene, fluoro-etonitazene and fluoro-etonitazepyne have strong chemical-structural similarities to the synthetic opioids etonitazene, etonitazepyne and etazene, which are already listed in the annexes to the BtMG. According to current estimates, these substances are very potent active substances and thus highly potent synthetic opioids, the analgesic potency of which significantly exceeds that of morphine. The high potency of synthetic opioids is associated with an increased risk of overdose and even death. There is reasonable evidence that etomethazene, fluoro-etonitazene and fluoro-etonitazepyne are being misused and pose a public health problem.

In Germany, the substances are mainly distributed via the Internet and are easily available. The lack of legal control to date may contribute to a misinterpretation of hazardousness among consumers, so action is urgently needed to protect the public health.

10. Reference to the basic texts: Basic texts have been sent within the framework of a previous notification: 2023/0199/D

11. Yes

12. In the view of the Federal Government, the extension of the Narcotic Drugs Act is urgent so as to protect the health of the population and individuals and to protect against the dangers arising from these substances, and so as to combat the further spread of the other psychoactive substances covered by the Ordinance. The availability of these substances has risen sharply within short periods, among other things, due to the ease of availability of corresponding products.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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