



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2024/0304/FR (France)

## Decision amending the list of substances classified as narcotic drugs - classification of the nitazene family

Date received : 05/06/2024

End of Standstill : Not applicable

### Message

Message 001

Communication from the Commission - TRIS/(2024) 1469

Directive (EU) 2015/1535

Notification: 2024/0304/FR

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 - Καμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéset - 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: 20241469.EN

1. MSG 001 IND 2024 0304 FR EN 05-06-2024 FR NOTIF

2. France

3A. Ministère de l'Economie et des Finances

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4. 2024/0304/FR - X00M - GOODS AND MISCELLANEOUS PRODUCTS

5. Decision amending the list of substances classified as narcotic drugs – classification of the nitazene family

6. Narcotic drugs – nitazenes



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7.

8. The ANSM draft Decision concerns the classification of the nitazene family on the list of narcotic drugs.

It is a family of new synthetic benzimidazole or nitazene opioids. Several substances in this class are already included in the list of narcotic drugs individually in France (isotonitazene, mesonitazene, etazene, etonitazepyne and protonitazene) in accordance with the decisions of the United Nations Commission on Narcotic Drugs (2021: Decision 64/1 for isotonitazene; 2022: Decision 65/2 for metonitazene; 2023: Decision 66/2 for etazene, Decision 66/3 for etonitazepyne, Decision 66/4 for protonitazene).

In France, from March 2023 onwards, several cases or clusters of cases of intoxications were reported to the French addictovigilance network in various regions.

As of 31/12/2023, a total of 12 cases (including one death), most often serious and life-threatening, involving a nitazene derivative had been reported. A new fatal case has since been reported in Ile-de-France, bringing the total number of deaths reported in France related to nitazene consumption to 2.

Since 2022 in Europe, there has been an increase in overdoses with nitazenes, particularly in the United Kingdom, and the number and diversity of substances identified increased significantly in 2023. In Ireland and the United Kingdom, several overdose clusters have been identified, with confirmation of circulation on the streets of nitazene derivatives offered as heroin. Dozens of deaths attributed to nitazene consumption were reported in the 2nd half of 2023, mainly in the United Kingdom and Eastern Europe (Estonia, Latvia).

The identification of counterfeit medicines containing a nitazene derivative from customs and police seizures is also increasing. In the Baltic countries (Estonia and Latvia) there is a reported circulation of these substances mixed with drugs or offered as heroin or in the form of counterfeit medicines (oxycodone, diazepam or alprazolam).

Some countries such as Germany, the United Kingdom, Switzerland and Canada have introduced a narcotic classification of the nitazene family.

9. The purpose of the draft Decision on classification on the list of narcotic drugs is to prohibit the circulation of these new drugs, the detection of which on French territory through the National Identification System of Toxics and Substances (SINTES) of the French Monitoring Centre for Drugs and Drug Addiction (OFDT) is increasing with the emergence of new substances identified that are constantly being identified which are not classified on European and French territory.

Indeed, nitazenes belong to a new class of synthetic opioids with a very high potency of action (most of them are 5 to 1 000 times more potent than morphine). These molecules are substances at risk of severe or even fatal overdose and, secondarily, present a risk of tolerance and high addiction.

This classification is therefore intended to prevent the risk of addiction, the occurrence of intoxications and deaths by overdose and thus to ensure better protection of public health in France, pending a European or international decision on these substances.

10. References to reference texts:

11. Yes

12. In view of the major risks to public health arising from the use of nitazenes currently circulating on the illicit drug market in Europe and France, replacing heroin (without the knowledge of users) or in combination with heroin or other drugs, or as counterfeit medicines, and in view of the constant emergence of new molecules in the class and the risk of severe, life-threatening overdose with these new highly powerful synthetic opioids and the risk of addiction to these products, the decision to classify the nitazene family as a narcotic substance must be taken as a matter of urgency in France.

The urgency is justified in the light of a challenge to protect the public in view of the serious and significant risks mentioned above in the context of an increase in the circulation of new synthetic opioids.

It should be noted that the next Olympic and Paralympic Games in France in July-August-September 2024 represent a particular and sensitive risk in terms of public health.

Pending a European or international decision on this family of substances, there is therefore an urgent need to publish



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this classification decision, which does not constitute an obstacle to freedom of trade and industry as these products are sold by drug trafficking networks.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

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European Commission

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