



European Monitoring Centre
for Drugs and Drug Addiction

GUIDANCE NOTE 2

Formal notification of a new psychoactive substance

EMCDDA operating guidelines for the European Union Early Warning System on new psychoactive substances

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1. Purpose

The purpose of this document is to provide the rationale, process, roles, and responsibilities for reporting a substance judged by a Member State to be a new psychoactive substance (NPS) and which leads to formal notification under the terms of Regulation (EC) No 1920/2006 (as amended) and Council Framework Decision 2004/757/JHA (as amended). This is in order to ensure that a systematic, uniform, reproducible, and transparent approach is used throughout.

In Europe, most NPS are identified for the first time following the chemical analysis of a seizure made by law enforcement. They may also be identified from collected samples or from biological samples. When a substance is judged to be a new psychoactive substance, the Reitox national focal point should report this to the EMCDDA. This should include chemical and analytical information, as well as the circumstances of the event. The submission of analytical data is also required, since, in most cases, analytical reference standards are not available when an NPS is first detected. Such data facilitates the identification of new psychoactive substances by laboratories across Europe.

Substances judged to be a new psychoactive substance are assessed by the EMCDDA on a case-by-case basis. The EMCDDA does this by assessing the substance based on:

- The definition of a NPS provided in Council Framework Decision 2004/757/JHA (as amended).
- The information reported by the Member State.
- Other relevant information that may be at the disposal of the EMCDDA. This may include the patent and scientific literature, and, analogy to better-studied substances, including controlled drugs ⁽¹⁾.

On the basis of this assessment, if the EMCDDA determines that the substance meets the definition of an NPS then a formal notification is issued to the Network on behalf of the reporting Member State. The notification includes the names and identifiers of the substance, chemical and physical properties, analytical methodologies used for its identification, as well as information on its pharmacology and toxicology, the circumstances of the detection, and any other relevant information that is available ⁽²⁾.

⁽¹⁾ Such an assessment may occur when the substance appears to share some pharmacological or toxicological similarities with better-studied substances. The assessment will also include relevant uncertainties and other limitations of using such an approach. Based on the information available, its experience, and, if necessary, in consultation with leading experts from Member States, the EMCDDA decides on the relevance of such assessments on a case-by-case basis.

⁽²⁾ The first time there is an analytically confirmed identification of a new psychoactive substance in Europe is known as a *first identification in Europe (FIE)*. The date of the first identification in Europe is recorded as the date

At the point of formal notification, the EMCDDA begins to formally monitor the substance as a new psychoactive substance. The formal notification process is essential to a successful early warning system as it ensures that the EWS Network is alerted as soon as possible to the identification of a new psychoactive substance in Europe. This allows the Network to detect and assess any risks at national level as well as to identify and implement any preparedness and response measures that might be needed. Importantly, the information provided in the formal notification allows forensic and toxicology laboratories to include the substance in their analytical screening allowing it to be identified and therefore monitored.

The guidance provided in this document will not fit every possible situation perfectly, and may need to be adapted in order to effectively respond to a specific event or situation. In such cases, the Reitox national focal points should contact the EMCDDA for advice as soon as possible.

→ You can contact us at: ews@emcdda.europa.eu

2. Scope

This document applies to the EMCDDA and the Reitox national focal points.

3. Changes since last revision

Not applicable. Initial Guidance Note.

4. Responsibilities

It is the responsibility of the EMCDDA and the Reitox national focal points to ensure that the process in this document is adhered to.

5. Documents needed for this Guidance Note:

- EMCDDA operating guidelines for the European Union Early Warning System on new psychoactive substances
- Guidance Note 3: Information that should be reported by the Member States on a new psychoactive substance

that the seizure, collected sample, or biological sample was made/taken rather than the date of analysis or date of reporting to the EMCDDA. For the reporting Member State, this will also be the *first identification in country (FIC)*.

- Guidance Note 4: Events of potential high impact on public health
- Guidance Note 5: Outbreaks
- Guidance Note 7: Substances of high concern

6. Related documents

- Regulation (EC) No 1920/2006 (as amended).
<http://data.europa.eu/eli/reg/2006/1920/2018-11-23>
- Council Framework Decision 2004/757/JHA (as amended).
http://data.europa.eu/eli/dec_framw/2004/757/2017-11-22

7. Terminology and definitions

- Guidance Note 1: Terminology and definitions.

8. List of abbreviations

AND: Action on New Drugs

EDND: European Database on New Drugs

EMCDDA: European Monitoring Centre for Drugs and Drug Addiction

NEWS: National early warning system

NFP: Reitox national focal point

NFPs: Reitox national focal points

NPS: New psychoactive substance

9. Process

- Start of process.
- Substance judged to be a NPS identified in a Member State by member of NEWS.
- NFP submits a case report on the substance to EMCDDA.

- NFP should ensure that the report is complete as possible and include relevant analytical data.
 - See Guidance Note 2.
- NFP should highlight any relevant information if the identification is linked to an event of potential high impact on public health (including an outbreak) or involves an NPS under intensive monitoring, or the identification of a substance of high concern.
 - See Guidance Note 3.
 - See Guidance Note 4.
 - See Guidance Note 5.
 - See Guidance Note 6.
 - EMCDDA assesses the substance.
 - If there is insufficient information to make an assessment:
 - EMCDDA requests additional information from NFP.
 - NFP requests additional information from relevant partner in NEWS.
 - If no additional information is available → report discarded by EMCDDA → end of process.
 - If the substance does not meet the definition of a new psychoactive substance:
 - EMCDDA informs NFP of assessment outcome along with the reasons why the substance does not meet the definition of an NPS → report discarded by the EMCDDA → end of process.
 - If the substance meets the definition of an NPS → process continues
- EMCDDA issues formal notification of the NPS to the Network on behalf of the Member State.
 - NFPs should review and assess the information in the formal notification.

- NFPs should transmit the formal notification or relevant information therein to their national early warning system and other partners as relevant.
- NFPs should report any available information on the new psychoactive substance to the EMCDDA in a timely manner.
 - NFPs should expedite reporting to the EMCDDA the first time the NPS is identified in their country (First identification in country).
 - See Guidance Note 3.
 - NFPs should report all identifications of the NPS in the annual situational report.
- End of process.

10. Additional information

None.

11. Changes since last version

Not applicable.

12. References

1. Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (recast). [Consolidated version]. <http://data.europa.eu/eli/reg/2006/1920/2018-11-23>
2. Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking. [Consolidated version]. http://data.europa.eu/eli/dec_framw/2004/757/2017-11-22