European Monitoring Centre
for Drugs and Drug Addiction

GUIDANCE NOTE 1

# Terminology and definitions

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

Document ID: EU-EWS-OG-GN-1
Authors: Michael Evans-Brown
Version: 1.0
Effective date: 1 January 2020
Supersedes: Not applicable
Status: Public

# 1. Purpose

The purpose of this document is to provide the common terminology and definitions developed by the EMCDDA for the operation of the EU Early Warning System. The EMCDDA has also developed a set of common reporting tools in order to standardise data collection across the Network. These allow interoperable communications and standardised reporting, leading to improved operational communication and coherent working across the Network. They also reduce the risk of potentially serious misunderstandings and errors, as well as reduce the burden on the Network in terms of the need to request and receive clarifications and corrections. Overall, this improves the accuracy and timeliness of the data as well as its reliability and comparability.

The terminology and definitions are provided with respect to the operation of the EU Early Warning System, including those related to relevant internal EMCDDA processes. Unless otherwise indicated, they are for operational use only and do not have legal meaning. They may differ from those used in other settings and by other organisations.

# 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 terminology and definitions in this document are adhered to.

# 5. Documents needed for this Guidance Note:

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

# 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

# 6. Terminology and Definitions

For the purposes of the operation of the EU Early Warning System and initial report, the following terms mean:

***Advisory:*** A risk communication issued by the EMCDDA to the Network that provides important information on a specific event or situation associated with a substance of interest and that is of relevance to Europe. An advisory may not require immediate attention by the Network.

An advisory may also provide options which the Network may want to consider as part of their preparedness and response activities. It also requests the Network to report to the EMCDDA any additional information at their disposal in order to strengthen understanding of the risks posed by the event, situation, or substance of interest.

See also: Advisory, Briefing, Formal notification, Risk communication.

***Alert:*** A risk communication issued by the EMCDDA to the Network that provides vital, time-sensitive information on a specific event or situation associated with a substance of interest that may pose a serious public health or social risk within Europe. An alert conveys the highest level of importance and requires immediate attention by the Network.

An alert may also provide options which the Network may want to consider as part of their preparedness and response activities. It also requests the Network to report to the EMCDDA any additional information at their disposal in order to strengthen understanding of the risks posed by the event, situation, or substance of interest.

See also: Advisory, Briefing, Formal notification, Risk communication.

***Analytical confirmation:*** An identification of a substance of interest or any other analyte of relevance which has been confirmed by one or more accepted methods and techniques of chemical analysis.

The term analytical confirmation is synonymous with identification. Typically, analytical confirmation is limited to seizures, biological samples, and collected samples.

***Biological sample:*** A biological specimen lawfully taken from a human. Types of specimen include, for example, blood, urine, hair, tissue, gastric contents, vitreous humour, etc.

***Briefing:*** A risk communication issued by the EMCDDA to the Network that provides important background information on a specific event or situation associated with a substance of interest. A briefing does not require immediate action by the Network.

A briefing may also provide options which the Network may want to consider as part of their preparedness and response activities. It also requests the Network to report to the EMCDDA any additional information at their disposal in order to strengthen understanding of the risks posed by the event, situation, or substance of interest.

See also: Advisory, Briefing, Formal notification, Risk communication.

***Case report:*** A report of an event in a Member State involving one or more new psychoactive substances and any other substances of interest which may be comprised of one or more datasets of seizures, collected samples, biological samples, and serious adverse events.

***Classification of the type of serious adverse event:***

For each serious adverse event, the type of event should be assessed and classed according to the following types:

- Unclassified (insufficient information in order to make a classification decision)
- Acute poisoning (the outcome should be reported as: non-fatal/fatal/unknown)
- Death (the type of investigation should be reported: post-mortem investigation/other)
- Substance dependency/withdrawal
- Birth defect/congenital anomaly
- Other (the reporter must specify as precisely as possible the type of event)

***Collected sample:*** A physical sample which is a result of lawful active collection by a drug monitoring system, healthcare service, law enforcement agency, research study, or other competent authority/agency.

Typically a collected sample is as a result of:

- Purchasing a product labelled with a brand name and/or with the name(s) of a new psychoactive substance(s) from a vendor. Also known as ‘test purchase’.

- Receiving a sample from a user that is submitted to a harm reduction drug checking service. Also known as: drug testing service, drug testing programme, or pill testing service.

- Collecting a sample of a substance from the residue of drug injecting equipment as part of a monitoring programme, such as residue from a hypodermic syringe.

- Collecting a sample of a substance from a person who has experienced a serious adverse event or from the scene of where the serious adverse event occurred. This type of sample is also known as an epidemiologically linked sample.

***Commercial use***: The use of a new psychoactive substance for legitimate commercial purposes.

***Competencies:*** The combinations of knowledge and skills that are required to perform a task effectively. The term 'competence' refers to the knowledge and skills that an individual person possesses. 'Competency' on the other hand, refers to an individual's behaviour when they put their competence into practice. Individuals are judged as competent if they demonstrate the knowledge and skills required in their particular profession, role, or task.

***Confirmed event:*** An event or situation that is confirmed by a Member State as a real event. A confirmed or real report does not necessarily mean that the event or situation poses a public health or social threat.

***Controlled drug:*** A substance covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances.

***Cutting agent:*** A substance that is used as a diluent or excipient.

***Distribution:*** Information on the types of ways that a new psychoactive substance is being distributed to users.

***Distribution methods:*** Information on how a new psychoactive substance is being distributed to users. Examples include, information concerning its sale on the surface web, darknet marketplaces, and street-level dealing. Such information should also include the size and scale of such operations and whether criminal groups are involved in its distribution.

***Dosage regimen:*** is information on the route of exposure, formulation (dosage form), as well as the schedule of doses of a new psychoactive substance, including the amount taken each time, time between doses, and the duration of use.

***Drug Exposure Classification System:***

For each serious adverse event, the certainty of exposure to the new psychoactive substance or other substance of interest by the patient case is assessed and classed according to the Drug Exposure Classification System (DECS). These classifications are described below:

- *Unable to assess* means there is insufficient information to make a classification on whether the case was exposed to the substance.
- *No exposure* means that from the available information the case was not exposed to the substance.
- *Suspected exposure* means that the information on exposure to the substance is limited to the name of the substance that the case or someone else linked to the event believes that the case has consumed and/or from packages containing the drugs that the case is thought to have consumed.
- *Possible exposure* means that the information on exposure to the substance is limited to an epidemiologically-linked physical or biological sample that has been analysed by a valid method of chemical analysis but there is no information to suggest that the case was exposed to that drug sample.
- *Probable exposure* means that information on exposure to the substance is limited to an epidemiologically-linked physical or biological sample that has been analysed by a valid method of chemical analysis and that there is a reasonable probability that the case was exposed to that drug sample.
- *Confirmed exposure* means that exposure to the substance was confirmed by a valid method of chemical analysis in one or more biological sample taken from the case.

***Early Warning System Network (EWS Network; Network):*** The group that comprises the members of the Early Warning System network, specifically: the EMCDDA, Europol, Reitox national focal points, and the Commission.

***European Database on New Drugs (EDND):*** The EMCDDA's information system for reporting and managing information on new psychoactive substances.

***Epidemiologically-linked sample (ELS):*** Either a physical sample (from a seizure or collected sample) or a biological sample that was taken as a result of an investigation into a serious adverse event.

Note: Even in cases where exposure to a substance has not been confirmed from a biological sample, epidemiologically-linked samples may provide a strong indication that a case has been exposed to the substance. Examples of such scenarios include when the substance is identified in swabs taken externally from the body, such as from the nostrils. In such an example, a case may have snorted a powder containing the substance and this is subsequently identified following analysis of the residue from a nasal swab. Similarly, such an ELS coupled to a biological sample could strengthen the causality

assessment as well as provide a strong indication of the dosage form (a powder) and the route of exposure (nasal insufflation).

***European Union Early Warning System on New Psychoactive Substances (EU Early Warning System; EWS):*** The information exchange and early warning system setup by Article 5a of Regulation (EC) No 1920/2006 (as amended).

***Event:*** A thing that happens or takes place that is suspected or analytically confirmed to involve a new psychoactive substance and/or other substance of interest. Events may be related to law enforcement activity (such as a seizure), serious adverse events (such as a non-fatal poisoning or death), and/or any other type of event involving a substance.

***Event-based data:*** Data concerning an event that is suspected or analytically confirmed to involve a new psychoactive substance and/or other substance of interest.

***Event of potential high public health impact:*** An event associated with a new psychoactive substance or any other substance of interest that may pose a high public health impact. They are subject to expedited reporting by the Member States.

Examples include cases of severe acute poisoning, severe chronic poisoning, deaths subject to medico-legal investigation, outbreaks, cross-border threats, and events involving substances under intensive monitoring. Further details are provided in Guidance Note 4.

***Expedited reporting:*** The reporting of an event or situation of a potential high public health impact in a timely manner and without undue delay to the EMCDDA.

***Extraction:*** The process of removing a new psychoactive substance from a plant or microorganism, such as a fungus.

***First identification in Europe (FIE):*** The first time there is an analytically confirmed identification of a new psychoactive substance in Europe. A FIE could be as a result of the detection of a new psychoactive substance in a seizure, collected sample, or biological sample. *The date of the first identification in Europe is set as the date that the seizure, collected sample, or biological sample was made/taken rather than the date of analysis or date of reporting to the EMCDDA.*

A FIE is reported to the EMCDDA by the Reitox national focal point or to Europol by the Europol National Unit on behalf of the Member State. Following assessment by the EMCDDA, if the data supporting the FIE are valid then the new psychoactive substance will be subject to formal notification (Guidance Note 2). For the reporting Member State, this will also be the first identification in country (FIC).

Note that it is possible that following a FIE, notifications that pre-date the FIE may be reported. This can reflect delays in analysing a sample and/or differences in reporting practices between different agencies and Member States.

***First identification in country (FIC):*** The first time there is an analytically confirmed identification of a new psychoactive substance within a Member State. This could be as a result of the identification of a new psychoactive substance in a seizure, collected sample, or biological sample. *The date of the first identification in country is set as the date that the seizure, collected sample, or biological sample was made rather than the date of analysis or date of reporting to the EMCDDA.*

A FIC is reported to the EMCDDA by the Reitox national focal point or to Europol by the Europol National Unit on behalf of the Member State.

Note that it is possible that following a FIC, notifications that pre-date the FIC may be reported. This can reflect delays in analysing a sample and/or differences in reporting practices between different agencies within the Member State.

***Formal notification:*** A risk communication issued by the EMCDDA to the Network that provides the notification of the first time there is an analytically confirmed identification of a new psychoactive substance in Europe (first identification in Europe) as well as other related important information for identifying, assessing, and understanding the threats that the new psychoactive substance may pose. A formal notification may not require immediate attention by the Network.

A formal notification may also provide options which the Network may want to consider as part of their preparedness and response activities. It also requests the Network to report to the EMCDDA any additional information at their disposal on the new psychoactive substances in order to strengthen the understanding of the risks that may be posed by the new psychoactive substance and/or an event or situation associated with the new psychoactive substance.

A formal notification is issued by the EMCDDA on behalf of the Member State that has reported the first identification in Europe.

See also: Advisory, Briefing, Formal notification, Risk communication.

***Hazard:*** Something that has a potential to cause harm. The hazard is intrinsic to the new psychoactive substance or other substance of interest.

***Identification:*** See analytical confirmation.

***Identified risk:*** An untoward occurrence for which there is adequate evidence of an association with the new psychoactive substance or other substance of interest.

***Mass gathering:*** A planned or unplanned event where the number of people attending could strain the planning and response resources at local, intermediate, or national level.

Examples of mass gatherings include music festivals, raves, cultural events, religious and spiritual events.

***Manufacture:*** The production of a new psychoactive substance and/or production of a finished product that contains a new psychoactive substance.

***Medical use:*** The use of a new psychoactive substance for legitimate medical purposes. Examples include use of a new psychoactive substance in a medicinal product for human use or veterinary use, use as an investigational medicinal product, or use in medical/diagnostic imaging.

***Member State:*** The member countries of the European Union.

***Monitoring:*** The systematic and on-going collection, collation, analysis, and assessment of data and the timely dissemination of the resulting information for the purposes of early warning, initial report, and/or risk assessment procedures as laid down in Article 5 of Regulation (EC) No 1920/2006 (as amended).

***National early warning system:*** The network within a Member State that reports information on new psychoactive substances to the Reitox national focal point.

***Network:*** See Early Warning System Network.

***Network report:*** Any report submitted to the EMCDDA by the Member States in the context of the operation of the Early Warning System.

***New psychoactive substance (NPS):*** As defined in Article 1 of Council Framework Decision 2004/757/JHA (as amended):

New psychoactive substance means a substance in pure form or in a preparation that is not covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances but may pose health or social risks similar to those posed by the substances covered by those Conventions.

Preparation means a mixture containing one or more new psychoactive substances.

***Outbreak:*** An increase in the number of cases of serious adverse events (such as poisoning, injury, or disease) in excess of what would normally be expected in a specific area or among a specific group of people over a particular period of time. An outbreak may occur in a restricted geographical area, or extend over several countries.

For the purposes of these guidelines, a ‘cluster’ should be regarded as a synonym for outbreak.

Further details on outbreaks and how to report them are provided in Guidance Note 5.

***Patterns of use:*** Information such as the extent and frequency of use of a new psychoactive substance or other substance of interest (including prevalence, doses, dose regimens) as well as routes of administration, physical, psychological, and behavioural effects. Further details on the types of information included under patterns of use are provided in Guidance Note 3.

***Personal data:*** Any information relating to an identified or identifiable natural person.

***Polydrug use:*** The use of more than one drug at the same time or sequentially by an individual.

***Potential risk:*** An untoward occurrence for which there is some basis for suspicion of an association with the new psychoactive substance or other substance of interest but where this association has not been confirmed.

Examples include:

- Non-clinical pharmacological and non-clinical toxicological findings.
- An event known to be associated with other new psychoactive substances or other substances of interest within the same class or which could be expected to occur based on the properties of the substance.
    * For example, an substance from the mu opioid receptor agonist-class could reasonably be expected to cause respiratory depression and which would be a potential risk to people who use the substance.

***Potential serious and urgent event (PSUE):*** Any event that represents an immediate threat to health and requires prompt action, e.g. response measures to protect the health of those at risk of exposure. This term includes events that have not yet led to disease but have the potential to cause disease should exposure occur.

***Recommendation for action:*** A response action assigned by the EMCDDA to a validated signal following its review. Depending on the type and level of threat that might be posed by the signal, one or more recommendations for action can be assigned. These are:

- Awareness/no further action required
- Monitoring
- Issuance of a risk communication
- Intensive monitoring
- Any other action within the competencies of the EMCDDA
- Assessment of the need to produce an initial report

As part of any response action, the EMCDDA may issue a request for information to one or more members of the Network and/or other partners.

As a minimum, the recommendation for action assigned by the EMCDDA to a validated signal is awareness/no further action required.

***Reitox national focal point:*** The focal point as designated in accordance with Article 5 of Regulation (EC) No 1920/2006 (as amended).

***Refuted event:*** An event or situation which the Member State shows to be false/incorrect.

***Restrictive measures:*** Any action designed to restrict availability of a new psychoactive substance. These include use of legislation related to controlled drugs, new psychoactive substances, medicines, food, chemicals, and, consumer protection.

***Retraction:*** Withdrawal of any data, information, or report made to the EMCDDA by a Member State. Retractions can be issued after verification and agreement between the EMCDDA and the notifying Member State.

***Request for information:*** A request from the EMCDDA to one or more members of the Network or other partners for information on a new psychoactive substance or other substance of interest and/or event or situation for the purposes of early warning, initial report, and/or risk assessment procedures as laid down in Article 5 of Regulation (EC) No 1920/2006.

***Risk:*** The likelihood that, under particular conditions of exposure, an intrinsic hazard of a new psychoactive substance, other substance of interest, or other type of hazard, will represent a health or social threat.

***Risk communication:*** The interactive exchange of information, opinions, and advice concerning risk associated with a new psychoactive substance or other substance of interest.

The EMCDDA issues four types of risk communications: Alerts, Formal notifications, Advisories, and Briefings.

***Scientific use:*** The use of a new psychoactive substance for legitimate scientific purposes. Examples include the use of a new psychoactive substance as an analytical reference standard in clinical and forensic laboratories, the use in research studies to characterise its pharmacology and toxicological properties, and use in non-diagnostic imaging studies.

***Seizure:*** A physical sample that is derived from a lawful confiscation made by a law enforcement agency. It also includes physical samples obtained from unauthorised/stopped/suspended shipments, controlled deliveries, and suspicious shipments.

Typically a seizure can be a result of:

- action by customs authorities at national borders;
- action by a police force;
- action by any other competent law enforcement agency;

- a substance seized from a patient (or other person linked to the case) who has experienced a serious adverse event or from the scene of where the serious adverse event occurred. This type of sample is also a type of epidemiologically linked sample (c.f. collected sample).

***Scientific evidence:*** Information furnishing a level of proof based on the established and accepted methods of science.

***Scientific principles:*** The accepted fundamental laws and facts of nature known through the methods of science.

***Serious adverse event (SAE):*** Any adverse event (such as poisoning, injury, or disease) in a human associated with the use of a new psychoactive substance or other substance of interest that:

- results in death;
- is life-threatening;
- requires intensive treatment in an emergency room and/or requires hospitalisation;
- results in persistent or significant disability or incapacity;
- results in substance dependency or substance abuse;
- consists of a congenital anomaly or birth defect; or
- is an important medical event that may not be immediately life-threatening or result in hospitalisation or death but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed above. Examples of such events are: convulsions that do not result in hospitalisation and the transmission of infectious diseases.

Serious adverse events may or may not be subject to analytical confirmation through analysis of a biological sample and/or a seizure and/or a collected sample. The likelihood of exposure to the substance is assessed and classed according to the Drug Exposure Classification System.

***Signal:*** The information arising from one or more sources that suggests a potential public health or social threat of European relevance associated with a new psychoactive substance or other substance of interest, and is judged to be of sufficient likelihood to justify verification, and, where necessary, a response.

Signals may be detected based on an analysis of:

1. data reported by the Member States through the Early Warning System; or
2. data identified from monitoring open source information;
3. any other data at the disposal of the EMCDDA; or

4. any combination of data derived from 1, 2, and 3.

Important types of events that are also classed as signals include:

- a first identification in Europe (FIE); and,
- a first identification in country (FIC).

***Signal management:*** A process covering seven steps that begins with the detection of a signal and ends either with its refutation or with its confirmation, the assignment of one or more recommendations for action which details how the EMCDDA will react to the signal, and the response action (including follow-up). The steps are:

- detection;
- validation — if the signal is invalid then it is refuted and no further action is taken unless communication is required with the Network and/other stakeholders due to concerns about rumours, etc; if the signal is valid it is confirmed;
- analysis and characterisation (an examination of the signal);
- assessment (when an evaluation/judgement is made about the signal);
- prioritisation;
- recommendation for action;
- response action (including follow-up).

***Signal review meeting:*** An internal EMCDDA meeting at which confirmed signals are analysed and characterised, assessed, and prioritised by the EMCDDA and one or more recommendations for actions are made.

***Substance of high concern:*** Any substance that is not a new psychoactive substance or controlled drug but that is toxic or otherwise hazardous and poses a high risk of acute or chronic poisoning or any other type of serious adverse event.

A list of substances of high concern is provide in *Guidance Note 7, Substances of high concern*.

***Substance of interest*** means:

- a new psychoactive substance; or
- controlled drug; or

- Any other relevant matter irrespective of origin which may be chemical (e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis), vegetable (e.g. plants, part of plants, vegetable secretions, extracts), micro-organism, animal (e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products), and, human (e.g. human blood and human blood products).

***Substance review meeting:*** An internal EMCDDA meeting at which the information on a new psychoactive substance reported by the Member States is analysed and characterised, and then assessed in order to determine if an initial report should be produced.

***Timely manner:*** Reporting occurring at a prompt or useful time for the purposes of early warning and/or initial report as required by Article 5 of Regulation (EC) No 1920/2006.

***Trace-back investigation:*** Any investigation that is done in order to identify the source of a new psychoactive substance, other substance of interest, or other hazard associated with an outbreak.

***Trafficking:*** The transportation, distribution, or sale of a new psychoactive substance across a national border.

***Use:*** The ingestion of a new psychoactive substance or other substance of interest by a human by any route of administration.

***Verification:*** The process whereby the EMCDDA requests information from a Reitox NFP in order to confirm or refute the status of an event or situation within the Member State. The Member State may confirm or refute the status of the event or situation.

# 7. Additional information

None.

# 8. Changes since last version

Not applicable.

# 9. References

Some of the terminology and definitions used in this guidance note were taken from or adapted from the following sources:

1. Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 amending Regulation (EC) No 1920/2006 as regards information exchange on, and an

early warning system and risk assessment procedure for, new psychoactive substances. Official J. L 305. 21.11.2017. p. 1–7. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R2101

2. 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. Official J. L 305. 21.11.2017. p. 12–18. https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32017L2103

3. 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). Official J. L 376. 27.12.2006. p. 1–13. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R1920

4. Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products. Official J. 022. 09.02.1965. p. 0369–0373.

5. World Health Organization. International health regulations (2005). 3rd Edition. 2016. https://www.who.int/ihr/publications/9789241580496/en/

6. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Clinical safety data management: definitions and standards for expedited reporting. 1994. https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2A/Step4/E2A_Guideline.pdf

7. European Centre for Disease Prevention and Control. Public health emergency preparedness – Core competencies for EU Member States. 2017. http://ecdc.europa.eu/en/publications-data/public-health-emergency-preparedness-core-competencies-eu-member-states

8. Miquel Porta (ed). A dictionary of epidemiology. 2014. Oxford University Press.

9. World Health Organization. Mass gatherings. https://www.who.int/features/qa/mass-gatherings/en/