European Monitoring Centre
for Drugs and Drug Addiction

GUIDANCE NOTE 1

Terminology and definitions

EMCDDA operating guidelines for the risk assessment of new psychoactive substances

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Authors: Michael Evans-Brown
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1. Purpose

The purpose of this document is to provide the common terminology and definitions developed by the EMCDDA for the risk assessment of new psychoactive substances. This is to help ensure that a systematic, reproducible and transparent approach is used throughout the risk assessment procedure.

The terminology and definitions are provided with respect to the risk assessment of new psychoactive substances, 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. They should be read and used in conjunction with the terminology and definitions used by the EU Early Warning System on new psychoactive substances, as found in *Guidance Note 1: Terminology and Definitions — EMCDDA Operating Guidelines for the European Union Early Warning System on New Psychoactive Substances* (EMCDDA, 2019).

2. Scope

This document applies to the EMCDDA and the Scientific Committee of the EMCDDA.

3. Changes since last revision

Not applicable, as this is an initial guidance note.

4. Responsibilities

It is the responsibility of the EMCDDA and the Scientific Committee of the EMCDDA 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 Risk Assessment of New Psychoactive Substances.
- EMCDDA Operating Guidelines for the European Union Early Warning System on New Psychoactive Substances.
- Guidance Note 1: Terminology and Definitions — EMCDDA Operating Guidelines for the European Union Early Warning System on New Psychoactive Substances.

6. Terminology and definitions

For the purposes of the risk assessment of new psychoactive substances, the terms used are defined as follows.

Abuse liability: the propensity of a particular psychoactive substance to be susceptible to abuse, defined in terms of the relative probability that use of the substance will result in social, psychological or physical problems for an individual or for society.

Criminal activities: the involvement of criminals, including organised crime groups, in criminal activities, associated with the new psychoactive substance, that are systematic and involve potentially significant harms to health, significant illicit profits or significant economic costs.

Dependence-producing potential: propensity of a new psychoactive substance to lead to a cluster of physiological, behavioural and cognitive phenomena of variable intensity, in which the use of a new psychoactive substance takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behaviour. Determinants and the problematic consequences of drug dependence may be biological, psychological or social, and usually interact.

Drug: 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; and any of the substances listed in the Annex to Council Framework Decision 2004/757/JHA.

Harm: injury or damage to the health of people or disruption of social functioning or public order resulting in injury or damage to the health of the user or other persons, damage to property or criminal activities.

Hazard: something that has a potential to cause harm. The hazard is intrinsic to the new psychoactive substance.

New psychoactive substance: 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.

Likelihood (of occurrence of harm): probability of occurrence of harm during 1 year within the EU population.

Risk: a combination of the likelihood of the occurrence of a hazard associated with a new psychoactive substance generating harm and the severity of that harm.

Risk level: expression of the extent or degree of a risk by combining the severity of harm and the likelihood of occurrence of that harm.

Risk-modifying factor: circumstances that may increase or decrease the likelihood of occurrence of harm, such as circumstances of use, manufacture and traffic of a new psychoactive substance or user characteristics.

Uncertainty: all types of limitations in available knowledge that affect the range and probability of possible answers to an assessment question.

Weight-of-evidence analysis: a process of the weighted integration of lines of evidence to determine relative support for hypotheses or answers to a questionnaire.

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:

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, OJ L 305, 21.11.2017, pp. 12-18 (https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32017L2103).

EMCDDA (European Monitoring Centre for Drugs and Drug Addiction) (2019), *Guidance note 1: terminology and definitions — EMCDDA operating guidelines for the European Union Early Warning System on new psychoactive substances*, Publications Office of the European Union, Luxembourg (https://www.emcdda.europa.eu/publications/guidelines/operating-guidelines-for-the-european-union-early-warning-system-on-new-psychoactive-substances_en).

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), OJ L 376, 27.12.2006, pp. 1-13 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R1920).

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, OJ L 305, 21.11.2017, pp. 1-7. (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R2101).

SCHEER (Scientific Committee on Health, Environmental and Emerging Risks) (2018), *Memorandum on weight of evidence and uncertainties — revision 2018*, European Commission (https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_014.pdf).