



**Working Arrangement between
the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
and
the European Food Safety Authority (EFSA)
for the implementation of the information exchange on,
and early warning system for, new psychoactive substances**

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the European Food Safety Authority (EFSA), each one hereinafter referred to as an “Agency” or jointly as the “Agencies” or “Parties”,

Having regard to Regulation (EC) No. 1920/2006 on the European Monitoring Centre for Drugs and Drug Addiction (recast)¹, as last amended by Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances, and in particular Article 5b and Article 20 thereof,

Having regard to Regulation (EC) No. 178/2002, as last amended, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety² and in particular Articles 22, 33 and 36 thereof.

Whereas:

- (1) The objective of the EMCDDA is to provide the Union and its Member States with factual, objective, reliable and comparable information at European level concerning drugs and drug addiction and their consequences; and to implement information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances
- (2) The purpose of EFSA is to contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the internal market;
- (3) Article 1 of Regulation (EU) 2017/2101, by amending Regulation (EC) No. 1920/2006, establishes that the EMCDDA shall, without undue delay, request EFSA to provide the information and data at its disposal on a new psychoactive substance for the purpose of the initial report referred to in this Article,
- (4) Pursuant to the above referred Article 1, the details of the cooperation between the EMCDDA and EFSA for this purpose shall be governed by a working arrangement and, in this context, the

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), OJ L 376, 27.12.2006

² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24 as last amended.

EMCDDA shall respect the conditions on use of the information, which are communicated to the EMCDDA, including conditions on access to documents, information and data security and protection of confidential data, including sensitive data and confidential business information,

- (5) The Agencies have a common interest to enhance further cooperation, while avoiding duplication of efforts and overlaps in their respective activities, and ensuring the best use of available resources,

Have agreed on the following Working Arrangement:

Article 1

Purpose of the Working Arrangement

The EMCDDA and EFSA shall commit to foster cooperation between the two Agencies in the field of activities identified below based on the principles of appropriateness, common interest, proportionality, reciprocity, and complementarity.

Article 2

Scope of the Working Arrangement

1. The cooperation between the two Agencies, as governed by this Working Arrangement, shall encompass the exchange of information and data on new psychoactive substances, in accordance with the Agencies' respective mandates and pursuant to the requirements of Article 5b of Regulation (EC) No. 1920/2006, as inserted by Article 1 of Regulation (EU) 2017/2101.
2. In this context, the EMCDDA shall exchange relevant information and data with EFSA about new psychoactive substances.
3. Upon formal request from the EMCDDA, EFSA shall provide the EMCDDA with the information and data at its disposal on new psychoactive substances. EFSA should provide the information and data, where available, no later than three weeks from the date of receipt of the request from the EMCDDA.

Article 3

Designated Contact Persons

Each Agency shall designate one or more staff members for the maintenance of close, direct and continuing contacts with a view to ensuring the implementation of the provisions of the present Working Arrangement.

Article 4

Confidentiality of Information and data shared between the Parties

1. Each Agency shall ensure that information and data received on the basis of the present Working Arrangement will be treated in accordance with applicable EU legal acts governing the processing and release of information, data and documents.
2. Exchange of information and data shall safeguard the legitimate rights of third parties, including their intellectual property rights, in accordance with the applicable legal framework and transparency requirements set out therein.
3. In the event of exchange of information or data that is not publicly available, each Agency shall ensure the application of confidentiality requirements as provided in their founding Regulations or other relevant legislation.

4. The Agencies shall respect each other's confidentiality policy when using the other's information and data.
5. The Agencies shall undertake to not allow any unauthorised use and processing of information and data provided by a third party for the benefit of another party.

Article 5

Liability

1. The information and data that EFSA shares with the EMCDDA represent those that are available to EFSA at the time of the relevant assessment.
2. EMCDDA acknowledges that the documents, data or information made available by EFSA may contain inaccuracies or errors.
3. EFSA accepts no responsibility or liability arising out of, or in connection with the information and data it shares with EMCDDA, including, but not limited to, any direct or consequential loss or damage that might occur to the EMCDDA and/or to any other third party.

Article 6

Divergences of Interpretation or Implementation

The Agencies undertake to cooperate in good faith with a view to resolving any divergence that may arise in the interpretation or implementation of the present Working Arrangement.

Article 7

Amendments

The present Working Arrangement may be amended in writing by mutual consent between the Agencies at any time. The amended arrangement will enter into force on the day following the date of signature by both Parties.


Article 8

Entry into force

The present Working Arrangement shall enter into force on the day following the date of signature by both Agencies.

For the EMCDDA
Alexis Goosdeel, Director

For EFSA
Bernhard Url, Executive Director



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Done at Brussels on 12 February 2019



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Done at Brussels on 12 February 2019

In duplicate in English