European Monitoring Centre
for Drugs and Drug Addiction

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

About the guidelines

These guidelines provide the rationale, steps, procedures, roles, and responsibilities for the operation of the EU Early Warning System. They reflect the requirements of Regulation (EC) No 1920/2006 (as amended) and Council Framework Decision 2004/757/JHA (as amended) with respect to information exchange and the early warning system, as well as for the initial report, risk assessment, and control measures.

Contents

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Feedback

The EMCDDA welcomes your feedback on these guidelines. As they are incorporated into practice we hope that users will suggest improvements. You can contact us at: ews@emcdda.europa.eu

Abbreviations	
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EDND	European Database on New Drugs
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
ENU	Europol National Unit
EU	European Union
EWS	European Union Early Warning System on new psychoactive substances
Europol	European Union Agency for Law Enforcement Cooperation
MS	Member State
NPS	New psychoactive substance
Reitox NFP	Reitox national focal point
UN	United Nations
WHO	World Health Organization

Notes

These guidelines serve to provide a common understanding for operating the European Union Early Warning System on new psychoactive substances (Early Warning System) by detailing the rationale, steps, procedures, roles, and responsibilities. They reflect the requirements of Regulation (EC) No 1920/2006 (as amended) and Council Framework Decision 2004/757/JHA (as amended) with respect to information exchange and the Early Warning System, as well as those for the initial report, risk assessment, and control measures with respect to accepted scientific principles and required scientific evidence.

It is a task of the Member States to implement the requirements of Regulation (EC) No 1920/2006 (as amended) and to ensure that its Reitox national focal point and Europol National Unit provide the required outputs. These should be reported using the common reporting tools developed by the EMCDDA. The organisation and functioning of the national early warning systems are a national responsibility. It is not the intention of these guidelines to direct the Member States on the organisation of their own national early-warning systems.

The term 'Member State' is used throughout these guidelines to reflect the requirements of Regulation (EC) No 1920/2006 (as amended) in reference to the Member States of the European Union. For the purposes of those countries that are not Member States but participate in the Early Warning System, references to roles and responsibilities of a 'Member State' in these guidelines should be read as also applying to these countries only for the purposes of operating the Early Warning System.

SECTION 1
Purpose of these guidelines

1.1 Purpose

New psychoactive substances can cause serious cross-border threats to health. In Europe, a three-step legal framework of early warning, risk assessment, and control measures allows the European Union to rapidly detect, assess, and respond to the public health and social threats caused by new psychoactive substances. The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is responsible for the first two steps in this system, namely, operating the EU Early Warning System on New Psychoactive Substances in close cooperation with Europol, and conducting risk assessments. The European Commission is responsible for proposing control measures.

On 23 November 2018, legislation came into effect that strengthened the EU's ability to respond to the threats posed by new psychoactive substances [1,2]. It is the third such legal framework over the last 20 years and builds on the experiences gained during this period.

The legislation comprises:

- 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; and

- 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.

Together, the two pieces of legislation replace the mechanism established by Council Decision 2005/387/JHA.

The purpose of these guidelines is to address the measures introduced by Regulation (EU) 2017/2101 into Regulation (EC) No 1920/2006 [3] in respect to the first step in the system, i.e. the information exchange and early warning system (Article 5a) which includes the initial report stage (Article 5b) ([1]). The guidelines replace those previously published by the EMCDDA in 2007. They are based on the requirements of Regulation (EC) No 1920/2006 (as amended) and Council Framework Decision 2004/757/JHA (as amended) and also draw from developments in the field of early warning as well as the practical experience gained and lessons learnt over the last ten years.

Operationally, the information exchange and early warning system are known as the EU Early Warning System on New Psychoactive Substances (Early Warning System; EWS).

These guidelines serve to provide a common understanding for the operation of the Early Warning System by detailing the rationale, steps, procedures, roles, and responsibilities. Together, these support the timely, accurate, and consistent reporting of data related to new psychoactive substances required for the operation of the EWS, and to support the initial report stage, risk assessment process, and decision making on control measures.

The guidelines should assist the Member States in implementing the requirements of Regulation (EC) No 1920/2006 (as amended) and provide transparency to the entire process. The guidelines aim to provide a framework that will allow the Member States to build, maintain, and strengthen national early warning systems that can provide the expected outputs required by the Regulation in a timely manner and without undue delay. This will help strengthen situational awareness, and help Europe prepare for, respond to, and recover from the public health and social threats associated with new psychoactive substances, with the overall aim of preventing or reducing the risk of harm.

It is a task of the Member States to implement the requirements of the Regulation and to ensure that its Reitox national focal point and Europol National Unit provide the required outputs using the common reporting tools developed by the EMCDDA. The organisation and functioning of the national early warning systems are a national responsibility. It is not the intention of these guidelines to direct the Member States on the organisation of their own national early-warning systems.

([1]) Reference to the legislation is hereafter referred to as Regulation (EC) No 1920/2006 (as amended) or simply 'the Regulation' and Council Framework Decision 2004/757/JHA (as amended) or simply 'the Council Framework Decision'.

The EMCDDA has developed a common terminology and definitions for operating the Early Warning System (Guidance Note 1). It has also developed a set of common reporting tools in order to harmonise data collection across the Network. In addition, the details of specific procedures are provided separately to these guidelines as Guidance Notes. Work instructions for carrying out specific reporting tasks and relevant internal EMCDDA processes are also provided.

→ You can download these documents at: http://www.emcdda.europa.eu/publications/topic-overviews/eu-early-warning-system_en

Together, these allow interoperable reporting and communications leading to consistent 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 for requesting clarifications and corrections. This can greatly improve the operational communication within the Network, and, ultimately, improves the timeliness, accuracy, reliability and comparability of the information.

1.2 What substances are included within the scope of the Early Warning System?

The primary role of the Early Warning System is to exchange information on new psychoactive substances ([2]), and, through monitoring, to detect, assess, and respond to public health and social threats. This includes threats that may not be directly caused by a new psychoactive substance but due to other hazards that are associated with their use. Examples include harmful adulterants, diluents, synthesis-related impurities and contaminants, the biological contamination of substances/products (such as with anthrax and botulism), as well as the transmission of infectious diseases (see *Substance of interest* and *Substance of high concern* in Guidance Note 1).

In addition to this role, the EWS may also be used to exchange information on new trends in the use of existing psychoactive substances and/or new combinations of psychoactive substances which pose a potential risk to public health as well as information on possible measures related to public health ([3]).

([2]) The definition of a new psychoactive substance is provided in Article 1 of Council Framework Decision 2004/757/JHA (as amended) (Section 3.1).

([3]) See Article 5(2) and Annex 1(A3), Regulation (EC) No 1920/2006 (as amended). Similarly to new psychoactive substances, this includes threats that may not be directly caused by existing psychoactive substances, but due to another substance that is present in the psychoactive substance/product. This includes harmful adulterants, diluents, synthesis-related impurities and contaminants, it also includes infectious diseases and biological contamination of substances/products (such as with anthrax and botulism) (see *Substance of interest* in Guidance Note 1).

1.3 Early detection, reporting, assessment, and response

The aim of the Early Warning System is to ensure that timely, accurate, and sufficiently detailed information on new psychoactive substances reaches the right people, at the right place, at the right time in order to allow them to assess the information, and, where necessary, respond through timely and effective actions to prevent or reduce the risk of harm.

The different types of response actions taken depend on the substance of interest, type and level of threat, the individuals who are at risk, as well as the role of the organisation and people who are responding. Actions may be taken at the level of practice, policy, and research.

For example, at national level, the formal notification of a new psychoactive substance (Section 4.2.1) ensures that members of the Network are alerted as soon as possible following the identification of a new psychoactive substance on the drug market in Europe. This allows the network to detect and assess any potential threats, as well as to identify and implement any response measures that might be required. Importantly, the information provided in the formal notification allows forensic science and toxicology laboratories to include the substance in their analytical screening allowing it to be identified and therefore monitored. Action may also include communicating risk to relevant agencies, as well as people who use drugs, such as when a toxic or otherwise dangerous substance or situation is detected; it may also include ensuring that sufficient preparations have been made to deal with an event or situation that has the potential to cause an outbreak, including mass poisoning events; related to this, it may also extend to ensuring that there is a sufficient supply and availability of medical countermeasures, such as the antidote naloxone should there be a sudden increase in the availability of highly potent opioids; while in other cases, actions may include formal risk assessment that leads to restrictive measures that are intended to reduce the supply and availability of a substance. As the amount of information is usually limited when a substance is first identified on the drug market, actions may also include research in order to better understand the risks of a particular substance. This may include research to understand its pharmacological and toxicological effects as well to understand its epidemiology (such as who is using the substance, how many people are using it, and how it is being used, etc.).

Experience shows that in order to function effectively, national early warning systems require a clear strategic aim and supporting objectives using a multisectoral, multiagency, and multidisciplinary approach. In order to detect, assess, report, and respond to events, there needs to be sufficient capacity (such as infrastructure, policies and procedures, knowledgeable and trained personnel) and capability (the ability to provide the outputs required by the Regulation).

In addition, such capacity and capability should be present at all levels within a Member State (local, intermediate, and national).

It is therefore recommended that the Reitox national focal points develop and maintain close cooperation and coordination with partners in their national early warning system. In particular, regular liaison should be maintained with forensic science and toxicology laboratories, poison centres, government departments responsible for implementing drugs policy, national medicines regulatory authorities, other drugs agencies, and the Europol national units (ENU) as appropriate. Further guidance is provided in Section 4.

The drug situation (including drug supply, use, public health and social problems, drug policy and responses) as well as country size, population, structure, geography, healthcare and public health systems, and resources are country specific. Member States should take these factors into consideration in designing their national early warning system, taking care to identify important gaps in national systems that may need to be developed or strengthened. The implementation at subnational levels may also follow the same guidance while considering factors such as drug situation, resources, the country's size, population, type of legal and administrative framework, and levels of devolution.

Note:

These guidelines will not fit every possible situation perfectly, and they 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 by email at: ews@emcdda.europa.eu*

SECTION 2

Responding to new psychoactive substances in Europe

2.1 A history of the EU response

2.1.1 Joint Action on New Synthetic Drugs, 1997–2005

For more than 20 years, a legal framework has been in place in the European Union that allows it to rapidly detect, assess, and respond to the appearance of new psychoactive substances on the drug market. The origins of this legislation lie in the surprise appearance and popularity of MDMA (ecstasy) and other similar synthetic drugs in Europe during the late 1980s and early 1990s where they were part of the acid house, electronic dance music and rave scenes. These substances were commonly referred to as 'designer drugs' — a reference to the fact that they had been 'designed' to circumvent drug laws, though, in reality, many had been previously described in the scientific and patent literature. As demand rose, some of these drugs were produced on a relatively large scale in illicit laboratories typically operated by organised crime groups. Their appearance raised questions about possible health risks and the problems that could arise in law enforcement and judicial cooperation between countries if such substances were controlled in some Member States but not others. As a result, governments agreed on the need to share information on these types of substances as well as to strengthen law enforcement and judicial cooperation [4,5].

In 1997 this led to the introduction of the first piece of EU legislation known as the Joint Action on New Synthetic Drugs [6]. The legislation defined a three-step process of information exchange (which commonly became known as 'early warning'), risk assessment and control measures. The scope of the Joint Action was limited to 'new synthetic drugs' which were defined as drugs not listed in any of the Schedules to the United Nations 1971 Convention on Psychotropic Substances, and which posed a comparable serious threat to public health as the substances listed in Schedules I or II thereto and which have a limited therapeutic value. More than 30 new synthetic drugs were notified under the Joint Action. Most were phenethylamines and tryptamines; less common were cathinones and piperazines. Few were seized in large amounts or were widespread. Most had a limited life on the drug market. Risk assessments were carried out on nine of them: MDMB, 4-MTA, GHB, ketamine, PMMA, TMA-2, 2C-T-2, 2C-T-7, and 2C-I. Although neither ketamine nor GHB strictly qualified as 'new synthetic drugs', it was considered appropriate to carry out risk assessments because at that time there was information of non-medical use and they were not under international control. A common feature of the remaining seven drugs was that they were often found as tablets marked with logos similar to those seen on 'ecstasy' (MDMA) tablets. By contrast, the reported tryptamines, none of which has so far been risk assessed, were more commonly seen as powders. Of the nine substances, 4-MTA, PMMA, TMA-2, 2C- T-2, 2C-T-7 and 2C-I were brought under control throughout the EU. Subsequently, 4-MTA and GHB were controlled in 2001 under the 1971 UN Convention on Psychotropic Substances, while PMMA was controlled in 2016.

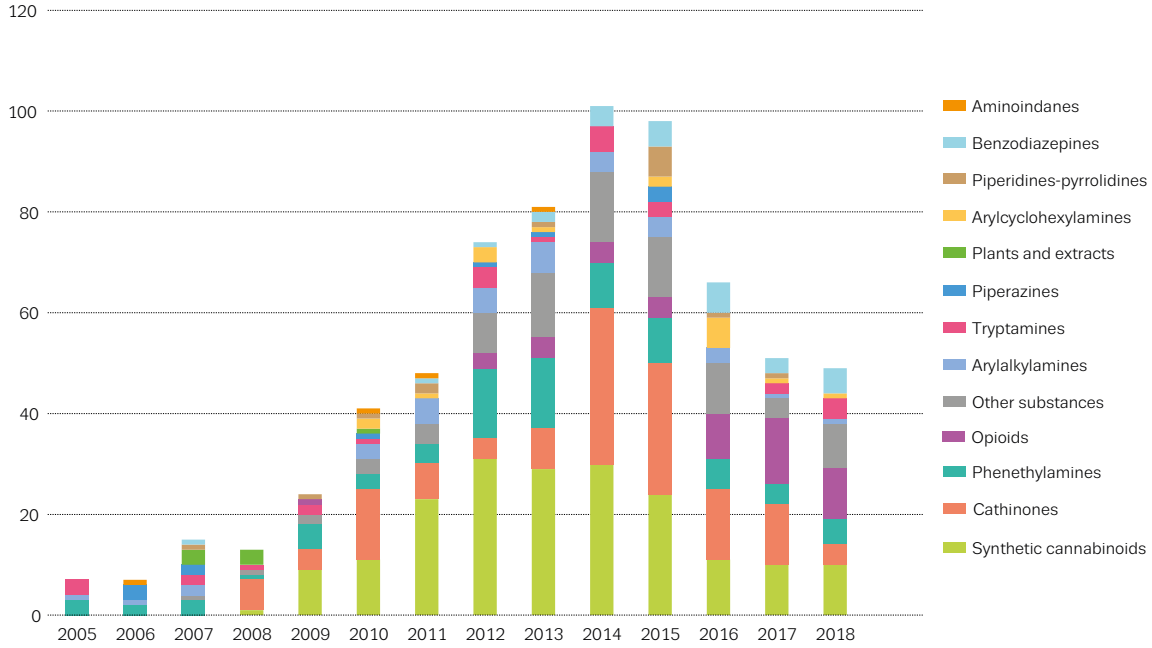
2.1.2 Council Decision on new psychoactive substances, 2005–2018

Following a review, the Joint Action was replaced by the Council Decision 2005/387/JHA in May 2005 [7]. The Council Decision kept the three-step approach but extended the scope and strengthened the overall system. The term 'new psychoactive substances' was also used for the first time and given legal meaning, being defined as substances not currently listed in any of the schedules to the United Nations 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, that may pose a comparable threat to the substances listed in Schedules I or II or IV thereof; and the United Nations 1971 Convention on Psychotropic Substances that may pose a comparable threat to public health as the substances listed in Schedule I or II or III or IV thereof. From the mid-2000s there was a large increase in new psychoactive substances in Europe (Figure 1). This was driven by globalisation and new technologies, such as the internet, that allowed them to be produced, sold, and supplied on an industrial scale [5,8,9].

At least initially, much of the growth in the market in new psychoactive substances was driven by their open sale in shops on the high street as well as online stores. They were available as a range of slickly packaged products advertised as 'legal highs' (emphasising 'legality'), 'research chemicals' (implying legitimate research use), and 'dietary supplements' (suggesting they were foods and natural products). In the case of 'legal highs', the marketing would often allude to them

FIGURE 1

Number of new psychoactive substances notified under the terms of Council Decision 2005/387/JHA, 21 May 2005–22 November 2018



having similar psychoactive effects to controlled drugs or even use street/slang names of drugs such as MDMA (ecstasy) or cocaine. They were also marketed in such a way as to appear to side-step consumer protection legislation, such as medicine legislation, that, at the time, was sometimes used to restrict sales. Such strategies included labelling products as 'not for human consumption' as well as advertising them as 'incense', 'plant food', or 'novelty items'. In addition to these innovative products, new psychoactive substances were also repackaged into smaller quantities or made into tablets and other dosage forms which were then sold on the illicit drug market; this is either under their own name or they are passed off as established controlled drugs to unsuspecting users. Some substances, such as benzodiazepines and synthetic opioids are also used to make falsified (fake) tablets of commonly prescribed benzodiazepine and opioid analgesic medicines; these too are sold on the illicit market. Sales are through existing street-level drug markets as well as online markets, including on the darknet [5].

The consumer base also grew in parallel with the range of substances and products that were offered. It included people who use them recreationally, those with problematic drug use, those who self-medicate, as well as people wanting to look better, get fitter, or enhance their performance at school or work. An increase in the number of severe and fatal poisonings was also reported [5].

This growth in the market led to a range of challenges for public health policy and practice. At least initially, national drug control laws struggled to keep up with a steady flow of new substances appearing — their open sale in shops on the high street and internet often adding to this problem [10]. Nonetheless, the number of new substances reported for the first time each year has dropped from a high of around 100 in 2014 and 2015 to around 50 since then [11]. This is thought to partly reflect recent policy responses in Europe, including efforts to control new psychoactive substances and their open sale. It may also reflect control measures and law enforcement activity in source countries, such as China. Despite this, at least one new substance is still detected every week, increasing the overall number that need to be monitored [5,11].

Major new challenges have also emerged. This includes what appears to be a general upward trend in more potent new psychoactive substances appearing on the market, especially substances such as the synthetic cannabinoids and fentanyl derivatives (fentanils) which can be highly potent. These types of substances pose a greater risk of life-threatening poisoning to users because their high potency makes it is easier to unintentionally overdose. This risk may be especially high when a substance first appears on the market because of a lack of experience with the substance, but also because, unknown to users, such substances may be passed off as highly sought after established drugs. As a result, these types of substances can also cause explosive outbreaks of mass poisonings that can overwhelm local healthcare systems. Although the picture differs greatly across Europe, outbreaks involving a range of different types of new psychoactive substances have occurred in recent years. In

some circumstances there may also be a risk of occupational exposure to personnel from such substances [5,11].

Potent substances are also easier to conceal and smuggle, making them an attractive option for traffickers. A few grams of substances, easily hidden in an envelope, can be sufficient to make many thousands of doses for the drug market. It is also concerning that synthetic cannabinoids (known as 'Spice') are now sought after by some vulnerable groups because they are cheap, easily available, and powerful, capable of causing 'mind-numbing' effects [5].

A total of 676 new psychoactive substances were notified under the Council Decision. Reflecting the growth of the 'legal highs' market, around half of these were synthetic cannabinoids (190) and synthetic cathinones (130). Reflecting changes in the market in the last few years an increasing number of new opioids and benzodiazepines have been notified.

Under the Council Decision, risk assessments were carried out on 23 new psychoactive substances: BZP, mephedrone, 4-MA, 5-IT, AH-7921, methoxetamine, 25I-NBOMe, MDPV, MT-45, 4,4'-DMAR, α-PVP, MDMB-CHMICA, acryloylfentanyl, furanylfentanyl, AB-CHMINACA, ADB-CHMINACA, 5F-MDMB-CHMINACA, CUMYL-4CN-BINACA, 4F-iBF, THF-F, carfentanil, cyclopropylfentanyl, and methoxyacetylfentanyl. Eighteen of these substances were brought under control throughout the EU: BZP, mephedrone, 4-MA, 5-IT, AH-7921, methoxetamine, 25I-NBOMe, MDPV, MT-45, 4,4'-DMAR, α-PVP, MDMB-CHMICA, acryloylfentanyl, furanylfentanyl, ADB-CHMINACA, CUMYL-4CN-BINACA, cyclopropylfentanyl, and methoxyacetylfentanyl. Four of the remaining substances, acetylfentanyl, 4-fluoroisobutyrylfentanyl, tetrahydrofuranylfentanyl, and carfentanil, were controlled under the United Nations 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol; while AB-CHMINACA was controlled under the 1971 Convention on Psychotropic Substances. This was because these substances were also assessed around the same time by the United Nations system.

2.1.3 Regulation (EU) 2017/2101 and Directive (EU) 2017/2103, 2018 – onwards

In response to the large growth in the market in new psychoactive substances since 2008, a review of the system identified the need to strengthen the EU response. This led to the Council Decision being replaced by new legislation on 23 November 2018. The legislation retains the effective three-step approach while significantly strengthening early warning activities as well as introducing shorter deadlines for each of the three-steps. The new legislative framework provides the European Union with a major tool to help protect the health and security of people living in Europe.

2.2 Global markets, glocal threats: the case for strengthened early warning, preparedness, and response

Over the last decade, globalisation of the drug markets and new technologies, such as the internet, has led to an increase in the number and types of risks for people who use psychoactive substances. These risks relate both to the growth in the availability of a large range of substances on the drug market, as well as new products, new ways of buying them, new ways of using them, and new user groups.

The appearance of a substance in a new geographical area or new groups of users should always be a cause of concern for public health, as, at least initially, the population will have little or no experience with its effects and how to use it. Similar concerns apply to new ways of using a substance, new products, or new patterns of use. While some risks might be known, others are unknown, and some are unknowable until larger numbers of people have been exposed to the substance. In addition, the very nature of unregulated markets means that these risks may be amplified by the uncertain doses that are used, as well as the potential for the desired substance to be substituted for another, or for it to be adulterated with another substance, all without the knowledge of the user.

A growing number of highly potent substances that pose a high risk of acute poisoning are also being reported. These include the synthetic cannabinoids and fentanils, but also a range of other substances. Strong links also exist between the trade in new psychoactive substances and markets in established controlled drugs, with the increasing use of new benzodiazepines to make fake versions of common anti-anxiety medications, such as fake alprazolam and diazepam, providing some indication of this. The use of new psychoactive substances by high risk drug users and other marginalised and vulnerable populations also appears to have increased in some places. In addition, unregulated, globalised supply chains and markets increase the opportunity for adulteration and contamination of new psychoactive substances and controlled drugs with a range of potentially dangerous and sometimes highly toxic substances. This can have major consequences for public health, including causing explosive outbreaks. Increasingly, threats have a cross-border nature due to globalised markets.

Given the growing complexity of the NPS market and its strong links with the broader illicit drug market, there is need to ensure that Europe continues to strengthen its ability to detect, assess, and respond to emerging threats in a timely and effective way in order to prevent or reduce the public health and social harms caused by new psychoactive substances. Early warning systems play a central role in helping us achieve this.

SECTION 3
Scope of the legislation and steps

3.1 Scope of the legislation and definition of a new psychoactive substance

On 23 November 2018, new legislation came into effect that strengthens the EU's ability to detect, assess, and respond to the threats posed by new psychoactive substances. It is the third such legal framework over the last 20 years and builds on the experiences gained during this period.

The legislation comprises:

- Regulation (EU) 2017/2101 amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances; and
- Directive (EU) 2017/2103 that amends 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.

Together, the two pieces of legislation replace the mechanism established by Council Decision 2005/387/JHA.

The legislation retains the three-step approach of early warning, risk, assessment, and control measures, but strengthens the provisions for early warning, makes the procedures for the initial report and risk assessment more efficient, and substantially shortens the deadlines for all stages of the procedures (Figure 2) ([4]).

Recital 1 and Recital 7 of Regulation (EU) 2017/2101 state that:

> New psychoactive substances can pose serious cross-border threats to health, in particular due to the large number and diversity of those substances and the speed with which they appear. In order to develop responses for addressing those threats, it is necessary to enhance monitoring and the early warning system and to assess the health and social risks associated with new psychoactive substances.
>
> Any Union action on new psychoactive substances should be based on scientific evidence and be subject to a specific procedures.

As a result there is a need to build, strengthen, and maintain early warning capacities and capabilities.

The definition of a new psychoactive substance is provided 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.

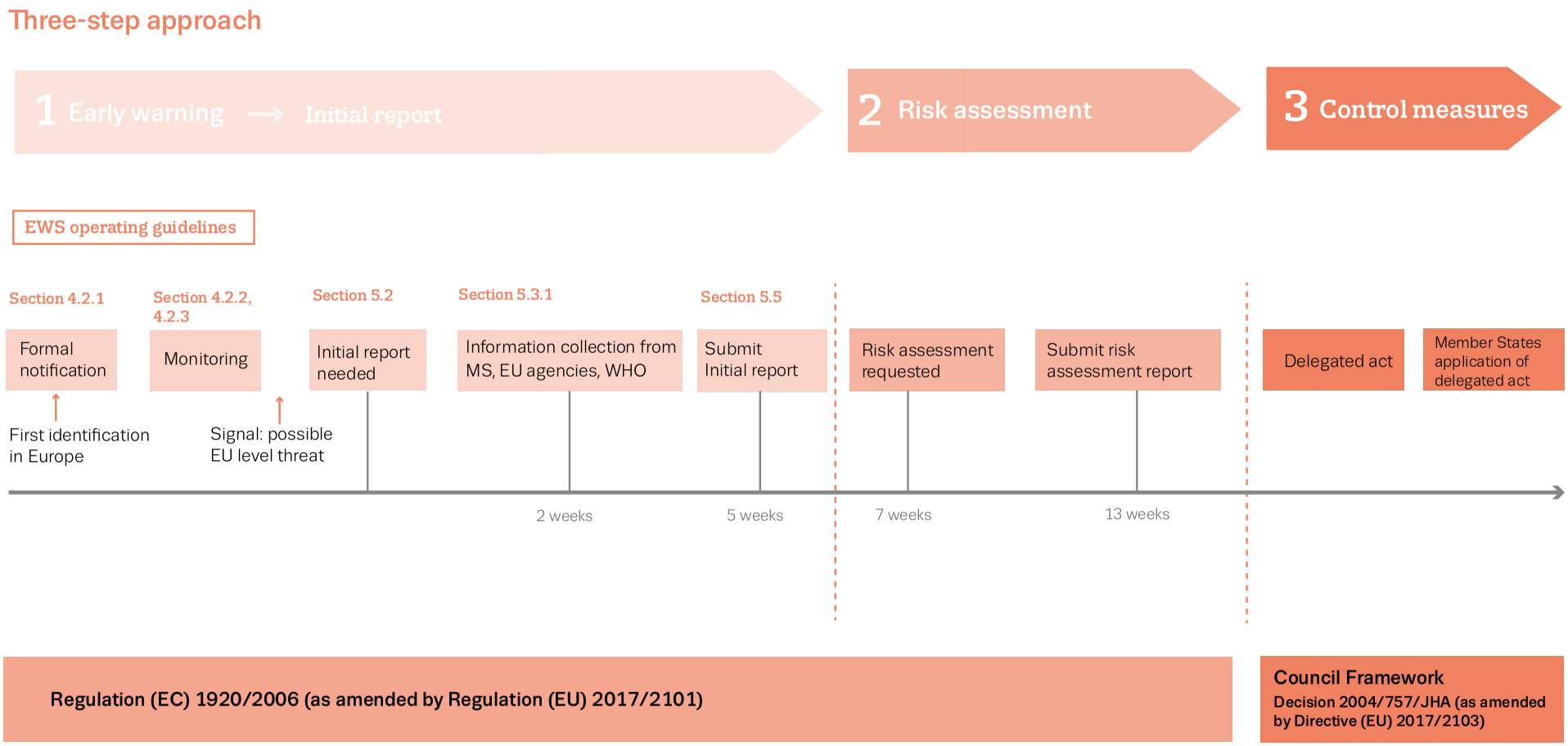
Based on this definition, Member States should report to the EMCDDA any substance that they judge to meet this definition (Guidance Note 2).

The definition does not distinguish between synthetic and natural substances. Therefore, substances derived from natural sources (plants, fungi, animals), either purified extracts or other preparations, and that are judged to be new psychoactive substances should be reported. In addition, an active substance used in medicinal products that are judged to be new psychoactive substances should also be reported.

([4]) You can find the legislation in all EU languages here:
Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R2101
Directive: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32017L2103

FIGURE 2

Responding to new psychoactive substances in Europe. Overview of the three-step approach



3.2 The three steps: early warning, risk assessment, and control measures

3.2.1 Step 1 — Early warning

When a new psychoactive substances is identified for the first time in a Member State, a formal notification is issued to the Network by the EMCDDA on behalf of the Member State that reported it (known as a first identification in Europe). The new psychoactive substance is then monitored by the EMCDDA for signals that suggest it may pose health or social risks. For this, the EMCDDA uses information reported by the Member States through the Early Warning System (Section 4.4.2) and other relevant sources at its disposal (Section 4.10.3). Member States ensure that relevant information on the new psychoactive substance is reported to the EMCDDA and Europol via the NFPs and ENUs (Section 4).

Following analysis of a signal by the EMCDDA, response actions may include intensive monitoring of the new psychoactive substance, risk communications, and the production of an initial report which may lead to a risk assessment.

If the EMCDDA, Commission, or a majority of the Member States consider that information reported through the Early Warning System on an new psychoactive substance in one or more Member States gives rise to concerns that it may pose health or social risks at Union level, the EMCDDA produces an initial report on the new psychoactive substance (Section 5) ([5]). The report is submitted to the Commission and Member States. On the basis of the initial report, a decision is made by the Commission on whether or not to request a risk assessment.

3.2.2 Step 2 — Risk assessment

Where there are indications in the initial report to believe that an new psychoactive substance may pose severe public health risks, and, where applicable, severe social risks, the Commission may decide to request the EMCDDA to assess the potential risks posed by the new psychoactive substance and to produce a risk assessment report ([6]).

The EMCDDA's Scientific Committee assesses the possible health and social risks. The Scientific Committee may be extended by additional experts from the Member States representing scientific fields necessary for ensuring a balanced assessment of the risks. The Commission, the EMCDDA, Europol and the EMA each have the right to nominate two observers. A risk assessment report is submitted to the Commission and the Member States.

3.2.3 Step 3 — Control measures

Based on the risk assessment report ([7]), the Commission may adopt a delegated act in order to add the new psychoactive substance in to the definition of a drug in the Annex of the Council Framework Decision 2004/757/JHA (as amended), provided that the new psychoactive substance poses severe public health risks and, where applicable, severe social risks at Union level.

Member States then need to bring into force the laws, regulations and administrative provisions necessary to apply the provisions of the Framework Decision to such new psychoactive substances as soon as possible but no later than six months after the entry into force of the delegated act amending the Annex.

Further details of the procedure can be found in Council Framework Decision 2004/757/JHA (as amended).

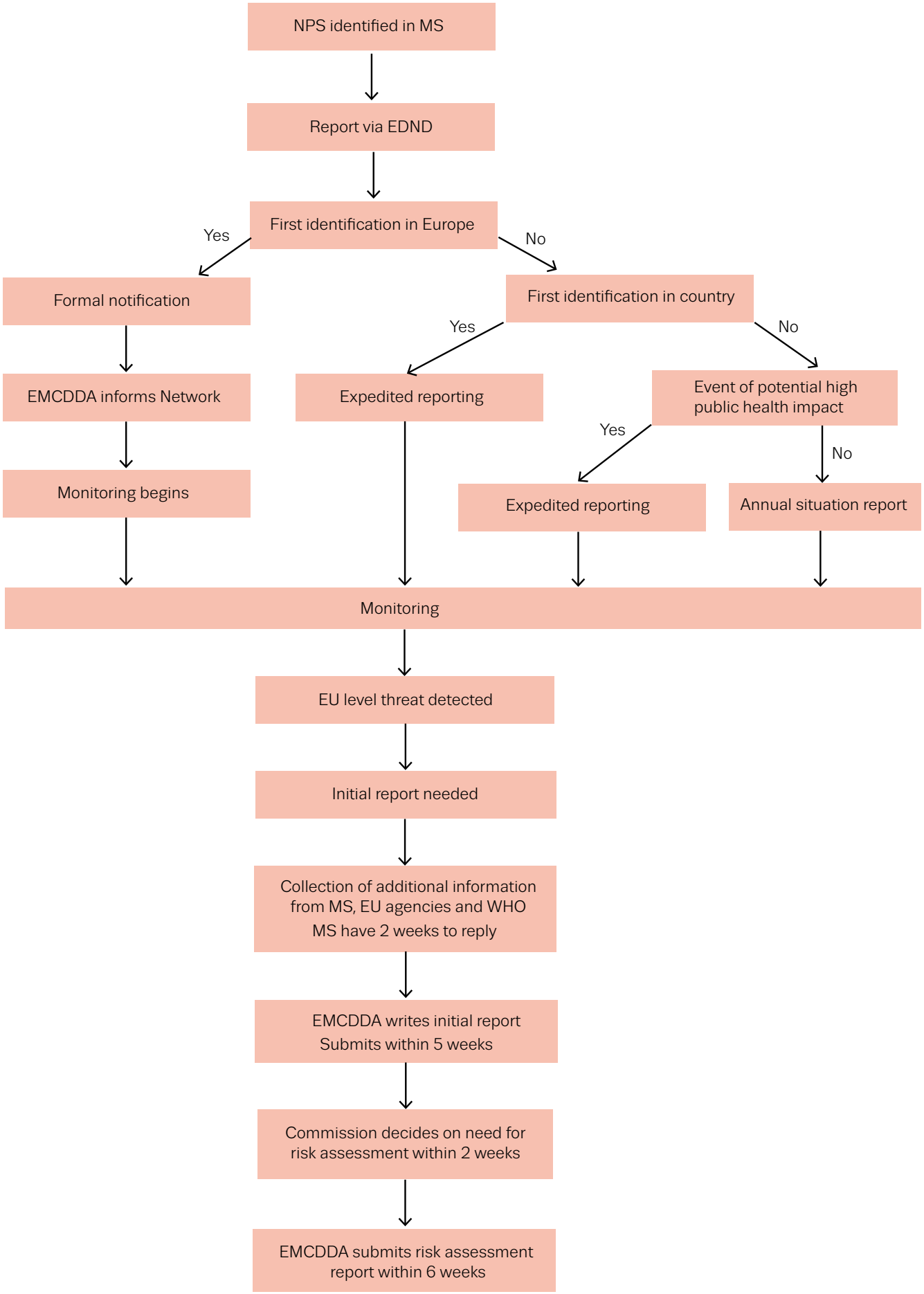
Figure 3 shows the flow of information in the Early Warning System.

([5]) Where the EMCDDA collects information on several new psychoactive substances that give rise to concerns that they may pose health or social risks at Union level and that are considered to be of similar chemical structure, it shall submit to the Commission and to the Member States individual initial reports, or combined initial reports dealing with several new psychoactive substances.

([6]) Alternatively, within two weeks of receipt of a combined initial report, the Commission may request the Centre to assess the potential risks posed by several new psychoactive substances with a similar chemical structure and to draw up a combined risk assessment report, where there are indications in the combined initial report to believe that the substances may pose severe public health risks and, where applicable, severe social risks. The combined risk assessment shall be carried out by the Scientific Committee.

([7]) Or combined risk assessment report.

FIGURE 3
Information flows in the Early Warning System



SECTION 4
EU Early Warning System

4.1 Legal basis and scope

Article 5a of Regulation (EC) No 1920/2006 (as amended) sets up the Early Warning System and sets out the roles, responsibilities, steps and general sequence of actions related to its operation, namely:

> Information exchange on, and early warning system for, new psychoactive substances
>
> Each Member State shall ensure that its national focal point, as referred to in Article 5, and its Europol national unit provide the Centre and Europol, taking into account their respective mandates, with the available information on new psychoactive substances in a timely manner and without undue delay. The information shall be related to the detection and identification, use and patterns of use, manufacture, extraction, distribution and distribution methods, trafficking, and commercial, medical and scientific use of, and potential and identified risks posed by, those substances.
>
> The Centre, in cooperation with Europol, shall collect, collate, analyse and assess the information and communicate it in a timely manner to the Reitox national focal points and the Europol national units as well as to the Commission with a view to providing them with any information required for the purposes of early warning and for the purposes of allowing the Centre to produce the initial report or the combined initial report pursuant to Article 5b.

4.2 Information collection and reporting by the Member States

4.2.1 Formal notification of a new psychoactive substance

Most new psychoactive substances 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 by a Member State to be a new psychoactive substance, the Reitox NFPs or the ENU should report this to the EMCDDA or Europol, respectively. This includes 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 a new psychoactive substance is first detected. Such data facilitates the identification of new psychoactive substances by laboratories across Europe.

The substance is then assessed by the EMCDDA based on:

- The definition of a new psychoactive substance 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 (such the patent and scientific literature, analogy to better-studied substances, including controlled drugs) ([8]).

On the basis of this assessment, if the EMCDDA confirms that the substance appears to meet 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 available information on the names and identifiers of the substance, chemical and physical properties, analytical methodologies used for its identification, pharmacology, toxicology, circumstances of the detection, and any other relevant information.

At this stage, the EMCDDA begins to formally monitor the substance as a new psychoactive substance. The formal notification process is one of the foundations of a successful early warning system as it ensures that members of the Network are alerted as soon as possible to the identification of a new psychoactive substance in Europe. This allows the network to detect and assess any potential threats at national-level, as well as to identify and implement any response measures that might be needed. Importantly, the

([8]) 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.

information provided in the formal notification allows forensic and toxicology laboratories to include the substance in their analytical screening so that it can be identified and therefore monitored.

→ See: Guidance Note 2. Formal notification of a new psychoactive substance.

4.2.2 Event-based monitoring of new psychoactive substances

Following formal notification, the NPS is then monitored by the EMCDDA for signals that suggest it may pose health or social risks. For this, the EMCDDA uses information reported by the Member States and other relevant sources at its disposal. Member States ensure that the available information on the NPS is reported to the EMCDDA and Europol via the NFPs and ENUs in a timely manner and without undue delay related to its:

- detection and identification;
- use and patterns of use;
- manufacture or extraction;
- distribution and distribution methods;
- trafficking;
- commercial, medical and scientific use; and
- potential and identified risks.

Typically, this information is from event-based data reported by the Member States as case reports related to seizures made by law enforcement, collected samples, biological samples, and serious adverse events.

→ Guidance on the information that should be reported by the Member States on a new psychoactive substance is provided in Guidance Note 3.

Following review of a signal by the EMCDDA during a signal review meeting, responses may include intensive monitoring of the NPS (Guidance Note 6), risk communications (Section 4.11.2), and the production of an initial report which may lead to a risk assessment (Section 5).

Subsequent identifications of the new psychoactive substance in that Member State should be reported by the Reitox NFPs and ENUs to the EMCDDA or Europol, respectively, typically as a case report or in the annual situation report (Section 4.2.5).

The form and speed of reporting will partly depend on the nature of that subsequent detection or event.

4.2.3 Events of potential high public health impact

The Reitox NFP should consider if the identification of a new psychoactive substance is linked to an event that has the potential to have a high public health impact. Reitox NFPs should expedite the reporting of such types of events to the EMCDDA.

Reporting events of a potential high public health impact (EPHPHI) in a timely manner can help the early detection of a serious public health or social risk and ensure that they are assessed and responded to in a timely manner. Such events may also reveal potentially serious public health risks that had previously gone unrecognised — so-called 'accidents waiting to happen' where an event or situation may lead to a serious public health threat or is a warning sign of a potentially more serious event. Where possible, Member States should endeavour to report supporting forensic (analytical) data from such events.

→ Guidance on the types of events that may have a high public health impact is provided in Guidance Note 4.

Note:

Member States should expedite the reporting of any events of a potential high public health impact, especially:

- outbreaks;
- cross-border threats;
- events involving substances that are subject to intensive monitoring; and,
- events involving substances of high concern

as these often provide important signals for early warning as well as the need for timely response actions, including deciding on the need to produce an initial report.

→ Guidance on outbreaks is provided in Guidance Note 5.
→ Guidance on intensive monitoring is provided in Guidance Note 6.
→ Guidance on substances of high concern is provided in Guidance Note 7.

4.2.4 Other information that should be routinely reported

Member States should routinely report to the EMCDDA any information on restrictive measures in a timely manner. Where available this should include a copy of the national risk assessment.

4.2.5 Reitox EWS annual situation report

The Reitox EWS annual situation report covers the 12 months between January and December; it should be submitted to the EMCDDA in the following January. It should include aggregated data on all analytically confirmed identifications of new psychoactive substances made during the course of the year by the members of the national early warning system. It should also contain an overview of developments within the national early warning system over the preceding year.

4.3 Information sources at Member State level

Experience shows that in order to function effectively, national early warning systems require a clear strategic aim and supporting objectives using a multisectoral, multiagency, and multidisciplinary approach. In order to detect, assess, report, and respond to events, there needs to be sufficient capacity (such as infrastructure, policies and procedures, knowledgeable and trained personnel) and capability (ability to provide the outputs required by the Regulation). In addition, such capacity and capability should be present at all levels within a Member State (local, intermediate, and national).

It is therefore recommended that the Reitox national focal points develop and maintain close cooperation and coordination with partners in their national early warning system. As part of this, Reitox national focal points should identify relevant partners and develop plans to share information. This may require consideration of whether data sharing or cooperation agreements are required. Consideration should also be given to the need for an electronic information system to manage data reported by the national network.

Experience shows that it is particularly important that Reitox national focal points maintain regular liaison with forensic science and toxicology laboratories, poison centres, and government departments responsible for implementing drugs policy, national medicines regulatory authorities, other drugs agencies, and the Europol national units (ENU) as appropriate.

Information sources at national level might include, for example:

- Law enforcement agencies and their laboratory networks responsible for the forensic analysis of seizures. These include police, specialised drug units, customs, border guards, prosecutors' offices, prisons, etc.
- Analytical toxicology laboratories that are responsible for clinical case work that involves the analysis of biological samples, particularly those related to serious adverse events such as poisoning cases presenting to hospital emergency departments.
- Forensic toxicology laboratories that are responsible for case work that involves the analysis of biological samples, particularly those related to medico-legal death investigations (such as post-mortem toxicology).
- Poison centres ([9]) and related toxicosurveillance systems.
- Health and care systems, including: hospital emergency departments, psychiatric departments, specialised and non-specialised treatment centres; outreach and street-work agencies, drug prevention and harm reduction establishments, low-threshold services, drug helplines, general practitioners, etc.
- Drug checking programmes.
- National medicines regulatory authorities and the national pharmacovigilance systems ([10]).
- Universities and research establishments.
- Key informants, including: service users, organisers of mass gathering events (festivals, concerts, raves, etc.), owners and staff of clubs, etc.
- Open sources, including those in national languages such as: online discussion groups and forums of people who use NPS and drugs, scientific publications and grey literature; printed and electronic media, the internet, etc.

([9]) Poison centres can play a central role in detecting, characterising, responding, and evaluating the effectiveness of response measures to emerging toxicological issues related to NPS and controlled drugs.
WHO maintains a list of poison centres at: https://www.who.int/gho/phe/chemical_safety/poisons_centres/en/

([10]) The EMA maintains a list of national medicines regulatory authorities (competent authorities).
Human medicines: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human
Veterinary medicines: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-veterinary

4.4 Health threats related to existing psychoactive substances

The Reitox national focal points may also provide the EMCDDA with information on new trends in the use of existing psychoactive substances and/or new combinations of psychoactive substances which pose a potential risk to public health as well as information on possible measures related to public health. Such information and events should be reported using the same procedures as those used for new psychoactive substances ([11]).

4.5 Communication within the Network

The EMCDDA has developed a common terminology and definitions for the operation of the EWS (Guidance Note 1). It has also developed a set of common reporting tools in order to harmonise data collection across the Network. This allows interoperable reporting and communications leading to consistent working across the Network. It also reduces the risk of potentially serious misunderstandings and errors, as well as reduces the burden on the Network in terms of the need for requesting clarifications and corrections. This improves the timeliness and accuracy of the information, as well as reliability and comparability. This can greatly improve operational communication within the Network.

All communications between the EMCDDA and the Network are generally carried out electronically either through the European Database on New Drugs (EDND) and by email. On an ad hoc basis, communication may also be carried out by telephone.

→ Communications from the Reitox NFPs to the EMCDDA by email should be addressed to: ews@emcdda.europa.eu

The EMCDDA issues updates to operational guidance including processes, through Guidance Notes. These are transmitted to the Network by email on an ad hoc basis and made available on the EMCDDA website.

In order to ensure efficient and timely receipt of email communications from the EMCDDA, the Reitox NFPs must provide the names, email addresses, and organisation of the individuals they want to receive emails communications from the EMCDDA related to the operation of the EWS. As a minimum, the Reitox NFP must designate an Early Warning System correspondent and provide their contact details (Section 4.6).

4.6 Reitox NFP Early Warning System Correspondents

As a minimum, the Reitox NFPs must designate an Early Warning System Correspondent and provide the EMCDDA with contact details of the correspondent. The correspondent acts as the day-to-day contact point between the Reitox NFP and the EMCDDA.

The contact details must include the name of the correspondent, their email address, and direct telephone numbers (including mobile phone number where available). The contact details shall be continuously updated and annually confirmed. Where necessary, NFPs should also ensure that they inform the EMCDDA of any temporary contact arrangements for cover/back-up should the designated correspondent be out of the office for a prolonged period of time.

In addition, the Reitox NFP may wish to consider use of a multi-user mailbox (sometimes called 'shared' or 'functional' mailboxes) and/or mailing lists in order for other relevant members of the Reitox NFP to receive email communications from the EMCDDA. This is particularly important for risk communications that may provide vital, time-sensitive information on a specific event or situation that warrants immediate attention from the Reitox NFP (Section 4.11.2, Risk Communications). It is also important for other operational matters related to the Early Warning System, such as when an initial report is prepared and there is a legally stipulated deadline for the submission of data to the EMCDDA.

→ It is the responsibility of the Reitox NFP to ensure that the EMCDDA is informed in a timely manner of any changes in personnel and/or contact details related to the operation of the national early warning system.

→ In order to ensure operational continuity between the Reitox NFP and the EMCDDA, changes in personnel and contact details should be provided to the EMCDDA in a timely manner, and, preferably, before the changes take place.

→ You can send these changes to us by email at: ews@emcdda.europa.eu

([11]) See Article 5(2) and Annex 1, Regulation (EC) No 1920/2006 (as amended). Similarly to new psychoactive substances, this includes threats that may not be directly caused by existing substances, but due to another substance that is present in the substance or product. This includes harmful adulterants, diluents, synthesis-related impurities and contaminants, it also includes infectious diseases and biological contamination of substances/products (such as anthrax and botulism) (see Substance of interest in Guidance Note 1).

4.7 Data protection

The information submitted to the EMCDDA and Europol by the Member States shall not include or refer to personal data. Consequently, there should be no confidentiality issues with depersonalised data.

4.8 Classified information

The information provided to the EMCDDA and Europol shall not provide information marked equivalent to SENSITIVE in the national marking system. Consequently, there should be no confidentiality issues with sensitive information on drug seizures or other events involving new psychoactive substances reported to the EMCDDA by the Member States.

Although most documents produced by the EMCDDA and Europol will be unclassified, some will need to be marked 'RESTREINT UE/EU RESTRICTED' until such time as the formal recipients of these documents have had an opportunity to take action. This includes the submission of the initial report to the Commission and the Member States by the EMCDDA (Section 5).

It is the responsibility of those reporting information to the EMCDDA or Europol, i.e. the NFPs and ENUs, to consider if their material qualifies for the classification 'RESTREINT UE/EU RESTRICTED' or their national equivalents. Such information shall be submitted via appropriate channels suitable to communicate classified information at the level 'RESTREINT UE/EU RESTRICTED'. Only the authors of documents can apply the classification level. It should be recognised that a wider use of such classification may restrict the degree to which the information can be circulated and used by others due to the application of the need-to-know principle for classified information.

4.9 Retraction of information

The Member States can retract any data, information, and report submitted to the EMCDDA either from their own proposal or after a proposal from the EMCDDA. Retractions can be issued after verification and agreement between the EMCDDA and the Reitox NFP of the notifying Member State.

4.10 EMCDDA Systems

The rapidly changing nature of the NPS market, its links with the established illicit market, and the overall large number of substances that need to be monitored have presented challenges for early warning activities in recent years.

In response to this, the EMCDDA has undertaken a programme of work to strengthen early warning activities. This includes developing a range of interconnected systems as part of the Early Warning System — including a toxicovigilance system, signal management system, open-source information monitoring system, and risk communication system — that allows it to better detect, assess, prioritise, and respond to the public health and social threats associated with NPS.

Toxicovigilance is the active process of detecting, reporting, assessing, understanding, monitoring, and responding to serious adverse events associated with new psychoactive substances. Information on serious adverse events allows the EMCDDA to identify emerging acute or chronic toxicological problems, allowing timely response at national and EU level.

Using information reported by the Member States and identified from the scientific literature, the toxicovigilance system allows the EMCDDA to detect, assess, and react to serious adverse events associated with NPS. A particular focus of this work has involved standardising the way information on acute non-fatal and fatal poisonings is reported and managed.

The signal management system provides a framework to detect, assess, and prioritise threats associated with new substances.

Related to this, the EMCDDA has also been developing a system to monitor open-source information that improves both general situational awareness and the capacity to detect signals of serious and urgent health threats that are of relevance to the European Union. In part, this is increasingly important both due to globalised supply chains for NPS (and other ingredients used in such products) and because of an increase of outbreaks of mass poisonings linked to some types of NPS. This multilingual system includes the use of the medical information system (MedISys), which is developed by the European Commission's Joint Research Centre, Google Alerts, Twitter, as well as other sources, and it monitors events from thousands of sources of information, such as the media, health agencies, and law enforcement. Important types of events detected by this system include outbreaks of mass poisonings caused by NPS. By monitoring a large range of sources, the open source information monitoring system (OSIMS) allows the EMCDDA to detect, assess, and respond to potential serious and urgent events of EU relevance in a timely manner. Although reports from such sources include official

government departments and agencies, for the purposes of monitoring, they are classed by the EMCDDA as unofficial information sources. The EMCDDA will attempt to obtain verification from the Reitox national focal points of an event in a Member State.

Finally, work has also been done on strengthening risk communication to the network related to important signals and threats that the EMCDDA identifies through its early warning and risk assessment activities (Section 4.11.2).

4.11 Outputs of the Early Warning System

Based on the information reported through the Early Warning System, the EMCDDA generates a number of outputs for the purposes of: providing the Member States and the Commission with information required for early warning; producing an initial report; and risk assessment. These include:

- European Database on New Drugs
- Risk communications
- Initial report
- Risk assessments
- EMCDDA publications

4.11.1 European Database on New Drugs

The European Database on New Drugs (EDND) is the information system operated by the EMCDDA that allows the reporting and management of the information on new psychoactive substances reported by the Member States and identified by the EMCDDA's other systems (such as OSIMS). The EDND provides round-the-clock access to information on new psychoactive substances for the purposes of early warning.

Access to the EDND is restricted to the members of the Network and selected members of the national early warning systems. Requests for access to the EDND at national level should be initiated by the Reitox NFPs in the first instance. Users are required to agree to the terms and conditions of use before being granted access to the EDND.

→ Requests for access to the EDND should be submitted by the Reitox NFPs by email to: ews@emcdda.europa.eu

4.11.2 Risk communication

The purpose of the risk communications issued by the EMCDDA is to provide timely, clear, credible, and consistent evidence-based messages to the Network that raise awareness, knowledge, and understanding, and, through discussion, build consensus on a broad range of public health and social threats related to new psychoactive substances. This includes highlighting important gaps in information as well as stimulating reporting of data that can facilitate further assessment and understanding. Risk communications may be issued related to threats associated with controlled drugs or other substances of interest too.

Risk communications are also used to provide any necessary information to help inform relevant and timely actions for preparedness planning and response activities at national and EU level. This may include providing information on specific options that might be used to prevent or mitigate the effects of an event or situation. In addition, risk communications may also be used to reduce confusion, misunderstanding, rumours and misinformation, and provide possible options for response measures to prevent or reduce the impact of such issues.

Risk communications may be used to proactively raise awareness of threats (such as potential risks) prior to an event or situation occurring so that the Network is better prepared to respond. In other cases, it may be a more reactive response to an existing event or situation.

Risk communications are addressed to the Network, specifically: the Reitox national focal points, the Commission, and Europol.

Types of risk communications

There are four types of risk communications that the EMCDDA issues for the purposes of early warning: alerts, formal notifications, advisories, and briefings. The main differences are in respect of the importance and time sensitivity of the information, with alerts conveying the highest level of importance requiring immediate attention by the Network.

Alert: Provides vital, time-sensitive information for a specific event or situation associated with a new psychoactive substance or other substance of interest that may pose a serious public health or social risk within Europe. Alerts convey the highest level of importance and require immediate attention by the Network.

Formal notification: 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 posed by

the new psychoactive substance. A formal notification may not require immediate attention by the Network.

Advisory: Provides important information for a specific event or situation associated with a new psychoactive substance or other substance of interest and that is of relevance to Europe. Advisories may not require immediate attention by the Network.

Briefing: Provides important background information for a specific event or situation associated with a new psychoactive substance or other substance of interest. Briefings do not require immediate action by the Network.

All risk communications may provide response options which the Network may want to consider as part of their preparedness planning and response activities. They also request 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, new psychoactive substance or other substance of interest. Following a risk communication, the EMCDDA may provide supplementary information to the Network by email.

Use of risk communications by the Network

Following receipt of a risk communication, the Network should review and assess the information according to its importance, time sensitivity, and relevance. Alerts require immediate attention by the Network.

The Network is free to use the information in a risk communication as they see fit. Although risk communications do not contain restricted information, they may contain information of a sensitive nature. Reitox NFPs should take this into account when using the information provided, especially when considering the use of the information with the public.

Note:

EMCDDA risk communications must not be placed in the public domain without prior authorisation from the EMCDDA.

Following review and assessment of the risk communication, it is recommended that as a minimum the Reitox NFPs should:

- Disseminate the risk communication or relevant information therein to the national early warning system and other partners as relevant.
- Report any additional information at their disposal to the EMCDDA in a timely manner. In some circumstances this may require an ad hoc request by the Reitox NFP to one or more of their partners for additional information.

Member States may wish to assess the relevance of the information reported in the risk communication to the national situation.

Europol and the Commission should disseminate the risk communication or relevant information therein to their networks/partners as relevant. They should also report any additional information at their disposal to the EMCDDA. In some circumstances this may require an ad hoc request to one or more of their networks/partners for additional information.

Questions arising from risk communications from national early warning systems should be directed to the Reitox NFP in the first instance. Should the Reitox NFP be unable to answer the question, they should submit it to the EMCDDA.

In order to use the information provided in risk communications effectively, Member States may wish to consider developing plans on how to share this information. This could include developing and maintaining a list of key contacts as well as developing a procedure for when and how specific agencies and officials at various levels of government should be contacted and informed about the information in the risk communication.

4.11.3 Initial report

See Section 5 for details on the initial report.

4.11.4 Risk assessment

Following the submission of an initial report, a risk assessment may be requested by the Commission. Information reported by the Member States through the Early Warning System is used to inform the risk assessment. Further details are provided in the EMCDDA operating guidelines for the risk assessment of new psychoactive substances.

4.11.5 EMCDDA publications

Information generated by the Early Warning System is also used to produce EMCDDA publications for the purposes of early warning as well as those publications related to the other tasks of the EMCDDA.

SECTION 5
Initial report

5.1 Background

The purpose of the initial report is to provide scientific evidence to the Commission in order to allow it to make an informed decision regarding whether or not there is a need to request a risk assessment on a new psychoactive substance as set out in Article 5c of Regulation (EC) No 1920/2006 (as amended).

Article 5b of the Regulation sets out the roles, responsibilities, steps, process, and general sequence of actions related to the production of an initial report.

The decision process leading to the production of an initial report is set out in Article 5b of the Regulation, namely:

> Where the Centre, the Commission or a majority of the Member States considers that information shared on a new psychoactive substance collected pursuant to Article 5a in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks at Union level, the Centre shall draw up an initial report on the new psychoactive substance.
>
> For the purpose of this paragraph, Member States shall inform the Commission and other Member States of their wish that an initial report be drawn up. Where the majority of Member States is reached, the Commission shall instruct the Centre accordingly and shall inform the Member States thereof.

The process is divided into two stages:

1. The assessment by the EMCDDA of existing information reported by the Member States;

2. The collection of additional information.

Note:

According to Article 5b(1) of the Regulation, where the EMCDDA collects information on several new psychoactive substances that it considers to be of similar chemical structure and may pose health or social risks at Union level, it shall submit to the Commission and to the Member States individual initial reports, or combined initial reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified.

5.2 Assessment of existing information

The initial report provides scientific evidence to the Commission in order to allow it to make an informed decision regarding whether or not there is a need to request a risk assessment on a new psychoactive substance. In order to determine if an initial report should be produced, the information on a new psychoactive substance reported by the Member States is analysed and then assessed by the EMCDDA during a specific meeting known as a substance review meeting ([12]). The assessment is based on the following five criteria:

- Reports of health problems
- Reports of social problems
- Reports of seized material
- Pharmacological and toxicological properties of the new psychoactive substance or analogy with better-studied substances
- Potential for further spread

([12]) Alternatively, if instructed by the Commission in accordance with the provisions of paragraph 2 of Article 5b of Regulation (EC) No 1920/2006 (as amended), the EMCDDA shall proceed directly to producing an initial report.

If the EMCDDA concludes that the assessment gives rise to concern that the new psychoactive substance may pose health or social risks at Union level, the EMCDDA will proceed to the production of an initial report. At this stage, the EMCDDA also decides on whether or not a request for additional information from the Reitox NFPs is required (Section 5.3).

If the EMCDDA concludes that the assessment does not give rise to concern that the new psychoactive substance may pose health or social risks at Union level, the EMCDDA will subject the substance to (continued) intensive monitoring and other response actions, including further assessments as relevant. The EMCDDA will also inform the Network of the conclusion of the assessment and any related response actions.

5.2.1 Reports of health problems

Assessment of this criterion is based on an analysis of the nature, number, scale, and timing of serious adverse events reported by the Member States.

5.2.2 Reports of social problems

Assessment of this criterion is based on an analysis of the nature, number, scale, and timing of social problems reported by the Member States.

5.2.3 Reports of seized material

Assessment of this criterion is based on an analysis of the frequency, quantities, circumstances, and timing of seizures reported by the Member States.

Information from collected samples may also be taken into consideration.

5.2.4 Pharmacological and toxicological properties of the new psychoactive substance or analogy with better-studied substances

Assessment of this criterion is based on an analysis of the information available on the pharmacological and toxicological properties of the new psychoactive substance.

In addition, where relevant, a new psychoactive substance may also be assessed by analogy to structurally-related and better-studied substances, including controlled drugs. Such an assessment may occur when the new psychoactive 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.

5.2.5 Potential for further spread

Assessment of this criterion is based on an analysis of the number and type of analytically confirmed identifications reported by the Member States, the circumstances of the detections, and timing. The risk of (further) cross-border spread is also assessed ([13]).

5.3 Collection of additional information

5.3.1 Information from the Reitox NFPs

For the purpose of the initial report, the EMCDDA will typically use the information that is already at its disposal from the Member States. However, if necessary, the EMCDDA will request the Reitox NFPs to provide additional information on the new psychoactive substance. The Reitox NFPs shall provide this information within two weeks of receipt of the request from the EMCDDA (Article 5b(4)).

The information required from the Member States will be collected by means of a structured reporting form provided to the Reitox NFPs. This will be based on the list of information types given in Guidance Note 3.

The amount of additional information required from the Member States will depend on what information has previously reported to the EMCDDA through the Early Warning System in accordance with the requirements of Article 5a of the Regulation.

Note:

As events of a potential high public health impact (EPHPHI) (Guidance Note 4), and events involving substances that are subject to intensive monitoring (Guidance Note 6) can provide important signals in informing the need for response actions, including the need to produce an initial report, Member States should expedite reporting of such events to the EMCDDA.

([13]) This factor is satisfied if the new psychoactive substance has been identified in more than one Member State or that the substance is becoming widespread throughout or beyond Europe within a relatively short time.

Note:

Member States are also encouraged to routinely report to the EMCDDA any information on restrictive measures. In particular, Member States should prioritise reporting of information on restrictive measures for those substances that are subject to intensive monitoring (Guidance Note 6). Where available this could include a copy of the national risk assessment.

5.3.2 Information from the WHO and EU Agencies

As part of the collection of additional information for the initial report, the EMCDDA, in accordance with the requirement of Article 5b, submits requests to:

- The World Health Organization (WHO) in order to determine if the new psychoactive substance is under assessment or has been under assessment within the system established by the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and the 1971 Convention on Psychotropic Substances ('United Nations system') (Article 5b(2d)).

- The European Medicines Agency (EMA) in order to determine if the new psychoactive substance is used as an active substance in a medicinal product for human or veterinary use at Union or national level (Article 5b(5)). Specifically, if the new psychoactive substance is an active substance in:

  - a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC of the European Parliament and of the Council ([14]), Directive 2001/82/EC of the European Parliament and of the Council ([15]) or Regulation (EC) No 726/2004 of the European Parliament and of the Council ([16]);
  - a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;
  - a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;
  - an unauthorised medicinal product for human use in accordance with Article 5 of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national law in accordance with point (c) of Article 10(1) of Directive 2001/82/EC;
  - an investigational medicinal product as defined in point (d) of Article 2 of Directive 2001/20/EC of the European Parliament and of the Council ([17]).

- Europol in order to provide information on the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance, and in any use of the new psychoactive substance (Article 5b(6)).

- The European Chemicals Agency (ECHA), the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA) in order to provide the information and data at their disposal on the new psychoactive substance (Article 5b(7)).

5.4 Production and structure of the initial report

Based on the information reported, the EMCDDA will then conduct an analysis and assessment of the information in order to produce the initial report.

The structure of the initial report is described in Article 5b(2) of the Regulation and contains a first indication of:

- the nature, number and scale of incidents showing health and social problems in which the new psychoactive substance may potentially be involved, and the patterns of use of the new psychoactive substance;

- the chemical and physical description of the new psychoactive substance and the methods and precursors used for its manufacture or extraction;

- the pharmacological and toxicological description of the new psychoactive substance;

- the involvement of criminal groups in the manufacture or distribution of the new psychoactive substance ([18]);

([14]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)

([15]) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

([16]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

([17]) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

([18]) Evidence of international trafficking: This includes information submitted to the EMCDDA and Europol by the NFPs and ENUs, respectively, on the total amount of seizures, countries of origin and destination plus various other indicators of trafficking on a new psychoactive substance appearing in the European Union. Evidence of involvement of criminal groups: Europol collects and assesses information, provided by Member States via their ENUs, on the suspected or known involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance, and

- information on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or in a veterinary medicinal product;
- information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;
- information on whether the new psychoactive substance is subject to any restrictive measures in the Member States;
- information on whether the new psychoactive substance is currently or has been under assessment within the United Nations system;
- other relevant information, where available.

5.5 Submission of the initial report

The deadline for the EMCDDA to submit the initial report to the Commission and the Member States is within five weeks of making the requests for information from the EMA, Europol, ECHA, ECDC, and EFSA (Article 5b(10)). Alternatively, in the case where the EMCDDA is submitting several initial reports, or a combined initial report, the deadline is within six weeks of the requests for additional information (Article 5b(11)).

Where there are indications in the initial report to believe that the substance may pose severe public health risks and, where applicable, severe social risks, the Commission may request the EMCDDA to assess the potential risks posed by the new psychoactive substance and to produce a risk assessment report. The risk assessment is carried out by the Scientific Committee of the EMCDDA (Article 5c).

Should the situation arise where an initial report is not followed by a request for a risk assessment, but concern about the new psychoactive substance persists, the EMCDDA will subject the substance to (continued) intensive monitoring and other relevant response actions, including further assessments (Section 5.2) as required.

in any use of the new psychoactive substance within the European Union. If an initial report is deemed appropriate, Europol will also request information on indications of violence and/or money laundering.

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About the EMCDDA

The EMCDDA is the central source and confirmed authority on drug-related issues in Europe. For over 20 years, it has been collecting, analysing and disseminating scientifically sound information on drugs and drug addiction and their consequences, providing its audiences with an evidence-based picture of the drug phenomenon at European level.

The EMCDDA's publications are a prime source of information for a wide range of audiences, including policymakers and their advisors; professionals and researchers working in the drugs field; and, more broadly, the media and general public. Based in Lisbon, the EMCDDA is one of the decentralised agencies of the European Union.

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