European Monitoring Centre
for Drugs and Drug Addiction

EUROPOL

Early-warning system on new psychoactive substances

Operating guidelines

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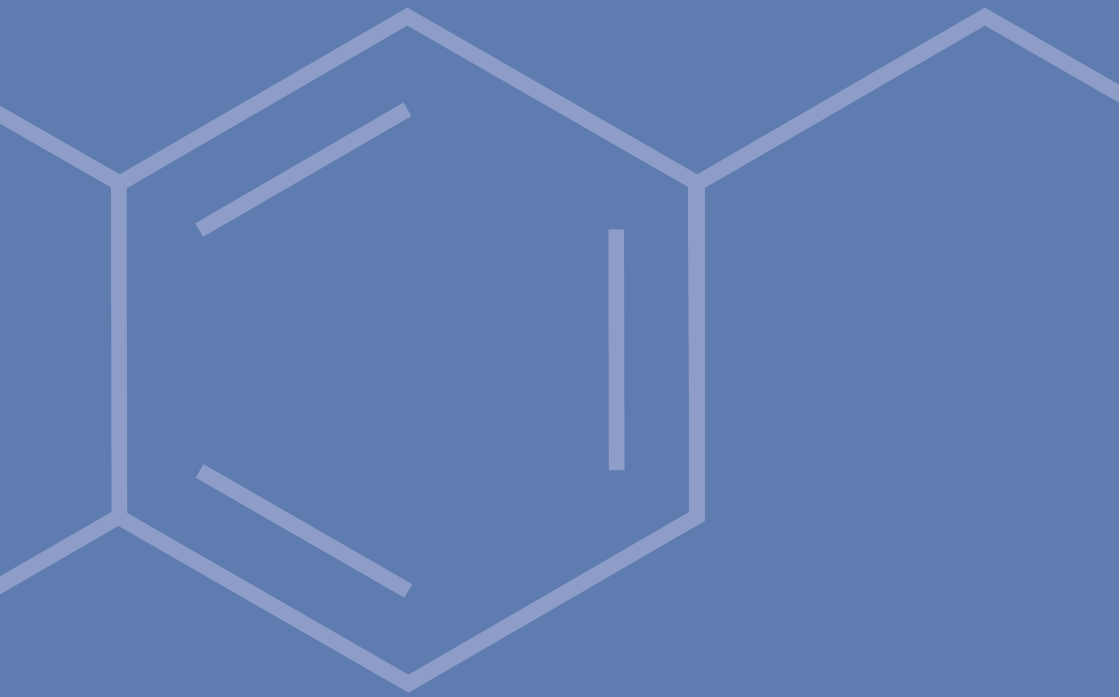


Foreword

It is with pleasure that I present the new operating guidelines for the early-warning system (EWS), which I trust will assist greatly the implementation of Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances.

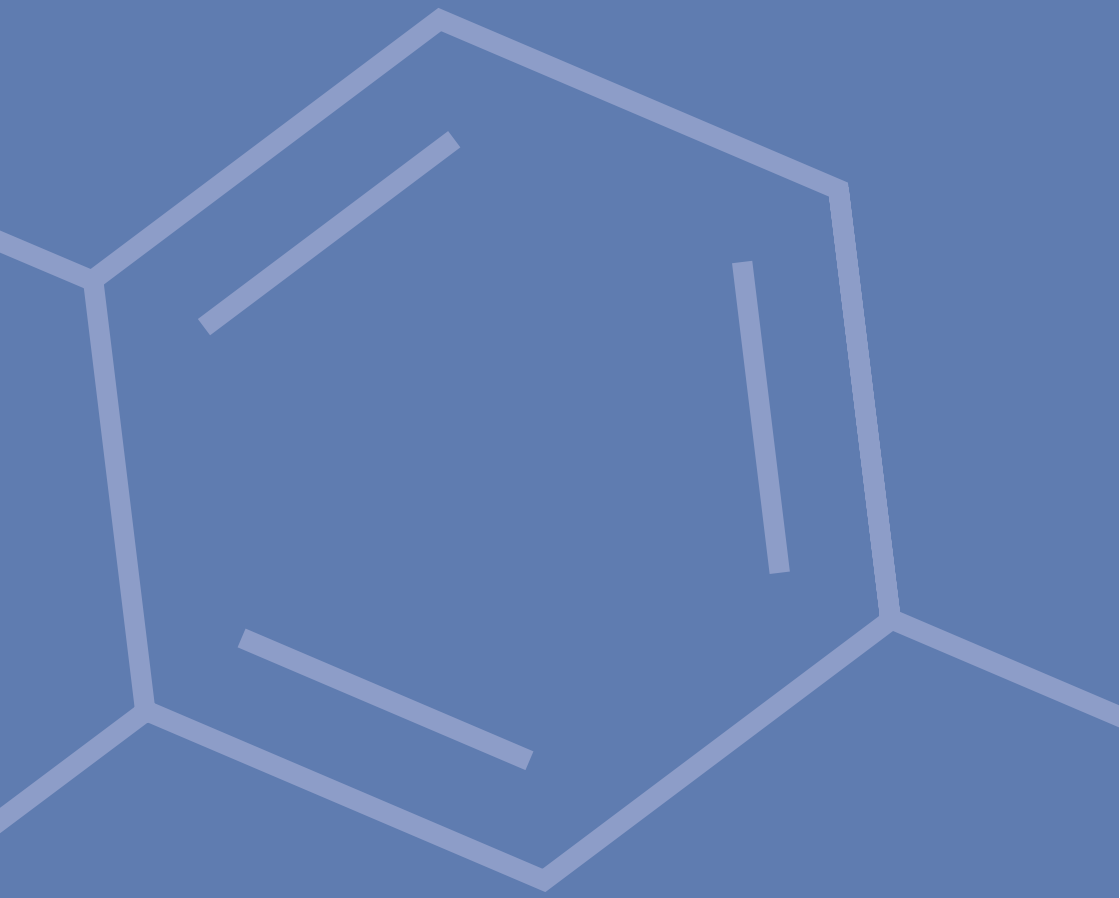
The first EWS guidelines were published in 2001 and they have largely fulfilled their purpose. However, a great deal has happened since then, in particular, Council Decision 2005/387/JHA has replaced the joint action of 16 June 1997 concerning the information exchange, risk assessment and control of new synthetic drugs. The decision maintains the mechanism for the rapid exchange of information established under the joint action but introduces stricter deadlines and broadens the scope beyond new synthetic drugs to include all new psychoactive substances that may pose public health and social threats, thus allowing European Union institutions and Member States to act on all new narcotic and psychotropic substances that appear on the European Union drug scene.

The EWS guidelines have been fully redrafted in order to reflect the scope and deadlines stipulated by the new legal instrument and in view of the experience accumulated in the initial implementation of the decision, which is now in its second year of implementation.

The new guidelines are the result of cooperation between the two organisations responsible for the EWS: EMCDDA and Europol. This cooperation was established already within the frame of the 1997 joint action and has been increasing ever since. In addition, the European Medicines Agency (EMEA) has provided valuable input, thus completing this multidisciplinary effort. I would like to acknowledge too the role of the respective networks in the Member States, both the Europol national units and the Reitox national focal points, which played an essential role in the preparation of the guidelines.

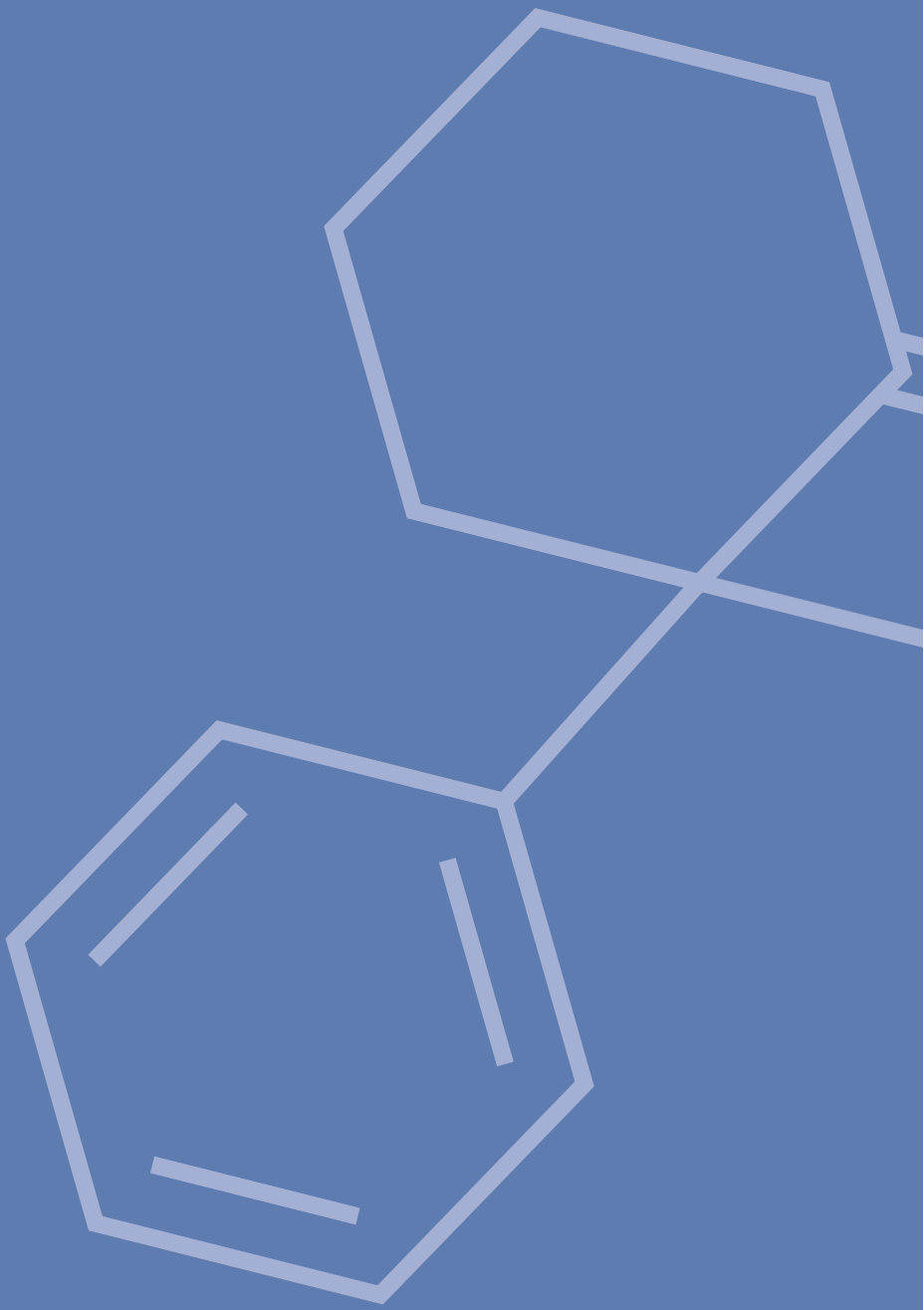
I am confident that the new EWS guidelines explain clearly all steps, procedures, roles, responsibilities and the sequence of actions, thereby enabling all partners at European level to play their part in ensuring that the EWS reinforces the European Union's actions to curb the use of new psychoactive substances.

Wolfgang Götz
Director, EMCDDA



Preface

The purpose of these guidelines is to address the measures introduced by Council Decision 2005/387/JHA. They are concerned only with the first stage, i.e. the early-warning system and information exchange, and replace the earlier guidelines published by the EMCDDA in 2002. They should assist the Member States in implementing that decision and provide transparency to the entire process. However, there is no mandate and it is not the intention to advise Member States on the structure of their own national early-warning systems; that is not the concern of the EMCDDA and Europol so long as the Member States are able to implement the requirements of the decision and produce the expected outputs. Nevertheless, it is recommended that the national focal points (NFP) should ensure that regular liaison is maintained with Europol national units (ENU), forensic science and toxicology laboratories, government departments responsible for enacting drugs legislation, national medicines agencies and other drugs agencies as appropriate.



Abbreviations

CND	Commission on Narcotic Drugs (UN)
EC	European Community
ECDD	Expert Committee on Drug Dependence (WHO)
EDND	European database on new drugs (EMCDDA)
EEC	European Economic Community
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EMEA	European Medicines Agency
ENU	Europol national unit
EU	European Union
Europol	European Police Office
EWS	early-warning system
HDG	Horizontal Drugs Group (JHA)
JHA	justice and home affairs
NFP	national focal point
Reitox	European Information Network on Drugs and Drug Addiction (EMCDDA)
UN	United Nations
WHO	World Health Organisation (UN)

The abbreviations (acronyms) and other details of many psychoactive substances (e.g. MBDB, PMMA, 2C-T-2) which appear throughout the guidelines can be found in the reference literature listed in the bibliography.

Chapter 1
Introduction

From the early 1990s, many so-called 'designer drugs' were regularly discovered in the European Union. They were often psychotropic substances related to amphetamine and MDMA. Their appearance raised questions about possible health risks and the problems that could arise in international law enforcement cooperation if such substances were controlled in some Member States, but not in others. It was agreed that progress could be made by sharing information and by establishing a risk-assessment procedure and a mechanism for their eventual EU-wide control. This led to the 'joint action concerning the information exchange, risk assessment and control of new synthetic drugs', which was adopted by the Council of the European Union under the Dutch Presidency on 16 June 1997 (OJ L 167, 25.06.1997). 'New synthetic drugs' were defined as those that had a limited therapeutic value and were not at that time listed in the 1971 UN Convention on Psychotropic Substances yet, which posed as serious a threat to public health as the substances listed in Schedules I and II to that Convention. The term 'new' did not refer to newly invented, but rather 'newly misused'; most of the drugs in question were first created many years ago.

The 1997 joint action introduced a three-step approach: (1) exchange of information/early-warning system; (2) risk assessment; (3) a procedure for bringing specific new synthetic drugs under control. Apart from the EMCDDA and its Scientific Committee, the main players were Europol, EMEA, the Commission, the Council and the Member States. Norway and the acceding and candidate countries also participated in the early-warning system.

Under the 1997 joint action, over 30 new synthetic drugs were reported through the EWS (see Annex 1). Some were identified in biological samples, but most were found in police or customs seizures. However, few occurred in large amounts or were widespread. Most have had a limited life on the illicit market. The drugs identified since 1997 have been largely phenethylamines (mostly listed in Shulgin and Shulgin, 1991), tryptamines (mostly listed in Shulgin and Shulgin, 1996) and, less commonly, substituted cathinones and aryl-piperazines. Risk assessments (see bibliography) were carried out on nine of them (MBDB, 4-MTA, GHB, ketamine, PMMA, TMA-2, 2C-T-2, 2C-T-7 and 2C-I). Although neither ketamine nor GHB (γ-hydroxybutyrate) strictly qualified as 'new

synthetic drugs', it was considered appropriate to carry out risk assessments because at that time there was information of misuse, but 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' tablets. By contrast, the reported tryptamines, none of which has so far been risk assessed, were more commonly seen as powders. Of the above nine substances, 4-MTA, PMMA, TMA-2, 2C-T-2, 2C-T-7 and 2C-I were brought under control throughout the EU. Subsequently, GHB was added to Schedule IV of the 1971 UN Convention on Psychotropic Substances.

In 2002, a review of the joint action was carried out under the terms of the EU action plan on drugs 2000–04. Suggestions for improvements led to a process that, in 2005, culminated in Council Decision 2005/387/JHA, hereinafter called the 'decision'. This was published in the *Official Journal of the European Union* L 127, pages 32 to 37 on 20 May 2005 and took effect the following day. The full text of the decision is shown in Annex II.

The 2005 Council decision broadens the scope of, and replaces, the 1997 joint action, while maintaining a three-step approach (see Figure 1).

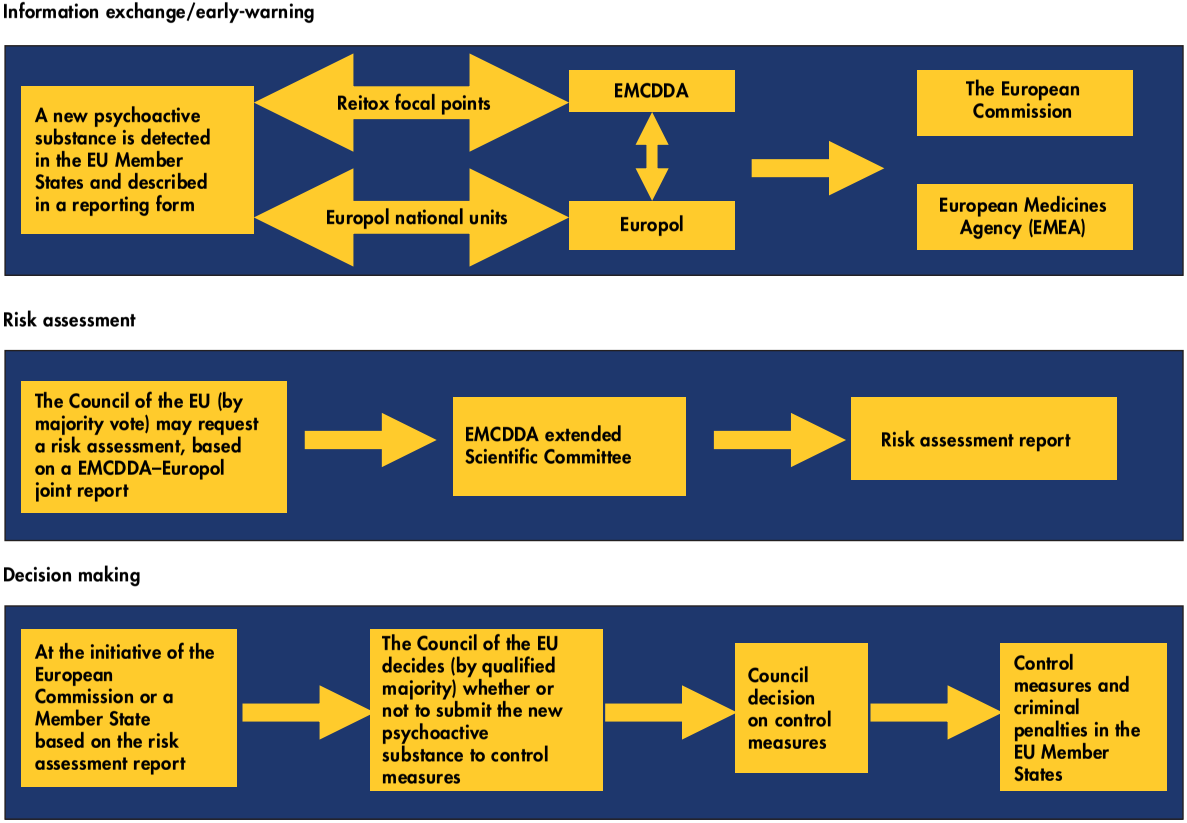
Step 1 — Information exchange/early warning

Once a new psychoactive substance is detected on the European market, Member States ensure that information on the manufacture, traffic and use of the drug is transmitted to the EMCDDA and Europol via the NFPs and ENUs. The data are also submitted by the EMCDDA or Europol for information to the European Commission and the European Medicines Agency (EMEA). Finally, if the EMCDDA and Europol consider that information collected on a new psychoactive substance merits an active follow up, a joint report is presented to the Council of the EU, the Commission and the EMEA. On the basis of this, a decision may be taken on whether or not to launch a risk assessment procedure.

Step 2 — Risk assessment

The Council may decide to launch a risk assessment procedure if at least a quarter of its members, or the European Commission, are in favour of this step. The EMCDDA's Scientific Committee — extended by additional experts from the Member States, the European Commission, Europol and the EMEA — assesses the possible health and social risks of the newly identified drug and the implications of placing it under control. A risk assessment report is presented to the Council, the Commission and the EMEA for consideration.

Figure 1: Council Decision 2005/387/JHA: a three-step process



Step 3 — Decision making

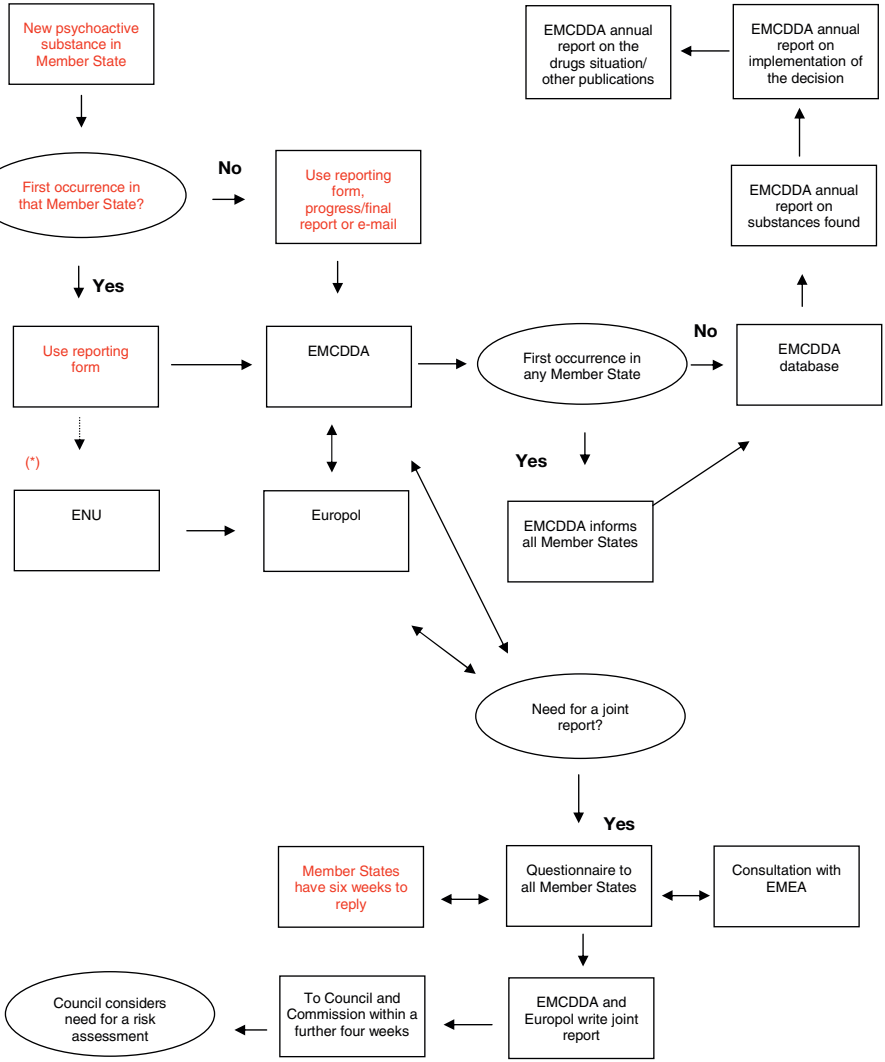
At the initiative of the European Commission or a Member State, and on the basis of the risk assessment report, the Council may decide (by qualified majority) to adopt a decision defining the drug to be subjected to control measures. Those measures and criminal penalties in the EU Member States are decided in line with national laws, which in turn comply with the UN Conventions. When psychoactive substances are brought within the scope of criminal law in all Member States, cooperation between countries on the control of these substances is enhanced. The Council decision does not prevent individual Member States from unilaterally introducing national control measures they consider appropriate once a new substance has been detected.

It is generally accepted that all communications between the EMCDDA, Europol, the Member States and other players are carried out electronically. The information provided to the EMCDDA and Europol shall not include or refer to personal data and the Member States are under no obligation to provide information classified as confidential under their national law. Consequently, there should be no confidentiality issues with depersonalised data and classification will not apply to information on drug seizures or other occurrences of new psychoactive substances submitted to the EMCDDA by Member States. Although most documents produced by the EMCDDA and Europol will be unclassified, some will need to be marked 'EU restricted' ([1]) (e.g. joint report) until such time as the formal recipients of those documents have had an opportunity to take action. It is the responsibility of those submitting information to the EMCDDA or Europol, i.e. the NFPs and ENUs, to consider if their material qualifies for the classification 'EU restricted'. Only the authors of documents can apply this classification. 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.

Figure 2 shows the flow of information in the EWS. The main stages are described in more detail in Chapter 3.

([1]) According to classification of documents (Commission Decision 2001/844//EC, ECSC, Euratom) 'EU restricted' shall be applied to information and material the unauthorised disclosure of which could be disadvantageous to the interest of the European Union or one or more of its Member States.

Figure 2: Information flows in the Reitox early-warning system



NB: Activities carried out by the national focal points are shown in red.

(*) Depending on the national EWS arrangements direct communication between the NFP and the ENU may not always occur.

Chapter 2
The scope of the Council decision

Council Decision 2005/387/JHA (Annex II) retains the three parts of the former joint action as shown in Figure 1, but modifies the scope in a number of ways.

Synthetic and naturally occurring substances

It is likely that new psychoactive substances will continue to be mostly synthetic products, but psychoactive drugs derived from natural (plant or animal) sources must also now be considered. A large number of naturally occurring psychoactive substances are known, but few are widely misused or ever come to the notice of law enforcement agencies. These may include substances that have been available for many years and are not strictly 'new'. The definition of a new psychoactive substance could also include industrial chemicals and related materials provided that they showed psychoactive properties and were being misused.

The 1961 and 1971 UN Conventions

In the 1997 joint action, consideration was only given to those substances that could pose a comparably serious threat to public health as those already listed in Schedules I and II of the 1971 UN Convention on Psychotropic Substances. Under Article 2 of the decision, the scope is extended to substances that might be controlled under any schedule of the 1971 UN Convention or Schedules I, II or IV of the 1961 UN Single Convention on Narcotic Drugs. A consequence of this statement is that substances already listed in the international schedules cannot be regarded as new psychoactive substances.

However, Article 7.1 excludes substances from risk assessment that are 'at an advanced stage of assessment within the United Nations system'. Within the UN system, an assessment of the medical aspects of substances in relation to their ability to cause dependence is carried out by the Expert Committee on Drug Dependence (ECDD) of the World Health Organisation (WHO). It is the responsibility of WHO to advise the Commission on Narcotic Drugs (CND) whether or not to include these substances in the schedules of the 1961 or 1971 UN Conventions. Article 5.2(e)

of the decision requires the EMCDDA–Europol joint report to include information on 'whether or not a new substance is currently under assessment, or has been under assessment, by the UN system'. To obtain such information, the EMCDDA has established cooperation with WHO's Department of Medicines Policy and Standards, which prepares work of the ECDD.

Precursor chemicals

Article 2 notes that precursor chemicals are excluded from the risk assessment and control mechanisms set by the decision:

> This decision relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances ([2]), and Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors ([3]) provide for a Community regime.

This exclusion could also extend to substances on the European Community voluntary monitoring list of non-controlled chemicals ([4]) or indeed any other chemical used as a precursor in the illicit manufacture of a drug of misuse. However, it is possible that if such precursors were to be misused in their own right, then they could at least be subject to information exchange.

([2]) OJ L 357, 20.12.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).
([3]) OJ L 47, 18.2.2004, p. 1.
([4]) The Drugs Precursors Committee, which was set up by Article 10 of Council Regulation (EEC) No 3677/90 of 13 December 1990, has established an informal list of chemical substances that are known to be diverted from their legitimate use, to be used for the production of drugs in the European Union. These chemical substances are not controlled under the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 and hence are not regulated by EU legislation on the intra- or extra-Community trade in drug precursors. The substances are thus referred to as 'non-scheduled' substances. The list is dynamically revised; it contains substances that have been agreed by EU Member States and serves as guidance for operators to be vigilant when placing these substances onto the Community market or in trade between the Community and third countries. Operators should be alert to the possibility of any circumstances that suggest such substances might be used for illicit manufacture of narcotics or psychotropic substances and inform their competent authority where appropriate.

Medicinal products

The preamble to the decision (indent 5) makes it clear that new psychoactive substances may include medicinal and veterinary products.

> The new psychoactive substances covered by this decision may include medicinal products as defined in 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 ([5]) and in 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 ([6]).

However, while information may be exchanged as part of the EWS, and even a joint report prepared, it is intended (indent 8 of the preamble to the decision) that medicinal products should be excluded from subsequent control:

> Substances of established and acknowledged medical value are therefore excluded from control measures based on this decision. Suitable regulatory and public-health related measures should be taken for substances of established and acknowledged medical value that are being misused.

Such measures are established in relevant Community pharmaceutical legislation (Directive 2001/82/EC, Directive 2001/83/EC, Regulation (EC) No 726/2004, Commission Regulation (EC) No 1084/2003, Commission Regulation (EC) No 1085/2003). Regulatory measures such as changes in the product information (e.g. warnings, restrictions of use), suspension or withdrawal of existing marketing authorisations may be taken when new information (e.g. serious adverse reactions) impacts significantly on the benefit–risk balance of medicinal products.

Although not explicitly mentioned in Article 7 of the decision, which stipulates the circumstances where no risk assessment is carried out, it must be assumed that medicinal products themselves are also excluded from risk assessment.

([5]) OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).
([6]) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136 30.4.2004, p. 34).

Substances used to manufacture a medicinal product

Furthermore, Article 7.3 excludes a new psychoactive substance from risk assessment that is:

> used to manufacture a medicinal product which has been granted a marketing authorisation; or… for which an application has been made for a marketing authorisation; or… for which a marketing authorisation has been suspended by a competent authority.

It should be noted that Article 7.3 only refers to exclusion from risk assessment and control measures, and does not prevent the collection of information or even the production of a joint report. A difficulty is that it may not be obvious to Member States, the EMCDDA or even EMEA that a particular new psychoactive substance is used in the manufacture of a medicinal product. The expression 'substance used to manufacture a medicinal product' should be interpreted to include an intermediate in the production of an active pharmaceutical ingredient as well as an active pharmaceutical ingredient used to manufacture a medicinal product.

The increased role of EMEA and its networks

Although the EMEA had some involvement in the joint action, in particular in the risk assessment phase, the 2005 Council decision increases this role.

> In addition to what is provided for under the pharmacovigilance systems as defined in Directive 2001/82/EC and in Directive 2001/83/EC, the exchange of information on abused or misused psychoactive substances needs to be reinforced and appropriate cooperation with the European Medicines Agency (hereinafter 'EMEA') ensured. (Preamble, indent 9)
>
> This decision establishes a mechanism for a rapid exchange of information on new psychoactive substances. It takes note of information on suspected adverse reactions to be reported under the pharmacovigilance system as established by Title IX of Directive 2001/83/EC. (Article 1)
>
> Member States and the EMEA shall ensure an appropriate exchange of information between the mechanism set up by means of this decision and the pharmacovigilance systems as defined and established under Title VII of Directive 2001/82/EC and Title IX of Directive 2001/83/EC. (Article 11)

Consequently, the EMCDDA and the EMEA agreed to establish stronger cooperation through the development of a mechanism of bilateral exchange of information on the basis of data available through the EWS set up by the decision and the EU pharmacovigilance system (which is designed to take note of adverse reactions to medicinal products). This exchange will mainly focus on available information on misuse of medicinal products. Electronic tools such as the existing databases EudraVigilance (EMEA) and the EDND (see page 26) would be used to allow a rapid and reliable exchange of information.

It is generally agreed that it is the responsibility of each NFP to establish links with the relevant national competent authorities in their country to help ensure an appropriate exchange of information between the mechanism set up by the decision and the pharmacovigilance system at a national level.

Chapter 3
Elements of the early-warning system

Types of information

Directly related to the implementation of the decision

Primary data on new psychoactive substances

The principal objective of the EWS is to implement the first stage of the decision, namely to collect and disseminate information on the appearance of new psychoactive substances in Member States. To facilitate the identification of new psychoactive substances, the channels of the EWS are used to circulate technical information. This often comprises analytical data and spectra (e.g. gas-chromatography retention times, mass and nuclear magnetic resonance spectra). To a certain extent, such data are substitutes for reference standards of new psychoactive substances, which are often not available (see Chapter 5). Beyond this commitment, which is legally binding on Member States, there are two further, essentially voluntary, parts to the EWS as set out in the next section.

Beyond the scope of the decision

Public-health related information

Other information, beyond the scope of the decision, may also be circulated. Examples, which are not easily met by other Community mechanisms, may include health alerts on unusual adulterants, seizures or detections of uncommon scheduled drugs, problems with established synthetic/psychoactive drugs, or the existence of dosage units (tablets, etc.) containing unusually large amounts of active substance. These reports serve a 'value-added' purpose and are distributed by the EMCDDA and Europol to NFPs and ENUs on an 'information only' basis. The use to which this information is put depends entirely on the needs of the recipient Member States.

Miscellaneous technical and background reports for information and stimulation of the network may be circulated.

Information collection

Europol–EMCDDA reporting form

When a new psychoactive substance is identified for the first time in a Member State, formal notification through the EMCDDA–Europol reporting form (Annex III) should be completed by the Reitox NFP or the ENU and forwarded to the EMCDDA or Europol respectively. The EMCDDA and Europol will share the received forms. If this is the first report of a particular new psychoactive substance in the EU, then the EMCDDA and Europol will circulate the form including any accompanying analytical data to all NFPs, ENUs, the European Commission and the EMEA.

Subsequent identifications of that same new psychoactive substance in that Member State should be communicated by the Reitox NFPs and ENUs to the EMCDDA or Europol either by e-mail, by further use of the reporting form or in the progress/final report (see below). The form and speed of communication will partly depend on the nature of that subsequent occurrence. In this respect, the six criteria used to launch a joint report (Chapter 4) may prove helpful. In other words, the Member State should consider if the later occurrence: provides new information; represents a large seizure/collection or shows widespread availability; shows evidence of organised crime involvement; shows evidence of international trafficking; shows evidence of cases of serious intoxication or fatalities, etc. Depending on their significance, these subsequent reports may be circulated by the EMCDDA and Europol to all NFPs and ENUs.

Reitox EWS progress and final reports

These should be completed at six-monthly intervals (Annex IV). The Reitox progress report covers the six-month period January to June; it should be submitted to the EMCDDA in July. The final report covers the 12 months January to December; it should be submitted to the EMCDDA in the following January. To assist Member States complete this form, the EMCDDA shall provide, at six-monthly intervals, an updated list of substances reported in the past 12 months.

Europol–EMCDDA joint report

If the preliminary information suggests that a joint report should be produced then further information will be requested from Member States by means of Europol

and EMCDDA questionnaires (Annex V). Before completing the questionnaire, the NFPs are advised to check the European database on new drugs (see page 26) to determine how much information is already known to the EMCDDA.

Active monitoring

In the situation where a joint report is not followed by a risk assessment, but concern about the specific new psychoactive substance persists, the Council or the Commission may request that information be collected for a further period. At suitable time intervals, to be decided by all parties, the EMCDDA and Europol shall send the same questionnaires (Annex V) to Member States as were used to collect information for the joint report.

Longer-term monitoring

Substances that have been risk assessed shall be the subject of longer-term monitoring. This will involve a request that those substances should always be mentioned in the progress/final report (Annex IV) even if only a nil response is required.

Information sources at Member State level

It is a task of the Member State to ensure that its NFP and ENU provide the information required by the Council decision. The organisation and functioning of the EWS at national level is therefore a national responsibility. However, it is recommended that the NFP should ensure that regular liaison is maintained with the ENU, forensic science and toxicology laboratories, government departments responsible for enacting drugs legislation, national medicines agencies and other drugs agencies as appropriate. A list of information sources at national level could include, for example:

- health and care system — specialised and non-specialised treatment centres, hospitals' emergency rooms, poisoning centres, psychiatric departments, outreach and street-work agencies, drug prevention and harm reduction establishments, low threshold services, drug help lines, general practitioners, etc., as well as the laboratory networks of the various healthcare establishments (toxicological analyses of specimens from deceased or living individuals, etc.);

- law enforcement agencies — police, specialised drug units, customs, border guards, prosecutors' offices, etc. and their laboratory networks (forensic analysis of seized drugs);
- national medicines agencies and the national pharmacovigilance systems;
- universities and research establishments;
- scientific publications and grey literature in national languages;
- key informants — users (including discussion groups and forums), organisers of youth events (festivals, concerts, raves, etc.), owners and staff of clubs, etc.;
- media sources — printed and electronic media, the Internet, etc.

Outputs of the EWS

At EU level, there are various outputs that use information on new psychoactive substances collected from Member States and the EMEA.

Europol–EMCDDA joint report

See Chapter 4 for further details. The primary recipients of this report are the Council, the Commission and the EMEA.

European database on new drugs (EDND)

This database presents dynamic information on the occurrence of new psychoactive substances in the EU; it is available, by password access, on the EMCDDA and Reitox websites to EWS correspondents in the Member States and selected members of the national EWS networks. The main users of this information will be the EWS correspondents in the NFPs, the EMCDDA and Europol.

EMCDDA annual report on the state of the drugs problem in Europe

A chapter of the annual report on the state of the drugs problem in Europe is, as a rule, devoted to psychotropic substances. Although primarily concerned with established drugs such as amphetamine and MDMA, some information is included

on those new psychoactive substances reported under the arrangements described in these guidelines. The annual report of the EMCDDA has a wide readership among policymakers, professionals and lay readers in the EU and beyond.

Annual report on the implementation of the decision

To ensure greater transparency in the implementation of the decision, Article 10 stipulates:

> The EMCDDA and Europol shall report annually to the European Parliament, the Council and the Commission on the implementation of this decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this decision. The report shall, in particular, include experience relating to coordination between the system set out in this decision and the pharmacovigilance system.

The EMCDDA and Europol present the annual report by the end of February of the following year.

Risk assessment

When a joint report has been issued, the Council and Member States may decide that the new psychoactive substance should be subjected to formal risk assessment as set out in Article 6 of the decision. The risk assessment is prepared by the EMCDDA and Europol and carried out under the auspices of the EMCDDA Scientific Committee. This Committee establishes its own detailed risk assessment guidelines that take into account all factors that, according to the UN drug control conventions, would warrant the placing of substances under international control. The risk assessment report is submitted to the Commission and Council.

Summary of substances reported to Europol and the EMCDDA

A list of substances reported in the preceding year is compiled annually by the EMCDDA. The main users of this information will be the EWS correspondents in the NFPs, the EMCDDA and Europol.

Other publications

Although a risk assessment will not be carried out on all new psychoactive substances reported to the EMCDDA, it is possible that, from time to time, sufficient information on a substance may be collected to warrant a separate technical publication.

Detecting, tracking and understanding emerging drug trends

In addition to its core objective, the Council decision stimulates the identification, monitoring and exchange of information on emerging trends in new uses of existing substances and on possible public health-related measures: a process that demands a different approach from the Reitox key indicators for estimating levels of drug use, associated problems and, consequently, responses. The EMCDDA has developed a practical tool — European perspective on drugs (E-POD) — to detect, track and understand emerging drug trends. This method aims to assess the veracity of accumulated information by triangulation of information from a wide range of different sources.

The early-warning system on new drugs has a proven capacity in responding proactively to new phenomena. Therefore, it should be a valuable asset and an active player in implementing E-POD through contributing and analysing information from various sources, including forensic science, toxicology, and law enforcement.

Chapter 4
The Europol–EMCDDA joint report

The process for launching a joint report is set out in Article 5.1 of the decision, namely:

> Where Europol and the EMCDDA, or the Council, acting by a majority of its members, consider that the information provided by the Member State on a new psychoactive substance merits the collection of further information, this information shall be collated and presented by Europol and the EMCDDA in the form of a joint report (hereinafter the 'joint report'). The joint report shall be submitted to the Council, the EMEA and the Commission.

This process divides into two stages as shown below, namely the assessment of existing information and the collection of further information.

Assessment of existing information

The joint report provides evidence-based advice to the Council and the Commission on the need to request a risk assessment. The information on a new psychoactive substance provided by Member States on the Europol–EMCDDA reporting form (Annex III), in the progress or final reports (Annex IV) or by less formal means will be assessed by the EMCDDA and Europol to determine if a joint report should be launched. This assessment is based on the following six criteria. The first three are the responsibility of Europol, while the remaining three fall within the competence of the EMCDDA. The decision to go ahead requires that the two institutions agree on the need for such a report.

Amount of seized material

This is based on information submitted to Europol and the EMCDDA via its ENUs and Reitox NFPs respectively, on the frequency, circumstances and quantities in which a new psychoactive substance is encountered.

Evidence of international trafficking

Europol assesses information, provided by Member States via their ENUs, on the total amount of seizures, countries of origin and destination plus various other trafficking/modus operandi indicators on a new psychoactive substance appearing in the European Union.

Evidence of organised crime involvement

Europol collects and assesses information, provided by Member States via their ENUs, on the suspected or known involvement of organised crime in the production, distribution and trafficking of a new psychoactive substance within the European Union. If a joint report is deemed appropriate, Europol will also request information on indications of violence and/or money laundering. If appropriate, and where more than two Member States are impacted, Europol may consider, in line with resources and priorities, the initiation and/or coordination of target-oriented investigations against an identified criminal group.

Toxicopharmacological properties of the new psychoactive substance or analogy with better-studied compounds

All available pharmacological and toxicological evidence should be considered. Furthermore, many of the drugs encountered in recent years have properties similar to those of existing scheduled drugs. There is an a priori assumption that analogous substances are potential candidates for control. 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 analogy in each case.

Evidence of the potential for further (rapid) spread

This point is satisfied if it is already clear that the new psychoactive substance has been seen in several Member States or that it is becoming widespread throughout or beyond Europe within a relatively short time (e.g. 6–12 months).

Evidence of intoxication or fatalities

The finding of a new psychoactive substance in either ante- or post-mortem samples is an immediate cause for concern since such analyses will often only have been carried out when there has been existing evidence of intoxication and a need for medical intervention.

Collection of further information

If there is strong evidence to support one or more of the above criteria, then the EMCDDA and Europol will request Member States and the EMEA to provide further updated information on the new psychoactive substance. The information required from the EMEA is set out in Article 5.3. The further information required from Member States will be collected by means of questionnaires sent to ENUs and NFPs (Annex V). Member States have six weeks to return the completed questionnaire.

The deadline for submitting the joint report is not more than four weeks after the date of receipt of the information from Member States and the EMEA. Europol or the EMCDDA, as appropriate, shall submit the report.

However, if a decision is subsequently made that a new psychoactive substance should be subjected to a risk assessment, then this could happen some months after the completion of the joint report. In this situation, it will be necessary for the EMCDDA and Europol to request that Member States complete an updated version of the questionnaires (Annex V).

The structure of the joint report

This is described in Article 5.2 and shall contain:

(a) a chemical and physical description, including the name under which the new psychoactive substance is known, including, if available, the scientific name (International Non-proprietary Name);

(b) information on the frequency, circumstances and/or quantities in which a new psychoactive substance is encountered, and information on the means and methods of manufacture of the new psychoactive substance;

(c) information on the involvement of organised crime in the manufacture or trafficking of the new psychoactive substance;

(d) a first indication of the risks associated with the new psychoactive substance, including the health and social risks, and the characteristics of users;

(e) information on whether or not the new substance is currently under assessment, or has been under assessment, by the UN system;

(f) the date of notification on the reporting form of the new psychoactive substance to the EMCDDA or to Europol;

(g) information on whether or not the new psychoactive substance is already subject to control measures at national level in a Member State;

(h) as far as possible, information will be made available on:

(i) the chemical precursors that are known to have been used for the manufacture of the substance,

(ii) the mode and scope of the established or expected use of the new substance,

(iii) any other use of the new psychoactive substance and the extent of such use, the risks associated with this use of the new psychoactive substance, including the health and social risks.

Furthermore, according to Article 5.3, the EMEA shall submit the following information on whether in the European Union or in any Member State:

(a) the new psychoactive substance has obtained a marketing authorisation;

(b) the new psychoactive substance is the subject of an application for a marketing authorisation;

(c) a marketing authorisation that had been granted in respect of the new psychoactive substance has been suspended.

Chapter 5
Reference compounds

When a laboratory encounters a new psychoactive substance then, regardless of whether it has been seen before in another Member State, that laboratory will need a reference sample for absolute identification and quantification. To a certain extent published analytical data may help in that identification. The use of 'recycled' seized drugs as reference materials may be acceptable if the active constituent has been isolated and adequately characterised by appropriate analytical techniques.

The provision of 'pure' reference compounds to all laboratories in Member States presents a number of challenges. Thus, few of the substances listed in Annex I are commercially available, but custom synthesis of a single substance may be costly. Unless the appearance of a new psychoactive substance can be anticipated (see bibliography) then the only reference materials that are likely to be synthesised are those that have already been reported by a Member State.

It is likely that synthetic psychoactive substances, rather than plant-based material, will continue to be predominantly notified in the framework of the information exchange mechanism set up by the decision. The availability of reference materials (seized substances or reference substances) is of the utmost importance if forensic and toxicology laboratories are to identify new psychoactive substances, especially in the case of a new synthetic drug about which limited scientific literature is available. However, in contrast to the exchange of samples of seized drugs, for which a procedure has been created at EU level by a Council decision of 28 May 2001 ([7]), there is no European Union arrangement for the synthesis of reference substances. If a system that can successfully function in the long term is to be implemented, it will be important to consider how coordination can be established and how access to reference materials can be facilitated.

([7]) The system organises the exchange of substances under control between European Union Member States. See Council Decision 2001/419/JHA of 28 May 2001 on the transmission of samples of controlled substances, Council recommendation of 30 March 2004 regarding guidelines for taking samples of seized drugs (2004/C 86/04) and the list of national contact points as referred to in Article 3(1) of the Council decision of 28 May 2001 (2002/C 253/02).

Glossary

Council decision
In the context of these guidelines, this refers specifically to Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances.

Early-warning system
The first part of the procedure described in Council Decision 2005/387/JHA (synonymous with the concept of 'information exchange').

Joint action
In the context of these guidelines, this refers specifically to the Joint Action 97/396/JHA of 16 June 1997 adopted by the Council on the basis of Article K.3 of the Treaty on European Union, concerning the information exchange, risk assessment and control of new synthetic drugs (OJ L 167, 25.6.1997, pp.1–3). It was replaced by Council Decision 2005/387/JHA in May 2005.

Medicinal product
A pharmaceutical preparation containing one or more active ingredients that has been licensed for therapeutic use in humans or animals. It may have the form of a dosage unit (tablet, capsule), injection solution, skin patch, etc. See Directives 2001/82/EC and 2001/83/EC.

New psychoactive substance
A substance, defined by Council Decision 2005/387/JHA, which has the potential to be listed in any of the schedules of the United Nations 1971 Convention on Psychotropic Substances or the 1961 Single Convention on Narcotic Drugs.

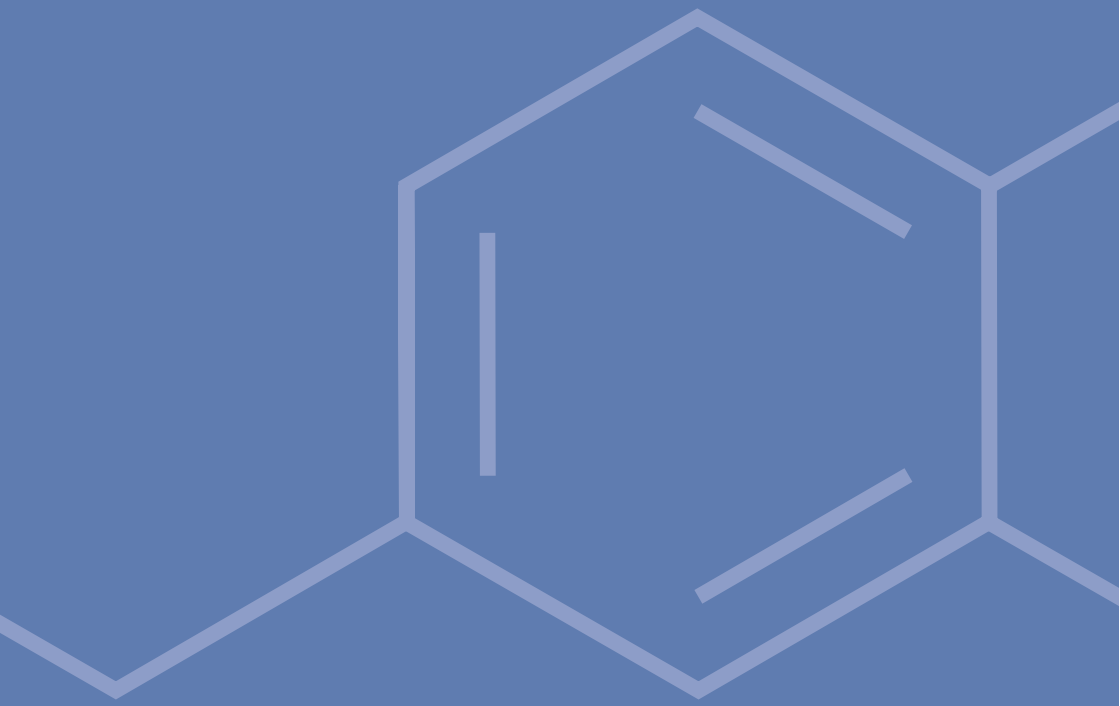
New synthetic drug
A substance that was defined by the earlier joint action (see above) and that had the potential to be listed in Schedules I or II of the United Nations 1971 Convention on Psychotropic Substances. The term is now obsolete within the context of current EU legislation.

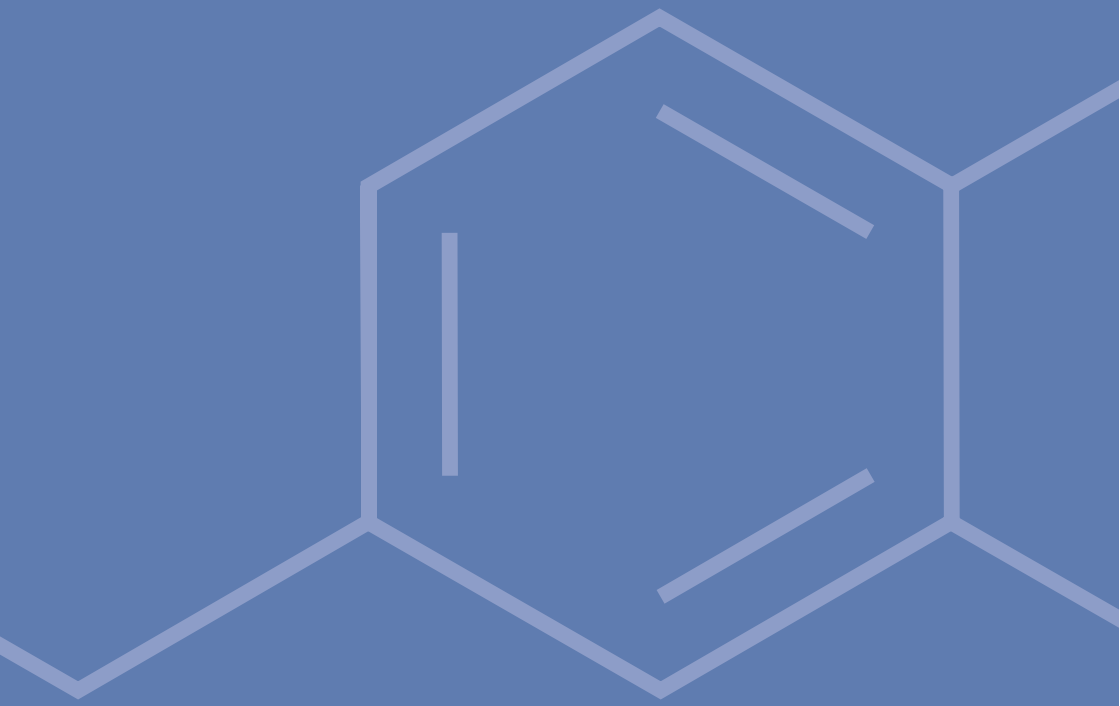
Precursor
A chemical substance that is used as a starting material or as an intermediate in the synthesis of a target substance. In EU legislation, it is restricted to those starting materials that can be used to manufacture certain substances listed in the United Nations 1971 Convention on Psychotropic Substances or the 1961 Single Convention on Narcotic Drugs.

Psychotropic substance
A material, which may or may not be chemically defined, that has an effect on the central nervous system. Psychotropic substances are often, but not restricted to, stimulants and hallucinogens.

Reference sample
A material, also known as a reference standard, that can be used to calibrate chemical analytical equipment such that test samples can be compared with the reference as a means of confirming identity. Reference standards ideally should also allow quantitative analysis.

Risk assessment
The second part of the procedure described in Council Decision 2005/387/JHA.





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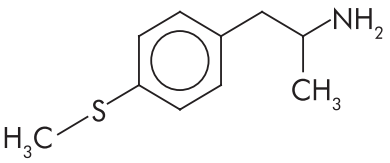
The EMCDDA risk assessment reports can be found at:
http://www.emcdda.europa.eu/?nnodeid=431

Annex I
New psychoactive substances reported to EMCDDA since 1997

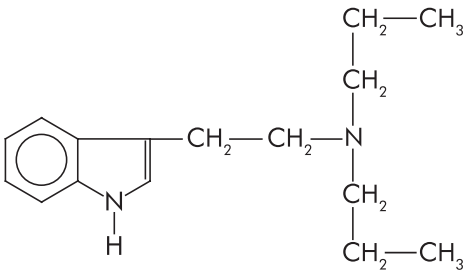
Phenethylamines



Chemical structure of 4-MTA

Other examples include: 2C-I, 2C-D, 2C-E, 2C-H, 2C-T-2, 2C-T-4, 2C-T-7, 2C-P, MBDB, TMA-2, DPIA, PMMA, MDHOET and chloro-MDMA. This list excludes phenethylamines already in the UN 1971 Convention (e.g. 2C-B, MDMA).

Tryptamines



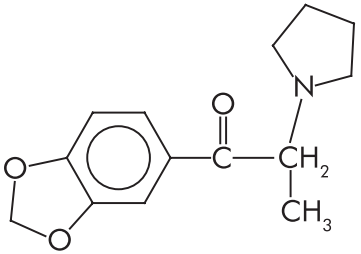
Chemical structure of *N,N*-di-*n*-propyltryptamine (DPT)

Other examples include: MIPT, 4-AcO-DIPT, AMT, DPT, 5-MeO-DMT, 5-MeO-AMT, 5-MeO-DIPT, 5-MeO-T, 4-AcO-DET, 4-HO-DIPT, 5-MeO-MIPT, 5-MeO-DET, 4-HO-DET, 5-HO-DMT, 4-HO-MIPT and 4-AcO-MIPT. This list excludes tryptamines already in the UN 1971 Convention (e.g. DMT, DET).

Miscellaneous

Ketamine and γ-hydroxybutyrate (GHB)

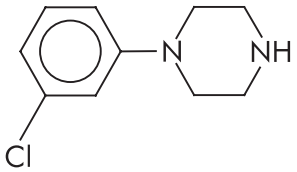
Cathinones



Chemical structure of 3,4-methylenedioxypyrrolidinopropiophenone (MDPPP)

Other examples include: methylone (3,4-methylenedioxymethcathinone; MDMCAT), 4-methylpyrrolidinopropiophenone (MPPP), α-pyrrolidinopropiophenone (PPP), 4-methoxy-α-pyrrolidinopropiophenone (MOPPP) and 4-methyl-α-pyrrolidino-hexanophenone (MPHP). This list excludes cathinones already in the UN 1971 Convention (i.e. cathinone, methcathinone and amfepramone).

Piperazines

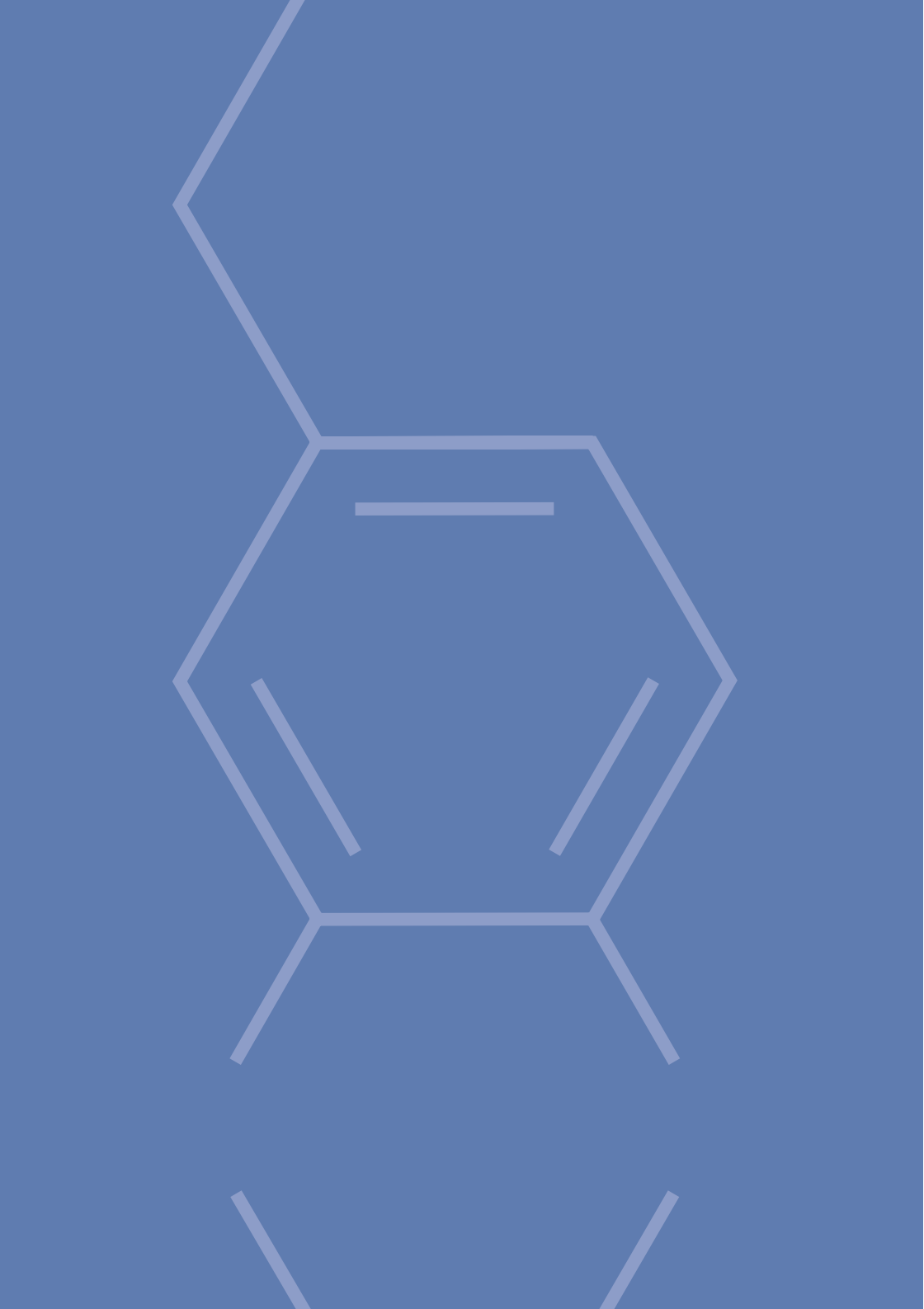


Chemical structure of m-chlorophenylpiperazine (mCPP)

Other examples include: 1-(4-methoxyphenyl)piperazine (MeOPP), 1-benzyl-4-methyl-piperazine (BZMeP), m-trifluoromethylphenylpiperazine (TFMPP),

p-fluorophenylpiperazine (pFPP) and benzylpiperazine (BZP). Aryl-piperazines are not listed in the UN Conventions.

NB: These lists are not exhaustive. Substances listed in Shulgin and Shulgin (1991 and 1996) as well as their simple derivatives and analogues are shown by acronyms only. Other synthetic drugs found in Europe before 1997 included 1-phenethylamine (PEA), *N*-methyl-1-phenethylamine (*N*-Me-PEA), 4-methyl-1-phenethyl-amine (4-Me-PEA), 1-phenyl-3-butanamine, *N*-acetylamphetamine, *N*-hydroxyamphetamine, dimethylamphetamine and MDDMA.



Annex II
Council Decision 2005/387/JHA

L 127/32 EN Official Journal of the European Union 20.5.2005

(Acts adopted under Title VI of the Treaty on European Union)

COUNCIL DECISION 2005/387/JHA

of 10 May 2005

on the information exchange, risk-assessment and control of new psychoactive substances

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 29, 31(1)(e) and 34 (2)(c) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [1],

Whereas:

(1) The particular dangers inherent in the development of psychoactive substances require rapid action by the Member States.

(2) When new psychoactive substances are not brought within the scope of criminal law in all Member States, problems may arise in cooperation between the judicial authorities and law enforcement agencies of Member States owing to the fact that the offence or offences in question are not punishable under the laws of both the requesting and the requested State.

(3) The European Union Action Plan on Drugs 2000-2004 provided for the Commission to organise an appropriate assessment of the Joint Action of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs [2] (herineafter 'the Joint Action') taking into account the external evaluation commissioned by the European Monitoring Centre on Drugs and Drug Addiction (hereinafter 'the EMCDDA') of the early warning system. The assessment showed that the Joint Action had fulfilled its expectations. Nevertheless, the outcome of the assessment made it clear that the Joint Action was in need of reinforcement and reorientation. In particular, its main objective, the clarity of its procedures and definitions, the transparency of its operation, and the relevance of its scope had to be redefined. The Communication from the Commission to the European Parliament and the Council on the mid-term evaluation of the EU Action Plan on Drugs (2000-2004) indicated that changes to the legislation would be introduced in order to enhance action against synthetic drugs. The mechanism as established by the Joint Action should therefore be adapted.

(4) New psychoactive substances can be harmful to health.

(5) The new psychoactive substances covered by this Decision may include medicinal products as defined in 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 [3] and in 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 [4].

(6) The information exchange under the early warning system, established under the Joint Action, has proved to be a valuable asset to the Member States.

(7) Nothing in this Decision should prevent Member States from exchanging information, within the European Information Network on Drugs and Drug Addiction (hereinafter 'the Reitox network'), on emerging trends in new uses of existing psychoactive substances which may pose a potential risk to public health, as well as information on possible public health related measures, in accordance with the mandate and procedures of the EMCDDA.

(8) No deterioration of either human or veterinary health care as a result of this Decision will be permitted. Substances of established and acknowledged medical value are therefore excluded from control measures based on this Decision. Suitable regulatory and public health related measures should be taken for substances of established and acknowledged medical value that are being misused.

[1] Opinion delivered on 13 January 2004 (not yet published in the Official Journal).
[2] OJ L 167, 25.6.1997, p. 1.
[3] OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).
[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

(9) In addition to what is provided for under the pharmacovigilance systems as defined in Directive 2001/82/EC and in Directive 2001/83/EC, the exchange of information on abused or misused psychoactive substances needs to be reinforced and appropriate cooperation with the European Medicines Agency (hereinafter 'EMEA') ensured. The United Nations Commission on Narcotic Drugs (hereinafter 'CND') Resolution 46/7 'Measures to promote the exchange of information on new patterns of drug use and on psychoactive substances consumed', provides a useful framework for action by the Member States.

(10) The introduction of deadlines into every phase of the procedure established by this Decision should guarantee that the instrument can react swiftly and enhances its ability to provide a quick-response mechanism.

(11) The Scientific Committee of the EMCDDA has a central role in the assessment of the risks associated with a new psychoactive substance, it will for the purpose of this Decision be extended to include experts from the Commission, Europol and the EMEA, and experts from scientific fields not represented, or not sufficiently represented, in the Scientific Committee of the EMCDDA.

(12) The extended Scientific Committee that assesses the risks associated with new psychoactive substances should remain a concise technical body of experts, capable of assessing effectively all risks associated with a new psychoactive substance. Therefore the extended Scientific Committee should be kept to a manageable size.

(13) Since the objectives of the proposed action, namely to bring about an exchange of information, a risk-assessment by a scientific committee and an EU-level procedure for bringing notified substances under control, cannot be sufficiently achieved by the Member States and can therefore, by reason of the effects of the envisaged action, be better achieved at European Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Decision does not go what is beyond what is necessary in order to achieve those objectives

(14) In conformity with Article 34(2)(c) of the Treaty, measures based upon this Decision can be taken by qualified majority as these measures are necessary to implement this Decision.

(15) This Decision respects fundamental rights and observes the principles recognised by Article 6 of the Treaty and reflected in the Charter of Fundamental Rights of the European Union,

HAS DECIDED AS FOLLOWS:

Article 1

Subject matter

This Decision establishes a mechanism for a rapid exchange of information on new psychoactive substances. It takes note of information on suspected adverse reactions to be reported under the pharmacovigilance system as established by Title IX of Directive 2001/83/EC.

This Decision also provides for an assessment of the risks associated with these new psychoactive substances in order to permit the measures applicable in the Member States for control of narcotic and psychotropic substances to be applied also to new psychoactive substances.

Article 2

Scope

This Decision applies to substances not currently listed in any of the schedules to:

(a) the 1961 United Nations Single Convention on Narcotic Drugs, that may pose a comparable threat to public health as the substances listed in Schedule I or II or IV thereof, and

(b) the 1971 United Nations 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.

This Decision relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances [1], and Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors [2] provide for a Community regime.

Article 3

Definitions

For the purpose of this Decision the following definitions shall apply:

(a) 'new psychoactive substance' means a new narcotic drug or a new psychotropic drug in pure form or in a preparation;

[1] OJ L 357, 20.12.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).
[2] OJ L 47, 18.2.2004, p. 1.

(b) 'new narcotic drug' means a substance in pure form or in a preparation, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs, and that may pose a threat to public health comparable to the substances listed in Schedule I, II or IV;

(c) 'new psychotropic drug' means a substance in pure form or in a preparation that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that may pose a threat to public health comparable to the substances listed in Schedule I, II, III or IV;

(d) 'marketing authorisation' means a permission to place a medicinal product on the market, granted by the competent authority of a Member State, as required by Title III of Directive 2001/83/EC (in the case of medicinal products for human use) or Title III of Directive 2001/82/EC (in the case of veterinary medicinal products) or a marketing authorisation granted by the European Commission under Article 3 of 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 [1];

(e) 'United Nations system' means the World Health Organisation (WHO), the Commission on Narcotic Drugs (CND) and/or the Economic and Social Committee acting in accordance with their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances;

(f) 'preparation' means a mixture containing a new psychoactive substance;

(g) 'Reporting Form' means a structured form for notification of a new psychoactive substance and/or of a preparation containing a new psychoactive substance agreed between the EMCDDA/Europol and their respective networks in the Member States' Reitox and the Europol National Units.

Article 4

Exchange of information

1. Each Member State shall ensure that its Europol National Unit and its representative in the Reitox network provide information on the manufacture, traffic and use, including supplementary information on possible medical use, of new psychoactive substances and of preparations containing new psychoactive substances, to Europol and the EMCDDA, taking into account the respective mandates of these two bodies.

[1] OJ L 136, 30.4.2004, p. 1.

Europol and the EMCDDA shall collect the information received from Member States through a Reporting Form and communicate this information immediately to each other and to the Europol National Units and the representatives of the Reitox network of the Member States, the Commission, and to the EMEA.

2. Should Europol and the EMCDDA consider that the information provided by a Member State on a new psychoactive substance does not merit the communication of information as described in paragraph 1, they shall inform the notifying Member State immediately thereof. Europol and the EMCDDA shall justify their decision to the Council within six weeks.

Article 5

Joint Report

1. Where Europol and the EMCDDA, or the Council, acting by a majority of its members, consider that the information provided by the Member State on a new psychoactive substance merits the collection of further information, this information shall be collated and presented by Europol and the EMCDDA in the form of a Joint Report (hereinafter the 'Joint Report'). The Joint Report shall be submitted to the Council, the EMEA and the Commission.

2. The Joint Report shall contain:

(a) a chemical and physical description, including the name under which the new psychoactive substance is known, including, if available, the scientific name (International Non-proprietary Name);

(b) information on the frequency, circumstances and/or quantities in which a new psychoactive substance is encountered, and information on the means and methods of manufacture of the new psychoactive substance;

(c) information on the involvement of organised crime in the manufacture or trafficking of the new psychoactive substance;

(d) a first indication of the risks associated with the new psychoactive substance, including the health and social risks, and the characteristics of users;

(e) information on whether or not the new substance is currently under assessment, or has been under assessment, by the UN system;

(f) the date of notification on the Reporting Form of the new psychoactive substance to the EMCDDA or to Europol;

(g) information on whether or not the new psychoactive substance is already subject to control measures at national level in a Member State;

(h) as far as possible, information will be made available on:

(i) the chemical precursors that are known to have been used for the manufacture of the substance,

(ii) the mode and scope of the established or expected use of the new substance,

(iii) any other use of the new psychoactive substance and the extent of such use, the risks associated with this use of the new psychoactive substance, including the health and social risks.

3. The EMEA shall submit to Europol and the EMCDDA the following information on whether in the European Union or in any Member State:

(a) the new psychoactive substance has obtained a marketing authorisation;

(b) the new psychoactive substance is the subject of an application for a marketing authorisation;

(c) a marketing authorisation that had been granted in respect of the new psychoactive substance has been suspended.

Where this information relates to marketing authorisations granted by Member States, these Member States shall provide the EMEA with this information if so requested by it.

4. Member States shall provide the details referred to under paragraph 2 within six weeks from the date of notification on the Reporting Form as set out in Article 4(1).

5. The Joint Report shall be submitted no more than four weeks after the date of receipt of the information from Member States and the EMEA. The Report shall be submitted by Europol or the EMCDDA, as appropriate, in accordance with Article 5(1) and (2).

Article 6

Risk assessment

1. The Council, taking into account the advice of Europol and the EMCDDA, and acting by a majority of its members, may request that the risks, including the health and social risks, caused by the use of, the manufacture of, and traffic in, a new psychoactive substance, the involvement of organised crime and possible consequences of control measures, be assessed in accordance with the procedure set out in paragraphs 2 to 4, provided that at least a quarter of its members or the Commission have informed the Council in writing that they are in favour of such an assessment. The Member States or the Commission shall inform the Council thereof as soon as possible, but in any case within four weeks of receipt of the Joint Report. The General Secretariat of the Council shall notify this information to the EMCDDA without delay.

2. In order to carry out the assessment, the EMCDDA shall convene a special meeting under the auspices of its Scientific Committee. In addition, for the purpose of this meeting the Scientific Committee may be extended by a further five experts at most, to be designated by the Director of the EMCDDA, acting on the advice of the Chairperson of the Scientific Committee, chosen from a panel of experts proposed by Member States and approved every three years by the Management Board of the EMCDDA. Such experts will be from scientific fields that are not represented, or not sufficiently represented, in the Scientific Committee, but whose contribution is necessary for the balanced and adequate assessment of the possible risks, including health and social risks. Furthermore, the Commission, Europol and the EMEA shall each be invited to send a maximum of two experts.

3. The risk assessment shall be carried out on the basis of information to be provided to the scientific Committee by the Member States, the EMCDDA, Europol, the EMEA, taking into account all factors which, according to the 1961 United Nations Single Convention on Narcotic Drugs or the 1971 United Nations Convention on Psychotropic Substances, would warrant the placing of a substance under international control.

4. On completion of the risk assessment, a report (hereinafter the 'Risk Assessment Report') shall be drawn up by the Scientific Committee. The Risk Assessment Report shall consist of an analysis of the scientific and law enforcement information available, and shall reflect all opinions held by the members of the Committee. The Risk Assessment Report shall be submitted to the Commission and Council by the chairperson of the Committee, on its behalf, within a period of twelve weeks from the date of the notification by the General Secretariat of the Council to the EMCDDA referred to in paragraph 1.

The Risk Assessment Report shall include:

(a) the physical and chemical description of the new psychoactive substance and its mechanisms of action, including its medical value;

(b) the health risks associated with the new psychoactive substance;

(c) the social risks associated with the new psychoactive substance;

(d) information on the level of involvement of organised crime and information on seizures and/or detections by the authorities, and the manufacture of the new psychoactive substance;

(e) information on any assessment of the new psychoactive substance in the United Nations system;

(f) where appropriate, a description of the control measures that are applicable to the new psychoactive substance in the Member States;

(g) options for control and the possible consequences of the control measures, and

(h) the chemical precursors that are used for the manufacture of the substance.

Article 7

Circumstances where no risk assessment is carried out

1. No risk assessment shall be carried out in the absence of a Europol/EMCDDA Joint Report. Nor shall a risk assessment be carried out where the new psychoactive substance concerned is at an advanced stage of assessment within the United Nations system, namely once the WHO expert committee on drug dependence has published its critical review together with a written recommendation, except where there is significant new information that is relevant in the framework of this Decision.

2. Where the new psychoactive substance has been assessed within the United Nations system, but it has been decided not to schedule the new psychoactive substance under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, a risk assessment shall be carried out only if there is significant new information that is relevant in the framework of this Decision.

3. No risk assessment shall be carried out on a new psychoactive substance if:

(a) the new psychoactive substance is used to manufacture a medicinal product which has been granted a marketing authorisation; or,

(b) the new psychoactive substance is used to manufacture a medicinal product for which an application has been made for a marketing authorisation or,

(c) the new psychoactive substance is used to manufacture a medicinal product for which a marketing authorisation has been suspended by a competent authority.

Where the new psychoactive substance falls into one of the categories listed under the first subparagraph, the Commission, on the basis of data collected by EMCDDA and Europol, shall assess with the EMEA the need for further action, in close cooperation with the EMCDDA and in accordance with the mandate and procedures of the EMEA.

The Commission shall report to the Council on the outcome.

Article 8

Procedure for bringing specific new psychoactive substances under control

1. Within six weeks from the date on which it received the Risk Assessment Report, the Commission shall present to the Council an initiative to have the new psychoactive substance subjected to control measures. If the Commission deems it is not necessary to present an initiative on submitting the new psychoactive substance to control measures, within six weeks from the date on which it received the Risk Assessment Report, the Commission shall present a report to the Council explaining its views.

2. Should the Commission deem it not necessary to present an initiative on submitting the new psychoactive substance to control measures, such an initiative may be presented to the Council by one or more Member States, preferably not later than six weeks from the date on which the Commission presented its report to the Council.

3. The Council shall decide, by qualified majority and acting on an initiative presented pursuant to paragraph 1 or 2, on the basis of Article 34(2) (c) of the Treaty, whether to submit the new psychoactive substance to control measures.

Article 9

Control measures taken by Member States

1. If the Council decides to submit a new psychoactive substance to control measures, Member States shall endeavour to take, as soon as possible, but no later than one year from the date of that decision, the necessary measures in accordance with their national law to submit:

(a) the new psychotropic drug to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances;

(b) the new narcotic drug to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1961 United Nations Single Convention on Narcotic Drugs.

2. Member States shall report the measures taken to both the Council and the Commission as soon as possible after the relevant decision has been taken. Thereafter this information shall be communicated to the EMCDDA, Europol, the EMEA, and the European Parliament.

3. Nothing in this Decision shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate once a new psychoactive substance has been identified by a Member State.

Article 10

Annual report

The EMCDDA and Europol shall report annually to the European Parliament, the Council and the Commission on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. The Report shall, in particular, include experience relating to coordination between the system set out in this Decision and the pharmacovigilance system.

Article 11

Pharmacovigilance system

Member States and the EMEA shall ensure an appropriate exchange of information between the mechanism set up by means of this Decision and the pharmacovigilance systems as defined and established under Title VII of Directive 2001/82/EC and Title IX of Directive 2001/83/EC.

Article 12

Repeal

The Joint Action on New Synthetic Drugs of 16 June 1997 is hereby repealed. Decisions taken by the Council based on Article 5 of that Joint Action shall continue to be legally valid.

Article 13

Publication and taking effect

This Decision shall take effect on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 10 May 2005.

For the Council
The President
J. KRECKÉ

Annex III
EMCDDA–Europol reporting form

EUROPOL	**REPORTING FORM ON NEW PSYCHOACTIVE DRUGS** In accordance with Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk assessment and control of new psychoactive substances.	emcdda.europa.eu

This section should be filled in by Europol or EMCDDA

Transmitted by Europol ☐ Transmitted by EMCDDA ☐

Ref. No: Date of transmission:

The following sections should be filled by the Europol national units (ENU) or Reitox national focal points (NFP) based on the information available and their respective competences

1. Member State:

Ref. No: Date:

Reporting authority:

ENU ☐ Reitox NFP ☐

2. Chemical name:

Other name(s):

Street name(s):

3. Source of information (fill one or more as appropriate)

Seizure(s) ☐ Specify amount (weight, number of tablets, etc.):

Seizing authority:

Date: Place:

Biological sample(s) (1) ☐ Specify type:

Identifying authority:

Date: Place:

Collected sample(s) (2) ☐ Specify amount (weight, number of tablets, etc.):

Collecting authority:

Date: Place:

Other substances present (if more than one case, specify for which one):

Psychoactive ingredients:

Other ingredients:

(1) Biological (human) samples e.g. body fluids (urine, blood), tissues, hair, etc.
(2) Actively collected by drug monitoring systems for monitoring or research purposes.

4. Physical description (in case of seizure/collection) Form: powder ☐ tablet ☐ capsule ☐ liquid ☐ other (specify): Colour: For dosage unit: weight: diameter: shape: logo/markings:
5. Circumstances: production ☐ trafficking ☐ distribution ☐ use ☐
6. Price: retail (per dosage unit): wholesale:
7. Chemical precursors:
8. Patterns of use:
9. Other possible uses ([3]):
10. Effects in man Objectively observed: Subjective (described by users):
11. Context of use User group(s): Setting(s): Availability at consumer level:
12. Indication on possible risks Health (individual): Public health: Social:
13. In case of production: large scale ☐ small scale ☐ unknown ☐ Has any form of organised crime been detected: yes ☐ no ☐
14. In case of trafficking: large scale ☐ small scale ☐ unknown ☐ national ☐ international ☐ Has any form of organised crime been detected: yes ☐ no ☐
15. In case of distribution: large scale ☐ small scale ☐ unknown ☐ Has any form of organised crime been detected: yes ☐ no ☐

([3]) For example, for medical, industrial, ritual, cosmetic, etc., purposes.

Explanatory note ([4])

Europol–EMCDDA reporting form for a new psychoactive drug
(In accordance with Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk assessment and control of new psychoactive substances)

In order to increase consistency between the completed forms, the EMCDDA has been requested by the EWS correspondents to prepare a short explanatory note specifying what is expected in each particular section of the reporting form. The explanatory note is addressed primarily to the Reitox national focal points (NFP). The Europol partners are not interested in having such a note — in their view, the reporting form should be self-evident and as simple as possible in order to be appropriate for a wide number of professionals who might be asked to complete it.

The EMCDDA and Europol have committed themselves that, as a rule, all information officially received by the two agencies from the Member States through a reporting form should be immediately transmitted to all partners. The only possible delay might occur in cases where the initial information provided by the Europol national units (ENU) or focal points is incomplete, e.g. basic information such as the name of the Member State; date of transmission or the chemical name of the new psychoactive drug is missing. In such cases, a specific request for completion/clarification will be made before the information is further communicated to all partners.

Each section below is numbered so as to correspond to the relevant section of the reporting form, which, for clarity, is also copied into the document.

Introductory section

This section should be filled in by Europol or EMCDDA	
Transmitted by Europol ☐	Transmitted by EMCDDA ☐
Ref. No:	Date of transmission:

The grey-coloured section below the reporting form's header is to be filled in by Europol or EMCDDA – please do not include any information here.

The Europol national units and/or Reitox national focal points, (NFP), based on the information available and their respective competences, should complete to the extent possible the remaining sections as follows:

Section 1

1. Member State:	Reporting authority:
Ref. No: Date:	ENU ☐ Reitox ☐

Please include your country's name (the name of the **Member State** is mandatory). The section also allows you to fill in your own reference number (if applicable) and the date on which you transmit the reporting form to the EMCDDA or Europol (the **date** is mandatory). The right-hand side of this section also requires you, as a reporting authority, to identify your function as either ENU or Reitox NFP — please check the appropriate box by clicking twice on it (the **reporting authority** field is mandatory).

([4]) The explanatory note is to be used in conjunction with the Europol–EMCDDA reporting form for a new psychoactive drug.

Section 2

2.	Chemical name: Other name(s): Street name(s):

Chemical name:
Please include only one chemical name (ideally this should be the systematic chemical name). If you have more than one chemical name consult the laboratory that identified the substance (the **chemical name** is mandatory).

In case you are not sure as to which is the systematic chemical name, enter one chemical name here and include all other chemical names available to you under the subsection **Other name(s)**.

Other name(s):
List only names, which have not appeared in **Chemical name** above. If available and possible (according to your knowledge), enter all other names in the following order:

(i) other chemical names;
(ii) common generic/code/trivial names;
(iii) WHO's international non-proprietary name — if possible indicate if it is a recommended or proposed international non-proprietary name;
(iv) other non-proprietary names;
(v) trade name(s) — if possible indicate the producer and/or the country of production.

Street name(s):
If known, indicate in brackets where (country, region, city, etc.) and how the street name is used (context); include common/code/trivial, international non-proprietary etc. names, if they are also used as street names, even if they have already appeared in **Other name(s)** above.

Section 3

3. Source of information (fill one or more as appropriate)	
Seizure(s) ☐	Specify amount (weight, number of tablets, etc.):
Seizing authority:	
Date:	Place:
Biological sample(s) ☐	Specify type:
Identifying authority:	
Date:	Place:
Collected sample(s) ☐	Specify amount (weight, number of tablets, ect.):
Collecting authority:	
Date:	Place:
Other substances present (if more than one case, specify for which one):	
Psychoactive ingredients: Other ingredients:	

This section presents the source of information: seizure, biological sample or collected sample — please check the appropriate box by clicking on it twice, then add the remaining information requested. Fill in one or more subsections as appropriate. Section 3 should be read and understood in conjunction with the sections that follow, in particular, Sections 4, 5 and 6.

Seizure means a substance available (seized) through law enforcement activities (police, customs, border guards, etc.). Please specify the **seizing authority**, location (**place**) and **date** as well as the **amount** (weight, number of tablets, etc.).

Biological sample means body fluids (urine, blood, etc.) and/or specimens (tissues, hair, etc.). Under subsection **Specify type**, please include the type of body fluids (urine, blood, etc.) and/or specimens (tissues, hair, etc.). Please indicate also if the analysed material is from deceased persons (post-mortem) or from living individuals (ante-mortem). Please include the **identifying authority**, location (**place**) and **date**.

Collected sample means that the analysed material is actively collected for monitoring or research purposes by an authorised and specifically designated national drug monitoring system. Please specify the **collecting authority**, location (**place**) and **date**.

Under **Other substances present** please explain if other **psychoactive ingredients** or **other ingredients** have been identified in the seized and/or biological and/or collected sample.

Section 4

4. Physical description (in case of seizure/collection)				
Form:	powder ☐	tablet ☐	capsule ☐	liquid ☐ other (specify):

Colour:
Dosage unit: weight: diameter: shape: logo/markings:

The section **Physical description** is to be completed only in the case of seizures and/or collected samples. Concerning the subsection **Form**, please check the appropriate box by clicking twice on it. If none of the four options is applicable, use the option **other** to specify the form of the seized/collected material. Furthermore, please complete the **Colour** subsection as precisely as possible. Subsection **Dosage unit** is mainly meant to describe tablets and/or capsules.

Section 5

5. Circumstances: production ☐ trafficking ☐ distribution ☐ use ☐

Please check the most appropriate box by clicking twice on it. Often making the difference between trafficking and distribution is difficult based on limited, initial information. For that reason, the information provided here is of a rather preliminary nature so simply fill in the section to the best of your judgement. This type of information would usually come from a law enforcement source and should be entered in conjunction with Sections 13, 14 and 15.

Section 6

6. Price:	retail (per dosage unit): ☐	wholesale: ☐

Please check the most appropriate box by clicking twice on it. Information from users (i.e. usually in the cases of collected samples) would typically refer to retail (per dosage unit) price.

Section 7

7. Chemical precursors:

Please include, as far as available, information on the main chemical precursors involved/identified in the particular case of manufacture of the new psychoactive substance that is a subject of this reporting form. If known, please indicate whether the precursors in question are commercially available (i.e. easy to obtain). If known, indicate if the synthesis method used in the particular case is easy or extensive and requiring sophisticated equipment. Do not include general information available from the literature, Internet, etc.

Section 8

8. Patterns of use:

Please include, as far as available, information on the patterns of use, as follows: extent and frequency of use, routes of administration (e.g. oral — ingestion, sublingual; sniffing/snorting; inhaling; smoking; intranasal; injecting — s.c., i.m., i.v., i.p.; patches, trips, etc.); dosage (as a rule should be described in mg). This section should be completed in conjunction with Section 4.

Section 9

9. Other possible uses:

Please include information about other reported possible uses, for example, for medical, industrial, ritual, cosmetic, nutritional, etc., purposes.

Section 10

10. Effects in man
Objectively observed:
Subjective (described by users):

Please describe the onset and duration of action as well as short-term psychological or physiological effects following the intake of the substance(s). Please, specify if the effects are objectively observed (i.e. by a trained professional) or subjective (i.e. described by the users).

Section 11

11. Context of use
User group(s):
Setting(s):
Availability at consumer level:

Please describe the characteristics and behaviours of users and user group(s) e.g. age, gender, social groups, behaviour associated with use; settings of use; and availability at consumer level e.g. (perceived) ease of obtaining the drug through the Internet, friends/peers, retailers, dealers, etc.

Section 12

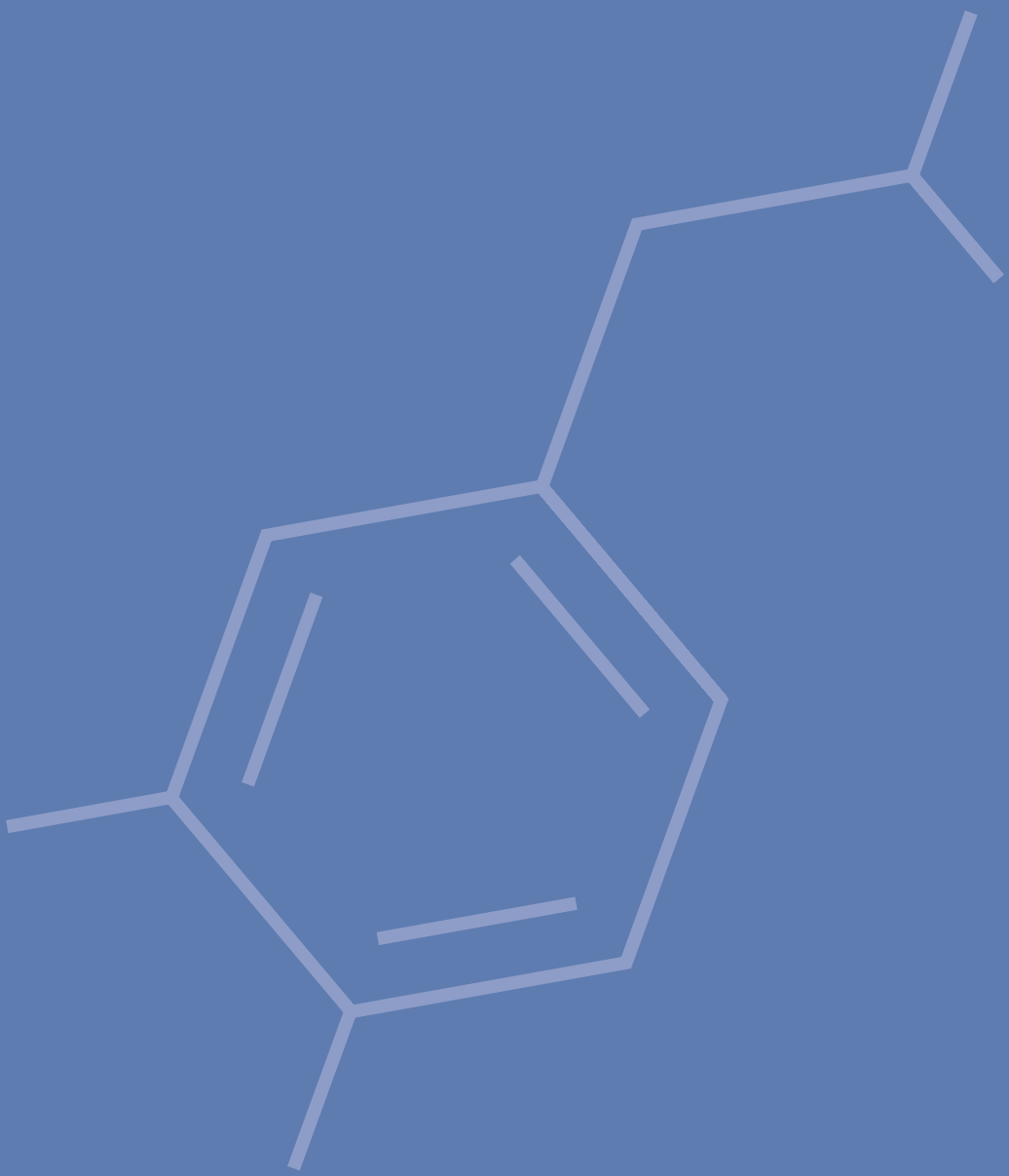
12. Indication on possible risks
Health (individual):
Public health:
Social:

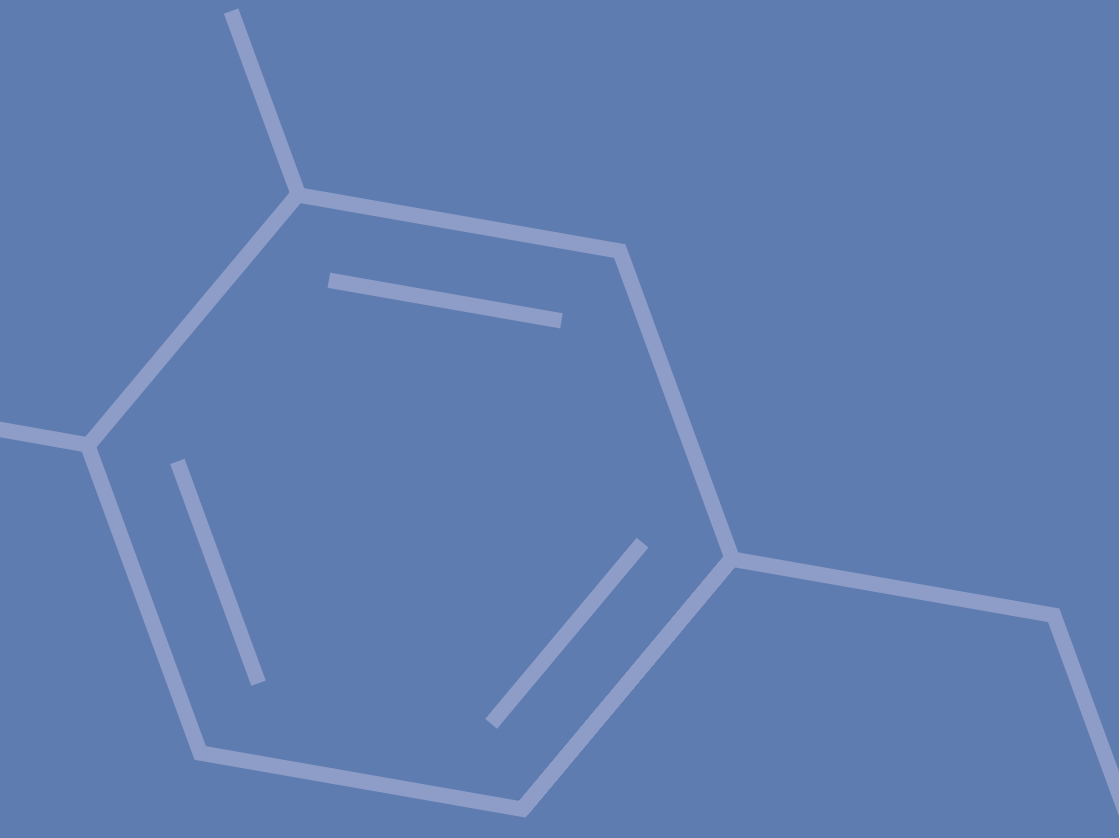
Please describe the individual and public health risks, e.g. reported non-fatal intoxications: hospital emergencies, traffic accidents, etc.; and/or fatalities: overdoses, direct and indirect deaths (e.g. fatal traffic accidents, etc.); effects on non-using population, etc.; indicate if any of those occurred in combination with other substance(s). Also, if available, provide details on toxicology.

Please describe the social risks: including social consequences and social behaviour consequences (crime, violence, disorderly conduct, traffic offences, etc.) of users; consequences from wholesale production (violence, involvement in organised crime and distribution); retail market (violence, public order and nuisance implications), etc.

Sections 13, 14, 15

Information to be included in these sections would usually come from law enforcement sources and be completed by the ENU or in cooperation with law enforcement professionals.





Annex IV
Progress and final report

European Monitoring Centre
for Drugs and Drug Addiction

Early-warning system
Progress/final reporting form [i]

(In accordance with Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk assessment and control of new psychoactive substances)

MEMBER STATE.....
DATE [ii].....
PERIOD COVERED BY THE REPORT [iii].....

New psychoactive substances identified during the period covered by this report [iv]

Substance [v]	Physical description [vi]	Sample type [vii]	No of cases [viii]	Total weight [ix]

Explanatory notes

(i) Delete as appropriate to show if this is a progress or a final report.

(ii) The date refers to the date on which this report is submitted to EMCDDA.

(iii) The period covered is either January to June (progress report) or January to December (final report).

(iv) Include all substances covered by the scope of Decision 2005/387/JHA. In addition, provide information on those substances already submitted to risk assessment (even if nil), i.e. GHB, Ketamine, MBDB, 4-MTA, PMMA, TMA-2, 2C-I, 2C-T-2 and 2C-T-7. The table should be expanded with extra rows as required. Include free text following each substance to show: drug purities, laboratory or other source of data; qualitative data; or other information as appropriate.

(v) Use recognised acronyms/abbreviations wherever possible (e.g. MIPT, DXM, 2C-T-4). Include a reference to the PIHKAL or TIHKAL sequence number where appropriate (e.g. PIHKAL #44).

(vi) Use the terms tablet (not pill), powder, capsule, liquid, blood, urine or other as appropriate. If 'other' then explain in a footnote.

(vii) Use the following abbreviations: S = seizure (law enforcement); C = collected sample; B = biological sample. Use a separate row for each sample type.

(viii) Number of cases means number of separate occurrences.

(ix) Total weight means the aggregate weight of all cases for that substance (if a powder), the total number of units (tablets, capsules) or the total volume (liquids). Wherever possible use a consistent system (e.g. g or ml). For biological samples enter '+' for qualitative detection or indicate concentration (e.g. g or ml).

Developments in the functioning of the early-warning national networks

Include here any relevant issues relating to the national focal point, training, staff changes, publications etc.

……
……
……

Legal developments

Include here any changes in the control status of new psychoactive substances at national level, etc.

……
……

Annex V
Request for further information

Information requested by Europol from the ENU

Where a joint report is deemed appropriate, in order for Europol to fulfil its obligations, in accordance with the requirements of Article 5.2, the following information will be requested from the Member States via their ENU:

1. the level of production of the new psychoactive substance in your country;
2. the level of distribution of the new psychoactive substance in your country;
3. the level of trafficking in your country, both for internal, transit or export purposes;
4. the number of seizures of the new psychoactive substance in your country; the total amount of the seizures; country of origin; details on the substance, including photos;
5. the role of organised crime, or criminal groups, in the production, distribution and trafficking of the new substance in your country;
6. any known aspect of violence and/or money laundering relating to the production and trafficking of the new psychoactive substance.

Information requested by the EMCDDA from the NFP

In order for the EMCDDA to produce the joint report in accordance with the requirements of Article 5.2, as complete as possible information is requested from the Reitox NFPs. The questionnaire, however, should be seen rather as a checklist of which only the available relevant information is to be provided. Moreover, in order to avoid duplication of efforts, before completing the questionnaire the NFPs are advised to check the EDND (see page 26) to determine how much information is already available with the EMCDDA.

Q1. The names under which the new psychoactive substance is known (Article 5.2(a) of the decision)

Please include where relevant and if available in the following order:

- chemical name(s);
- common, code or trivial names;
- official synonyms and non-proprietary names other than international non-proprietary names;
- trademark/trade name(s) — indicate the name of the country and the corresponding manufacturer;
- street names — if known indicate where and how the street name is used (region, context, etc.); include here common/code/trivial name, trade name, international non-proprietary names or non-proprietary names, in case it is used as a street name.

Q2. Information on the frequency, circumstances and/or quantities in which a new psychoactive substance is encountered (Article 5.2(b) of the decision)

Please include where relevant and if available in the following order:

Frequency, circumstances and/or quantities clearly identifying the source of information as follows: seizure, biological sample or collected sample. Please specify if other psychoactive ingredients or other ingredients have been identified in the seized and/or biological and/or collected sample.

- For seizures, please specify the seizing authority, location (place) and date as well as the physical form (powder, liquid, tablets, capsules, etc.), colour, weight, number of tablets or capsules, etc. For dosage units specify the item weight (mg), diameter (mm), shape, logo/markings, etc.
- For biological samples, please include the identifying authority, location (place) and date; include the type of body fluids (urine, blood, etc.) and/or specimens (tissues, hair, etc.); indicate also if the analysed material is from deceased persons (post-mortem) or from living individuals (ante-mortem).
- For collected samples, please specify the collecting authority location (place) and date as well as the context; if possible, include all information as described in seizures above.

Q3. A first indication of the risks associated with the new psychoactive substance, including the health and social risks, and the characteristics of users (Article 5.2(d) of the decision)

Please include where relevant and if available in the following order:

First indication of the health and social risks associated with the substance, if relevant, including also in combinations with other substances. Specify the source of information: subjectively described by users; observed by peers, family members, etc.; objectively observed by health professionals; or from published literature on the new psychoactive substance in question or on similar substances, etc.

If possible, give details on number of cases for each condition and the timeframe:

- non-fatal intoxications involving the substance, substance-related hospital emergencies;
- direct deaths (overdoses);
- indirect deaths (e.g. fatal traffic accidents);
- information on toxicity, tolerance and dependence potential.

Provide available information on:

- physical effects (positive and negative) as subjectively described by users and/or objectively observed;
- psychological effects (positive, negative) as subjectively described by users and/or objectively observed;
- route of administration, for example: oral (eat, drink, sublingual); intranasal (snort), inhale (sniff, smoke); injection (intravenous, intramuscular, etc.); transdermal (patches); etc.;
- onset of action, duration, after-effects;
- dosage (mg), dosage units (tablets, capsules, etc.);
- use in combination with other psychoactive substances;
- users' knowledge about the substance, attractiveness to users;
- social and behavioural consequences for users;

- how new psychoactive substance is marketed, who the intended users are;
- main characteristics of the user population (age, gender, social groups, and behaviours associated with the use).

Q4. Information on whether or not the new psychoactive substance is already subject to control measures at national level in a Member State (Article 5.2(g) of the decision)

Please provide reference to the relevant legislation:

- under drug control legislation;
- under precursors control legislation;
- under medicinal products legislation;
- under any other type of legislation (such as licensing or registrations for trade, distribution, hazardous materials, chemicals, etc.).

Q5. The chemical precursors and the means and methods that are known to have been used for the manufacture of the substance (Article 5.2(b) and 5.2(h) of the decision)

Please include any information available on the precursors and manufacture of the substance:

- list the precursors and indicate if they are readily available or difficult to obtain (e.g. already controlled, expensive, etc.);
- explain the means and methods for manufacture, indicate whether the method of synthesis is easy or difficult (e.g. requires sophisticated equipment).

Q6. The mode and scope of the established or expected use of the new substance (Article 5.2(h) of the decision)

Please include any available information concerning:

- the patterns of use (extent, frequency, age groups, gender); include as much information as possible on the context of use, for example: used in private settings (at home); in public settings (various recreational settings such as bodybuilding

establishments, in parks, streets, pubs, discos, etc.); used in urban/rural areas; etc.;

- market or specific demand for the substance; name by which it is sold/bought, which may be its own name or that of a controlled substance in place of which it is offered (e.g. as a legal alternative);
- the price (in euro) at street level (indicated by users, observed by professionals on health services, from published literature, studies, etc.);
- the perceived availability at consumer level.

Q7. Any other use of the new psychoactive substance and the extent of such use, the risks associated with this use of the new psychoactive substance, including the health and social risks (Article 5.2(h) of the decision)

Please include any available information concerning:

- any known uses of the substance as an end-product, for example, medical, research, industrial, cosmetic, religious, ritual, etc.; the risks associated with such uses;
- is the substance an active pharmaceutical ingredient of a medicinal product?
- is the substance used for synthesis (starting/intermediate material) of a medicinal product or an active pharmaceutical ingredient of a medicinal product? Is the substance a metabolite of a known medicinal product or psychoactive drug?

Q8. Additional relevant information gathered in the investigation of the substance

Please share analytical data, scientific publications or web resources that you might have come across while preparing the above answers.

European Monitoring Centre for Drugs and Drug Addiction

Early-warning system on new psychoactive substances — Operating guidelines

Luxembourg: Office for Official Publications of the European Communities

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The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is one of the European Union's decentralised agencies. Established in 1993 and based in Lisbon, it is the central source of comprehensive information on drugs and drug addiction in Europe.

The EMCDDA collects, analyses and disseminates objective, reliable and comparable information on drugs and drug addiction. In doing so, it provides its audiences with an evidence-based picture of the drug phenomenon at European level.

The Centre'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.

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