



European Monitoring Centre  
for Drugs and Drug Addiction

# Risk assessment of new psychoactive substances

## Operating guidelines





European Monitoring Centre  
for Drugs and Drug Addiction

# **Risk assessment of new psychoactive substances**

Operating guidelines

## Legal notice

This publication of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is protected by copyright. The EMCDDA accepts no responsibility or liability for any consequences arising from the use of the data contained in this document. The contents of this publication do not necessarily reflect the official opinions of the EMCDDA's partners, any EU Member State or any agency or institution of the European Union or European Communities.

A great deal of additional information on the European Union is available on the Internet. It can be accessed through the Europa server (<http://europa.eu>).

Europe Direct is a service to help you find answers to your questions about the European Union

Freephone number (\*):

**00 800 6 7 8 9 10 11**

(\* ) Certain mobile telephone operators do not allow access to 00 800 numbers or these calls may be billed.

Cataloguing data can be found at the end of the publication.

Luxembourg: The Publications Office of the European Union, 2009.

ISBN 978-92-9168-402-1

doi: 10.2810/2428

© European Monitoring Centre for Drugs and Drug Addiction, 2009

Reproduction is authorised provided the source is acknowledged.

*Printed in Luxembourg*

PRINTED ON WHITE CHLORINE-FREE PAPER



European Monitoring Centre  
for Drugs and Drug Addiction

Cais do Sodré, 1249-289 Lisbon, Portugal  
Tel. + 351 211210200 • Fax + 351 218131711  
[info@emcdda.europa.eu](mailto:info@emcdda.europa.eu) • <http://www.emcdda.europa.eu>

## Contents

Acknowledgements	5
Foreword	7
Introduction	11
Chapter 1: Legal basis and scope	15
Chapter 2: General considerations for risk assessment	21
Chapter 3: A conceptual framework for risk assessment	27
Chapter 4: Headings for the Risk Assessment Report	33
Chapter 5: Assessing the risks relative to other substances	43
Chapter 6: Conclusion	45
References	47
Annex I: Technical report	49
Annex II: Semi-quantitative assessment procedure	57
Annex III: Expert's scoring form	63
Appendix: Council Decision 2005/387/JHA	75



## Acknowledgements

The EMCDDA would like to thank the following for their contribution in producing these guidelines:

- The members of the EMCDDA's Scientific Committee;
- The members of the Drugs Policy Coordination Unit, Directorate-General for Justice, Freedom and Security, European Commission;
- Europol and the European Medicines Agency (EMA);
- Dr Leon van Aerts of the Dutch National Institute for Public Health and the Environment (RIVM) who produced the final draft of the guidelines;
- Dr Jan van Amsterdam from the Dutch National Institute for Public Health and the Environment (RIVM), Dr Raymond Niesink, Dutch National Institute of Mental Health and Addiction (Trimbos Institute), the Netherlands, and Dr Leon van Aerts, RIVM, for preparing the conceptual framework for risk assessment and the first draft of the guidelines;
- Dr Leslie A. King, the UK Reitox national focal point; Dr Bertjan Baars, RIVM; Dr Jan Ramaekers, University of Maastricht; Prof. Dr Henk Garretsen, University of Tilburg; Prof. Dr Henk Rigter, University of Rotterdam; Dr M. van Laar, Trimbos Institute and Dr Marcel de Kort, Ministry of Health, Welfare and Sport, the Netherlands, for providing valuable advice;
- EMCDDA colleagues Paul Griffiths, Julián Vicente and Ana Gallegos from the Epidemiology, crime and markets unit and Marie-Christine Ashby, who edited and managed the production of the publication.



## Foreword

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is the central source of comprehensive information on drugs in the European Union. Its main task is to collect and disseminate data on the use of substances controlled by the United Nations drug conventions. However, in recent years, the Centre has become increasingly active in monitoring new substances not listed in these conventions, but which may pose health and social risks to our societies. Today, this activity is carried out under the terms of a specific legal instrument adopted by the Council of the European Union in 2005 — Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances.

This Decision allows the EU institutions and Member States to act on all new and potentially threatening narcotic and psychotropic drugs (natural and synthetic alike) that appear on the European drug scene. Under the terms of the Decision, the EMCDDA and Europol, in collaboration with their respective networks, the European Medicines Agency (EMA) and the European Commission, play a central role in detecting new psychoactive drugs, assessing their risks and paving the way for eventual control measures.

In this process, the EMCDDA's Scientific Committee — extended by additional experts from the Member States, the European Commission, Europol and the EMA — 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 then presented to the Commission and the Council for consideration.

It is with great pleasure that I present the guidelines for the risk assessment of new psychoactive substances. In order to support the implementation of the Council Decision, this innovative work compiled in a systematic manner by professionals from a range of scientific disciplines ensures that new substances are subjected to as rigorous scientific assessment as is possible.

The considerable work required to prepare the guidelines is the result of a broad collaboration of experts from both within and outside the EMCDDA, namely the EMCDDA's Scientific Committee, the Commission, Europol, the EMA and the

Member States. It is an illustration of the cooperation that is needed when trying to respond effectively to the ever-evolving new drugs phenomenon.

I am confident that these concise guidelines clearly present the steps, procedures, roles and responsibilities of all partners involved in this process and will therefore be a vital tool in the risk assessment of new psychoactive substances.

**Wolfgang Götz**

Director, EMCDDA





## Introduction

These guidelines are a revision of the *Guidelines for the risk assessment of new synthetic drugs* <sup>(1)</sup>. A revision was deemed necessary as a result of the replacement of the Joint Action of 16 June 1997 concerning the information exchange, risk-assessment and control of new synthetic drugs <sup>(2)</sup> (hereafter the 'Joint Action') by Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances <sup>(3)</sup> (hereafter the 'Council Decision'). An evaluation of the Joint Action concluded that it needed a re-orientation with respect to its objective and scope. Furthermore, the evaluation made clear that clarification of the applicable procedures and enhancement of the transparency of its operations were necessary <sup>(4)</sup>.

The principal aim of these guidelines is to put in place a sound methodological and procedural basis for carrying out each risk assessment. The risk assessment has regard to the health and social risks of the use of, manufacture of, and traffic in the new psychoactive substance, the involvement of organised crime and the possible consequences of control measures.

The guidelines fully reflect the scope and requirements of Council Decision 2005/387/JHA as well as the knowledge accumulated in the Member States and by the EMCDDA over the years. The text includes appropriate references to the legal framework and the full text of the Decision is provided in the Appendix for added clarity.

The guidelines were finalised and adopted by the EMCDDA's Scientific Committee during its 29<sup>th</sup> meeting on 17–18 November 2008. However, they are the result of extensive developmental work undertaken by the EMCDDA through a complex and laborious process. In this respect, I would like to acknowledge the

---

<sup>(1)</sup> EMCDDA (1999), *Guidelines for the risk assessment of new synthetic drugs*, European Monitoring Centre for Drugs and Drug Addiction, Lisbon.

<sup>(2)</sup> OJ L 167, 25.6.1997.

<sup>(3)</sup> OJ L 127, 20.5.2005.

<sup>(4)</sup> Proposal for a Council decision on the information exchange, risk-assessment and the control of new narcotic drugs and new synthetic drugs (Brussels, 3.10.2003; COM (2003) 560 final 2003/0215 (CNS)).

considerable commitment of my colleagues from the Scientific Committee who enjoyed a fruitful collaboration with EMCDDA staff and experts from the Dutch National Institute for Public Health and the Environment (RIVM) and the Dutch National Institute of Mental Health and Addiction (Trimbos Institute). Furthermore, the contributions made by the European Commission, Europol and the European Medicines Agency (EMA) were crucial for ensuring the truly multidisciplinary approach of the guidelines.

Finally, any risk assessment at an early stage of knowledge and scientific evidence will inevitably contain some degree of inconclusiveness. However, I am optimistic that through their implementation, the risk assessment guidelines will be further operationalised so as to allow the EMCDDA's Scientific Committee to present to the Commission and the Council analytical and sound evidence-based risk assessment reports.

**Dr Michael Farrell**

Chair of the EMCDDA's Scientific Committee





# Chapter 1

## Legal basis and scope

### 1.1 Legal basis

The legal basis for the risk assessment is given in the Council Decision, particularly Article 6. The Council Decision in its turn has regard to the Treaty of the European Union <sup>(5)</sup>, in particular Articles 29, 31(1)(e) and 34 therein. These articles are provisions on police and judicial cooperation in criminal matters (Title VI of the Amsterdam Treaty). Thus, the overall objective of the Council Decision is to provide citizens with a high level of safety within an area of freedom, security and justice by developing common actions among the Member States in the fields of police and judicial cooperation in criminal matters.

The Council Decision also clearly relates to the 1961 United Nations Single Convention on Narcotic Drugs <sup>(6)</sup> (hereafter the 1961 UN Convention) and the 1971 United Nations Convention on Psychotropic Substances <sup>(7)</sup> (hereafter the 1971 UN Convention). These conventions are relevant with regard to defining the scope of the Council Decision (Article 2) and the definition of new psychoactive substances (Article 3). Furthermore, they: affect the nature of the risk assessment (Article 6); can provide a basis for exclusion of a new psychoactive substance from risk assessment (Article 7) and; affect the measures of control to be taken by the Member States (Article 9). The relevance of the UN conventions for the risk assessment lies also in indicating the factors that should be taken into account when a risk assessment is carried out.

Further information on the procedures relating to the Early-warning system under the Council Decision can be found in the *Early-warning system on new psychoactive substances – operating guidelines* <sup>(8)</sup>.

---

<sup>(5)</sup> OJ C 325, 24.12.2002.

<sup>(6)</sup> *Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961*, United Nations.

<sup>(7)</sup> *Convention on Psychotropic Substances, 1971*, United Nations.

<sup>(8)</sup> EMCDDA (2007), *Early-warning system on new psychoactive substances – Operating guidelines*, European Monitoring Centre for Drugs and Drug Addiction, Lisbon.

## 1.2 Scope

The scope of the Council Decision is defined in Article 2, which states that the Decision applies to substances not currently listed in any of the schedules to:

- (a) the 1961 UN Convention, 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 UN Convention, that may pose a comparable threat to public health as the substances listed in Schedule I or II or III or IV thereof.

The above implies that substances already listed under the UN conventions are excluded from the scope of the Council Decision. Important differences with the Joint Action are the inclusion of narcotic drugs as specified under (a) above and psychotropic substances posing a comparable threat as substances listed in Schedules III or IV of the 1971 UN Convention.

Although the new psychoactive substances concerned may include human or veterinary medicinal products (point 5 of the recital to the Council Decision), such products are excluded from a risk assessment under Article 7.3 of the Council Decision when the new psychoactive substance 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.

Precursors used for the illicit manufacture of narcotic drugs and psychotropic substances are also excluded from the scope of the Council Decision. These are governed by different Regulations <sup>(\*)</sup>.

## 1.3 Factors to be considered in a risk assessment

According to Article 6.3 of the Council Decision, a risk assessment should take into account all factors which, according to the 1961 UN Convention or the 1971 UN Convention, would warrant placing a substance under international control. The

---

(\*) 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 substance (OJ L 357, 20.12.1990); Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004).

factors that would warrant such action are described in Articles 3.3. (iii) and 3.5 of the 1961 UN Convention and Article 2.4 of the 1971 UN Convention.

Based on the provisions in the UN conventions, the following need to be taken into account:

1. Whether a new psychoactive substance is liable to similar abuse<sup>(10)</sup> and produces similar ill effects as the drugs in Schedule I or Schedule II of the 1961 UN Convention;
2. Whether a new psychoactive substance is convertible into a drug as meant under point 1;
3. Whether a new psychoactive substance is particularly liable to abuse and to produce ill effects and that such liability is not offset by substantial therapeutic advantages, which would qualify it for placement under Schedule IV of the 1961 UN Convention;
4. Whether the new psychoactive substance has the capacity to produce a state of dependence<sup>(11)</sup> and central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behaviour or perception or mood;
5. Whether the new psychoactive substance is liable to similar abuse and similar ill effects as a substance listed in Schedules I, II, III or IV of the 1971 UN Convention;

---

<sup>(10)</sup> The terms 'abuse' and 'use' are used concomitantly throughout the guidelines. Whenever the text refers to the UN conventions or established terminology such as 'abuse potential', the term 'abuse' is maintained. The EMCDDA preferred term 'use' appears when, for example, prevalence is discussed.

<sup>(11)</sup> Dependence was defined by the WHO 28<sup>th</sup> Expert Committee on Drug Dependence as: 'A cluster of physiological, behavioural and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or drugs) takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behaviour. Determinants and the problematic consequences of drug dependence may be biological, psychological or social, and usually interact' (WHO, 1993, *WHO Expert Committee on Drug Dependence 28<sup>th</sup> Report*, World Health Organization, Technical Report Series, Volume 386, Geneva.

6. If there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social threat warranting placing the substance under international control.

According to Article 6.1 of the Council Decision, besides the above factors derived from the UN conventions, other aspects also need to be assessed. These are:

7. The involvement of organised crime; and
8. The possible consequences of control measures.

Furthermore, according to Article 6.4 (g) of the Council Decision:

9. Options for control and the possible consequences of control measures need to be reported.





## Chapter 2

# General considerations for risk assessment

When assessing the factors listed under section 1.3 in the previous chapter, the following general principles need to be taken into consideration.

### 2.1 A dual definition of risk

The concept of risk should be understood in its dual sense, which includes both the element of probability that some harm may occur (usually defined as 'risk') and the degree of seriousness of such a harm (usually defined as 'hazard'). If possible, both elements should be evaluated in the final phase of the risk-assessment process.

### 2.2 Prevalence of use

Assessment if there is sufficient evidence that the substance is being or is likely to be used so as to constitute a public health and social threat is obligatory when the new psychoactive substance is a substance similar to those listed in the 1971 UN Convention. However, it is also logical to consider this aspect for substances similar to those listed under the 1961 UN Convention. A substance for which it is anticipated that the extent of use will remain limited would not warrant measures of international control.

When a new psychoactive substance is notified within the framework of the Council Decision, reporting will generally be based on anecdotal reports on the use of the new psychoactive substance or reports from laboratories or the police, or a combination thereof. At that stage, the spread of the substance will usually be low and prevalence of use likewise and triangulation of ethno-epidemiological methods will be needed to assess the extent of use among limited user groups. In most cases, an expert judgement will be needed on the likelihood that use of a new psychoactive substance will spread. This judgement will primarily be based on a comparison of the characteristics and accessibility of the new psychoactive substance and the setting in which the new psychoactive substance is used with the characteristics, accessibility and setting of use of other well-known substances.

Also, prevalence of use of the new psychoactive substance among specific groups could be indicative. Such groups may be drug users familiar with the use of similar psychoactive substances, e.g. stimulant users or users of opioids.

## **2.3 Potential benefits of the substance**

In addition, and where feasible, the beneficial use of a new substance also needs to be considered to assess the risk-benefit ratio of each new substance. When new psychoactive substances have a therapeutic value, they will in some cases not be subjected to a risk assessment since such substances may, in line with Article 7.3 of the Council Decision, be exempted from risk assessment. Furthermore, other factors such as economic value and industrial use may imply a benefit of the substance that also needs to be considered.

## **2.4 Risks of a substance, independently of its legal status**

The scientific risk assessment of a particular substance should be carried out independently of its legal status in one or more of the European Union Member States.

## **2.5 Scientific evidence in relation to better-known substances**

Since scientific evidence on new psychoactive substances will, by definition, often be limited, it will thus be necessary to evaluate the possible risks of these substances with reference to similar known substances. Such comparisons need not be restricted to illicit substances but may include licit substances with similar chemical characteristics, pharmacological actions or psychological and behavioural effects, or which offer relevant insights into the social risks presented by the substance. Similarly, when assessing the possible consequences of control measures, as presented in Chapter 4, it may be appropriate to examine relevant examples of control models involving licit or illicit substances.

## 2.6 Quality of data

In the final evaluation, the reliability of information (quality) needs to be weighed. As implied by the very nature of the assignment at hand, it will often be impossible to base the risk assessment of a new psychoactive substance on the evaluation of sound (reliable and valid) scientific knowledge. Pharmacological and socio-scientific knowledge will accumulate over time and will therefore be compiled as social experience with the drug phenomenon in question develops. In the interim, risk assessments will have to be based on a broad range of available evidence. The quality of this evidence should be appraised according to the two following criteria:

### 2.6.1 Methodological characteristics of the available evidence

From a methodological point of view, evidence for risk assessment may be produced by more or less rigorous scientific procedures. Detailed biomedical data, based on systematic pharmacological and toxicological studies, will rarely be available for new psychoactive substances. In the case of socio-scientific data, evidence from preliminary, impressionistic accounts may be more available than evidence from more methodologically rigorous and objective studies, such as surveys or panel studies.

### 2.6.2 Sources of available evidence

The risk-assessment procedure should include a strategy for using data from sources of different quality. Evidence is likely to originate from sources with a wide range of reliability from peer-reviewed publications in prominent scientific journals, through, for example, reports by youth workers or psycho-medical institutions, to unsubstantiated media or Internet reports. A possible method of classifying this information is to use the type of ranking listed in the box below.

Adopting a differential strategy when accepting information may be the most sensible approach. In the first instance, the identification and collection of available data will involve accepting a wide range of information — including information that may be useful for signalling phenomena of possible relevance — and then applying different weights based on a hierarchy of data quality when screening the evidence to be considered in the final evaluation process.

## Classification of information sources

- Peer-reviewed scientific publications
- Official reports of international organisations and governmental institutions
- Other reports and/or scientific publications
- Unpublished data from forensic and clinical laboratories
- Other sources (EU databases, media, individual reports, unofficial publications and the Internet)

As data on new psychoactive substances is usually limited, the Scientific Committee should consider if the conclusions reached are justifiable, based on an assessment using incomplete data.

### 2.7 Weighing the issues of reliability and relevance separately

In the final evaluation, the issues of reliability of information (quality) as well as the relevance of the specific issues involved (health and social risks, involvement of organised crime and consequences of control measures) should be weighed separately. For example, unpublished recent data may be considered to have a lower formal quality, but still may be considered very relevant as often very recent data have not yet reached the status of a scientific publication in a peer-reviewed journal, or data might never be published.





## Chapter 3

# A conceptual framework for risk assessment

Risks related to any psychoactive substance — whether licit or illicit, medical or recreational — can originate from several sources and assume many shapes and forms. For both analytical and pragmatic purposes, it is essential to clarify both the type and origin of substance-related risks as they manifest themselves in society.

The following presents a conceptual framework within which elements of substance-related risk may be located and evaluated. The framework is built on the distinction between the sources from which substance hazards emanate (see box on p. 28) and the type of hazardous effects that may be caused by substance use (see box on p. 30).

### 3.1 Sources of hazards

Within the social reality of substance use, harmful effects may emanate from several domains which may exist independently of each other. Cannabis will serve as an example. Possible harmful consequences of use may be 'caused' by the substance's pharmacological effects (properties of the substance), for instance when acute intoxication impedes the ability to drive a car and hence increases the chance of traffic accidents. Possible long-term effects on memory functions may be another case in point.

It is possible that careful and moderate use of cannabis may not coincide with any apparent undesirable psychological or somatic effect. However, harmful effects could emanate from moral stigmatisation or criminalisation of use of cannabis which, for instance, could result in the dismissal of cannabis users from school (measures of social control). In other cases, the undesirable effects might be contingent on the specific patterns and context of substance use.

## Sources of hazard

Sources of hazard emanating from:

- intrinsic properties of the substance (pharmacology and toxicology)
- measures of social control (regulatory policies and informal norms)
- modalities of substance use (patterns, context of use)
- individual characteristics of users (age, gender, genetics, personality)

For clear examples, substances other than cannabis will need to be considered. Some of the well-known harmful effects of MDMA (ecstasy) are linked to the 'rave' party context — prolonged and intensive dancing in badly ventilated, crowded areas which accentuate a pharmacological effect on body temperature. A well-known case of specific use patterns as a source of substance hazard is the relationship between intravenous substance use and HIV infection. The high prevalence of HIV infection in populations of drug users has less to do with the substances themselves and more to do with lifestyles (modalities of substance use).

There may also be interaction between the different sources of hazard themselves and this must also be taken into account. For example, whether or not pharmacological tolerance to opioids leads to injection is influenced by factors such as cultural setting, economic factors, formal policies and informal norms. Distinguishing domains from which the harmful effects of substances originate has obvious consequences for the drug policy options to be taken after the risk assessment procedure.

### 3.2 Hazardous effects

The harmful effects of substances and the drugs market can be conceived as having an impact on the user, the social environment of substance use and on society in general. In this case, it is inappropriate to assume that different hazardous effects are independent of each other.

Harmful effects on the user (biological, psychological, behavioural) tend to be directly linked to harmful effects on the social environment of substance use

(family, neighbourhood and community, society at large) making dividing lines difficult to draw. Similarly, it is hard to make a clear distinction between the different 'levels' of harm caused to the user or to his or her social environment.

Somatic effects will often have obvious consequences for psychological functions which, in turn, are also relevant for social behaviour. The example of alcohol illustrates this point: alcohol intoxication may cause cognitive dysfunction which, in turn, may lead to irresponsible social behaviour.

Three aggregate levels can be distinguished in the social environment: the micro level (family); the meso level (neighbourhood and community); and the macro level (society at large). Particularly on the meso and macro levels, it is advisable to take note of the consequences of the substance distribution system separately. Independent of the properties of the substance, the nature of the illicit market may cause harmful effects, such as problems of public order and safety on the streets. On the macro level, the drug trade may be harmful for the integrity of economic or law-enforcement institutions.

Despite the difficulties associated with interactions between different domains of harm and quantifying the level of harm, from a pragmatic view and to facilitate comparisons between different substances within certain domains, a semi-quantitative approach is considered feasible on the basis of expert judgement. Thus, for analytical purposes and policy options, it is still useful to distinguish between different domains of harm. A semi-quantitative system of scoring is further addressed in Chapter 5 and Annex II and Annex III.

## Hazardous effects of a substance

(a) On the user:

- biological (toxicity, dependence)
- psychological (functional impairment, effects on personality)
- behavioural (neglect of social roles, violence, etc.)

(b) On the social environment:

- family — micro level (disruption, neglect, violence)
- neighbourhood and community — meso level (public order and safety)
- society at large — macro level (economy, public health and judicial systems)





## Chapter 4

### Headings for the Risk Assessment Report

In any risk-assessment procedure, a number of headings are included under which the information is organised in a systematic manner. Article 6.4 of the Council Decision lists the headings as outlined below. To prepare the risk assessment and to facilitate the risk assessment process, the EMCDDA drafts a technical report using the format annexed to these guidelines (Annex I).

As outlined in Chapter 2, the probability (risk) and seriousness of the adverse consequences of a substance (hazard) should be taken into account at the beginning of the risk-assessment procedure. Under all headings, the specific substance should be studied in terms of its similarities to, and differences from, other relevant psychoactive substances, especially those for which established scientific literature exists. As also stated in Chapter 2, other relevant substances should be selected on the basis of their chemical and/or pharmacological resemblance to the substance concerned, or with regard to the insights they offer concerning social risks and the involvement of organised crime. This selection should not necessarily be restricted to illicit substances.

In assessing the risks of a particular psychoactive substance, six key variables likely to affect the hazards and risks related to that substance should be taken into consideration as outlined in the following box.

## Key variables

- Dose and frequency of use
- Short-term and especially long-term effects
- Interactions with other substances (including alcohol and medicines)
- Individual characteristics (e.g. genetic susceptibility, presence of interacting risk factors)
- Characteristics of the social and cultural environment
- Involvement of organised crime

The information gathered during any risk-assessment process is likely to be based on different types of evidence as outlined in the following box.

## Types of evidence

- Laboratory evidence, either *in vitro* or *in vivo* (mainly animals)
- Evidence of effects on humans (biological and psychological)
- Epidemiological evidence
- Sociological evidence
- Criminological evidence

In evaluating the consistency between laboratory-based and population-based evidence, special account must be taken of social context factors, and of the selection of population groups and individual users as potential sources of bias when inferring the social and health risks of a specific substance.

### (a) Physical, chemical and pharmacological description

The description of the new psychoactive substance should include its mechanism of action and its medical value. The description should include the elements set out in the following box.

## Descriptive elements

- Name of the substance, physical description and chemical composition. With cross-reference to section (h) below, known or expected side-products or impurities should be mentioned
- Known uses, and similarity to other relevant substances
- Pharmacological effects in animal and human studies, including its pharmacodynamic actions on the central nervous system and on other organs and systems, its pharmacokinetics, and its psychological and behavioural effects on humans (cognition, mood, personality, behaviour, motor function)

### (b) Health risks

Possible health risks associated with the new psychoactive substance include both the risks to individual health, resulting from use, and the public health risks, affecting the broader community. There is not always a clear dividing line between individual and public health risks, nor between public health risks and social risks. Most health risks, especially individual ones, are likely to be the consequence of using the substance. However, some of the public health consequences may also be linked to the nature of the production and trafficking of the substance (e.g. the purity and quality of the substance on the market). Obviously, the extent of (anticipated) use ('prevalence') will mainly determine the level of concern for public health.

#### *Individual health risks*

Assessment of the individual health risks of a new psychoactive substance should cover physical and psychological, short-term and long-term aspects and should include the elements listed in the box below. Dose, frequency, route of administration and interactions with other substances are important factors to consider.

## Elements for assessing individual health risks

- Acute toxicity, including safety profile and information on poisonings
- Chronic toxicity, including functional brain damage, reproductive toxicity, genotoxicity and carcinogenic potential
- Dependence potential (physical and psychological)
- Psycho-social dysfunction
- Similarities and differences to other reference substances

### *Public health risks*

Assessment of the public health risks of a new psychoactive substance should include epidemiological and other evidence as listed in the following box.

## Elements for assessing public health risks

- Extent, frequency and patterns of use
- Availability and quality of the new psychoactive substance on the market (purity, adulterants, etc.)
- Availability of information, degree of knowledge and perceptions amongst users concerning the psychoactive substance and its effects
- Characteristics and behaviour of users (including risk factors, vulnerability, etc.)
- Nature and extent of health consequences (e.g. acute emergencies, poisonings, road traffic accidents)
- Long-term consequences of use (e.g. irreversible toxicity leading to deterioration of health at later stages of life)
- Conditions under which the new psychoactive substance is obtained and used, including context-related effects and risks (e.g. continuous dancing in hot environments, other substances used)

### (c) Social risks

Some public health risks (e.g. road traffic accidents) could also be listed under the heading of social risks. Apart from such examples, social risks associated with the new psychoactive substance include the elements summarised in the following box.

#### Elements for assessing social risks

- Individual social risks (e.g. impact on education or career, problems with personal relationships)
- Possible effects on direct social environment (e.g. neglect of family, violence)
- Possible effects on society as a whole (public order and safety, acquisitive crime)
- Economic costs (demands on health care)
- Possible effects related to cultural context, for example marginalisation
- Possible appeal of the new psychoactive substance to specific population groups within the general population

### (d) Involvement of organised crime

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 should be provided.

There is no established definition of organised crime <sup>(12)</sup>. However, for the purpose of these guidelines a broad definition by the UN <sup>(13)</sup> may be used: 'Organised crime is understood to be the large-scale and complex criminal activity carried out by groups of persons, however loosely or tightly organised, for the enrichment of those participating and at the expense of the community and its members.

---

<sup>(12)</sup> Definitions of Organised Crime (collected by Klaus von Lampe): <http://www.organized-crime.de/OCDEF1.htm>

<sup>(13)</sup> United Nations, *Changes in Forms and Dimensions of Criminality — Transnational and National*, Working paper prepared by the Secretariat for the Fifth United Nations Congress on the Prevention of Crime and the Treatment of Offenders (Toronto, Canada, 1–12 September 1975).

It is frequently accomplished through ruthless disregard of any law, including offences against the person, and frequently in connection with political corruption'. A second useful and more contemporary definition is the one proposed by the European Commission <sup>(14)</sup> that incorporates part of the definition contained in Joint Action 98/733/JHA <sup>(15)</sup> and takes into consideration the advances reflected in the 2000 United Nations Convention against Transnational Organised Crime. It defines a criminal organisation as 'a structured association, established over a period of time, of more than two persons, acting in concert with a view to committing offences which are punishable by deprivation of liberty or a detention order of a maximum of at least four years or a more serious penalty, as a means of obtaining, directly or indirectly, financial or other material benefits.'

Thus, important characteristics of organised crime that can be recognised are:

- it is an activity of groups of people primarily aimed at financial gain;
- criminal offences are committed by these groups in a systematic way with serious consequences for society; and
- these groups are prepared to protect themselves from law enforcement, especially by means of the use of intimidation or violence, or by corruption.

Based on these characteristics, a number of elements are considered relevant for the involvement of organised crime in the production, trafficking and distribution of new psychoactive substances. These are summarised in the box below.

### Elements for assessing the involvement of organised crime

- Evidence that criminal groups are systematically involved in production, trafficking and distribution for financial gain
- Impact on the production, trafficking and distribution of other substances, including existing as well as new psychoactive substances

---

<sup>(14)</sup> Brussels, 19 January 2005, COM/2005/0006 final — CNS/2005/0003.

<sup>(15)</sup> Joint Action adopted by the Council on the basis of Article K.3 of the Treaty on European Union, on making it a criminal offence to participate in a criminal organisation in the Member States of the European Union (OJ L 351 of 29.12.1998, p. 1).

- Evidence that the same groups or people are involved in different kinds of crime
- Impact of violence from criminal groups on society as a whole or on social groups or local communities (public order and safety)
- Evidence of money-laundering practices, or impact of organised crime on other socio-economical factors in society
- Economic costs and consequences (evasion of taxes or duties, costs to the judicial system)
- Use of violence between or within criminal groups
- Evidence of strategies to prevent prosecution, for example through corruption or intimidation

### **(e) Assessment of the new psychoactive substance in the United Nations system**

In line with Article 2 of the Council Decision, substances that are listed in any of the schedules to the 1961 United Nations Single Convention on Narcotic Drugs (Schedules I, II or IV) or the 1971 United Nations Convention on Psychotropic Substances (Schedules I, II, III or IV) are excluded from a risk assessment. Similarly, as stated in Articles 7.1 and 7.2 of the Council Decision, the substance concerned may be at an advanced stage of assessment within the United Nations system or the new psychoactive substance has been assessed within the United Nations system, but a decision has been taken not to schedule it under the 1961 UN Convention or the 1971 UN Convention. In such cases, a risk assessment shall be carried out only if there is significant new information that is relevant in the framework of this Council Decision. It is therefore important to be informed about possible assessment procedures for the new psychoactive substance concerned within the United Nations system.

### **(f) Current control measures within the Member States**

Where appropriate, a description of the control measures that are currently applicable to the new psychoactive substance in the Member States shall be

provided. Thus, a description of various types of measures could be included (see box below).

## Examples of types of measures

- Prevention/education
- Legally bound labelling
- Establishing an age limit for users
- Active monitoring
- Intervention in production chain (precursors)
- Legislation on medicines, poisons, food or consumer products
- Control measures in accordance with 1961 and 1971 UN conventions

### **(g) Options for control and possible consequences of the control measures**

Under Article 9.1 of the Decision, the available control options are for the Member States to submit a new psychotropic substance 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 or the 1961 United Nations Single Convention on Narcotic Drugs. However, Article 6.4 (g) requires the Risk Assessment Report to include the options for control and the possible consequences of the control measures.

In assessing the possible consequences of control measures, it is appropriate to examine a range of control models (e.g. administrative or public health regulatory frameworks for alcohol, tobacco, medicines or poisons). The assessment should examine the consequences of different control options on the factors listed in the following box.

## Elements for examining the consequences of control options

- Production, trafficking and organised crime
- Distribution and availability
- Quality and price of the substance on the market
- Impact on the market and on the use of other substances (including the likelihood of alternative new substances emerging)
- Prevalence and patterns of use of the substance
- Health consequences
- Social consequences
- Other uses of the substance in pharmaceutical research, medicine, industry, trade, etc.
- Existing legislation, law enforcement, judicial and other control systems
- Specific cost implications (e.g. additional costs of product testing or forensic analysis)

## (h) Chemical precursors used within the manufacturing process

Information on the chemical precursors that are used for the manufacture of the substance should be provided. Such information may come from analyses of chemicals found at production sites or from the literature. The description should include the elements set out in the box below.

### Elements for description of chemical precursors

- Chemicals found at production sites
- Likely routes of synthesis
- Impurities/side products of synthesis, if known



## Chapter 5

### Assessing the risks relative to other substances

In a final appraisal of the health and social risks in relation to the use of, manufacture of, and traffic in the new psychoactive substance, and the involvement of organised crime and the possible consequences of control measures, it is often very informative to make comparisons with other licit or illicit substances. For this, a method for quantifying these risks can be very helpful. However, few attempts have been made to introduce a quantitative method (van Amsterdam et al., 2004; Nutt et al., 2007).

The use of a quantitative method is not obligatory, as the Council Decision does not describe in detail how such risks should be assessed. A methodology to aid the risk assessment derived from experience in the Netherlands and the UK has been annexed to these guidelines as a useful tool (see Annex II). Further progress in this field should be monitored for state-of-the-art knowledge.



## Chapter 6

### **Conclusion**

The Risk Assessment Report should conclude by summarising the main issues addressed under the headings for the Risk Assessment Report as stipulated in Article 6.4, points (a) to (h) (see Chapter 4). It shall present a summary analysis of the scientific and law enforcement information available, and shall reflect all opinions held by the members of the Committee.



## References

Nutt, D., King, L., Saulsbury, W., Blakemore, C. (2007), 'Development of a rational scale to assess the harm of drugs of potential misuse', *The Lancet* 369, pp. 1047–1053.

van Amsterdam, J. G., Best, W., Opperhuizen, A., de Wolff, F. A. (2004), 'Evaluation of a procedure to assess the adverse effects of illicit drugs', *Regulatory Toxicology and Pharmacology* 39(1), pp. 1–4.



# Annex I

## Technical report

The EMCDDA is responsible for the collection and assembly of data for a technical report, which should be prepared before the risk assessment takes place to facilitate the task.

The technical report should be as thorough as possible, and balanced in its presentation. It should include the adequate and relevant data, including information already present in the Joint Report from the EMCDDA and Europol regarding the new psychoactive substance at hand, and any additional relevant information obtained from the Member States, the EMCDDA, Europol, the EMEA, WHO and the scientific literature. In order to accomplish this, the EMCDDA may seek assistance from advisers and ad hoc working groups.

The technical report should include, if available, information under the following headings:

- A. Physical, chemical, pharmaceutical and pharmacological information
- B. Dependence and abuse potential
- C. Prevalence of use
- D. Health risks
- E. Social risks
- F. Involvement of organised crime

Information on assessments within the United Nations system and on current control measures in Member States is already presented in the Europol-EMCDDA Joint Report on a new psychoactive substance and should only be updated by the EMCDDA if appropriate.

The report should contain a summary of approximately 800 words.

## **Section A      Physical, chemical, pharmaceutical and pharmacological information**

The first section of the technical report describes basic information on the new psychoactive substance, its use, and its similarity to other substances.

- A1.      *Physical, chemical, and pharmaceutical information*
  - A1.1.    Physical and chemical description (including methods of synthesis, precursors, impurities if known – type and level)
  - A1.2.    Physical/pharmaceutical form (i.e. powder, capsules, tablets, liquids, injectables, cigarettes. Any distinctive markings, logos, etc., to be noted)
  - A1.3.    Route of administration and dosage (e.g. oral, inhalation, intravenous, etc.)
- A2.      *Pharmacology, including pharmacodynamics and pharmacokinetics*
- A3.      *Psychological and behavioural effects*
- A4.      *Legitimate uses of the product*

## **Section B      Dependence and abuse potential**

- B1.      *Animal in vivo and in vitro data*
- B2.      *Human data*

## **Section C      Prevalence of use**

For new psychoactive substances, there will usually be a lack of epidemiological prevalence data. Any information based on reports of use or seizures of the new psychoactive substance that can contribute to an estimate of the extent of use and any trends in extent, frequency and patterns of use should be included.

## **Section D      Health risks**

When describing the health effects, similarities and dissimilarities with other better known psychoactive substances, both licit and illicit, should be made.

- D1.      *Acute health effects*

- D1.1. Animal data  
Here, data regarding acute toxicity studies in animals, as well as safety pharmacology data can be mentioned, if available.
- D1.2. Human data  
Relevant acute adverse effects, both physical and psychological, reported by users, admissions to emergency rooms and reports on overdoses or fatal intoxications can be included. However, side effects noted in laboratory studies can also be included, if available.
- D2. *Chronic health effects*
- D2.1. Animal data  
Chronic studies in animals are usually not available for new psychoactive substances. However, if available, any data on repeated dose toxicity, genotoxicity, carcinogenicity, reproductive toxicity or other forms of toxicity, including neurotoxicity can be mentioned in this section.
- D2.2. Human data  
For new psychoactive substances, long-term data on health effects in humans will usually be limited, if available at all. A description based on reports from users may be included, but also epidemiological data, if there is any. For chronic effects, the causal link with the use of the new psychoactive substance will in most cases be very difficult to establish, since numerous confounding factors will also be present. Both aspects of physical and psychological well-being should be considered.
- D3. *Factors affecting public health risks*
- One factor of utmost importance affecting any potential health impact at population level is the prevalence of use. This aspect is described in Section C. Other factors influencing the impact on public health are:
- D3.1. Availability and quality of the new psychoactive substance on the market (purity, adulterants, etc.).
- D3.2. Availability of information, degree of knowledge and perceptions amongst users concerning the psychoactive substance and its effects.

- D3.3. Characteristics and behaviours of users (including risk factors, vulnerability, etc.).
- D3.4. Nature and extent of health consequences (e.g. acute emergencies, road traffic accidents).

Relevant information may already feature under section D.1. However, factors affecting the potential consequences for others are considered to be a public health issue (e.g. the likelihood of irresponsible behaviour, the extent of disturbance of executive function, decision making and the ability to control one's movements).
- D3.5. Long-term consequences of use (e.g. irreversible toxicity leading to deterioration of health later in life).
- D3.6. Conditions under which the new psychoactive substance is obtained and used, including context-related effects and risks (e.g. continuous dancing in hot environments, other substances used).

## Section E Social risks

- E1. *Individual social risks*

Any effects known to impact on the social functioning of the individual user, e.g. impact on education or career and effects on personal relationships.
- E2. *Possible effects on direct social environment*

Here, the consequences for the user's social environment should be mentioned, such as neglect of family or violent behaviour.
- E3. *Possible effects on society as a whole*

Effects such as disturbance of public order and safety and acquisitive crime should be described here.
- E4. *Economic costs*

The economic impact of the use of the new psychoactive substance not related to the involvement of organised crime (which is mentioned under F), such as demands on health care, may be mentioned here.
- E5. *Possible effects related to the cultural context, for example marginalisation*

- E6. *Possible appeal of the new psychoactive substance to specific population groups within the general population.*

## **Section F    Involvement of organised crime**

- F1. *Evidence that criminal groups are systematically involved in production, trafficking and distribution for financial gain*  
Information on seizures and/or detections by the authorities, illegal laboratories or other production sites and distribution networks may be included here.
- F2. *Impact on the production, trafficking and distribution of other substances, including existing psychoactive substances as well as new psychoactive substances*  
Information on the new psychoactive substance being produced at the same sites where other psychoactive substances are produced, the mixture of the new psychoactive substance with other psychoactive substances in the same product, and the use of the same distribution networks as those used for other psychoactive substances should be mentioned.
- F3. *Evidence of the same groups or people being involved in different kinds of crime*  
Mixing of different kinds of criminal activities by criminal groups is considered a characteristic of organised crime. Therefore, information on other kinds of crime committed by those involved should be mentioned here.
- F4. *Impact of violence from criminal groups on society as a whole or on social groups or local communities (public order and safety)*  
Evidence of adverse consequences of the use of violence by criminal groups involved on society or parts of it should be mentioned here. Also, possible consequences of unsafe production sites may be included here. Although not considered as 'violence' per se, it is indicative of the criminal group's disregard for public safety.
- F5. *Evidence of money-laundering practices, or impact of organised crime on other socio-economical factors in society*

Any adverse effects on the structure and function of financial and other markets, especially money laundering, should be mentioned here.

- F6. *Economic costs and consequences (evasion of taxes or duties, costs to the judicial system)*
- F7. *Use of violence between or within criminal groups*
- F8. *Evidence of strategies to prevent prosecution, for example through corruption or intimidation*





## Annex II

### Semi-quantitative assessment procedure

There are five major domains affecting the extent of risk: B (Dependence and abuse potential); C (Prevalence of use); D (Health risks); E (Social risks), and F (Involvement of organised crime). These five domains are further specified in Annex I: Technical report. Section A in the technical report is merely descriptive and does not determine the extent of risks associated with the new psychoactive substance.

Four of the five domains are divided into subgroups (B.1, B.2, etc.). Each subgroup receives a score based on expert judgement, taking into account the principles set out in the guidelines. The score obtained for each subgroup is called 'risk level' (RL). Domain C (Prevalence) receives only a single score.

As indicated in Chapter 2.1 of the guidelines, risk is to be understood and considered in its dual sense: both the degree of seriousness of harm (hazard) and the probability of harm. The expert is expected to make a judgement of the risk level comprised of an integrated assessment of both hazard and probability. In this respect, probability should be judged independently of prevalence of use, which is assessed separately under C. Thus, probability means the likelihood that a single user will be harmed.

Note that assigning scores for the sub-categories of the subgroups (i.e. D1.1 and D1.2) is not a requirement, as a panel of scientists is apt to give an integral (semi-) quantitative judgement on each subgroup, provided their judgement is embedded in a Delphi-like environment.

The Scientific Committee of the EMCDDA (if necessary, extended by a further five experts at most, and with up to two experts from the Commission, Europol and the EMEA (Article 6.2)) has the task to produce a report which gives a science-based (semi-)quantitative judgement on all aspects mentioned in the domains B to F. Based on this report, the Scientific Committee gives a final overall judgement of the risks of the new psychoactive substance and formulates a conclusion.

## Summary

- The EMCDDA issues a technical report on the new psychoactive substance containing information as specified in Annex I. The technical report also contains a summary of up to 800 words. This report forms the basis for the assessment of the new psychoactive substance.
- The Scientific Committee of the EMCDDA produces a draft assessment report which contains:
  - the technical report
  - the (semi-)quantitative judgment of the risks of the new psychoactive substance (or of the risk/benefit, if applicable).
- The draft assessment report is produced according to the procedure described in this publication.
- Based on this draft report, the Scientific Committee produces the final Risk Assessment Report and formulates a conclusion.

## Procedure

### Step 1

The EMCDDA's Scientific Committee consists of scientists with a variety of expertise, coming from different disciplinary backgrounds. If required, the Director of the EMCDDA, acting on the advice of the Chair of the Scientific Committee, can nominate up to five additional experts. Disciplines that may be necessary to complete a judgement of the new drug are: toxicology, pharmacology, neurology, psychology, psychiatry, sociology, economy, epidemiology, criminology, public health, trafficking (socio-psychology), judicial matters, medicines, teratology, and pulmonology (not limiting).

### Step 2

All members receive the technical report and a sheet where they fill in their scores (see Annex III). For each of the 19 subgroups listed in domains B, D, E and F a judgement must be given, based on the technical report. Domain B has 2 subgroups; domain D: 3 subgroups; domain E: 6 subgroups; domain F:

8 subgroups. All members give numerical scores — on a scale from 0 to 4 — on the first written judgement sheet.

0 = No risk

1 = Minimal risk

2 = Slight/small risk

3 = Moderate risk

4 = Severe risk

In addition to their numerical scores, experts may write short remarks or comments on the sheet to motivate their score or to draw attention to specific aspects.

Remarks to numerical scores:

- Experts only score subgroups where they have expertise. In a separate box on the first judgement sheet the expert can also indicate that the subgroup was not scored (reason for not scoring may be no expertise or no data available).
- Definition: the 19 numerical scores are the 19 'risk levels' (RL).
- Definition: the five (mean) values of the five domains are the five 'average risk' values (AR).

In addition, a score must be assigned to the prevalence factor (domain C), which is a modifying parameter affecting the extent (impact) of (public) health risks and social risks.

Although precise figures for prevalence of use will not usually be available, the expert is expected to make a judgement based on available ethno-epidemiological data. Moreover, as the risk assessment takes place within the framework of the Council Decision, which is aimed at assessment at an early phase, prevalence of use will in most cases still be very limited. Instead of looking at prevalence among the general population, prevalence among specific groups could be indicative. Such groups can be groups of drug users, familiar with the use of similar psychoactive substances, e.g. stimulant users or users of opioids.

Furthermore, the Scientific Committee is expected to consider evidence that the substance is being or is likely to be used in a manner that constitutes a public health and/or social threat. An expert judgement can therefore be given on

the anticipated level of use, based on a comparison of the characteristics and accessibility of the new psychoactive substance and the settings in which it is used with the characteristics, accessibility and settings of use of other well-known substances.

Based on these two approaches, the following matrix can be used to score 'prevalence':

Prevalence score	Prevalence of use in specific drug user groups	Anticipated level of use in general population
0	Only a few individuals have been reported	Only a few individuals
1 (low)	More than anecdotal reports, but last year prevalence (LYP) < 5 %	LYP < 0.2 %
2 (moderate)	LYP ≥ 5 %	LYP ≥ 0.2 %
3 (high)	LYP ≥ 20 %	LYP ≥ 1 %

### Step 3

The experts send their sheets with the scores (and remarks) by e-mail to the Chair of the Scientific Committee who makes an overall summary of the judgement sheets. This will contain:

- i) a copy of all judgement sheets
- ii) the mean value of the individual RLS given for the 19 subgroups, arranged per subgroup
- iii) the average risk (AR) value of the five domains
- iv) the list with subgroups on which there is agreement/consensus (similar score by all experts; variation in score ≤ 1)
- v) the list with subgroups on which there is apparent disagreement (a range of different RLS given for a subgroup in which the variation > 1)
- vi) the list of all remarks arranged per subgroup.

The overall summary is distributed to all members by e-mail.

#### **Step 4**

Delphi approach:

On the day of decision, the Chair discusses with all members of the Scientific Committee points v and vi of the overall summary.

#### **Step 5**

Following a Delphi approach/discussion, each expert is allowed to change his/her numerical score on the second judgement sheet.

#### **Step 6**

The Chair produces the draft assessment report that includes:

- a copy of all second judgement sheets
- the mean value of the (revised) individual RLs for the 19 subgroups, arranged per subgroup
- the average risk (AR) value of the five domains.

#### **Step 7**

The EMCDDA's Scientific Committee makes a final judgement on the risks of the new psychoactive substance taking into account the draft assessment report, formulates a conclusion and produces the final Risk Assessment Report.



## Annex III

### Expert's scoring form

Name of the expert:

Date:

Substance under evaluation:

Meaning of the Risk Level (RL) values

0 = No risk

1 = Minimal risk

2 = Slight/small risk

3 = Moderate risk

4 = Severe risk

n = No expertise/no data/not relevant

## **Summary of the technical report**

Summary of a maximum of 800 words, to be provided by the EMCDDA.

## Domain B: Dependence and abuse potential

B1. Animal *in vivo* and *in vitro* data

RL: 0  1  2  3  4

n

Expert's comments:

B2. Human data

RL: 0  1  2  3  4

n

Expert's comments:

## Domain C: Prevalence of use

Prevalence score	Prevalence of use in specific drug user groups	Anticipated level of use in general population
0	Only a few individuals have been reported	Only a few individuals
1 (low)	More than anecdotal reports, but last year prevalence (LYP) < 5 %	LYP < 0.2 %
2 (moderate)	LYP ≥ 5 %	LYP ≥ 0.2 %
3 (high)	LYP ≥ 20 %	LYP ≥ 1 %

RL: 0  1  2  3

n

Expert's comments:

## Domain D: Health risks

D1. Acute health effects

RL: 0  1  2  3  4

n

Expert's comments:

D2. Chronic health effects

RL: 0  1  2  3  4

n

Expert's comments:

D3. Factors affecting public health risks

RL: 0  1  2  3  4

n

Expert's comments:

## Domain E: Social risks

### E1. Individual social risks

RL: 0  1  2  3  4

n

Expert's comments:

### E2. Possible effects on direct social environment

RL: 0  1  2  3  4

n

Expert's comments:

### E3. Possible effects on society as a whole

RL: 0  1  2  3  4

n

Expert's comments:

E4. Economic costs

RL: 0  1  2  3  4

n

Expert's comments:

E5. Possible effects related to the cultural context, for example marginalisation

RL: 0  1  2  3  4

n

Expert's comments:

E6. Possible appeal of the new psychoactive substance to specific population groups within the general population

RL: 0  1  2  3  4

n

Expert's comments:

## Domain F: Involvement of organised crime

F1. Evidence that criminal groups are systematically involved in production, trafficking and distribution for financial gain

RL: 0  1  2  3  4  n

Expert's comments:

F2. Impact on the production, trafficking and distribution of other substances, including existing psychoactive substances as well as new psychoactive substances

RL: 0  1  2  3  4  n

Expert's comments:

F3. Evidence of the same groups or people being involved in different kinds of crime

RL: 0  1  2  3  4  n

Expert's comments:

F4. Impact of violence from criminal groups on society as a whole or on social groups or local communities (public order and safety)

RL: 0  1  2  3  4  n

Expert's comments:

F5. Evidence of money-laundering practices, or impact of organised crime on other socio-economical factors in society

RL: 0  1  2  3  4  n

Expert's comments:

F6. Economic costs and consequences (evasion of taxes or duties, costs to the judicial system)

RL: 0  1  2  3  4  n

Expert's comments:

F7. Use of violence between or within criminal groups

RL: 0  1  2  3  4

n

Expert's comments:

F8. Evidence of strategies to prevent prosecution, for example through corruption or intimidation

RL: 0  1  2  3  4

n

Expert's comments:





## Appendix

# 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 <sup>[16]</sup>,

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 <sup>[17]</sup> (hereinafter '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

---

<sup>[16]</sup> Opinion delivered on 13 January 2004 (not yet published in the Official Journal).

<sup>[17]</sup> OJ L 167, 25.6.1997, p. 1.

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 [<sup>18</sup>] 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 [<sup>19</sup>].
- (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

---

[<sup>18</sup>] 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).

[<sup>19</sup>] 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).

Decision. Suitable regulatory and public health related measures should be taken for substances of established and acknowledged medical value that are being misused.

- (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 'EMA') 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 EMA, 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 [20], and Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors [21] 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;
- (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

---

[20] 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).

[21] OJ L 47, 18.2.2004, p. 1.

products for human and veterinary use and establishing a European Medicines Agency [22];

- (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.

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

---

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

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

European Monitoring Centre for Drugs and Drug Addiction

**Risk assessment of new psychoactive substances: operating guidelines**

Luxembourg: The Publications Office of the European Union

2009 — 87 pp. — 14.8 x 21 cm

ISBN: 978-92-9168-402-1

doi: 10.2810/2428

## **How to obtain EU publications**

Our priced publications are available from EU Bookshop (<http://bookshop.europa.eu>), where you can place an order with the sales agent of your choice.

The Publications Office has a worldwide network of sales agents. You can obtain their contact details by sending a fax to +352 292942758.

## About the EMCDDA

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 factual, 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 advisers; professionals and researchers working in the drugs field; and, more broadly, the media and general public.



Publications Office

ISBN 978-92-9168-402-1



9 789291 684021