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**EMCDDA–Europol 2006 Annual Report on the implementation of
Council Decision 2005/387/JHA**

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

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Overview

This is the second EMCDDA-Europol Annual Report on activities in support of the Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances ⁽¹⁾.

Council Decision 2005/387/JHA, which replaces the 1997 Joint Action on new synthetic drugs ⁽²⁾, is in its second implementation year and there is increasing evidence which enables a better assessment to be made of the efficacy and achievements of the system created by this Decision, in particular regarding the information collection phase of the mechanism. However, since a risk assessment procedure is still to be launched under this legal instrument, a comprehensive and more conclusive assessment is not yet possible.

During 2006, seven new psychoactive substances were officially notified for the first time through the information exchange/early-warning mechanism set up by the Decision. These were all psychotropic substances (synthetic drugs) similar to those listed in Schedules I and II of the 1971 UN Convention on Psychotropic Substances. It should be noted that some of the newly identified substances are from chemical groups never reported before via the early-warning system (EWS) since its establishment in 1997. Furthermore, of significance is the fact that of the seven new substances, three belong to the group of synthetic drugs called piperazines – a large group of chemicals that have drawn increased attention and concern over the last two years. The proactive response of the EWS to such new challenges proves its high sensitivity towards the production and subsequent appearance of new psychoactive (synthetic) substances on the European Union drug scene.

In 2006, upon a request from the Commission, the EMCDDA and Europol implemented an active monitoring of the new psychoactive substance 1-(3-chlorophenyl)piperazine (mCPP). By the end of March 2007, the EMCDDA and Europol will submit to the Commission a detailed report with the findings of this active monitoring exercise. Furthermore, in the last quarter of 2006, the EMCDDA and Europol have accumulated sufficient evidence about another psychoactive piperazine – benzylpiperazine (BZP) – to launch information collection for production of a Joint Report (in accordance with Article 5). In compliance with deadlines stipulated by the Decision, it is planned that the resulting Joint Report on BZP will be submitted to the Council, the Commission and the European Medicines Agency (EMA) on 23 February 2007.

Furthermore, the Annual Report notes that there are still challenges to overcome with respect to identifying comprehensive information sources and cost-effective mechanisms to allow a clear identification of the use of notified substances in the manufacture of medicinal products by the pharmaceutical industries. In addition, there are issues of a more general nature related to the identification of new substances and analysis of known drugs which the system has to face up to in the coming years, in order to maintain the operationality of the EWS and to embark upon a sound emerging trends monitoring exercise.

⁽¹⁾ OJ L 127, 20.5.2005, p. 32; See Annex 1.

⁽²⁾ OJ L 167, 25.6.1997, p. 1.

1. Introduction

Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances (hereinafter the 'Decision') establishes a mechanism for the rapid exchange of information on new psychoactive substances that may pose public health and social threats, including the involvement of organised crime, 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 ⁽³⁾. The Decision also provides for an assessment of the risks associated with these new substances so that measures applicable in the Member States for the control of narcotic and psychotropic substances can also be applied to new psychoactive substances ⁽⁴⁾.

The Decision broadened the scope of, and replaced, the Joint Action of 16 June 1997 concerning the information exchange, risk assessment and control of new synthetic drugs, which was devoted exclusively to new synthetic drugs. The Decision, however, maintained the three-step approach piloted by the Joint Action: information exchange/early-warning, risk assessment and decision-making.

Under the terms of the Decision, the EMCDDA and Europol, in close collaboration with their networks – the Reitox national focal points (NFPs) and Europol National Units (ENUs) respectively – are assigned a central role in detecting new psychoactive substances (Article 4). Furthermore, in cooperation with the EMEA, the responsible institutions may collect, analyse and present information on a new psychoactive substance in the form of a Joint Report (Article 5). The Joint Report provides evidence-based advice to the Council and the Commission on the need to request a risk assessment on any new psychoactive substance. Such a risk assessment examines the health and social risks posed by the use of, the manufacture of, and traffic in, a new psychoactive substance, the involvement of organised crime and the possible consequences of control measures. In order to carry out the risk assessment, the EMCDDA convenes a special meeting under the auspices of its Scientific Committee (Article 6).

To ensure greater transparency in the implementation of the Decision, Article 10 stipulates that '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.'

⁽³⁾ This report uses strictly the definitions provided by the Council Decision where 'new psychoactive substance' means a new narcotic drug or a new psychotropic drug in pure form or in a preparation; '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; '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.

⁽⁴⁾ In compliance with the provisions of the 1961 UN Single Convention on Narcotic Drugs and the 1971 UN Convention on Psychotropic Substances.

In compliance with the above provision, the EMCDDA and Europol herein present the second Annual Report on the implementation of the Decision for the period January to December 2006. The report utilises the same reporting structure as the first Annual Report, which was submitted to the European Parliament, the Council and the Commission in February 2006 (11096/06 CORDROGUE 67). The report frequently refers to articles of the Decision; therefore, to facilitate its reading the full text of the Decision is annexed (Annex 1). When describing the relevant new psychoactive substances, the report presents sufficiently detailed and comprehensible information, whilst avoiding to overload the recipient Institutions with highly technical details. The report outlines the results of the implementation and describes some issues arising from the accumulated experiences. Thus, the report also serves as a monitoring tool which provides to the Commission information for its annual progress review on the implementation of the EU drugs action plan (2005–2008).

2. Arrangements for information exchange

2.1 *EMCDDA-Europol Operating Guidelines – early-warning system on new psychoactive substances*

To operationalise further the implementation of the information exchange/early-warning under the Decision, the EMCDDA and Europol have prepared, tested and are implementing new Operating Guidelines of the EWS.

The purpose of the Operating Guidelines is to address the measures introduced by Council Decision 2005/387/JHA. The guidelines 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 aim to assist the Member States in implementing the Decision and provide transparency to the entire process. However, there is no mandate and it is not the intention of the guidelines to advise Member States on the structure of their own national EWS; this is not a preoccupation 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. However, it is recommended that the national focal points ensure that regular liaison is maintained with Europol National Units, forensic science and toxicology laboratories, Government departments responsible for enacting drugs legislation, national medicines agencies and other drugs agencies as appropriate.

The guidelines include as annexes the EMCDDA–Europol reporting form for notification of a new psychoactive substance; the template for the Reitox NFPs progress and final report to the EMCDDA; as well as the Europol and EMCDDA questionnaires for the request of further information for preparation of a Joint Report. The guidelines are already being implemented and it is planned to publish them in the first half of 2007.

2.2 *Active monitoring*

In 2006, at the request of the Commission, the EMCDDA and Europol implemented an active monitoring of 1-(3-chlorophenyl)piperazine (mCPP). ‘Active monitoring’ is an intensive, focused monitoring modality, which has been implemented only once (for GHB and ketamine) during the eight years of implementation of the 1997 Joint Action. It is not prescribed by the Decision and, therefore, the EMCDDA and Europol have designed and implemented it to fit into the current reporting structures and deadlines.

It is the understanding of the EMCDDA and Europol, that active monitoring of a new psychoactive substance can be implemented only following the submission of a Joint Report on the respective substance to the Council and the Commission, and only if either of those parties has explicitly requested that a further period of information collection is required. The organisation and expected results of the active monitoring exercise on mCPP are described in section 3.2.

2.3 Cooperation with EMEA and the pharmacovigilance system

The cooperation between the EMCDDA and EMEA takes place in the framework of the Council Decision 2005/387/JHA and the EMEA's initiative on cooperation with other European Union bodies for early identification and management of potential conflicts over scientific opinions. To implement successfully the Decision, the EMCDDA and EMEA have established a mechanism for bilateral exchange of information on the basis of data available through the EWS set up by the Decision and the European Union pharmacovigilance system. Electronic tools such as the existing databases – EudraVigilance (EMEA) and the European Database on New Drugs (EMCDDA) are being used to allow a rapid and reliable exchange of information.

The EMCDDA, Europol and EMEA are fully committed to the spirit of the Decision to ensure that 'no deterioration of either human or veterinary health care as a result of this Decision will be permitted'. Therefore, precautions are taken to guarantee that substances of established and acknowledged medical value are excluded from risk control measures based on this Decision. Furthermore, the Operating Guidelines of the EWS clarify that 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 assessments. By analogy, this applies to veterinary medicinal products as well. It should be noted however that Article 7.3 only refers to exclusion of a substance from risk assessment and control measures, but does not prevent the EMCDDA, Europol and EMEA from collecting relevant information.

The Decision establishes that 'suitable regulatory and public health related measures should be taken for substances of established and acknowledged medical value that are being misused'. The EWS guidelines, therefore, clarify that '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.'

The European pharmacovigilance system involves surveillance of authorised medicinal products through the collection and evaluation of information on adverse drug reactions (ADRs) under normal conditions of use, as well as on misuse and abuse that may have an impact on the evaluation of benefits and risks. Common understanding has been reached between the two Agencies that the surveillance systems for substance misuse (including the EMCDDA epidemiological indicators and EWS, and the European pharmacovigilance system) require further coordinated surveillance strategies and warning systems. The EMCDDA will pursue this not only within the provisions of the Council Decision 2005/387/JHA but also in view of the recast of the EMCDDA founding

regulation (EC No 1920/2006) which broadens the scope of the Centre's monitoring work to include increased emphasis on new patterns of drugs use and poly-drug use, including the misuse of medicinal products. The EMCDDA has proposed that the technical level cooperation with EMEA on this will be strengthened in 2007 through the preparation of a position paper.

2.4 Cooperation with the United Nations

The World Health Organisation (WHO) is the specialised UN Agency designated for the evaluation of the medical, scientific and public health aspects of psychoactive substances under the 1961 and 1971 UN Conventions.

Article 5.2(e) of the Decision requires the Europol-EMCDDA 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 a permanent communication channel with the Department of Medicines Policy and Standards at the WHO. The cooperation is fully operational and the required information is obtained practically without a delay. In recognition of the EMCDDA experience in assessing the risks of new substances, at the end of 2006, the Centre was invited to join the working group for the revision of the WHO Guidelines for the review of dependence-producing psychoactive substances for international control.

3. Implementation of the Decision and results

3.1 New psychoactive substances notified in 2006

During 2006, a total of seven new psychoactive substances were officially notified for the first time through the EWS to the EMCDDA and/or Europol (see Annex 2). The substances notified in 2006 were all psychotropic (synthetic) drugs, similar to those listed in Schedule I and Schedule II of the 1971 UN Convention on Psychotropic Substances. Subsequently, all seven new compounds were added to the list of substances monitored by the EMCDDA and Europol and in the EMCDDA's database on new drugs (EDND).

The number of new substances notified in 2006 is smaller than those notified in 2005 when fourteen new psychotropic substances were reported for the first time. However, the chemical make-up of the newly reported substances is more diverse – some of them belong to chemical groups never reported before through the early-warning system, such as indans⁽⁵⁾ and benzodifuranyls. Two of the seven newly reported substances⁽⁶⁾ have pronounced hallucinogenic effects, whereas all others exhibit predominantly stimulant effects. These two hallucinogens are rarely encountered and, at present, seem to have limited potential for further (rapid) spread. However, vigilance is required as both are potent hallucinogens active in very small doses (from less than 0.5 mg).

⁽⁵⁾ Little is known about the aminoindans as recreational drugs of choice. There is some information on the Internet about 2-aminoindan being used as a short-acting stimulant. It is also available from various chemical suppliers as a 'research chemical'.

⁽⁶⁾ DOI and Bromo-dragonfly: DOI (2,5-dimethoxy-4-iodoamphetamine) a phenethylamine, seems to be active in humans in small doses (similarly to DOB), it has high binding capacity towards the serotonin receptors (agonist) and is better studied in animals; Bromo-dragonfly (bromo-benzodifuranyl-isopropylamine) a benzodifuranyl, is also reportedly active in very small doses, it is a new and little studied chemical.

It may be of significance that three of the newly notified substances, belong to the group of synthetic drugs called piperazines. The (aryl-substituted) piperazines are a group of chemicals that includes, amongst others, benzylpiperazine (BZP), 1-(3-chlorophenyl)piperazine (mCPP), m-trifluoromethylphenylpiperazine (TFMPP), 1-(4-methoxyphenyl)-piperazine (pMeOPP), p-fluorophenylpiperazine (pFPP), dibenzylpiperazine (DBZP), etc. All of these have been notified through the early-warning system (EWS), in the case of BZP as early as 1999 and in the case of DBZP as recently as November 2006. In general, the members of this chemical group exhibit mild stimulant properties and are often marketed and used in various combinations. Some of these combinations, in particular BZP in combination with TFMPP, are thought to be intentionally designed in order to mimic the effects of MDMA (ecstasy). In other combinations, such as BZP with DBZP, the latter might form as an impurity in the synthesis process of the former. More information on BZP and mCPP can be found in section 3.2 and 3.3 below.

The appearance and spread of various piperazines is an interesting new phenomenon, given the fact that a vast majority of the reported psychotropic substances since the establishment of the EWS in 1997 belong to two 'traditional' chemical groups with psychotropic properties – phenethylamines ⁽⁷⁾ and tryptamines ⁽⁸⁾. However, only two of the new psychotropic substances notified for the first time in 2006 are of the former group and none of the latter. It is worth noting that, of the nine new synthetic drugs that underwent risk assessment between 1997 and 2004 under the Joint Action ⁽⁹⁾, all six substances that were subsequently controlled are phenethylamines.

The first Annual Report on the implementation of the Decision (11096/06 CORDROGUE 67) singled out two substances (methylone and DPIA), as exhibiting characteristics suggesting that they were particularly appropriate for further vigilance. None of them, however, appeared to have gained popularity and caused specific concern in 2006. Nevertheless, the group of chemicals with predominantly stimulant properties called cathinones to which methylone ⁽¹⁰⁾ belongs, continue to be closely monitored by the EWS.

3.2 Active monitoring of mCPP

The detection of the new psychoactive substance, 1-(3-chlorophenyl)piperazine (mCPP) in the European Union was first notified to the EMCDDA and Europol in February and March 2005 by France and Sweden respectively. Between August and October 2005, the EMCDDA and Europol produced a Joint Report as stipulated by Article 5.1 of the Decision. The Joint Report was submitted to the Council, the Commission and the

⁽⁷⁾ Phenylethylamines are a large group of chemicals which includes many uncontrolled and various controlled substances, e.g. amphetamine, mescaline, MDMA (ecstasy) etc., i.e. substances that may exhibit stimulant, hallucinogenic and entactogenic effects.

⁽⁸⁾ Tryptamines are indole alkaloids, to this group belong e.g. LSD, psilocybin, etc., all exhibiting mainly hallucinogenic effects, i.e. the ability to produce distortions in sensations, and to markedly alter mood and thought processes.

⁽⁹⁾ The related risk assessment reports and the respective Council Decisions on control measures are available at <http://www.emcdda.europa.eu> under Action on New Drugs.

⁽¹⁰⁾ Methylone is 3,4-methylenedioxyamphetaminone (or MDMCAT) is the benzylic ketone derivative of 3,4-methylenedioxyamphetamine (MDMA). Methylone and related compounds can be described as ring-substituted cathinones, where cathinone, the parent compound and a scheduled drug in the 1971 UN Convention on Psychotropic Substances, is an active constituent of khat.

EMEA on 28 October 2005 (14409/05 CORDROGUE 73). The Horizontal Working Party on Drugs (HDG) examined the Joint Report at its meetings of 7 November 2005 and 8 December 2005. In a letter from the Secretary General, the Commission explained its decision that no risk assessment should be carried out since the substance falls under the provisions of Article 7.3 of the Decision. Based on a room document presented by the Commission, the December HDG agreed that no risk assessment on mCPP should be carried out (15832/05 CORDROGUE 88).

Given the concern mCPP is causing and taking into account the relatively large quantities of mCPP seized by the Member States, the Commission proposed at the May 2006 HDG meeting, that the EMCDDA and Europol 'carry out further work in accordance with their mandates and the resources available to assess the importance of mCPP in the EU illicit drugs market'. Furthermore, the Commission suggested that the two organisations through their networks monitor and collect further data on mCPP and the risks it poses, and inform the Commission of their findings by the end of the first quarter of 2007. Such a report should include a scientific evaluation of the potential threat of mCPP and involve input from national experts, the Commission and the EMEA. The report should also include the lessons learned from the experiences (preventive and law enforcement) of the Member States that already control mCPP.

Between June 2006 and January 2007, the EMCDDA and Europol, respecting their competences, continued to collect the following information on mCPP: (a) detections (seizures, collected and biological samples); (b) intoxications and other health and/or social consequences; and (c) changes in the legal status. This information has been collected via the standard reporting tools – the EMCDDA/Europol reporting form, the Reitox EWS progress and final reports (i.e. in July 2006 and January 2007) as well as on an *ad hoc* basis through the information exchange mechanism set up by the Decision. All collected data has been entered without delay into the European database on new drugs (EDND) – access to which is currently provided to the Reitox NFPs, Europol, EMEA and the Commission.

In February 2007, the EMCDDA will organise a technical expert meeting in order to evaluate the scientific evidence on the potential threat of mCPP. This meeting, however, will have neither the mandate of a risk assessment nor such an extent and depth. The meeting will involve input from Europol, national experts, the Commission and the EMEA. As a result, by the end of the first quarter of 2007, the EMCDDA and Europol will submit a concise report to the Commission informing of their findings, including the lessons learned from the experiences (preventive and law enforcement) of the Member States that already control mCPP.

3.3 Joint Report on benzylpiperazine (BZP)

Article 5.1 of the Decision stipulates that '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, EMEA and the Commission'.

In December 2006, the EMCDDA and Europol examined the available information on a new psychoactive substance, 1-benzylpiperazine (BZP) through a joint assessment based upon the following criteria: 1) the amount of the material seized; 2) evidence of

organised crime involvement; 3) evidence of international trafficking; 4) analogy with better-studied compounds; 5) evidence of the potential for further (rapid) spread; and 6) evidence of cases of serious intoxication or fatalities.

The EMCDDA and Europol agreed that the information collected on BZP satisfies at least criteria 1, 3, 5 and 6. The two organisations, therefore, concluded that sufficient information has been accumulated to merit the production of a Joint Report on BZP as stipulated by Article 5.1 of the Decision. Accordingly, the Reitox NFPs, the ENUs, the EMEA and the WHO have been formally requested to provide the relevant information within six weeks from the date of the request, i.e. by 23 January 2007 at the latest.

In accordance with Article 5.3 of the Decision, the EMCDDA requested from the EMEA information on the marketing authorisation status of BZP in the European Union or in any Member State. Furthermore, as in the case of mCPP, in anticipation of Article 7.3 of the Decision, the EMCDDA informed the EMEA that there are at least four other active substances of medicinal products with structures closely related to BZP which may metabolise to BZP or where BZP could theoretically be used in their synthesis.

Considering the information already collected on BZP by the EMCDDA and Europol, there is a high probability that the Council will request a risk assessment of this compound. Such a risk assessment, if requested, will allow a better understanding to be gained not only of this particular substance, but as a wider effect will enable a better overall understanding of the piperazines group. The EMCDDA's Scientific Committee has already undertaken to adapt the guidelines for risk assessment so as to make them appropriate for the new scope and requirements of the Decision.

In compliance with deadlines stipulated by the Decision, it is planned that the resulting Joint Report on BZP will be submitted to the Council, the Commission and the European Medicines Agency (EMA) on 23 February 2007.

3.4 Information exchange beyond the immediate scope of the Decision

In addition to its core objective, the 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. A thematic paper on hallucinogenic mushrooms was prepared and published in 2006 ⁽¹¹⁾ and work is in progress on a second case study on Gamma-hydroxybutyrate (GHB).

The early-warning system on new psychoactive substances 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, such as forensic science, toxicology, law enforcement, etc.

⁽¹¹⁾ Available at <http://www.emcdda.europa.eu>

On a few occasions in 2006, the EWS (EMCDDA) has issued public health-relevant warnings to the Reitox network concerning unusual hazards related to controlled substances ⁽¹²⁾. However, the lack of fully verified scientific information and, to some extent, the limitations of the EMCDDA's mandate make the definition and follow-up of such actions difficult.

4. Issues arising from the implementation experiences

4.1 Scope and deadlines set by the Decision

The Decision broadened the scope of the Joint Action on new synthetic drugs, albeit that, until now, the substances notified by the Member States to the EMCDDA and/or Europol via the information exchange mechanism have been exclusively psychotropic (synthetic) drugs, similar to those listed in Schedule I and Schedule II of the 1971 UN Convention on Psychotropic Substances. The EMCDDA-Europol EWS is well positioned to carry out the timely and thorough collection of available information about the types of substances that until now have been notified within the framework of the Decision.

In the case of mCPP, the system faced a challenge related to its use by the pharmaceutical industry for manufacturing of a medicinal product. Consequently, the new EWS Operating Guidelines specify that the 'substance used to manufacture a medicinal product' should be interpreted to include an intermediate in the production of an active pharmaceutical ingredient (API) as well as an API used to manufacture a medicinal product. There is, however, concern since such substances will not be present in the medicinal product in question and would not be a part of the risk/benefit assessment made for this medicinal product. Such a situation places the psychoactive substances that are starting materials/intermediates for an active substance of a medicinal product (or API) in a regulatory vacuum at European Union-level since they are also exempted from risk assessment and control measures under the Decision.

In the case of mCPP, the system also faces an interesting question on how to deal with a substance, which based on the available scientific evidence, appears not to pose a substantial threat to individual health, but is being largely distributed via the illegal drugs market. Although mCPP seems unlikely to establish itself as a recreational drug in its own right, it creates certain risks related to manufacture, trafficking, organised crime, violence, etc.

The first piperazines were notified via the EWS back in 1999. However, the emergence of BZP as a recreational drug with potential for rapid widespread in Europe laid relatively latent until 2005 and 2006 when it began to be aggressively marketed on the Internet, sometimes misrepresented as a 'natural' product, thus prompting the EMCDDA and Europol to launch the preparation of a Joint Report on BZP.

Currently, on the EMCDDA-Europol monitoring list of substances notified via the EWS, there are about fifty chemicals from three major chemical groups, some of which were notified via the EWS already in the late nineties. However, it cannot be excluded that some of the substances already known will resurface within a different context and become eligible for further action under the provisions of the Decision. Over the next

⁽¹²⁾ For example, concerning fentanyl-laced heroin or dangerous paper trips containing a high dosage of fentanyl.

years, the list of monitored substances is likely to grow and diversify to include new psychotropic (synthetic) as well as new narcotic substances (natural or synthetic). This may require different approaches for analytical identification, notification, monitoring and, ultimately risk assessment of the new psychoactive substances. The availability of reference materials will continue to be of utmost importance if forensic and toxicology laboratories are to identify new psychoactive substances, especially in cases where limited scientific literature is available.

Finally, combinations of various substances of the same or different groups may result in new pharmacological properties which may require simultaneous action on more than one substance under the provision of the Decision.

4.2 Implementation of Article 7.3

Establishing the authorisation status of new psychoactive substances (including medical products) in the European Union (Article 5.3) is relatively easy as each Member State has its own individual database, while the EMEA maintains a database of products authorised via the Centralised Procedure. However, the present rise in the appearance of piperazines – a group of widely used simple chemicals – continues to pose challenges regarding the type of information that the EMCDDA and the EMEA are expected to generate or collect in a comprehensive and cost-effective manner.

Article 7.3 of the Council Decision stipulates that ‘no risk assessment shall be carried out on a new psychoactive substance if the new psychoactive substance is used to manufacture a medicinal product’. In anticipation of Article 7.3 of the Council Decision in the preparation of the Joint report on BZP, it is appropriate to recall that establishing whether new substances are used in the manufacture of medicinal products might present a substantial challenge. Such type of information may not come to light until a very late stage in the implementation of the Decision, for example, not until after the risk assessment procedure is under way. Therefore, the possibility for initiating and carrying out a risk assessment of intermediates in the production of active substances (including those of herbal origin) of medicinal products (including veterinary medicinal products) also abused or used for preparation of substances of abuse, or belonging to the same chemical class of those of abuse cannot be fully excluded.

5. Summary

- Council Decision 2005/387/JHA is in its second implementation year and there is increasing evidence which enables a better assessment to be made of the efficacy, achievements and, indeed, the challenges faced by the system created by this Decision, in particular regarding the information collection phase of the mechanism. However, since a risk assessment procedure is still to be launched under this legal instrument, a comprehensive and more conclusive overall assessment is not yet possible.
- The proactive response of the EWS in identifying and reacting to the present trend of the appearance of piperazines on the European Union drugs scene proves its high sensitivity and operationality.
- The appearance of various chemicals of the piperazine group continues to pose challenges regarding the type of information that the EMCDDA and the EMEA are expected to generate or collect in a comprehensive and cost-effective

manner. A difficulty that remains is that it may not be obvious to the Member States, the EMCDDA or even EMEA that a particular new psychoactive substance is used in the manufacture of a medicinal product.

- The information exchange on the misuse of medicinal products is still limited, probably owing to the historical and structural division of the systems for monitoring 'illicit' and 'licit' substances at European Union and national level.
- Despite the possibilities presented by the extended scope of the Decision, no new narcotic substances have yet been notified through the information exchange mechanism. Over the next years, the number of monitored new substances is likely to diversify to include new unreported groups of psychotropic as well as new narcotic substances. This may require different approaches for analytical identification. Furthermore, this will inevitably lead to diversification of the chemical precursors used for the production and manufacturing of such substances – a phenomenon that may pose further challenges to the related control mechanism.
- Combinations of various substances of the same or different chemical groups may result in new pharmacological properties, which could necessitate simultaneous action on more than one substance.
- The EMCDDA has advanced the process of developing an integrated approach towards the collection, monitoring and exchange of information on emerging trends in the use of existing substances and on possible public health-related measures.
- The EMCDDA, Europol and EMEA have put in place most of the organisational prerequisites and monitoring tools for the dynamic functioning of the information exchange/early warning system within the immediate scope of the Decision.

Annexes

Annex 1 – COUNCIL DECISION 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances

Annex 2 – New psychoactive substances reported for the first time in 2006 to EMCDDA and Europol under the terms of Council Decision 2005/387/JHA

(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⁾ (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 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.

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;

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.

- (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 2

New psychoactive substances reported for the first time in 2006 to EMCDDA and Europol under the terms of Council Decision 2005/387/JHA

pFPP (p-Fluorophenylpiperazine) – 19 April 2006 – United Kingdom

pCPP (1-4 chloro phenyl piperazine) – 6 November 2006 – France

DBZP (1, 4-Dibenzylpiperazine) – 9 November 2006 – United Kingdom

2,4-DMA (2,4-dimethoxy-alpha-methylbenzeneethanamine) (or 2,5-DMA (2,5-dimethoxy-alpha-methylbenzeneethanamine)) – 20 November 2006 – Finland

2-aminoindan (1H-Inden-2-amine, 2,3-dihydro; or 1-aminoindan (1H-Inden-1-amine, 2,3-dihydro) – 21 November 2006 – Finland

Bromo-Dragonfly (Bromo-benzodifuranyl-isopropylamine) – 21 November 2006 – Sweden

DOI (4-iodo-2,5-dimethoxyamphetamine) – 21 November 2006 – Sweden