European Monitoring Centre for Drugs and Drug Addiction

EUROPOL

EMCDDA–Europol 2010 Annual Report on the implementation of Council Decision 2005/387/JHA

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

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Overview

This report presents the activities implemented by the EMCDDA and Europol in 2010 in support of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances (hereinafter referred to as the Decision) ([1]).

During 2010, 41 new psychoactive substances were officially notified for the first time in the European Union through the information exchange mechanism, the Early-Warning System (EWS), which was set up by the Decision. The number of new compounds reported in 2010 was higher than ever; the list of newly notified substances was rather diverse and included a plant-based substance, synthetic derivatives of well-established drugs, as well as substances that can be described as 'designer medicines'. Under the so-called 'Spice' phenomenon, 11 new synthetic cannabinoids were reported, bringing the total number of synthetic cannabinoids monitored by the EWS to 21. The report also highlights the emergence of 15 new synthetic cathinone derivatives and notes the appearance for the first time of derivatives of phencyclidine (PCP) and ketamine.

Furthermore, the report describes the increased availability of a large number of new unregulated synthetic compounds marketed on the Internet as 'legal highs' ([2]) as well as the EMCDDA's activities in monitoring the online shops selling these products.

In January 2010, after examining the available information collected on mephedrone (4-methylmethcathinone), the EMCDDA and Europol decided to launch a procedure for the production of a joint report. Pursuant to the findings of this report, the Council of the EU formally requested a risk assessment of the substance. The risk assessment exercise was undertaken on 15 July by the EMCDDA Scientific Committee, with the participation of additional experts from the EU Member States, the European Commission, Europol and the European Medicines Agency (EMA). Based on the findings of the risk assessment report, on 2 December 2010, the Council decided to submit mephedrone to control measures and criminal penalties throughout the European Union.

Finally, the last two sections include a brief review of the key developments in the period 2005–10 and a look at some of the challenges for the coming years. In particular, the focus is on issues that relate to the challenges for identifying, monitoring and assessing the risks of various new substances, which increasingly appear on the Internet and on the European drug markets.

In view of the ongoing assessment of the Council Decision 2005/387/JHA undertaken by the European Commission in the framework of the EU drugs action plan for 2009–12 ([3]), this report may provide additional insight into the functioning of the Decision.

([1]) OJ L 127, 20.5.2005, p. 32.

([2]) 'Legal highs' is an umbrella term for internationally unregulated psychoactive compounds or products containing them, specifically designed to mimic the effects of known (established) drugs in order to circumvent existing drug controls. The term encompasses a wide range of synthetic and plant-derived substances and products, including 'research chemicals', 'party pills', 'herbal highs', etc., which are usually sold via the Internet or in smart/head shops, advertised with aggressive and sophisticated marketing strategies, and in some cases intentionally mislabelled with purported ingredients differing from the actual composition. The 'legal highs' market is distinguished by the speed at which suppliers circumvent drug controls by offering new alternatives to restricted products.

([3]) EU drugs action plan for 2009–2012, (2008/C 326/09) [Official Journal of the European Union C 326/7 IV, 20.12.2008].

1. Introduction and background

The Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances 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. This allows European Union institutions and Member States to act on all new narcotic and psychotropic substances that appear on the European Union drug scene ([4]). 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 ([5]).

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 and reporting new psychoactive substances (Article 4 of the Decision). Furthermore, in cooperation with the European Medicines Agency (EMA), the two organisations 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 a new psychoactive substance. Such a risk assessment examines the health and social risks posed by the use of, 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 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.'

In compliance with the above provision, the EMCDDA and Europol herein present the sixth Annual Report on the implementation of the Decision for the period January to December 2010. The report outlines the results of the implementation and describes key issues arising from accumulated experiences. Thus, the report also serves as a monitoring tool, which provides the Commission with information for the ongoing assessment of the functioning of Council Decision 2005/387/JHA included in the EU drugs action plan for 2009–12.

The report is written as a stand-alone document with its annexes kept to a minimum. 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 notified new psychoactive substances, the report presents sufficiently detailed information, while avoiding highly technical descriptions (the complete list of newly notified psychoactive substances, which includes detailed information on the chemical names, the reporting Member State, and date of notification is presented in Annex 2). More comprehensive information on the new substances described in the report is available from the EMCDDA and Europol.

([4]) Under the definitions of the Council Decision, '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 Schedules 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 Schedules I, II, III or IV.

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

2. Implementation arrangements and cooperation with the EU Pharmacovigilance system

2.1 Specific implementation arrangements

2.1.1 Implementation of the new Operating guidelines for the risk assessment

The new *Operating guidelines for the risk assessment of new psychoactive substances* ([6]), elaborated by the EMCDDA's Scientific Committee, were published in 2010. The guidelines, which were implemented for the first time for the risk assessment of mephedrone (see Section 3.2), are not only a useful tool to support the implementation of the Council Decision, but also provide an overall conceptual framework for conducting scientifically sound risk assessment in a timely fashion and where information sources are limited.

2.1.2 Cooperation with the United Nations system

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'. In compliance with the above, information was requested from the World Health Organization (WHO) ([7]) on the assessment status of mephedrone in the UN system (see Section 3.2). The WHO informed the EMCDDA that mephedrone was not under assessment in the UN system.

2.1.3 Assistance to national EWSs

The European EWS regularly provides support to partners from the national EWSs assisting them in the identification of new substances. This is done by providing analytical data, exchanging data between forensic laboratories, cross-checking information from the national databases and facilitating the exchange of drug samples where this is possible. Such activities prove to be useful for the identification of new psychoactive substances in the absence of reference materials, or where limited resources are available at national level. Moreover, the EMCDDA coordinates the information exchange related to relevant national projects. For example, some Member States have launched specific activities to monitor new drugs through test-purchases from the Internet and from specialised shops (smart, head, etc.). As a result, a significant number of new substances have been identified in 'legal high' products.

The EWS is frequently consulted by the Member States, individual experts, scientists and, increasingly, the media ([8]) in relation to various new psychoactive substances. The EMCDDA is currently coordinating the preparation of a publication on national early-warning systems, with the objective of presenting a comprehensive overview of these systems. The publication, which is due in 2011, will promote best practices and enhance the exchange of experiences.

2.1.4 Structured monitoring of the Internet — online availability of 'legal highs'

Leading-edge indicators such as monitoring the online availability of new psychoactive substances can be considered particularly sensitive to change. However, this sensitivity, by definition, is associated with volatility. As such, leading-edge indicators may be unreliable in the medium term if viewed in isolation and not triangulated with other data sources. Therefore, to complement the main EWS data sources such as seizures, reports on use and toxicity, the EMCDDA actively monitors the online availability of unregulated psychoactive products ('legal highs'). One of the

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([6]) EMCDDA, 2010. *Operating guidelines for risk assessment of new psychoactive substances*. Also available at: http://www.emcdda.europa.eu/html.cfm/index100978EN.html

([7]) The World Health Organization (WHO) is the specialised United Nations Agency designated for the evaluation of medical, scientific and public health aspects of psychoactive substances under the 1961 and 1971 United Nations drug control conventions.

([8]) More than 50 television, radio and press interviews were given in 2010 to major European media, as follows: TVI, BBC, The Guardian, The Daily Telegraph, The Wall Street Journal, Wales online, Irish Sunday Mirror, Irish Independent, EU Observer, Diário de Notícias (Portugal), Público (Spain), Público (Portugal), El Mundo, El País, Metro France, Metroxpress and 24timer, Antena 1 (Portugal), Radio TSF, A2prl, Europe 1, etc.) on issues related to new drugs, 'legal highs', mephedrone, etc.

main potentials for the EMCDDA to be of added value in this area resides in the multilingual approach to this global phenomenon and the utilisation of sound methodology over time.

In 2010, an EMCDDA steering group for Internet monitoring was set up to define the scope and to develop a conceptual framework and methodology for structured Internet monitoring. A paper on 'EMCDDA Internet monitoring methodology and results' was prepared and will be published in 2011 as an EMCDDA Technical paper.

Internet monitoring is carried out in the form of snapshots, which are performed during a short time window on one or more substances and/or products. The EMCDDA has undertaken a number of snapshots relating to the availability of different kinds of new psychoactive substances. Earlier EMCDDA snapshot exercises focused on magic mushrooms in 2006 ([9]) and GHB/GBL in 2007 ([10]). In 2008, the scope was widened to 'legal highs' and in 2009 a snapshot was carried out on 'Spice' ([11]). The 2010 annual snapshot was multilingual and its objective was to establish the online availability of 'legal highs' (including 'Spice'), GHB/GBL or hallucinogenic mushrooms. Additional EMCDDA snapshots were carried out in 2010, some of which focused on mephedrone as well as other substances of interest such as naphyrone, MDAI, etc.

The 2011 annual snapshot (in 15 EU languages) was wider in scope (including mephedrone) and preliminary results suggest a considerable increase since 2010 in the online availability of 'legal highs', GBL or hallucinogenic mushrooms. The total number of online drugs shops offering at least one of the substances/products mentioned rose from 170 to 277. The increase was found to be mostly of generic sites selling 'legal highs' (often named as 'herbal highs' or 'research chemicals'). With regards to a specific substance such as GBL, the 2010 snapshot found four online shops offering it, whereas twelve such shops were identified in the 2011.

There were also examples of products, such as 'Spice', for which online availability decreased. In the 2011 snapshot, the number of online shops offering 'Spice' (under this generic name, e.g. Spice Gold/Diamond/Silver/Arctic/Tropical, etc.) dropped to four. This was down from the 21 and 55 such shops identified in 2010 and 2009 respectively.

Ad hoc snapshots for mephedrone in English showed a peak in March 2010 with 77 online shops offering it. The number of online mephedrone shops then decreased to seven in July 2010, but has risen since then to fifteen in February 2011. Similarly, an increasing availability of mephedrone through online shops seemingly located in Central Europe has been observed from 2010 to 2011.

2.2 Cooperation with the EMA and the Pharmacovigilance system

The European Medicines Agency (EMA) is a key partner in the implementation of the system set up by the Decision. The EMCDDA and EMA have established a mechanism for bilateral exchange of information on the basis of data available through the Early-Warning System and the European Union Pharmacovigilance system. Electronic tools such as the existing databases — EudraVigilance (EMA) and the European Database on New Drugs (EDND, EMCDDA) are being used to allow a rapid and reliable exchange of information. The regular information exchange between the EMCDDA and EMA includes formal reports on new psychoactive substances through a Reporting Form, as well as *ad hoc* reports on misused medicinal products in order to complement the reporting via the EU Pharmacovigilance system. In 2010, a *Working arrangement* was signed between the two Agencies in order to enhance further the cooperation while avoiding duplication of efforts and overlaps and to ensure the best use of available resources.

In 2010, in accordance with Article 5.3 of the Decision, the EMA was requested to submit to the EMCDDA information on 'whether in the European Union or in any Member State: (a) mephedrone

([9]) EMCDDA, 2006. *Hallucinogenic mushrooms*. Thematic papers, European Monitoring Centre for Drugs and Drug Addiction. Available at: http://www.emcdda.europa.eu/html.cfm/index31208EN.html

([10]) EMCDDA, 2008. *GHB and its precursor GBL: an emerging trend case study*. Thematic papers, European Monitoring Centre for Drugs and Drug Addiction. Available at: http://www.emcdda.europa.eu/publications/thematic-papers/ghb

([11]) EMCDDA, 2009. *Understanding the 'Spice' phenomenon*, Thematic papers, European Monitoring Centre for Drugs and Drug Addiction. Available at: http://www.emcdda.europa.eu/publications/thematic-papers/spice

had obtained a marketing authorisation; (b) mephedrone was the subject of an application for a marketing authorisation; (c) a marketing authorisation that had been granted in respect to mephedrone had been suspended' (see Section 3.2). The EMA collected information through its network of competent authorities for medicinal products and informed that mephedrone has no known medical use (human or veterinary) in the European Union and that there is no marketing authorisation (existing, ongoing or suspended) for mephedrone in the EU or in the Member States that responded to the EMA.

During the reporting period, consultations and exchange of information took place on pregabalin — a prescription medicine marketed under the name Lyrica and used to treat neuropathic pain, epilepsy and generalised anxiety disorder (GAD). User reports suggest that pregabalin is used in recreational settings, with effects similar to those of alcohol, GHB (gamma-hydroxybutyric acid) and benzodiazepines. It is also reported to alleviate heroin (opioid) withdrawal symptoms.

As reported in last year's report, a review of pharmacovigilance data indicated concerns related to its misuse in Finland, Sweden and Norway. Furthermore, information from the EWS indicated that pregabalin may have been involved in the deaths of a number of users in Finland and the United Kingdom, where it was found in forensic toxicological analyses.

Based on the information provided, the EMA felt that a specific warning should be given in the section *Special warnings and precautions* of the Summary of Product Characteristics (SPC) of Lyrica. The Pharmacovigilance Working Group (PhVWG) is expecting the results of a study ([12]) which will be submitted in January 2012. The objective of the study is to provide general long-term efficacy and safety information on Lyrica in the treatment of patients with GAD and to characterise the effects of pregabalin dose and treatment duration on drug discontinuation symptoms and rebound anxiety.

Finally, in 2010 the EMCDDA launched a study to conceptualise a methodology for monitoring the misuse of medicines at European level. The results of the study will be available at the beginning of 2011.

([12]) GAD Study A0081147.

3. Results achieved in 2010

3.1 New psychoactive substances notified in 2010

During 2010, a total of 41 new psychoactive substances were officially notified for the first time in European Union via the EWS (cp. Annex 2). This is the largest number of substances ever reported in a single year. The marked increase in the number of substances notified takes place in the context of the rapid development of the 'legal highs' phenomenon and may reflect both, the number of substances available in the EU as well as the improved reporting capacities of national early-warning systems due to the increased awareness about new drugs amongst various professionals. Many of the newly identified substances have been actively sought through test-purchases of 'legal highs' products on the Internet and from specialised (smart, head, etc.) shops (see also Section 2.1.3).

Of the newly identified substances, 15 were synthetic cathinones ([13],[14]) thus becoming one of the largest drug families monitored by the EWS. Furthermore, 11 new synthetic cannabinoids ([15],[16]) were reported (these are dealt separately in Section 3.3). Substances belonging to more 'traditional' chemical families were also reported — five phenethylamines ([17]), one tryptamine (cp. Annex 2, substance 26) and one piperazine (cp. Annex 2, substance 1).

The list of newly notified substances was rather diverse and also included a plant-based substance (cp. Annex 2, substance 37), a synthetic cocaine derivative (cp. Annex 2, substance 12) ([18]), a ketamine derivative (cp. Annex 2, substance 32), a phencyclidine derivative (Annex 2, substance 35), an aminoindane (cp. Annex 2, substance 2), a benzofuran (cp. Annex 2, substance 40), a simple aliphatic amine (cp. Annex 2, substance 11), as well as a substance which can be described as a 'designer medicine' (cp. Annex 2, substance 41).

From the above list, it is worth noting the appearance for the first time of derivatives of two well-established drugs: phencyclidine (PCP) — an internationally controlled substance, and ketamine — a human and veterinary medicine. It can be anticipated that further derivatives of these drugs may appear in future.

Following the formal notifications received through a Reporting Form, 41 new profiles for the new substances were created in the European Database on New Drugs (EDND). In addition, EMCDDA implements a longer-term monitoring through biannual EWS reports. Based on the information collected and analysed, the list of all notified substances is reviewed regularly by the EMCDDA and Europol in order to identify those with a potential to trigger a joint report.

3.2 Risk assessment of mephedrone

At the end of 2009 and in January 2010, the EMCDDA and Europol examined the available information on mephedrone, through a joint assessment based upon the criteria set out in the *EWS operating guidelines* ([19]). The Agencies agreed that the information available on mephedrone satisfied all criteria. Therefore, the two organisations concluded that sufficient evidence had been

([13]) Annex 2, substances 9, 10, 14, 15, 18, 20, 21, 23, 24, 27, 29, 34, 36, 38, 39.

([14]) EMCDDA Drug profile (2010), *Synthetic cathinones*. Also available at: http://www.emcdda.europa.eu/publications/drug-profiles/synthetic-cathinones

([15]) Annex 2, substances 7, 8, 13, 16, 17, 19, 22, 28, 30, 31, 33.

([16]) EMCDDA Drug profile (2009), *Synthetic cannabinoids and 'Spice'*. Also available at: http://www.emcdda.europa.eu/publications/drug-profiles/synthetic-cannabinoids

([17]) Annex 2, substances 3, 4, 5, 6, 25.

([18]) EMCDDA Drug profile (2010), *Synthetic cocaine derivatives*. Also available at: http://www.emcdda.europa.eu/publications/drug-profiles/synthetic-cocaine-derivatives

([19]) EMCDDA, 2007. *Early-warning system on new psychoactive substances – operating guidelines*. Also available at: http://www.emcdda.europa.eu/themes/new-drugs/early-warning

gathered and decided to launch a formal procedure for the collection of information for the production of a joint report ([20]).

In view of the above, the Reitox NFPs and the ENUs provided the information as requested by Article 5 of the Decision within six weeks from the date of the request. On 29 March 2010, the *Europol–EMCDDA joint report on the new psychoactive substance 4-methylmethcathinone (mephedrone)* with its annexes was submitted to the Council, the Commission and the EMA ([21]). Consequently, on 26 May 2010 the Council upon an initiative from the Commission decided to authorise a formal risk assessment on mephedrone (Article 6).

The risk assessment exercise on mephedrone was prepared by the EMCDDA and all available information was presented in three separate reports (*'Technical report on mephedrone'*, *'Mephedrone: assessment of health risks and harms'*, and *'Mephedrone: additional studies — Overview of prevalence, use patterns, effects)'*. The risk assessment meeting of the EMCDDA's extended Scientific Committee ([22]) was organised on 15 July, resulting in a *Risk assessment report on mephedrone*, which was submitted to the Commission and the Council ([23]).

On the basis of the *Risk assessment report,* on 2 December 2010 the Council, upon an initiative of the Commission, decided to submit mephedrone to control measures and criminal penalties throughout the EU according to Article 8 (3) of the Decision. These measures entered into force on 9 December 2010. By that time, sixteen Member States had already introduced control measures on mephedrone ([24]). The remaining Member States ([25]) have one year to take the necessary measures, in accordance with their national law (Article 9).

Mephedrone is the first cathinone derivative to be risk-assessed by the extended Scientific Committee of the EMCDDA, as part of the process established by Council Decision 2005/387/JHA. This risk assessment built on the lessons learnt during previous exercises, in particular the risk assessment of BZP (2007) ([26]), but also introduced a new methodological approach through the implementation, for the first time, of the new EMCDDA *Operating guidelines for risk assessment of new psychoactive substances* (cp. Section 2.1.1).

The risk assessment on mephedrone was particularly difficult, due not only to limited data available on this substance, but also to the fact that there was very little similarity to other compounds which have been previously risk-assessed through the Council Decision mechanism. It is worth noting that for this risk assessment, the EMCDDA made it possible to conduct a toxicological screening in the framework of an exploratory study, which examined the patterns of use and adverse effects of mephedrone amongst a group of self-reported cathinone users. This study presented the Scientific Committee with important additional information, thus greatly facilitating the work and allowing the findings to be better grounded in evidence.

([20]) 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.'

([21]) EMCDDA, 2010. *Europol–EMCDDA Joint Report on a new psychoactive substance: 4-methylmethcathinone (mephedrone).* Also available at: http://www.emcdda.europa.eu/themes/new-drugs/early-warning

([22]) The EMCDDA's extended Scientific Committee included the participation of additional experts from the EU Member States, European Commission, Europol and the European Medicines Agency (EMA).

([23]) EMCDDA, 2010. *Risk assessment report of a new psychoactive substance: 4-methylmethcathinone (mephedrone).* Also available at: http://www.emcdda.europa.eu/html.cfm/index116639EN.html

([24]) Austria, Belgium, Denmark, Estonia, France, Germany, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Romania, Sweden, the United Kingdom, as well as Croatia and Norway.

([25]) At the time of writing this report, control measures had also been introduced by Bulgaria, Greece, Hungary and Spain, and there were indications that several other countries were considering them.

([26]) EMCDDA, 2009. *Report on the risk assessment of BZP in the framework of the Council decision on new psychoactive substances*. Also available at: http://www.emcdda.europa.eu/publications/risk-assessments/bzp

Concluding the risk assessment report, the Scientific Committee noted that a decision to control this drug has the potential to bring with it both positive and negative consequences. Potential positive consequences may include reduced availability and use of the drug. It is important, however, to anticipate and minimise any potential negative consequences of control. Control measures could create an illegal market in mephedrone with the associated risk of criminal activity. Furthermore, control should not inhibit the gathering and dissemination of accurate information on mephedrone to users and to relevant professionals.

3.3 'Spice' and synthetic cannabinoids

Since 2008, the 'Spice' phenomenon and the related psychoactive constituents, synthetic cannabinoid receptor agonists, have received considerable attention. In 2010, 11 new synthetic cannabinoids were reported via the EWS, bringing a total number of synthetic cannabinoids reported to more than 20. The compounds reported so far belong to six different chemical groups: naphthoylindoles (most of the JWH-compounds), phenylacetylindoles (JWH-250 and JWH-203), cyclohexylphenols (CP-compounds), classical cannabinoids (HU-210); and the two newly reported families in 2010 — benzoylindoles ([27]) and naphthoylnaphthalenes ([28]). These substances, often encountered in various combinations, are difficult to identify analytically and clearly pose challenges to forensic scientists.

The extent to which these products are used is largely unknown. A number of surveys aiming at examining the prevalence of use of 'Spice'-like products have been launched but the coverage and representativeness of the studies carried out are very limited.

Neither the purported herbal ingredients of 'Spice' and 'Spice'-like products, nor any of the synthetic cannabinoids found in them are internationally controlled under the 1961 or 1971 United Nations drug control conventions.

Responding to potential health concerns, at least 16 European countries have taken legal actions to ban or otherwise control 'Spice' products and related compounds as follows (in chronological order): Austria (January 2009), Germany (January 2009, emergency regulation; January 2010 permanent control), France (February 2009), Luxembourg (generic/analogue approach, May 2009), Poland (May 2009), Lithuania (May 2009), Estonia (July 2009), Sweden (September 2009), Latvia (November 2009), the United Kingdom (generic approach, December 2009), Romania (February 2010), Denmark (March 2010), Ireland (generic approach, May 2010), Italy (June 2010), Turkey (January 2011) and Bulgaria (February 2011).

Some Member States have placed one or more of the claimed herbal ingredients of 'Spice', such as *Leonotis leonurus* and *Nymphaea caerulea* (Poland and Latvia control both and Romania only the latter), on their lists of controlled substances. From May 2009, Switzerland controls 'Spice herbal mixes' under food regulation (5 grams allowed for personal use). Furthermore, in Belgium, synthetic cannabinoids are included in doping control measures.

Health-related adverse effects have been associated to 'Spice'-like products. At the end of 2010, Italy reported a number of hospitalisations due to adverse effects allegedly associated to JWH-122, found in 'Forest green' and 'Jungle Mistic Incense' products. In addition, Germany reported adverse effects attributed to the 'Lava red' product, which also contained JWH-122. This synthetic cannabinoid, which is a highly potent agonist at the CB_1 receptor, is monitored closely by the EWS. It was first notified in July 2010 and since then it has been encountered in at least eleven Member States, and in considerable amounts.

3.4 Public health warnings

The Council Decision stimulates the identification, monitoring and exchange of information on emerging trends in new uses of existing substances and on possible public health-related

([27]) RCS-4, 3-(4-hydroxymethylbenzoyl)-1-pentylindole, and AM-694.

([28]) CRA-13, notified in January 2011.

measures. The warning on adverse health effects of new psychoactive substances through timely and rapid public health alerts is one of the core activities of the EMCDDA EWS. In addition, in 2010, the EWS issued public health warnings to the Reitox network concerning unusual hazards of occurrences related to controlled drugs.

3.4.1 Adverse health effects related to new drugs

In 2010, the EWS issued public health warnings concerning adverse health effects of the following new psychoactive substances:

- MDPV

MDPV ([29]), first reported in 2008 by the United Kingdom and by Finland, is a derivative of pyrovalerone, which is controlled under Schedule IV of the 1971 UN Convention. Some fatalities and adverse health effects associated to the use of MDPV were reported in Finland and in the UK.

- Fluorotropacocaine (pFBT)

Fluorotropacocaine (first reported in 2008 by Finland) is a tropane derivative drug, which acts as a stimulant and local anaesthetic. Adverse effects associated to fluorotropacocaine were reported by Ireland in June 2010, where the substance was identified in two head shop products. The symptoms included increased heart rate, increased breathing rates and raised blood pressure. The majority of the patients experienced differing levels of anxiety and at least seven cases of psychotic episodes.

- Para-methoxyamphetamine (PMA) and para-methoxymethylamphetamine (PMMA)

Both PMA ([30]) and PMMA are known to have considerable toxicity and to have been responsible for fatal overdoses in the past. PMMA was risk assessed in 2001 in the framework of the 1997 Joint action on new synthetic drugs ([31]) and consequently controlled at European level.

In October 2010, the Dutch Drug Information Monitoring System (DIMS) alerted about their findings of powders sold as amphetamine, which contained up to 5–10% PMA and tablets with high content of PMMA sold as ecstasy. In the meantime it became clear that in Norway and in the Netherlands there had been a number of health incidents and fatalities related to PMMA, and a considerable number of PMMA seizures in Norway.

- Desoxypipradol (2-DPMP)

Desoxypipradrol (first reported in 2009 by Finland) is a close relative of pipradrol, which is listed in Schedule IV of the UN 1971 Convention. In October 2010, the United Kingdom NFP reported three fatal cases associated to desoxypipradol, one of which was related to the consumption of a sample of 'Ivory Wave', which contained the substance.

- 2-(Diphenylmethyl)pyrrolidine (desoxy-D2PM)

This stimulant substance, which is structurally related to diphenylprolinol (D2PM) and desoxypipradrol (which is in turn a derivative of pipradrol), has been reported in body-building products and is commercially available. In the United Kingdom, adverse health effects including severe and prolonged psychosis, raised heart rate and blood pressure were associated to the product 'A3A Methano', which contained desoxy-D2PM.

3.4.2 Unusual hazards of occurrences related to controlled drugs

In December 2009, an outbreak of anthrax among heroin injecting drug users was reported in Scotland, followed by additional fatalities in Germany and England. The European Centre for Disease Prevention and Control (ECDC) and the EMCDDA conducted a Joint threat assessment

([29]) MDPV (3,4-Methylenedioxypyrovalerone) is a cathinone.

([30]) Listed in Schedule I of the 1971 UN Convention on Psychotropic Substances since 1986.

([31]) EMCDDA, 2003. *Report on the risk assessment of PMMA in the framework of the joint action on new synthetic drugs*. Also available at: http://www.emcdda.europa.eu/html.cfm/index33349EN.html

([32]) and the EWS also issued an alert to the Reitox NFPs. In 2010, a follow up of the outbreak revealed additional related fatalities in the United Kingdom and Germany.

In June 2010, the UK Health Protection Agency issued an alert on the risks of wound botulism among injecting heroin users, after a case reported in London. Wound botulism is caused by *botulinum* toxin that is commonly found as spores in soil, and the source of the infection in the reported case was likely due to a batch of heroin contaminated with the bacteria. Following this alert, another case was reported in Germany.

In November 2010, information from the media about heroin shortage in the United Kingdom and Ireland prompted the EWS to issue an alert and to launch a revealing information collection on national situations. The results showed that while in some countries there seemed to be no evidence of such shortage (Romania, Portugal, France), the information received from Bulgaria, Poland, Slovenia, Switzerland, and Malta supported that information.

In Switzerland, several intoxications and fatalities among habitual cocaine users occurred due to unsuspected consumption of heroin. An alert was sent to the EWS of the neighbouring countries in January 2010, which allowed the identification of similar cases in Italy. In September 2010, a case of white heroin sold as cocaine was reported also in Switzerland, where the samples had been cut with more than 60 % of phenacetin, an adulterant typically used for cocaine. Following this alert, some Member States provided composition analysis of adulterated heroin samples.

([32]) Joint ECDC–EMCDDA threat assessment of the anthrax outbreak among heroin injecting drug users in Scotland and Germany (2009).

4. Key developments in the period 2005–10

The new drugs phenomenon has been going through a period of dynamic change during the last few years. The appearance of a large number of new unregulated synthetic compounds marketed on the Internet as 'legal highs' or 'not for human consumption' and specifically designed to circumvent drug controls shows the speed and sophistication at which the market reacts to control measures, and how globalisation and innovation present a growing challenge to current approaches to new psychoactive substances. This is illustrated not only in the increased number, but also in the diversity in type, of substances that have appeared on the European market. The spring and diversity of new drug families is largely due to the increased complexity and volatility of the European drugs market and to the way that these substances are being produced, distributed and marketed.

To 'design' a drug to replace a controlled substance is not a new concept. In the past, though, designer drugs were illicitly produced and marketed directly on the illicit market (from those based on fentanyl in the 1980s, to ring-substituted phenethylamines in the late 1980s and tryptamines in 1990s; to piperazines and cathinone derivatives in the early 2000s). An important difference today is the new interaction between the illicit and non-illicit markets, where chemicals are legally sourced but then sold as replacements for illicit psychoactive substances. In this context, it is important to consider the threat posed by the undesirable transition from a mostly online 'legal highs' market, originally driven by individual entrepreneurship, to one that involves organised crime.

The vast majority of the substances notified after the Council Decision 2005/387/JHA came into effect, i.e. after 21 May 2005, were new psychotropic substances (i.e. synthetic drugs) similar to those listed in Schedules I and II of the 1971 UN Convention on Psychotropic Substances. It seems likely that synthetic psychoactive substances will continue to play a major role and will be predominantly notified through the EWS. With rapid technological advances, for example, cheap organic synthesis coupled with the increased use of the Internet for marketing and selling new drugs, it may be expected that synthetic analogues of various drug groups will continue to appear. In the context of the 'legal highs' phenomenon it can be anticipated that the concept of new drugs will continue to evolve at an unprecedented speed. The appearance of synthetic cannabinoids, synthetic cocaine derivatives, ketamine and phencyclidine derivatives mark the latest stages in this development.

In 2009–10, the EWS received reports of substances that were based on slight modifications of the chemical structures of medicines with known abuse potential. The rise of new 'designer medicines' would be an unwelcome addition to the task of ensuring that prescribed medicines are not diverted and misused. It is also another example of how innovation in the illicit market requires a robust and joined-up response from pharmaceutical and drug control regulatory frameworks. This issue is more of a potential threat than an immediate problem, but given the speed at which new developments occur in this area, it is important to anticipate future challenges. The suggestion that in the future we will see increasing numbers of new drugs based on existing pharmaceutical products but intended for non-therapeutic use would be particularly worrying.

The discovery of a psychoactive substance outside legal control allows suppliers to make a profit, but at an unknown risk to the consumers' health. One of the new developments of the 'legal highs' phenomenon is the rising and alarming potential health-related adverse effects associated to 'legal highs' products (see Section 3.3 and Section 3.4.1), and also the dynamic changes in the composition of the products.

In the period 2005–10, three substances satisfied the criteria for the launch of a joint report. From the information collected, Europol concluded that in each case organised crime was involved, even though this was often related to illicit tableting, distribution and sale of tablets with logo imprints usually associated with ecstasy (MDMA).

5. Outlook on future challenges

5.1 Identification of new substances

Over the last years, the number and diversity of new drugs are not only increasing rapidly but also becoming widespread. The flood of new substances requires substantial efforts to keep abreast of new developments. The effective recognition of substances presents not only analytical challenges but also requires the synergic cooperation of different laboratories (not only among different national services, but also internationally) and increased resources to provide for new-generation sophisticated analytical techniques. Owing to limited resources in forensic science laboratories, not all substances or components of all mixtures are necessarily identified, particularly those that at the time of analysis were not controlled. Furthermore, in the absence of reference standards, the complexity of some analytes causes further difficulties, particularly when mixtures or difficult matrices are present or when isomers may exist. The analysis of metabolites in body fluids also presents additional challenges.

Among the initiatives to keep pace with new developments are projects on national test-purchase and analysis of the content of 'legal highs' products, which provide a snapshot of what is available on the EU market during a given (short) period of time and can contribute effectively to the dynamisation of drug monitoring systems. However, these projects, which are expensive and time consuming, are often based on the initiative of individual researchers, rather than on a structured European strategy.

In this context, the availability of reference materials is of the utmost importance if forensic and toxicology laboratories are to identify new psychoactive substances, especially in the case of a new synthetic drug about which limited scientific literature is available. However, there is no European Union system for the synthesis and sharing of reference substances. If a system that can successfully function in the long term is to be implemented, it will be important to consider how coordination can be established and how access to reference materials can be facilitated as this is a key information challenge and an area in which coordinated actions bring clear added value.

5.2 Risk assessment

The need for more pre-risk assessment research (pharmacology, toxicology, epidemiology) as well as post-risk assessment monitoring (including research on impact of control measures) is increasingly recognised. However, as a response to some of the new developments, there have also been calls for a more ‘generic approach’ to assessing the risks (and consequently controlling) new substances. Although this kind of approach would be more cost-effective, it would also be more difficult practically and less scientifically robust, for example, there will be substantial variations in the effects, potential harms, etc., between the different substances included in any generic group. Furthermore, the size/composition of the group or class would be difficult to determine and unlikely ever to be sufficiently inclusive.

6. Conclusion

Recent developments have led to new psychoactive substances becoming widely available at an unprecedented pace. The speed at which they appear and the way they can be distributed challenges the established procedures for monitoring, responding to and controlling the use of new psychoactive substances. This is in turn reflected in much higher political, general public (media, society at large) and scientific interest and concern about the 'legal highs' phenomenon.

Responding to the need to remain vigilant and react rapidly to new substances and products identified, the EWS network has increased its operational capacity and expanded to include not only new forensic science and toxicological laboratories, but also many independent researchers as well as a range of drug and law enforcement professionals. The use of quantitative routine epidemiological indicators, qualitative research and a wide range of multidisciplinary and supplementary information sources and leading-edge indicators (e.g. Internet monitoring) are increasingly combined in order to obtain a holistic picture of new trends at European level.

All these have increased the profile of the EWS and the workload of the networks at national and European levels while resources often remain unchanged. A further observation of the current system is that it remains reactive rather than proactive. So whilst significant reporting capabilities now exist which facilitate the speedy exchange and triangulation of information from existing sources, the current system lacks the ability to anticipate emerging threats, by actively purchasing, synthesising, and studying new compounds. This deficiency could be addressed through investment to improve capacity for investigative forensic analysis and research at the European level, linked to the EWS. Both, the information exchange mechanism and the risk assessment would benefit if there was a clear mandate to purchase new psychoactive substances and analyse them; to purchase and synthesise reference samples; to disseminate analytical information to Member States and to carry out toxicological and epidemiological studies.

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 to the EMCDDA and Europol for the first time in 2010 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] (herineafter 'the Joint Action') taking into account the external evaluation commissioned by the European Monitoring Centre on Drugs and Drug Addiction (hereinafter 'the EMCDDA') of the early warning system. The assessment showed that the Joint Action had fulfilled its expectations. Nevertheless, the outcome of the assessment made it clear that the Joint Action was in need of reinforcement and reorientation. In particular, its main objective, the clarity of its procedures and definitions, the transparency of its operation, and the relevance of its scope had to be redefined. The Communication from the Commission to the European Parliament and the Council on the mid-term evaluation of the EU Action Plan on Drugs (2000-2004) indicated that changes to the legislation would be introduced in order to enhance action against synthetic drugs. The mechanism as established by the Joint Action should therefore be adapted.

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

(5) The new psychoactive substances covered by this Decision may include medicinal products as defined in Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products [3] and in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use [4].

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

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

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

[1] Opinion delivered on 13 January 2004 (not yet published in the Official Journal).

[2] OJ L 167, 25.6.1997, p. 1.

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

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

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

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

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

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

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

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

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

HAS DECIDED AS FOLLOWS:

Article 1

Subject matter

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

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

Article 2

Scope

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

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

(b) the 1971 United Nations Convention on Psychotropic Substances, that may pose a comparable threat to public health as the substances listed in Schedule I or II or III or IV thereof.

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

Article 3

Definitions

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

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

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

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

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

(d) 'marketing authorisation' means a permission to place a medicinal product on the market, granted by the competent authority of a Member State, as required by Title III of Directive 2001/83/EC (in the case of medicinal products for human use) or Title III of Directive 2001/82/EC (in the case of veterinary medicinal products) or a marketing authorisation granted by the European Commission under Article 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ([1]);

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

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

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

Article 4

Exchange of information

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

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

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

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

Article 5

Joint Report

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

2. The Joint Report shall contain:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 6

Risk assessment

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

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

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

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

The Risk Assessment Report shall include:

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

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

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

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

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

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

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

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

Article 7

Circumstances where no risk assessment is carried out

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

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

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

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

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

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

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

The Commission shall report to the Council on the outcome.

Article 8

Procedure for bringing specific new psychoactive substances under control

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

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

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

Article 9

Control measures taken by Member States

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

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

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

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

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

Article 10

Annual report

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

Article 11

Pharmacovigilance system

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

Article 12

Repeal

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

Article 13

Publication and taking effect

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

Done at Brussels, 10 May 2005.

For the Council
The President
J. KRECKÉ

European Monitoring Centre for Drugs and Drug Addiction

EUROPOL

EMCDDA–Europol 2010 Annual Report on the implementation of Council Decision 2005/387/JHA

Annex 2 — New psychoactive substances reported to the EMCDDA and Europol for the first time in 2010 under the terms of Council Decision 2005/387/JHA

1. **2C-B-BZP** (1-(4-bromo-2,5-dimethoxybenzyl)piperazine) – 18 January 2010 – Germany
2. **MDAI** (5,6-methylenedioxy-2-aminoindane) – 26 February 2010 – Sweden
3. **β-Me-PEA** (2-phenylpropan-1-amine) – 26 February 2010 – Norway
4. **N-benzyl-1-phenethylamine** – 26 February 2010 – Norway
5. **N,N-dimethylphenethylamine** – 26 February 2010 – Norway
6. **4-FMA** (4-fluoromethamphetamine) – 24 March 2010 – Norway
7. **RCS-4** ((4-methoxyphenyl)(1-pentyl-1H-indol-3-yl)methanone) – 25 May 2010 – Hungary
8. **JWH-081** (1-pentyl-3-(4-methoxy-1-naphthoyl)indole) – 2 June 2010 – Latvia
9. **Naphyrone** (naphthylpyrovalerone) – 11 June 2010 – Sweden
10. **Iso-ethcathinone** (1-ethylamino-1-phenyl-propan-2-one) – 18 June 2010 – Ireland
11. **DMAA** (1,3-dimethylamylamine) – 21 June 2010 – Ireland
12. **Dimethocaine** ((3-diethylamino-2,2-dimethylpropyl)-4-aminobenzoate) – 21 June 2010 – Ireland
13. **JWH-073 methyl derivative** (1-Butyl-3-(1-(4-methyl)naphthoyl)indole)) – 30 June 2010 – Germany
14. **Buphedrone** (2-(methylamino)-1-phenylbutan-1-one) – 5 July 2010 – Finland
15. **4-methylethcathinone** (2-Ethylamino-1-(4-methylphenyl)-1-propanone) – 8 July 2010 – United Kingdom
16. **AM-694** (1-[(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophenyl)methanone) – 19 July 2010 – Ireland
17. **JWH-122** (1-pentyl-3-(4-methyl-1-naphthoyl)indole)) – 23 July 2010 – Latvia
18. **MPBP** (4'-methyl-α-pyrrolidinobutyrophenone) – 27 July 2010 – Bulgaria
19. **JWH-015** (1-propyl-2-methyl-3-(1-naphthoyl)indole)) – 27 July 2010 – Austria
20. **4-MBC** (4-methyl-N-benzylcathinone) – 16 August 2010 – United Kingdom
21. **MPPP** (4'-Methyl-α-pyrrolidinopropiophenone) – 16 August 2010 – United Kingdom
22. **CP47,497 (C8 + C2) variant** – 17 August 2010 – United Kingdom

23. **1-naphthalen-1-yl-2-pyrrolidin-1-yl-pentan-1-one** – 18 August 2010 – United Kingdom

24. **Pentylone** (2-Methylamino-1-(3,4-methylenedioxyphenyl)pentan-1-one) – 3 September 2010 – United Kingdom

25. **M-ALPHA** (1-methylamino-1-(3,4-methylenedioxy-phenyl)propane) – 3 September 2010 – United Kingdom

26. **5-MeO-DPT** (5-methoxy-N,N-dipropyltryptamine) – 13 September 2010 – Finland

27. **β-Ethyl-Methcathinone** (2-methylamino-1-phenyl-1-pentanone) – 17 September 2010 – Austria

28. **JWH- 210** (4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone) – 22 September 2010 – Germany

29. **3,4-Dimethylmethcathinone** (1-(3,4-dimethylphenyl)-2-(methylamino)propan-1-one) – 13 October 2010 – Hungary

30. **JWH-203** (2-(2-chlorophenyl)-1-(1-pentylindol-3-yl)ethanone) – 14 October 2010 – Latvia

31. **JWH-019** (1-hexyl-3-(1-naphthoyl)indole) – 26 October 2010 – Finland

32. **Methoxetamine** (2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone) – 9 November 2010 – United Kingdom

33. **3-(4-Hydroxymethylbenzoyl)-1-pentylindole** – 9 November 2010 – United Kingdom

34. **MDPBP** (3',4'-methylenedioxy-α-pyrrolidinobutyrophenone) – 17 November 2010 – United Kingdom

35. **3-MeO-PCE** (3-methoxyeticyclidine) – 17 November 2010 – United Kingdom

36. **DiButylone or bk-MMBDB** (2-dimethylamino-1-(3,4-methylenedioxyphenyl)-butan-1-one) – 18 November 2010 – Finland

37. **Arecoline** (methyl methyl-1,2,5,6-tetrahydropyridine-3-carboxylate) – 22 November 2010 – United Kingdom

38. **BMDP** (2-benzylamino-1-(3,4-methylenedioxyphenyl)propan-1-one) – 9 December 2010 – United Kingdom

39. **BMDB** (2-benzylamino-1-(3,4-methylenedioxyphenyl)butan-1-one) – 9 December 2010 – United Kingdom

40. **5-APB** (5-(2-aminopropyl)benzofuran) – 14 December 2010 – United Kingdom

41. **Desoxy-D2PM** (2-(diphenylmethyl)pyrrolidine) – 23 December 2010 – United Kingdom