European Monitoring Centre for Drugs and Drug Addiction

EUROPOL

EMCDDA–Europol 2009 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 is the fifth EMCDDA–Europol Annual Report on activities 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 2009, 24 new psychoactive substances were officially notified for the first time in the European Union through the information exchange, the Early-Warning System (EWS) which was set up by the Decision. The number of new compounds reported in 2009 was higher than ever; all were synthetic, including two substances with medicinal properties.

The emergence of new, smokable herbal products laced with synthetic cannabinoids and the growing popularity of various synthetic cathinones can be seen as significant new developments in the field of so-called 'designer drugs', better known now as 'legal highs'. 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 presents a growing challenge to current approaches to monitoring, responding to and controlling the use of new psychoactive substances. The report, therefore, details this important development. Under the so-called 'Spice' phenomenon a total of nine synthetic cannabinoids were reported via the EWS. This phenomenon received considerable attention from legislators, policymakers, experts and the media.

At the end of 2009 and in January 2010, the EMCDDA and Europol examined the available information on mephedrone (4-methylmethcathinone), through a joint assessment based upon the criteria set out in the EWS operating guidelines ([2]). The two organisations agreed that the information collected on mephedrone satisfied the assessment criteria and concluded that sufficient evidence on mephedrone had been accumulated so as to launch a procedure for the collection of further information for the production of a joint report, in accordance with Article 5 of the Decision. As this report deals in detail with issues related to mephedrone, it was considered important to include information that became available during the first two months of 2010, rather than only that for the reporting period of 2009.

Furthermore, the report includes a brief follow-up on the piperazine derivative *m*CPP, which was covered extensively in previous reports. Data from different sources highlight a marked increase of the percentage of 'ecstasy' tablets containing *m*CPP while the availability of MDMA on the market seems to be decreasing. This finding corresponds with the growing number of legal alternatives to controlled drugs, including synthetic cathinone derivatives, such as mephedrone.

Finally, the last two sections include a brief threat assessment, a review of the Early-Warning System's achievements, and a look into some of the challenges which it may encounter during the coming years. In particular, the focus is on issues that relate to identifying, monitoring and understanding the nature of various new substances, which

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

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

increasingly appear on the Internet and on the European drug markets, as well as the innovation and sophistication of their marketing.

In view of the 2010 assessment of the functioning of Council Decision 2005/387/JHA, which was called for in the EU Drugs Action Plan for 2009–12 ([3]), the report may play a useful role by highlighting additional factors to those already reported in previous annual reports concerning the implementation of the Decision.

([3]) EU Drugs Action Plan for 2009–12 (2008/C 326/09).

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). 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 fifth Annual Report on the implementation of the Decision for the period January to December 2009. 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 forthcoming 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

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([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.

psychoactive substances, the report presents sufficiently detailed information, while avoiding highly technical descriptions. However, more comprehensive information on the new substances described in the report is available from the EMCDDA and Europol.

2. Implementation arrangements and cooperation with the EU pharmacovigilance system

2.1 Specific implementation arrangements

2.1.1 Risk assessment of new psychoactive substances – operating guidelines

The new operating guidelines are fully in line with the scope of the Decision; they provide a sound methodological and procedural basis for carrying out the risk assessment. Thus, the guidelines are a useful tool for the EMCDDA's Scientific Committee, assisting its efforts to present to the Council and Commission a state of the art review of the available scientific and law enforcement evidence on the potential health and social risks posed by any new psychoactive substance under assessment. The official publication of the guidelines will be available in April 2010.

2.1.2 Cooperation with the United Nations system

Article 5.2(e) of the Decision requires EMCDDA–Europol joint reports 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) ([6]) on the assessment status of mephedrone in the UN system (see Section 3.2). The WHO has already informed the EMCDDA that mephedrone is not under assessment in the UN system.

2.1.3 Assistance to national EWSs

The European EWS regularly provides assistance to partners from the national EWSs assisting them in the identification of new substances. This is done by: providing analytical data; facilitating the exchange of data between forensic laboratories; and cross-checking information from the national databases. The EWS is frequently consulted by the Member States, individual experts and scientists in relation to various new psychoactive substances. Where necessary, assistance and technical support is provided to some Member States and candidate countries.

2.1.4 Legal highs and structured monitoring of the Internet

The EWS actively monitors unregulated psychoactive products – the so-called 'legal highs' – sold via Internet or specialised (smart, head) shops, advertised with aggressive and sophisticated marketing strategies, and in some cases intentionally mislabelled with purported ingredients differing from the actual composition. A distinct feature of the 'legal highs' phenomenon is the speed at which the suppliers circumvent drug controls by offering new unregulated alternatives that target specific groups of recreational drug users.

The 'legal highs' phenomenon encompasses: a wide range of products, from herbal mixtures to synthetic or 'designer' drugs; varied advertising strategies, from room odorisers, through herbal incenses, to bath salts; and different patterns of use, including

([6]) 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.

herbal smokable mixes, snorting powders, tablets and liquid preparations for oral consumption.

Monitoring the on-line emergence, availability and sales of new psychoactive substances has been an integral part of the EWS in recent years. Between 2007 and 2009 the EMCDDA has carried out three thematic Internet snapshots. However, as of the last quarter of the 2009, the EMCDDA has elaborated and is currently piloting a methodologically sound, multilingual audit of on-line shops which are EU-based or dispatch to EU Member States. The Internet snapshots are seen as complementary to other EWS data sources such as seizures, reports on use and toxicity.

The 2010 snapshot focuses on 'legal highs', GHB/GBL and hallucinogenic ('magic') mushrooms. In the period 18 January to 5 February the EMCDDA audited websites in fourteen EU languages (Spanish, Czech, Danish, German, Greek, English, French, Italian, Hungarian, Dutch, Polish, Portuguese, Slovak, and Swedish). Preliminary results from the snapshot will be available in March 2010.

2.2 Cooperation with the EMA and the pharmacovigilance system

The EMA is a key partner in the implementation of the system set up by the Decision. Within the framework of the Decision, to ensure that no deterioration of either human or veterinary healthcare is permitted, all possible precautions are taken by the EMCDDA and the EMA to guarantee that substances of established and acknowledged medical value are identified at an early stage.

The EMCDDA and the EMA are implementing a bilateral exchange of data available through the Reitox EWS and the European Union pharmacovigilance system. Formalising the scope and nature of the information exchange on the misuse of substances with medical value (i.e. medicinal products authorised in the Community) is an area under development. A memorandum of understanding between the two agencies was drafted during 2009 and early 2010, and is expected to be signed by the end of the year. Once agreed, the text of the memorandum of understanding will be presented to the EMCDDA and EMA management boards.

During the reporting period, consultations and exchange of information took place between the EMCDDA and the pharmacovigilance system on the following substances with medicinal properties: etaqualone ([7]); benzydamine hydrochloride ([8]) (Tantum rosa); and pregabalin ([9]) (Lyrica). No information on etaqualone was available in the pharmacovigilance database as it is not a centrally authorised medicinal product; whereas benzydamine is a marketed product but no information related to misuse has been reported so far.

([7]) Etaqualone (3-(2-ethylphenyl)-2-methyl-quinazolin-4-one) is closely related to methaqualone. It has sedative and hypnotic properties and in the past it was used for treatment of insomnia

([8]) Benzydamine hydrochloride is reportedly a central nervous system stimulant and hallucinogen with local anaesthetic and analgesic properties, which is used as an anti-inflammatory and pain reliever. Recreational use of this drug has been reported to the EWS by Romania and Poland. Benzydamine has not been formally reported via the EWS.

([9]) Pregabalin is a prescription medicine marketed by Pfizer under the trade name Lyrica. It is used to treat several conditions, including neuropathic pain, epilepsy, and anxiety. Pregabalin is structurally related to the naturally occurring mammalian neurotransmitter gamma-aminobutyric acid, and although its precise mechanism of action is still unclear, it is reported to decrease central neuronal excitability and to reduce the release of several neurotransmitters, including glutamate, and noradrenaline.

A clinical assessment conducted in 2004 by the EMA concluded that the risk–benefit ratio of Lyrica was favourable and marketing authorisation was granted. However, a recent review of pharmacovigilance data indicates that there might be concerns related to misuse. Consequently, the product's summary characteristics (SPC) are currently being revised to include a warning of possible misuse related to prescribing to individuals with drug-use history.

The misuse of pregabalin (Lyrica) seems to be a concern in Finland, Sweden and Norway and has been reported through the pharmacovigilance system by these countries. In addition, the EMCDDA presented information reported via the EWS about deaths in Finland, Sweden and the United Kingdom where pregabalin has been found in forensic toxicological analysis.

User reports on the Internet suggest that pregabalin is used in recreational settings with reported effects similar to those of GHB, ecstasy, and benzodiazepines. It is reported to have sedative effects and to alleviate heroin (opiate) withdrawal symptoms. In addition, pregabalin is reported to be used in combination with other substances to potentiate their effects.

3. Results achieved in 2009

3.1 New psychoactive substances notified in 2009

During 2009, a total of 24 new psychoactive substances were officially notified for the first time in Europe via the EWS (Annex 2). This is the largest number of substances ever reported in a single year. This may be explained by the high number of synthetic cannabinoids reported over a short period of time. Notably, all 24 new substances were synthetic.

Nine of the 24 new psychoactive substances reported were synthetic cannabinoids from four distinct chemical groups (Annex 2 — substances 4 to 8, 11, 15, 16, 22). Beyond these, there has been a mix of substances belonging to more established chemical families – five phenethylamines (Annex 2 — substances 1, 10, 14, 21, 23), two tryptamines (Annex 2 — substances 9, 13) and four synthetic cathinones (Annex 2 — substances 2, 17, 19, 20). It is worth noting that no new piperazines or psychoactive plants were reported in 2009. Synthetic cannabinoids and synthetic cathinone derivatives are dealt separately in Sections 3.4 and 3.3.1, respectively.

Furthermore, two substances with medicinal properties have been reported (Annex 2 — substances 18, 24) as well as a narcotic analgesic ODT (10), which is a metabolite of the medicinal product tramadol (Annex 2 — substance 12).

In addition to the formal notifications received through a Reporting Form, the Member States also provide biannual updates through Reitox EWS progress and final reports. Subsequently, profiles for all new substances are created in the European database on new drugs (EDND). In 2009, 24 new substance profiles were created in the EDND. The list of newly notified substances is reviewed regularly by the EMCDDA and Europol in order to identify those with a potential to trigger a joint report (see Section 3.2).

([10]) o-Desmethyltramadol (3-{-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl}phenol) is a potent μ-opioid agonist which is a centrally acting synthetic opioid analgesic.

3.2 Information collection for a joint report on mephedrone (Article 5.1)

In the last few years, synthetic cathinones have been increasingly reported via the EWS. At present, fifteen synthetic cathinones are being monitored by the EMCDDA and Europol. These 'designer' compounds are derivatives of the parent compound cathinone, which is one of the psychoactive principles in the plant khat (*Catha edulis*), and structurally related to amphetamine. Two drug profiles, khat and synthetic cathinone derivatives, will be published by the EMCDDA in 2010 ([11]).

In October 2009, the EMCDDA and Europol convened a meeting to review the list of substances with potential to trigger the launch of a joint report under Article 5 of the Council Decision 2005/387/JHA (see Section 3.3). The substances examined belong to three different chemical groups: cathinones (mephedrone, methylone and methedrone); phenethylamines (4-fluoroamphetamine); and benzodifurans (bromo-dragonfly).

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 following criteria set out in the EWS operating guidelines:

1. the amount of the material seized;

2. evidence of organised crime involvement;

3. evidence of international trafficking;

4. toxicopharmacological properties;

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 available on mephedrone satisfied all of the above criteria. Therefore, the two organisations concluded that sufficient evidence had been accumulated to launch a formal procedure for the collection of further information for the production of a joint report, in accordance with Article 5.1 of Council Decision 2005/387/JHA ([12]).

Mephedrone (4-methylmetcathinone) is the *para*-methyl derivative of methcathinone – a scheduled drug in the 1971 UN Convention. Reported for the first time via the EWS in 2008, mephedrone seems to have gained popularity among drug users leading to specific demand for the substance. This has also brought high media attention, mainly in the United Kingdom, but also in other Member States. In 2009, seizures of relatively important quantities have been reported in Germany, the Netherlands, Sweden and the United Kingdom. Furthermore, there has been one toxicologically confirmed mephedrone-related death in Sweden as well as some suspected cases in the United Kingdom. Some Member States – Denmark, Germany, Estonia, Romania and Sweden –

([11]) EMCDDA drug profiles, available at: http://www.emcdda.europa.eu/publications/drug-profiles

([12]) Article 5.1 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.'

as well as Croatia and Norway have recently introduced control measures on this substance. There are indications that Ireland and the United Kingdom are also considering control measures. In addition, it is possible that mephedrone may be controlled under medicines legislation in some Member States.

Mephedrone is readily available on the Internet, where it may be sold as a 'legal high', a 'legal' alternative to cocaine or 'ecstasy'. Alternative advertising strategies employed by the vendors included offering mephedrone as a 'research chemical', 'bath salts', 'for botanical research', 'plant food', 'plant feeder', often with a note saying 'not for human consumption' in order to circumvent potential control mechanisms. However, the co-existence on some sites of 'plant food' and 'rave equipment' for sale suggests a different market. Often no indication of the presence of psychoactive substances is given in the list of ingredients of the marketed products.

3.3 Substances with a potential to trigger a joint report

3.3.1 Synthetic cathinones

Methylone (3,4-methylenedioxymethcathinone) is the β-keto-cathinone derivative of MDMA – a scheduled drug in the 1971 UN Convention. Reported for the first time in 2004 as a liquid solution sold as a vanilla-scented room odoriser, it was already singled out in the 2005 EMCDDA–Europol Annual Report on the implementation of Council Decision 2005/387/JHA. Although methylone resembles MDMA in its behavioural and pharmacological profile, the observed subjective effects of both are not identical. Denmark, Sweden and Romania have implemented control measures on this substance.

Methedrone (4-methoxymethcathinone) is the cathinone derivative of PMMA ([13]), a substance that was risk assessed in 2003 and is now controlled throughout the EU Member States. It may have a similar pharmacological profile and health risks to PMMA and PMA ([14]). Notified for the first time via the EWS in October 2009, methedrone was found in the toxicology of two deaths in Sweden. In Sweden and also Romania methedrone is listed as a controlled substance.

A third substance worth mentioning is 3,4-methylenedioxypyrovalerone (MDPV), a derivative of pyrovalerone ([15]), which is controlled under Schedule IV of the 1971 UN Convention. MDPV was first reported via the EWS at the end of 2008, it acts by releasing and inhibiting the reuptake of the monoamine neurotransmitters, and is reported to have amphetamine-like stimulant effects. Denmark and Sweden have implemented control measures on this substance, while other Member States, for example Cyprus, are also considering doing so.

3.3.2 Other substances

4-Fluoroamphetamine (4-FMP) is the *para*-fluoro derivative of amphetamine, and reportedly exhibits weaker stimulant effects. Officially notified for the first time via the EWS in December 2008, 4-FMP has been seized in relatively important quantities in several Member States. 4-FMP has often been encountered as an ingredient in 'ecstasy' tablets, probably due to the lack of the chemical precursor BMK. In 2009, control

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([13]) Para-methoxymethylamphetamine

([14]) Para-methoxyamphetamine

([15]) 4-Methyl-α-pyrrolidino-valerophenone

measures for this substance were implemented in Denmark, Lithuania and Sweden. Norway is also considering control measures.

Bromo-dragonfly ([16]) (BDF) is a stimulant benzodifuran reportedly active in very small doses. BDF was already reported in the 2006 and 2007 EMCDDA–Europol Annual Reports on the implementation of Council Decision 2005/387/JHA and singled out as a substance that causes specific concern in terms of its potency and toxicity. In October 2009, BDF was toxicologically associated with one death in Denmark, where it is controlled. BDF is also controlled in Norway, Sweden and Romania.

3.4 'Spice' and synthetic cannabinoids

At the end of 2008 it was found that a 'smoking mixture', known as "Spice" and monitored by the EWS under this name was not the innocuous herbal product that it purported to be. The real psychoactive constituents first identified in December 2008 were synthetic additives/substances, in particular the cannabinoid receptor agonist ([17]) JWH-018, which mimic the effects of tetrahydrocannabinol (Δ^9-THC or THC) in cannabis.

3.4.1 Synthetic cannabinoids added to 'Spice' products

In 2009, the so-called 'Spice phenomenon' continued to receive considerable attention by policymakers, experts and the media. Significant efforts have been devoted by the Member States to the identification of its synthetic and herbal ingredients. A Thematic paper: *Understanding the 'Spice' phenomenon* was published by the EMCDDA in 2009 ([18]). Throughout the year, the names and brand packaging of 'Spice'-like products have continued to diversify. Above all, their actual composition in terms of synthetic additives is dynamically changing and rapidly responding to the newly implemented control measures.

After the identification of JWH-018 in December 2008, nine new synthetic cannabinoids have been reported through the EWS in 2009. Similarly to JWH-018, three of the new reported compounds (JWH-073, JWH-298 and JWH-200) belong to the naphthoylindole family, while the remaining compounds belong to different chemical groups: phenylacetylindoles (JWH-250); cyclohexylphenols (CP-47,497 and its three homologues); and dibenzopyrans (HU-210). The latter is also referred to as a 'classical cannabinoid', since it is a synthetic compound structurally closely related to THC.

It remains an open question if there will be a wider, specific demand for any of these particular substances. With this in mind, the need for further action as stipulated by Council Decision 2005/387/JHA remains an option for future review. The EWS will remain vigilant in this respect, as various new ('Spice' or 'Spice'-like) herbal products with different packaging and names seem to be continuously appearing. This, together with the variety and number of synthetic cannabinoids (or other substances) that could be potentially added to the herbal products, continues to pose challenges for identification, monitoring and risk appraisal of the phenomenon.

([16]) Bromo-benzodifuranyl-isoprophylamine

([17]) An agonist is a chemical substance that binds to a specific receptor of a cell and triggers an activity by the cell. An agonist often mimics the action of endogenous or naturally occurring substances.

([18]) 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

Detailed information on the chemistry of all the identified synthetic cannabinoids is available in the EMCDDA's drugs profile published in 2009 ([19]) and in Annex 3.

3.4.2 Control measures

None of the synthetic cannabinoids is under international control by virtue of the UN drug control conventions and there is no information on any of them having been authorised as medicinal products in the European Union. Responding to potential health concerns, some Member States have taken legal action to ban or otherwise control 'Spice' products and related compounds. At the time of the writing of this report, the following Member States control some or all of the above-described compounds: Austria, Denmark, Estonia, France, Germany, Latvia, Lithuania, Luxembourg, Poland, Romania, Sweden and the United Kingdom. Cyprus, Ireland and Slovakia are also considering control measures.

The purported herbal ingredients of 'Spice' products are not internationally controlled under the 1961 and 1971 UN conventions. 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 instigated control measures for 'Spice herbal mixes' under its food regulation.

3.5 Follow up on mCPP and BZP

Both 1-(3-chlorophenyl) piperazine (*m*CPP) and 1-benzylpiperazine (BZP) continue to be monitored through the EWS reporting mechanism.

In 2009, *m*CPP still appeared to be the most widely available 'new synthetic drug' (i.e. internationally non-controlled) on the European illicit drug market, which was encountered alone or in combination with MDMA ('ecstasy'). Data from the EWS originating from different sources and Member States (Denmark, the Netherlands and the United Kingdom) point at a marked increase in the percentage of ecstasy tablets containing *m*CPP, while the percentage of ecstasy tablets containing MDMA as well as the amount of MDMA in ecstasy tablets decreased in the first half of 2009. This fact could be explained by fluctuations in the availability of MDMA precursor chemical PMK, but the aggressive marketing of novel psychoactive substances and their appeal to users should also be considered. For example, seizure data from the United Kingdom indicates that towards the end of 2009 there was a decline in seizures of both piperazines and MDMA, which was partly compensated by an increase in mephedrone seizures. However, the specific dynamic is difficult to interpret and no definitive conclusion can be drawn, as the ecstasy market cannot be understood without taking into account the availability of other established stimulant drugs such as cocaine and amphetamine.

Following the 2008 Council Decision to submit BZP to control measures, consequently this was adopted throughout all the European Union Member States, it seems that the availability and the popularity of BZP among users has been decreasing. However, occasional large seizures continue to occur in addition to a number of smaller ones.

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

3.6 Additional Information exchange

The Council Decision stimulates the identification, monitoring and exchange of information on emerging trends in new uses of existing substances and on possible public health-related measures. By contributing information and analysis from various sources, forensic and toxicological laboratories and law enforcement organisations, the EWS is an active player in the EMCDDA–Europol efforts to detect, track and understand emerging drug trends.

In addition, in 2009, the EWS issued public health warnings to the Reitox network partners concerning unusual hazards of occurrences related to controlled drugs, adulterants, etc.

3.6.1 Unusual adulterants of cocaine and heroin

According to reports from the United Kingdom and Dutch Reitox NFPs, levamisole ([20]) was increasingly found as an adulterant in cocaine samples seized in 2009. This is significant, as in the USA, levamisole was recently detected in over 70% of cocaine samples analysed and was found to cause severe health complications ([21]).

In September 2009, the EMCDDA issued a warning and launched an audit among the Reitox NFPs. The questionnaire was completed by 22 Member States ([22]) with the participation of national toxicology, forensic science and custom services. The results are not conclusive, but they seem to confirm that there has been an increase in the percentage of cocaine samples adulterated with levamisole and that its concentration has also increased.

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 Control (ECDC) and the EMCDDA conducted a Joint Threat Assessment and the EWS also issued an alert to the Reitox NFPs.

In Switzerland, several intoxications and fatalities among habitual cocaine users occurred due to unsuspected consumption of heroin. An alert was sent to the EWS correspondents of the neighbouring countries which allowed the identification of similar cases in Italy.

3.6.2 Other substances in recreational drugs

Information on various uncommon controlled or non-controlled substances, with or without psychoactive properties, is occasionally exchanged through the EWS and placed in a 'Miscellaneous section' at the EDND. For instance, EWS alerts have been issued on substances such as carbaryl, 2,4-dinitrophenol and piperonal.

([20]) Levamisole is a veterinary anti-parasitic agent and in the past it was also used in human medicine as an immunostimulant. It has been encountered earlier as an adulterant in Europe (for example, in December 2004, it was reported in cocaine seizures to the Early-Warning System in Belgium, France and the Netherlands).

([21]) A number of adverse effects of levamisole have been reported, of which the most alarming is agranulocytosis – a haematologic condition that involves severe leukopenia (decrease in the number of white blood cells) and can lead to rapidly-developing life threatening infections. Although it is unclear what is the toxic dose for levamisole, agranulocytosis appears to occur in continuous dose regimens.

([22]) Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Lithuania, Malta, the Netherlands, Portugal, Romania, Slovenia, Spain, Sweden, United Kingdom, and Croatia and Norway

Carbaryl, a widely used pesticide that belongs to the carbamate chemical group, was found in illicit drug tablets in Turkey. Although it is unclear if it was added intentionally or accidentally, information on the details of the tablets was circulated for cross-checking with national databases for similar cases.

2,4-Dinitrophenol (DNP), a synthetic compound primarily used for scientific research and in industry, was seized in Sweden in the form of powder and capsules. Like other nitrophenols, DNP is highly toxic and may cause poisoning by inhalational, dermal and oral routes. In addition, DNP is assumed to have embryotoxic, carcinogenic and mutagenic effects.

The drug precursor piperonal was found in recreational drug tablets in Bulgaria and Italy. Piperonal is an aromatic aldehyde used as flavouring and in perfume. It can also be used as a chemical for the production of amphetamine type stimulants, such as MDMA and MDA. Although it is not a new psychoactive substance as defined by the Decision, the seizure occurred in the form of tablets that resembled recreational drug tablets.

4. Outlook on future challenges

The emergence of new, smokable herbal products laced with synthetic cannabinoids and the growing popularity of synthetic cathinones can be seen as significant new developments in the field of so-called 'designer drugs' – better known now as 'legal highs'. An immediate challenge could be that, in 2010 various combinations of synthetic cathinones or synthetic cannabinoids are encountered (as was the case with piperazine derivatives) leading to further difficulties in their analytical identification.

It can be anticipated that the concept of 'designer drugs' from those based on fentanyl in the 1980's, to ring-substituted phenethylamines in the late 1980's and tryptamines in 1990's; to piperazines and cathinone derivatives in the 2000's, will continue to change at an unprecedented speed. With rapid technological developments, for example cheap organic synthesis coupled with the increased use of the Internet for marketing and selling new of drugs, it may be expected that synthetic analogues of other major drug groups will appear. New synthetic opioids and cocaine derivatives have already been identified via the EWS, albeit as isolated cases.

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 monitoring, responding to and controlling the use of new psychoactive substances.

One example is 'Spice', which was sold as a commodity only available through the Internet, or in specialised shops, rather than through clandestine production and illegal circulation. This approach did not generate seizures or indicate criminality, which might otherwise have attracted the attention of specialised law enforcement agencies. Furthermore, the limited knowledge about the chemistry and effects of the new compounds contributed to the creation of a 'grey zone' where the potentially responsible institutions (public health authorities or the competent authorities for medicinal products) did not assume immediate responsibility. This raises the question of what sort of mechanisms are appropriate for monitoring the appearance of products such as 'Spice' and accessing their possible impact. It appears likely that if such developments are to be detected at an early stage, a more proactive strategy may be necessary.

Finally, special attention should be given to the marked increase of 'ecstasy' tablets containing *m*CPP on the illicit drugs market and specifically to the increasing appearance of legal alternatives to established drugs, including synthetic cathinone derivatives such as mephedrone. In view of the growing popularity and sales of mephedrone, it is important to consider the threat that this may pose by creating momentum for an undesirable transition, from a mostly online 'legal-highs' market, originally driven by individual entrepreneurship, to one that involves organised crime.

5. Conclusion

Since the establishment of the information exchange mechanism, the Early-Warning System, at the end of 1997, more than 110 substances have been identified and notified to the EMCDDA and Europol by the Member States. Most of the substances notified after Council Decision 2005/387/JHA came into effect, i.e. after 21 May 2005, were 'new synthetic drugs', which would have been notified under the previous legal instrument, the 1997 Joint Action. Notably, all of the new substances notified in 2009 were synthetic. Only a few psychoactive plants and medicinal products have been notified in the last five years.

It is likely that synthetic psychoactive substances will continue to be predominantly notified (identified) in the framework of the Early-Warning System. Therefore, the availability of reference materials (reference substances or seized substances) is of 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. If a system that can successfully function in the long term is to be implemented, it will be important to consider how access to reference materials can be facilitated. The EWS has high reporting capabilities, but despite its speediness and capacity to triangulate information from different sources, it has no mandate or resources to anticipate and research the future market by actively purchasing, synthesising and studying new compounds.

In view of the forthcoming assessment of the functioning of the Decision ([23]), it is worth highlighting the key achievements of the mechanism that need to be maintained and strengthened in the future: the existence of highly operational European dynamically linked to forensic science networks; the excellent cooperation between the EMCDDA and Europol at EU level; and the well-established cooperation with the European Medicines Agency (EMA) and the EU pharmacovigilance system.

The EMCDDA and Europol have reported annually to the European Parliament, the Council and the Commission on the implementation of the Decision. These reports take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. Therefore, an in-depth assessment of the mechanism should also take into consideration the annual implementation reports for the period 2005–09, as they provide useful and comprehensive information.

([23]) under Objective 23, Action 69 of the EU Drugs Action Plan for 2009-2012 (2008/C 326/09)

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 2009 under the terms of Council Decision 2005/387/JHA

Annex 3 — THC and six synthetic cannabinoids with high affinity for cannabinoid (CB_1) receptors found in 'Spice' products

(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 2009 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 2009 under the terms of Council Decision 2005/387/JHA

1. **2- or 3-fluoroamphetamine** – 8 January 2009 – Belgium

2. **PPP**
(α-pyrrolidinopropiophenone) – 27 January 2009 – Denmark; and 2 February 2009 – Finland

3. **2-DPMP**
(2-diphenylmethylpiperidine) – 2 February 2009 – Finland

4. **CP 47,497**
(5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol) – 23 February 2009 – Germany

5. **CP 47,497-C6 homologue**
(5-(1,1-dimethylhexyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol) – 23 February 2009 – Germany

6. **CP 47,497-C8 homologue**
(5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol) – 23 February 2009 – Germany

7. **CP 47,497-C9 homologue**
(5-(1,1-dimethylnonyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol) – 23 February 2009 – Germany

8. **JWH-073**
(1-butyl-3-(1-naphthoyl)indole) – 6 March 2009 – Denmark

9. **4-AcO-MET**
(4-acetoxy-N-methyl-N-ethyltryptamine) – 24 April 2009 – Finland

10. **TMA-6**
(2,4,6-trimethoxyamphetamine) – 3 June 2009 – Denmark

11. **HU-210**
(1,1-dimethylheptyl-11-hydroxytetrahydrocannabinol) – 22 June 2009 – United Kingdom

12. **ODT**
(o-desmethyltramadol) – 26 June 2009 – Germany

13. 4-AcO-DMT
(4-acetoxy-N,N-dimethyltryptamine) – 17 August 2009 – Finland

14. 2-PEA
(2-phenethylamine) – 2 October 2009 – Finland

15. JWH-398
(1-pentyl-3-(4-chloro-1-naphthoyl)indole) – 6 October 2009 – United Kingdom

16. JWH-250
(1-pentyl-3-(2-methoxyphenylacetyl)indole) – 6 October 2009 – Germany

17. bk-PMMA / methedrone
(4-Methoxymethcathinone) – 12 October 2009 – Sweden

18. Etaqualone
(3-(2-ethylphenyl)-2-methyl-quinazolin-4-one): – 12 November 2009 – Denmark

19. MDPPP
(3',4'-methylenedioxy-α-pyrrolidinopropiophenone) – 12 November 2009 – Denmark

20. Metamfepramone
(N,N-dimethylcathinone) – 12 November 2009 – Denmark

21. 3-FMA
(3-fluoromethamphetamine) – 17 November 2009 – Finland

22. JWH-200
(1-[2-(4-morpholino)ethyl]-3-(1-naphthoyl)indole) – 3 December 2009 – Lithuania

23. 4-MA
(4-methylamphetamine) – 14 December 2009 – Belgium

24. Pregabalin
((S)-3-(aminomethyl)-5-methylhexanoic acid) – 16 December 2009 – Finland

European Monitoring Centre for Drugs and Drug Addiction

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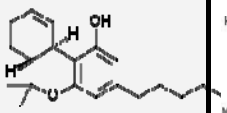
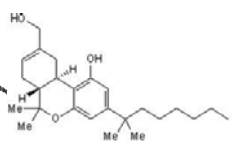
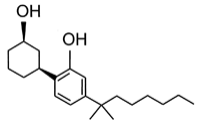
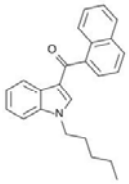
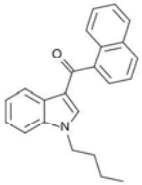
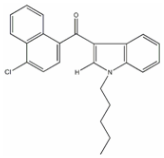
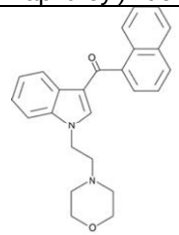
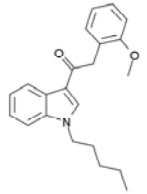
EMCDDA–Europol 2009 Annual Report on the implementation of Council Decision 2005/387/JHA

Annex 3 — THC and seven synthetic cannabinoids with high affinity for cannabinoid (CB_1) receptors found in 'Spice' products

NAME / FIELD	Δ⁹-THC	HU-210	CP 47,497	JWH-018	JWH-073	JWH-398	JWH-200	JWH-250
Family / Group	Naturally occurring dibenzopyran	'Classical' CB – dibenzopyran	Cyclohexylphenol	Naphthoylindole	Naphthoylindole	Naphthoylindole	Naphthoylindole	Phenylacetylindole / benzoylindole
Subgroup	Chiral tricyclic terpenoid derivative with a dibenzopyran ring	THC analogue	AC-bicyclic cyclohexylphenol	1-alkyl-3-(1-naphthoyl)indole	1-alkyl-3-(1-naphthoyl)indole	3-(4-halo-1-naphthoyl)indole	1-[2-(4-morpholino)alkyl]-3-(1-naphthoyl)indole	1-pentyl-3-phenylacetylindole
Structure								
Potency and selectivity	Partial agonist at CB_1	Full non-selective agonist at CB_1/CB_2	Potent selective CB_1 agonist	Very potent selective CB_2 agonist (also potent CB_1 agonist)	Potent selective CB_1 agonist (also weaker CB_2 agonist)	Very potent non-selective CB_1/CB_2 agonist	CB_1 agonist	Potent selective CB_1 agonist (also weaker CB_2 agonist)
Binding affinity for CB_1 – Ki [nM]	10.2 (ACMD 2009)	0.06 (Howlett et al. 2002)	9.54 (Auwärter et al. 2009)	9 (Huffman 2009; Huffman et al. 2003)	8.9 (Huffman 2009; Huffman et al. 2003)	2.3 (Huffman 2009)	42 (Huffman 2009)	11 (Huffman 2009)
Synthesised by	Naturally occurring phytochemical	R. Mechoulam	Pfizer	J.W. Huffman	J.W. Huffman	J.W. Huffman	J.W. Huffman	J.W. Huffman
First notified by	N/A	United Kingdom	Germany	Austria	Netherlands	United Kingdom	Lithuania	Germany
Control measures	Internationally controlled	AT, DK, EE, FR, LV, LT, LU, SE, UK	AT, DK, EE, FR, DE, LV, LT, LU, RO, SE, UK	AT, DK, EE, FR, DE, LV, LT, LU, PL, RO, SE, UK	DK, EE, DE, LV, LT, LU, SE, UK	DK, LV, LU, UK	DK, LU, UK	DK, LV, LU, UK