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**EMCDDA–Europol 2008 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 fourth 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 the Decision) <sup>(1)</sup>.

During 2008, 13 new psychoactive substances were officially notified for the first time in the European Union through the information exchange/early-warning system (EWS) set up by the Decision. Most of these new psychotropic substances were stimulants, similar to those listed in Schedules I and II of the 1971 United Nations Convention on Psychotropic Substances.

The report details two important developments which took place during 2008. The first was the finalisation and adoption of a new ‘Guidelines for the risk assessment of new psychoactive substances’, which was the result of major developmental work undertaken by the EMCDDA’s Scientific Committee. Secondly, at the end of 2008 it was found that a ‘smoking mixture’, known and monitored by the EWS as ‘Spice’ was not the herbal product that it purported to be. The real psychoactive constituents were identified as synthetic additives — substances, such as the cannabinoid receptor agonist JWH-018, that mimic the effects of tetrahydrocannabinol ( $\Delta^9$ -THC) in cannabis. As the report deals extensively with issues related to Spice products and the corresponding synthetic compounds, it was considered important to also include information that became available during the first two months of 2009, rather than only that for the reporting period of 2008. A brief follow up of the two piperazine derivatives mCPP and BZP, which were dealt with in last year’s report is also provided.

Finally, the report includes some of the challenges which the information exchange mechanism may encounter during the coming years, in order to maintain the operational level of the EWS. In particular, issues that relate to identification, monitoring and understanding the nature of various uncommon chemicals, plant or herbal materials which increasingly appear on the Internet and on the European drug markets as ‘research chemicals’, ‘herbal highs’, ‘legal highs’, etc. The report concludes that the EWS set up by the Decision has high reporting capabilities, but despite its speediness and capacity to triangulate information from different sources, it does not have a mandate or means to anticipate and research the future market by actively purchasing, synthesizing and studying new compounds.

In view of the forthcoming assessment of the functioning of Council Decision 2005/387/JHA foreseen by the EU Drugs Action Plan for 2009–12 <sup>(2)</sup>, the report may also play a useful role by highlighting additional factors to those already reported in previous annual reports concerning the implementation of the Decision.

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<sup>(1)</sup> OJ L 127, 20.5.2005, p. 32.

<sup>(2)</sup> EU Drugs Action Plan for 2009–12 (2008/C 326/09).

## 1. Introduction and background

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 <sup>(3)</sup>. 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 <sup>(4)</sup>.

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 EMEA, 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 fourth annual report on the implementation of the Decision for the period January to December 2008. 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 as foreseen by the EU Drugs Action Plan for 2009–12.

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<sup>(3)</sup> 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.

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

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, whilst avoiding highly technical descriptions. However, more comprehensive information on new substances described in the report is available from the EMCDDA and Europol.

## **2. Implementation of the Decision and results**

### **2.1 Specific implementation arrangements**

#### *2.1.1 Guidelines for the risk assessment of new psychoactive substances*

The new guidelines are a revision of the *Guidelines for the risk assessment of new synthetic drugs* <sup>(5)</sup>. This modification was deemed necessary as a result of the replacement of the Joint Action of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs <sup>(6)</sup> (the 'Joint Action') by Council Decision 2005/387/JHA.

The principle aim of the new guidelines is to provide a sound methodological and procedural basis for carrying out the risk assessment in line with the scope of the Decision. Therefore, providing an evidence-based recommendation to assist the Council's decision as to whether or not a new psychoactive substance should be subject to control measures and criminal penalties in the EU Member States. The new guidelines introduce major conceptual and implementation innovations for the risk assessment, which make them a unique contribution to this field at international level.

Risks related to any psychoactive substance, whether legal or illegal, can originate from several sources and assume various forms. For both analytical and pragmatic purposes, it is essential to clarify the type and origin of substance-related risks as they manifest themselves in individuals and the society at large. Therefore, the new guidelines define a new conceptual framework within which various elements of substance-related risk may be located and assessed. Both the probability (risk) and seriousness of the adverse consequences of a substance (hazard) are taken into account by the risk-assessment procedure. The framework is built on the distinction between the sources from which substance hazards emanate and the type of hazardous effects that may be caused by substance use.

Despite the difficulties associated with interactions between different domains of harm and quantifying the level of harm, from a pragmatic view and to facilitate comparisons between different substances within certain domains, the guidelines introduce for the first time a semi-quantitative approach on the basis of expert judgement.

In assessing the risks of a particular psychoactive substance, six key variables likely to affect the hazards and risks related to that substance are taken into consideration: (a) dose and frequency of use; (b) short-term and long-term effects; (c) interactions with

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<sup>5</sup> European Monitoring Centre for Drugs and Drug Addiction, *Guidelines for the risk assessment of new synthetic drugs*, Luxembourg: Office for Official Publications of the European Communities, 1999.

<sup>6</sup> OJ L 167, 25.6.1997.

other substances (including alcohol and medicines); (d) individual characteristics of the users; (e) characteristics of the social and cultural environment; and (f) involvement of organised crime.

The Council Decision does not require the EMCDDA Scientific Committee to include a recommendation in the risk assessment report. However, based on past experience, it is clear that it is good risk assessment practice to do so. The Council has to decide whether to submit the new psychoactive substance to control measures (Article 8.3). Therefore, a recommendation should include science-based advice to this end. The guidelines specify that a recommendation should indicate whether a new psychoactive substance is considered a narcotic drug similar to those in the Schedules annexed to the 1961 UN Convention, or a psychotropic substance similar to those included in the Schedules annexed to the 1971 UN Convention. In addition, as far as possible from the data available, it should be indicated which of the Schedules under the UN Conventions, contain substances most similar to the new psychoactive substance. If the new psychoactive substance is not similar to those listed in the Schedules annexed to the UN Conventions, but the Scientific Committee still conclude that it is recommended to submit the new psychoactive substance to control measures, then the reason for this recommendation should be further justified. If the Scientific Committee concludes that the new psychoactive substance should not be recommended for submission to control measures, the reason for this recommendation should also be justified.

The new risk assessment guidelines will be officially published in 2009 and a copy of this document may be obtained from the EMCDDA.

#### *2.1.2 Cooperation with the United Nations system*

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. Article 5.2(e) of the Decision requires the EMCDDA–Europol joint reports and risk assessment reports to include information on ‘whether or not a new substance is currently under assessment, or has been under assessment by the UN system’. However, no such requests were made in 2008.

The WHO’s Department of Medicines Policy and Standards was consulted and provided valuable feedback in the process of elaboration of the above-described *Guidelines for the risk assessment of new psychoactive substances*. Furthermore, elements of the EWS on new psychoactive substances have been presented to the United Nations Office on Drugs and Crime (UNODC), and it is expected that these will be considered in the implementation of the recently launched ‘Global synthetics monitoring: analyses reporting and trends (SMART) programme’. To this end, the EMCDDA has been invited as a member of the programme’s advisory group.

#### **2.2 Cooperation with the EMEA and the pharmacovigilance system**

The EMEA 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 EMEA to guarantee that substances of established and acknowledged medical value are excluded from risk assessment and control measures based on the Decision.

The EMCDDA and the EMEA have implemented on an ad hoc basis, bilateral information 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 of collaboration, which continues to be under development. While there is awareness that any appropriate opportunity to strengthen the basis of EMCDDA–EMEA cooperation should be facilitated, it is clearly recognised by the management of the two Agencies that any further formalisation of the collaboration should evolve within the mandates of the institutions, whilst taking into account the operational priorities and resources available. The preparation of a cooperation framework between the two agencies has been postponed to 2009, or until the legislative proposal to strengthen and rationalise the European Union pharmacovigilance system is adopted.

### **2.3 New psychoactive substances notified in 2008**

Since 1997, more than 90 substances have been reported via the EWS. Until recently, phenethylamines <sup>(7)</sup> and tryptamines accounted for most of the notifications. However, in the past few years a much more diverse range of substances has appeared. These included numerous piperazine and cathinone derivatives. Beyond these, there has been a heterogeneous mix of substances, including plant products, a few unusual stimulants and hallucinogens and some medicinal products.

During 2008, a total of 13 new psychoactive substances were officially notified for the first time in the European Union via the EWS (Annex 2). As well as the formal notifications through a Reporting Form to the EMCDDA and/or Europol, the Member States also provided biannual updates through the Reitox EWS reporting mechanism. Subsequently, all new compounds are being entered into the EMCDDA's database on new drugs (EDND) and added to the list of monitored substances. The list is reviewed annually by the two organisations.

The number of new substances notified in 2008 is comparable to the notifications in 2007, when 15 new psychoactive substances were reported for the first time. In 2008, the group of newly notified substances included two plants, but no medicinal products. The majority of the newly reported compounds (nine) were psychotropic substances, i.e. synthetic drugs, similar to those listed in Schedules I and II of the 1971 United Nations Convention on Psychotropic Substances (see Annex 2 — substances 1, 2, 3, 5, 7, 8, 9, 11 and 12). Altogether, the group consisted predominantly of compounds with stimulant properties, whilst only two substances had pronounced hallucinogenic effects (see Annex 2 — substances 5 and 9). Notably, in 2008 fewer new substances were reported than in previous years from the better known chemical groups: phenethylamines (one); tryptamines (two) and piperazines (none). Six of the newly notified substances belonged to the cathinone derivatives group (see Annex 2 — substances 1, 2, 3, 5, 6 and 11).

Furthermore, from a chemical point of view, it is worth noting one interesting compound; pFBT (see Annex 2 – substance 10) <sup>(8)</sup>. pFBT is a 'designer drug' based on cocaine, though very little is known about this compound. It is reported to have stimulant and local

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<sup>(7)</sup> Phenethylamines are often referred to as amphetamine type stimulants (ATS).

<sup>(8)</sup> Also known as 3-(p-Fluorobenzoyl)tropane or (4-fluorotropacocaine).

anaesthetic properties and seems to have been researched in the mid-1980s for potential neuroleptic activity <sup>(9)</sup>. pFBT is being offered online by some chemical suppliers.

Although quite complex, the chemical make-up of the two plants reported — kratom and kava (see Annex 2 — substances 4 and 6) — is relatively well known from literature. They have been traditionally used in other parts of the world and the significance of their appearance on the European drug market seems to be limited at present.

Finally, JWH-018, which was reported during 2008 (see Annex 2 — substance 13) needs to be singled out as this is the first synthetic cannabinoid ever reported through the EWS. This compound is dealt with extensively in the specific section on Spice products and related compounds (see 2.4 below).

## **2.4 Spice and related compounds (JWH-018, CP 47,4797 and its ‘analogues’)**

### *2.4.1 Description and background information*

Spice products have been available on the Internet and in some specialised shops at least since 2006. Although Spice products may be advertised/offered, for example, as incense, when smoked they are reported by some users to have effects similar to those of cannabis. Following a report from Sweden, the EWS is monitoring those products from the beginning of 2008.

There are a number of Spice products and some examples are: Spice Silver, Spice Gold, Spice Diamond, Spice Arctic Synergy, Spice Tropical Synergy, Spice Egypt, Spice Yukatan Fire. In addition, there seem to be other ‘herbal’ preparations which may have similar compositions, for example, Smoke, Sence, ChillX, Highdi's Almdröhner, Earth Impact, Gorillaz, etc.

Spice products are a mixture (blend) reportedly containing the following plant/herbal ingredients: Baybean, Blue Lotus, Lion's Tail, Lousewort, Indian Warrior, Dwarf Scullcap, Maconha Brava, Pink Lotus, Marshmallow, Red Clover, Rose, Siberian Motherwort, Vanilla, and Honey. Based on their chemical compositions, it can be assumed that, at least two of the listed ingredients — ‘Indian Warrior’ (*Pedicularis densiflora*) and ‘Lion's Tail’ (*Leonotis leonurus*) — may have some psychoactive effect. However, there is a lack of information about the complete chemical composition, and little is known about the pharmacology and toxicology of the plant materials purportedly contained in the Spice products. Thus, no definite answers can be provided at present, with regard to the potential health risks related to the possible psychoactive effects, but also in general for these products. On the packaging of the Spice products, there is no mention of any synthetic ingredients.

Spice products can be purchased from specialised online shops. In a recent EMCDDA study on ‘legal highs’ sold on the Internet conducted at the beginning of 2008, Spice was found to be frequently offered — 10 out of 27 online shops investigated (37 %). The majority of all online retailers included in this study were located in the UK (52 %) and the Netherlands (37 %). In 2008, Spice products were available, or have been available,

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<sup>(9)</sup> Neuroleptic is a term that refers to the effects of antipsychotic drugs on a patient, especially on cognition and behaviour (<http://www.medterms.com/script/main/art.asp?articlekey=10983>).

on the market in various 'smart', 'head' and 'fun' shops in at least 8 Member States (Austria, Germany, Latvia, Lithuania, Luxembourg, Poland, Portugal and the United Kingdom).

#### 2.4.2 Synthetic cannabinoids added to Spice products

Extensive forensic science investigations have been undertaken by the Member States in order to identify the psychoactive ingredients of Spice products. On 19 December, through an EWS Reporting Form, the Austrian NFP formally notified to the EMCDDA the new psychoactive substance JWH-018 (Naphthalen-1-yl-(1-pentylindol-3-yl)methanon) <sup>(10)</sup> — a cannabinoid receptor agonist <sup>(11)</sup> as being identified in Spice products in Austria by AGES PharmMed (through work commissioned by the Ministry of Health, Family and Youth). The compound has been detected in at least three Spice products (Gold, Silver and Diamond). Furthermore, according to information received from the German NFP, JWH-018 has also been identified in Spice products in Germany by THC-Pharm (Frankfurt am Main).

JWH-018 is a synthetic substance first synthesized in 1995 in the United States for experimental purposes. It is a naphthoylindole which belongs to the aminoalkylindole family, i.e. the chemical structure differs substantially from tetrahydrocannabinol ( $\Delta^9$ -THC), but it produces the same effects in experimental animals and has been reported to be more potent than THC. There is no information of JWH-018 having been authorised as a medicinal product in the European Union and very importantly, almost nothing is known about its effect on man; there is no officially published safety data.

Currently there is no clarity if JWH-018 is present in all Spice products or batches of the same product <sup>(12)</sup>. However, it appears that different amounts of JWH-018 (and/or CP 47,497 and its 'analogues') may have been used in the various Spice products to produce a range of subjective effects <sup>(13)</sup>. Aside from their uncommon chemical structure, some of the characteristics of these compounds, e.g. volatility (and hence 'smokability') and activity in small doses (e.g. less than 1 mg), are likely to present further analytical and toxicological challenges.

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<sup>(10)</sup> The other chemical name is 1-Pentyl-3-(1-Naphthoyl)Indole.

<sup>(11)</sup> 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.

<sup>(12)</sup> Additional information beyond the reporting period is covered by this report: on 20 January 2009, the German NFP informed the EMCDDA that a team of German forensic experts has identified in Spice products the synthetic cannabinoid CP 47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol) — another synthetic substance and a potent cannabinoid receptor agonist (CB<sub>1</sub>), which is reported to have analgesic effects. According to a recent publication, not only CP 47,497, but three further analogues of CP 47,497 have been identified in few Spice products, thus bringing the total number of synthetic cannabinoids identified in Spice products in Europe to five.

<sup>(13)</sup> According to Internet sources (not confirmed by any institutional source) a third potent synthetic cannabinoid, HU-210, has been reported to have been found in Spice seized by the US Customs and Border Protection

### *2.4.3 Control measures*

Responding to potential health concerns, Germany, Austria and France have taken legal actions to ban or otherwise control Spice products and related compounds.

In Austria, a directive under the Medicines Act of 7 January 2009 declares that 'smoking mixes containing JWH-018' are prohibited from being imported or marketed in the country. Moreover, the Austrian authorities will continue to review whether control is required under its Narcotic Drugs Law.

In Germany, following a rapid control under the Pharmaceutical Law, an emergency regulation, in effect from 22 January, brought under Table II of the Narcotic Drugs Law, five cannabinoids found in Spice mixes which include JWH-018, CP 47,497 and its three analogues (for comparison, also listed in this table are BZP and some barbiturates).

In February 2009, the French Minister of Health and Sports classified six synthetic cannabinoids found in 'Spice or Gorilla' products in France as narcotics.

The herbal ingredients of Spice products do not seem to be controlled under drugs control legislation (i.e. national legislation implementing the 1961 and 1971 UN conventions) in the European Union Member States. However, the UK Medicinal and Healthcare Products Regulatory Agency (MHRA) stated in a communication to importers (October 2008), that it considers Spice gold 3g a medicinal product for which a marketing authorisation has to be granted before it can be sold or supplied in the United Kingdom.

### *2.4.4 EMCDDA–Europol actions on Spice products and related compounds*

In 2008, the EMCDDA and Europol have monitored the situation carefully through the information exchange mechanism of the Council Decision (the EWS).

- At the beginning of 2008, the EMCDDA carried out a study on the availability of legal highs (including Spice products) on the Internet (see above).
- The EWS facilitated the exchange of information between the Member States, initially assisting the efforts to identify the potential psychoactive components in the herbal ingredients of Spice.
- As a result of information received by the Austrian authorities (Ministry of Health, Family and Youth and the NFP) and later from the UK NFP (information from MHRA), the EMCDDA was able to provide the EWS partners (Reitox NFPs, Europol, the EMEA and the Commission) with three sets of analytical information (LC-MS spectrum of JWH-018 plus some additional chemical information), which may be useful for the identification of this new substance in the Member States. The analytical data of JWH-018 was also provided to the European Network of Forensic Science Institutes (ENFSI).
- An embargoed scientific article (under publication) received from the German NFP about the identification of CP 47,497 and its 'analogues' has also been circulated.

- As a result of this, the EMCDDA has created profiles of Spice, JWH-018 and CP 47,497 and uploaded relevant information on the European database on new drugs (EDND).
- On request, the German and Austrian legal correspondents have provided to the EMCDDA copies of their respective control decrees, providing the exact chemical names of the controlled substances.
- At the beginning of 2009, a meeting took place between the EMCDDA and Europol to examine the information available on Spice and related compounds and to decide upon the necessity of further actions. The two agencies concluded that at present JWH-018, CP 47,497 and its 'analogues' do not fulfil the criteria set up by the 'EWS Operating guidelines' for the launch of a Europol–EMCDDA Joint Report, because: (a) there are no large seizures; (b) there is no evidence of international trafficking; (c) there is no evidence of organised crime involvement; (d) there is little evidence of intoxications and no reported fatalities; (e) there is limited information on the toxicopharmacological properties of the substances; and (f) there is insufficient evidence about the potential for further (rapid) spread of the substances. However, this situation may change rapidly so the EWS needs to remain vigilant.
- In response to the substantial interest of policymakers, experts and the media, the EMCDDA launched an ad hoc survey amongst the Reitox NFPs in January 2009, in order to collect additional information and to gain a more comprehensive picture of the phenomenon. The first results of the study will be available in March 2009, and will be presented to the Commission and the Horizontal Working Party on Drugs (HDG) of the Council.
- In the first week of March 2009, the EMCDDA plans to convene an expert meeting to examine the data and information available on Spice products and related synthetic cannabinoids. Experts from the Member States, the EMCDDA Scientific Committee and the EMEA will participate.

## **2.5 Follow up on mCPP and BZP**

Both 1-benzylpiperazine (BZP) and 1-(3-chlorophenyl) piperazine (mCPP) have been extensively discussed in last year's report due to the risk assessment of the former and the active monitoring of the latter.

In 2007, the active monitoring report on mCPP concluded that this substance has no particular appeal to users and seems unlikely to establish itself as a recreational drug in its own right. In 2008, mCPP still appears to be the most widely available 'new synthetic drug' (i.e. internationally non-controlled) on the illicit drug market, encountered alone or in combination with ecstasy (MDMA). This is evidenced both by the number of seizures and the amount of seized material reported to Europol and the EMCDDA. It is still unclear if the substance is used to enhance or mimic (some) of the effects of MDMA or

simply as a 'cutting agent'. It is likely that mCPP seizures will continue to be under-reported as this substance is non-controlled in most Member States <sup>(14)</sup>.

On 3 March 2008, the Council decided that the European Union Member States shall take the necessary measures, in accordance with their national law, to submit BZP to control measures proportionate to the risks of the substance, and criminal penalties, as provided for under their legislation complying with their obligations under the 1971 United Nations Convention on Psychotropic Substances <sup>(15)</sup>. In accordance with Article 9.2 of the Decision, Member States shall implement measures for this substance, as soon as possible, but no later than one year from the date of the decision. At the time of the preparation of this report, 13 Member States <sup>(16)</sup> have reported to the EMCDDA that they have controlled BZP accordingly.

### **2.6 Information exchange beyond the immediate scope of the Decision**

The early-warning system on new psychoactive substances has a proven capacity to provide value beyond the immediate scope of the Decision. For example, on a few occasions during 2008, the EMCDDA issued public health-relevant warnings to the Reitox network partners concerning unusual hazards related to well established, controlled substances, e.g. intoxications due to cocaine adulterated with atropine; clusters of heroin-related deaths; botulism in injecting drug users, etc.

Furthermore, information on various other uncommon controlled or non-controlled substances, with or without psychoactive properties, is occasionally exchanged through the EWS. For instance, a warning has been issued based on information received from the Dutch NFP about detection of tablets containing 2,4-dichlorophenoxyacetic acid (2,4-D) which were sold as ecstasy. 2,4-D is a WHO Class II 'moderately hazardous' pesticide used in agriculture, which cannot be classified as a psychoactive substance.

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, such as forensic and toxicological laboratories, law enforcement organisations, etc., the EWS is an active player in the EMCDDA's efforts to detect, track and understand emerging drug trends. In 2008, the EMCDDA published a thematic paper on gamma-hydroxybutyrate (GHB) and its precursor gamma-butyrolactone (GBL) <sup>(17)</sup>.

## **3. Issues arising from the implementation experiences**

In 2008, the range of substances notified by the Member States to the EMCDDA and/or Europol via the information exchange mechanism continued to broaden. With the appearance, for the first time, of synthetic cannabinoids, it can be anticipated that the concept of 'designer drugs' being almost exclusively linked to fentanyls,

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<sup>(14)</sup> Currently, eight Member States control mCPP under drug control or equivalent legislation as follows: Belgium, Cyprus, Denmark, Germany, Greece, Hungary, Lithuania, Malta and Slovakia.

<sup>(15)</sup> Council Decision 2008/206/JHA of 3 March 2008 on defining 1-benzylpiperazine (BZP) as a new psychoactive substance which is to be made subject to control measures and criminal provisions.

<sup>(16)</sup> Belgium, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Lithuania, Malta, Slovakia and Sweden; as well as Croatia, Turkey and Norway.

<sup>(17)</sup> See <http://www.emcdda.europa.eu/html.cfm/index7079EN.html>

phenethylamines and tryptamines will change. There are hundreds of compounds with cannabinoid receptor activity and it can be assumed that further derivatives of such substances from different chemical groups will appear in the research laboratories and on the market. All this presents an ongoing challenge, not only for their forensic and toxicological identification, but also for their risk assessment and possible control. At present, little if anything is known about the pharmacology, toxicology, safety profile, etc. of such compounds.

Furthermore, it is important to note that the information exchange mechanism of the Council Decision is designed and geared towards notification and monitoring of individual substances which is technically a sound practice. Therefore, groups of substances (so-called 'analogues') cannot be notified, monitored and risk assessed as such. Information collection and monitoring, potentially leading to risk assessment(s) should be done separately for each individual substance.

Although the scope of the Council Decision includes naturally occurring substances, notification and subsequent monitoring of psychoactive plants via the EWS requires a different reporting approach, since issues related to the presence of more than one plant material (mixtures), more than one psychoactive ingredient within a given plant, the potency, etc. need to be appropriately addressed.

Some of the reported new substances, plants or herbal mixtures may have many uses, including some medical value. Therefore, it will not always be clear whether the product containing the substances will fall within the definition of a medicinal product. This poses a challenge in terms of interpreting the scope of the Decision and, consequently, on possible decisions for further action on borderline substances which are not authorised medicinal products, but may fall under the control of medicine-related legislation.

#### **4. Conclusion**

The decision-making process set up in the framework of the Council Decision, both at the level of information exchange and risk assessment is transparent and, as far as possible, evidence-based. According to the present state of knowledge, the substances JWH-018, CP 47,497 and its 'analogues' have not been widely used as psychoactive drugs in their own rights, but have been surreptitiously added to Spice products, which have been misrepresented as purely herbal. Therefore, it is still to be established if there is or will be a wider, specific demand for these particular substances and to decide on the need for further action as stipulated by the Decision. The uncommon chemical structure and some of the properties of these compounds are likely to present further analytical, toxicological and possibly legal challenges.

The rapid developments in the last few years in terms of distribution of psychoactive substances over the Internet as 'legal highs', 'herbal highs' 'research chemicals', etc., as well as the fast diversification of the chemicals reported, raise questions about how well placed the Member States are to detect the huge number of novel substances from uncommon chemical groups. Even the best equipped laboratories can struggle to identify new substances, particularly if, as it is so often the case, neither pure reference materials nor analytical data are available.

The information exchange mechanism (the EWS) set up by the Decision has high reporting capabilities, but despite its speediness and capacity to triangulate information

from different sources, it is to a certain extent a reactive tool without a mandate or resources to anticipate and research the future market by actively purchasing, synthesising and studying new compounds.

In 2008, further evidence has been gathered, allowing for a better understanding of the key achievements and challenges faced by the information collection mechanism set up by the Decision. However, an in-depth assessment of the mechanism should also take into consideration the annual implementation reports for the period 2005–08 as they collectively provide useful and comprehensive information.

**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 2008 under the terms of Council Decision 2005/387/JHA