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on the assessment of the functioning of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances

Accompanying the document

REPORT FROM THE COMMISSION

on the assessment of the functioning of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances

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1. INTRODUCTION

Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances[1] ('the Council Decision') enables the exchange of information and assessment of new psychoactive substances and, if necessary, may make them subject to control measures and criminal penalties across the EU. This Decision has replaced Joint Action 97/396/JHA[2] ('the Joint Action') and broadened its scope.

The Joint Action defined **new synthetic drugs** as being psychoactive substances with limited therapeutic value not listed under the 1971 United Nations Convention on Psychotropic Substances[3] ('UN 1971 Convention'), but which posed a comparably serious threat to public health as those substances listed in Schedules I and II to that Convention. The term 'new' referred not only to a newly invented substance, but also to a 'newly available' or a 'newly misused' substance. In practice, most such substances were created a long time ago, but had not been widely available or used before.

The Council Decision defines a **new psychoactive substance** as a 'new narcotic or psychotropic drug, in pure form or in preparation, that is not controlled by the 1961 United Nations Single Convention on Narcotic Drugs[4] ('UN 1961 Convention') or the UN 1971 Convention, but which may pose a public health threat comparable to that posed by substances listed in Schedule I or II or IV of the former and in Schedule I or II or III or IV of the latter Convention'[5]. This means that the Council Decision covers not only synthetic substances but also those based on herbs. Substances notified through the information exchange mechanism set up by the Council Decision, namely the Early Warning System (EWS), may include medicines or substances used to manufacture medicinal products[6], but such substances cannot be subjected to a risk assessment[7], because they are covered by other types of legislation. Furthermore, chemicals used to manufacture illicit drugs (drugs precursors) are also excluded from the scope of the Council Decision, since they are governed by different regulations[8].

The Council Decision provides an official definition of new psychoactive substances, but several terms are used in common language to designate such substances. Although the Joint Action referred to new psychoactive substances as 'designer drugs', nowadays the term 'legal highs' is more often used.

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1 OJ L 127, 20.5.2005, p. 32-37.

2 Joint Action 97/396/JHA of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs, OJ L 167, 25.6.1997, p. 1-3.

3 UN 1971 Convention on Psychotropic Substances.

4 UN 1961 Single Convention on Narcotic Drugs as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs.

5 Article 3 of the Council Decision.

6 Recital 5 of the Council Decision.

7 Article 7(3).

8 Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004); Regulation (EC) No 111/2005 of the European Parliament and of the Council of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005); Commission Regulation (EC) No 1277/2005 of 27 July 2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and of Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 202, 3.8.2005).

A **'designer drug'** is a psychoactive substance produced from chemical precursors in a (clandestine) laboratory, which is designed to mimic the properties of known psychoactive substances, has a limited therapeutic value and is not internationally controlled. The term **'legal highs'** covers all unregulated psychoactive substances or products containing them, specifically designed to mimic the effects of known illicit drugs in order to circumvent existing drug controls. The term encompasses a fairly wide range of synthetic and plant-derived substances and products, including **'research chemicals', 'party pills' and 'herbal highs'**, which are usually sold over the internet or in specialised shops (head shops). These are often advertised with aggressive marketing strategies and sometimes intentionally mislabelled with purported ingredients differing from the actual composition. Suppliers easily circumvent drug controls by rapidly offering new alternatives to products that are subjected to control.

The Council Decision was developed taking into account the findings of an independent evaluation of the Joint Action, conducted in 2002[9] *(see section 3)*. The final evaluation of the EU Drugs Action Plan 2005-2008[10] highlighted the fact that the Council Decision may need to be amended, in order to improve the exchange of information and cover gaps between the Decision and other EU legislation, including that setting up the pharmacovigilance system[11]. Subsequently, the EU Drugs Action Plan 2009-2012[12] requested the Commission to "*assess the functioning"* of the Council Decision and *"amend, if necessary"*.

2. METHODOLOGY

The European Commission has conducted this assessment with the support of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol. The purpose of the assessment is to determine whether the objectives, scope and instruments of the Council Decision are adequate to efficiently tackle the rapidly evolving market for new psychoactive substances. The report and this annexed document explore the main developments in this market since 2005, the functioning of the Council Decision, and its strengths and weaknesses. Lastly, it seeks to determine to what extent the Council Decision has added value.

The assessment included:

(a) An evaluation of the main challenges posed by developments in the market for new psychoactive substances, including an EMCDDA overview report of key developments related to the implementation of the Council Decision (see section 4 for an overview of trends and developments).

(b) A mapping of existing EU directives and regulations that are relevant for tackling new psychoactive substances, including those on food safety, consumer protection, dangerous substances and products, and the pharmacovigilance system. It also involved a brief screening of the use of the provisions of Directive 98/34/EC by

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9 The Evaluation Partnership Ltd., Assessment of the Joint Action on new Synthetic Drugs, contract JAI/B5831/200/C2.

10 SEC (2008) 2456, 18.9.2008.

11 The process of monitoring the safety of medicines and taking action to reduce their risks and increase their benefits. 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. OJ L 136, 30.4.2004, 28.11.2001, p. 1-32.

12 OJ C 326, 20.12.2008, p. 7–25. Action 69.

Member States to limit the free movement of goods that may pose a public health risk (see section 5 for an overview).

(c) An assessment of the functioning of the Council Decision, identifying its strengths and weaknesses in terms of procedures, as well as its practical impact.

(d) A survey among Member States on the functioning of the Council Decision and their responses to the emergence of new psychoactive substances (see section 7 for a summary).

Specific documents and reports were reviewed, including annual reports on the implementation of the Council Decision[13], the Joint Reports on *m*CPP, BZP and mephedrone produced by the EMCDDA and Europol, and the Risk Assessment reports on BZP and mephedrone, the information report on Spice, the evaluation report of the 2002 Joint Action and various media reports.

3. KEY FINDINGS FROM THE 2002 EVALUATION OF THE JOINT ACTION ON SYNTHETIC DRUGS

In 2002 the predecessor of the Council Decision was evaluated. The evaluation identified a number of important strengths and weaknesses, as well as policy relevant questions, some of which continue to be relevant today as well. The evaluation of the Joint Action had three main objectives: a) to assess the effectiveness of the Joint Action in meeting the requirements of the EU Action Plan on Drugs 2000-2004, b) to examine the operation of all aspects of the Joint Action since its adoption in 1997, including strengths and weaknesses, and c) to provide conclusions to help the Commission draft a revised instrument (the current Council Decision).

The report concluded that, during its implementation, the Joint Action had **changed** from being a control instrument, as reflected in its legal basis, **to a less clearly defined** policy instrument where the different actors involved had different, and not fully compatible, objectives. These included the monitoring of new substances appearing in the market and public health campaigns.

The report revealed that the Joint Action was undermined by **fundamental disagreements** among Member States on how to assess risks of new psychoactive substances, the evidence needed to submit them to control and the timing of the control process. There was no consensus among the Member States on the **risk threshold** that should trigger the procedure leading to control. For some Member States, simply the appearance of a psychoactive substance seemed to justify introducing control measures. In most cases these countries decided to take measures independently of the risk assessments conducted under the Joint Action. However, the Joint Action was seen as providing a framework for debating different positions and achieving balanced positions.

The evaluation highlighted the fact that the information-exchange mechanism introduced by the Joint Action, namely the **EWS**, had not functioned properly. There were no clear criteria for requesting a risk assessment and for introducing control measures, which resulted in Member States developing different approaches. Member States were hesitant to exchange information, as they were concerned about confidentiality of data and potential public anxiety if information was made public. Certain Member States did not prioritise or properly resource their participation in the EWS.

[13] Article 10.

The assessment also revealed problems of representation in the Scientific Committee of the EMCDDA, which conducts the **risk assessment** of substances. The committee's composition was not sufficiently balanced to provide the expertise necessary to properly assess new psychoactive substances and was not extended to include external experts, although this would have been possible. The risk assessment lacked EU-wide analysis of societal and market aspects of substance use.

On **decision making**, the report concluded that the tight deadlines for the Commission to issue its opinion on the basis of the risk assessment report left little room for proper evaluation of the conclusions. It pointed out that several Member States were in favour of modifying procedures for introducing control measures and wanted **alternative options** for tackling new psychoactive substances, not just the option of criminal control.

The **relevance** of the Joint Action was considered to be limited, because new psychoactive substances had not become as big a problem as had been feared when it was adopted in 1997. However, Member States found the Joint Action broadly useful and wanted its **scope** to be extended. The practical **impact** of the Joint Action was hard to assess as no proof could be found that it had contributed to coordinating law enforcement operations across Member States in the way it was originally meant to do. The evaluators concluded that the effectiveness of the Joint Action was **limited** and they identified **two potential reform strategies** to tackle this. A **radical strategy** was to split the Joint Action into two instruments, one aimed at combating designer drugs and one focusing on monitoring new trends in drug consumption covering all substances. The evaluators pointed out that, while this would address some of the tensions, it might affect cooperation between the law enforcement and public health sectors. The second strategy proposed was **incremental change**, through smaller operational improvements, including:

- Strengthening the National Focal Point primary data collection networks (on new drugs);
- Defining clear criteria and responsibilities for initiating the EWS progress report (in the Council Decision this is called the Joint Report);
- Improving the transparency of the Joint Action process;
- Complementing existing resources with centralised monitoring of the internet and 'outbreak' investigations;
- Establishing exchanges among forensic laboratories;
- Introducing framework contracts to shorten tendering for risk assessment and for contracting out of work on sociological/criminological aspects to external experts;
- Reviewing the mechanism for appointment to the Scientific Committee;
- Strengthening existing databases within EMCDDA and the European Medicines Agency (EMA) on the legal status of substances;
- Establishing procedures to request further scientific information during the risk assessment, if necessary, and;
- Providing funding for additional research in support of scientific information.

The drafting of the Council Decision took many of these recommendations on board.

4. OVERVIEW OF NOTIFICATIONS, TYPES OF SUBSTANCES AND TRENDS AT EU LEVEL 2005-2010

New psychoactive substances can be classified in chemical families, based on their chemical structure (*see Table 4.1*). Synthetic cannabinoids are an exception: they are placed in a category based on their mode of action rather than on their chemical composition, which varies considerably.

Since the entry into force of the Council Decision in 2005, 115 new psychoactive substances[14] have been notified for the first time through the EWS. A record number of new substances (41) were reported in 2010, i.e. more than a third of all substances notified since 2005. This increase in the number of substances notified may reflect not only the rise in the number of substances available in the EU, but also improved reporting capacities due to increased awareness about new substances.

Table 4.1. – New psychoactive substances notified in 2005-2010

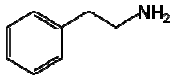
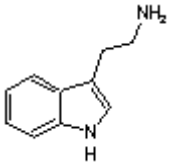
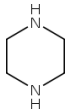
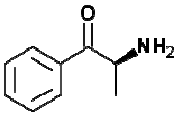
Year	Nr.	Types of substances first notified
2005	**14**	All newly-notified substances belonged to three major chemical groups – phenethylamines, tryptamines and piperazines. Of these 14 substances, methylone, DPIA and *m*CPP exhibited characteristics which suggested that they were particularly appropriate for targeted monitoring and further vigilance[15].
2006	**7**	In 2006 the chemical make-up of the reported substances was more diverse – some of them belonged to chemical groups never previously reported through the EWS, such as indanes and benzodifuranyls. Two of the seven reported substances had pronounced hallucinogenic effects, whereas all of the others exhibited predominantly stimulant effects. Three of the seven new substances belonged to the piperazine family.
2007	**16**	The group of notified substances was varied and, in addition to new synthetic drugs, included medicinal products, a metabolite/derivative of a medicinal product and naturally occurring substances. These included phenethylamines, tryptamines and piperazines, as well as substances with a less common chemical make-up. The group was evenly split between substances that had pronounced hallucinogenic effects and those that exhibited predominantly stimulant properties.
2008	**13**	In 2008, the group of notified substances included two plants, but no medicinal products. Altogether, the group consisted predominantly of compounds with stimulant properties, whilst two substances presented pronounced hallucinogenic effects. In particular, fewer new substances than in previous years were reported from the better known chemical groups: phenethylamines (one); tryptamines (two) and piperazines (none). Six of the notified substances belonged to the group of cathinone derivatives. Furthermore, pFBT, a 'designer drug' based on cocaine, is one chemically interesting compound that is worth noting.
2009	**24**	All new compounds were synthetic, including two substances with medicinal properties. Nine of the reported substances were synthetic cannabinoids from four distinct chemical groups (naphthoylindoles, phenylacetylindoles, cyclohexylphenols and dibenzopyrans). Apart from these, there was a mix of substances belonging to more established chemical families – five phenethylamines, two tryptamines and four synthetic cathinones. No new

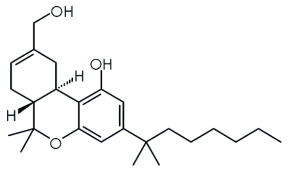
[14] A full list of the substances notified can be found in section 8 of this report.

[15] Six of these substances were notified under the terms of 1997 Joint action (period January – May 2005).

		piperazines or psychoactive plants were reported in 2009.
2010	**41**	Of the 41 compounds, 15 were synthetic cathinones and 11 were synthetic cannabinoids. Substances belonging to more established chemical families – five phenethylamines, one tryptamine and one piperazine – were also reported. The list of newly notified substances was diverse and included a plant-based substance, a synthetic cocaine, a ketamine derivative, a phencyclidine derivative, an indane and a benzofuran, as well as a designer medicine which belongs to a group that can be denominated diphenyl-R-amine.

Table 4.2. Main families of new psychoactive substances

Family	Parent compound	Chemical structure of the parent compound	Effects	Representatives	No of substances notified (2005-10)	EMCDDA Publications
Phenethylamines	phenethylamine (N)		stimulant and/or hallucinogenic	amphetamine, methamphetamine, MDMA, mescaline (N)	21	Risk assessment publications: 4-MTA (2002), PMMA (2003), TMA-2 (2004), and 2C-I, 2C-T-2, 2C-T-7 (2004)
Tryptamines	tryptamine (N)		hallucinogenic	psilocin and psilocybin (N), dimethyltryptamine / DMT, lysergide / LSD (S)	12	Thematic paper Hallucinogenic mushrooms (2006) Drug profile Hallucinogenic mushrooms
Piperazines	piperazine		stimulant and/or hallucinogenic	*m*CPP, BZP, TFMPP	8	Risk assessment publication: BZP (2009); Active monitoring report: *m*CPP Drug profile BZP and other piperazines
Cathinones	cathinone (N)		stimulant	cathinone (N), mephedrone, methylone, methcathinone (S)	26	Risk assessment publication: Mephedrone (2010); Drug profile Synthetic cathinones
Synthetic cannabinoids	N/A – the category includes a number of chemically unrelated but functionally similar families of cannabinoid receptor agonists that mimic the effects of Δ^9 – THC	(HU-210)	hallucinogenic, sedative, depressant	JWH-018, CP 47,497, HU-210, etc.	21	Thematic paper Understanding the 'Spice' phenomenon (2009); Drug profile Synthetic

						cannabinoids and 'Spice'
Miscellaneous substances	N/A – the category includes new psychoactive plants as well as synthetic psychoactive substances, derivatives of well-established drugs not belonging to any of the families listed above, designer medicines, narcotic analgesics, etc.	N/A	stimulant, hallucinogenic, narcotic analgesic / opiate, depressant, etc.	N/A	27	Risk assessment publication: GHB (2002) and Ketamine (2002) Thematic paper GHB and its precursor GBL: an emerging trend case study (2008)

(N) naturally occurring

(S) semi-synthetic

(N/A) non applicable

Thematic papers: http://www.emcdda.europa.eu/publications/searchresults?action=list&type=PUBLICATIONS&SERIES_PUB=w205

Risk assessments: http://www.emcdda.europa.eu/publications/searchresults?action=list&type=PUBLICATIONS&SERIES_PUB=w12

Drug profiles: http://www.emcdda.europa.eu/publications/drug-profiles

As Table 4.3 shows, five countries accounted for 75% of all first notifications, with the UK reporting one third of new substances. More than half of these notifications had been filed in the past two years. Authorities in certain countries have actively sought after many of these substances through test-purchases on the internet and from specialised shops. This proactive searching may partially explain the increased number of notifications in previous years. However, as not all Member States follow a proactive approach, the number of new substances present in the market may be underreported.

Table 4.3. – Number of new psychoactive substances first notified by a Member State

Country	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**Total**
United Kingdom	5	2	7	3	2	16	**35**
Finland	-	2	5	4	6	4	**21**
Sweden	5	2	-	1	1	2	**11**
Germany	-	-	-	-	6	3	**9**
Denmark	-	-	-	2	6	-	**8**
Austria	-	-	1	2	-	2	**5**
France	2	1	1	-	-	-	**4**
Ireland	-	-	-	-	-	4	**4**
Belgium	-	-	1	-	2	-	**3**
Latvia	-	-	-	-	-	3	**3**
Bulgaria	-	-	-	1	-	1	**2**
Hungary	-	-	-	-	-	2	**2**
Lithuania	-	-	-	-	1	-	**1**
Malta	1	-	-	-	-	-	**1**
Netherlands	1	-	-	-	-	-	**1**
Poland	-	-	1	-	-	-	**1**
Norway	-	-	-	-	-	4	**4**
Total	**14**	**7**	**16**	**13**	**24**	**41**	**115**

Most of the substances notified since the Council Decision came into effect were new psychotropic substances (**synthetic drugs**) similar to those listed in Schedules I and II of the 1971 UN Convention. The emergence of a large number of synthetic compounds illustrates the speed and sophistication with which the market reacts to control measures. The complexity and volatility of the EU drugs market largely explains the diversity of new drug 'families'. With rapid technological advances, such as cheap organic synthesis, coupled with the increased use of the internet for marketing and selling new drugs, it is likely that **synthetic analogues of other major drug groups** will continue to appear. The emergence of synthetic cannabinoids, synthetic cocaine derivatives, ketamine and phencyclidine derivatives marks the latest stage in this development.

'Designing' a drug to replace a controlled substance is not a new concept. In the past, however, designer drugs were produced illicitly and marketed directly on the illicit market (from those based on fentanyl in the 1980s, to tryptamines in the 1990s or piperazines and cathinone derivatives in the 2000s). An important difference today is that the chemicals are legally sourced but then sold as replacements for illicit drugs. One example is 'Spice', which was only sold over the internet or in specialised shops, rather than illicit networks. A relevant question asked in many Member States concerns the issue of which mechanisms are most effective for monitoring the emergence of such products and for assessing their possible impact. The limited knowledge about the chemical composition and effects of new compounds has, in practice, facilitated the emergence of a regulatory 'grey area' as authorities in charge of public health or medicinal products have often failed to assume responsibility for these substances.

Information on these substances is scarce, and therefore the availability of reference materials (substances) is important in order to enable forensic and toxicology laboratories to identify them. However, there is no EU system for sharing reference substances, as there is for the exchange of samples of seized illicit drugs, for which a procedure was created at EU level by a Council Decision[16]. Improving access to reference materials would help provide a comprehensive solution to new psychoactive substances.

5. OTHER EU LEGISLATION RELEVANT FOR THE REGULATION OF NEW PSYCHOACTIVE SUBSTANCES

Member States use different approaches to regulate or control new psychoactive substances, the most frequent being legislation on drug control and medicines. The Council Decision does not prevent Member States from maintaining or introducing measures to control new psychoactive substances on their territory [17]. However, in accordance with internal market rules, Member States are obliged to notify the Commission of any draft technical regulation (i.e. a decision to control or limit availability through medicines legislation). A number of EU directives and regulations enable Member States to adopt such decisions. They include the following:

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16 Council Decision 2001/419/JHA of 28 May on the transmission of samples of controlled substances. OJ L 150, 6.6.2001.0

17 Article 9(3).

- **Directive 98/34/EC[18] of the European Parliament and of the Council of 22 June 1998 1aying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services.**

This Directive requires Member States to report immediately to the Commission technical regulations[19] that may impede the internal market for goods. When Member States seek to limit the marketing or use of a chemical substance on grounds of public health, or the protection of consumers or the environment, they *"shall also communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate"*.

Member States *"shall postpone the adoption of a draft technical regulation for three months from the date of receipt by the Commission"* unless they are obliged to introduced it immediately *"for urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health or safety, (….) also for public policy, notably the protection of minors"*.

Few Member States have notified control measures to the Commission since 2005, although there has been a rapid increase since 2009[20]. Member States increasingly request the application of the urgency procedure for reasons of protection of public health, even though the evidence justifying theurgency requests is sometimes questionable or not fully documented, or concerns wide ranging legislation covering a variety of individual substances.

- **Regulation (EC) No 726/2004[21] 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.**

Some Member States also use medicines legislation to limit the manufacture and trade of new psychoactive substances, while not criminalising possession for personal use and use of a substance. In this case the substance is labelled as a medicinal product[22], which means a product that is either *presented* as a medicine (e.g. as a box of capsules) or claims to have a specific medical *function* (e.g. in treating a medical problem). Member States are free to make specific substances subject to medicines legislation, provided they fall under the definition of

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18 OJ L 24, 21.7.1998, p. 37

19 Art. 1(11): Technical specifications and other requirements, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in Article 10, prohibiting the manufacture, importation, marketing or use of a product.

20 Most notifications received by the Commission concern amendments of national drug control legislation. From 2005 to 2010, the Commission received 33 notifications, from Sweden (16), Ireland (5), Austria (2), Germany (2) Poland (2), Romania (2), Finland, Hungary, Latvia and the Czech Republic (all 1). The number of notifications increased since 2009: 2005 (2), 2006 (1), 2007 (5), 2008 (2), 2009 (9), 2010 (14).

21 OJ L 136, 30.4.2004, 28.11.2001, p. 1-32.

22 The directive defines a medicinal product as *"a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or, b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis"* (Article 1(1).

a medicinal product. The EU pharmacovigilance system primarily monitors the potential adverse effects of medicinal products as well as their proper use.

- **Regulation Regulation (EC) No 764/2008[23] of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.**

The Mutual Recognition Regulation lays down procedures relating to the application of certain national technical rules on products lawfully marketed in another Member State. The main aim is to make the mutual recognition principle fully operational. The Regulation it should applies to administrative decisions addressed to economic operators on the basis of a technical rules in respect of any product lawfully marketed in another Member State.

As regards psychoactive substances, the Mutual Recognition Regulation should apply in particular cases and on a case by case basis. In particular, when competent authorities of a Member State intend to adopt a decision that could prohibit the marketing of those substances lawfully marketed in another Member State on other than safety or health grounds[24], the Regulation should apply. This is the case, for example, when a psychoactive substance lawfully marketed in another Member State is denied for reasons based on technical rules (denomination, size, composition, etc.).

- **Directive 2001/95/EC[25] of the European Parliament and of the Council of 3 December 2001 on general product safety.**

The RAPEX system, coordinated by the Commission, enables national authorities competent for product safety to exchange very quickly and efficiently information on risk assessment, dangerous products and national restrictive measures taken in respect of these products. In cases of serious risk to the health and safety of consumers in the various Member States, the Commission may decide, subject to strict conditions, to withdraw the product from the market for one year, following a comitology procedure[26] (Article 13)

- **Regulation (EC) No 178/2002[27] of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.**

When it is clear that a food or feed may pose serious risks to human health, the Commission can adopt emergency measures following a comitology procedure, or in extreme cases can adopt emergency measures on its own, to be confirmed by the Committee within ten days. These measures include withdrawal from the market, laying down of special conditions, or

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23 OJ L 218/21, 13.08.2008, p. 21-29.

24 When the decision to prohibit the marketing of certain psychoactive substances lawfully marketed in another Member State is on safety or health grounds, Directive 2001/35/EC on general product safety should apply.

25 OJ L 11, 15.1.2002, p. 4–17.

26 For example, DMF, a solvent used in the fabrication of plastics and which may cause cancer and other serious illnesses, was banned from all products under this procedure in December 2007.

27 OJ L 31, 1.2.2002, p. 1–24.

any appropriate interim measures[28]. Member States exchange information and introduce alerts through the RAS (Rapid Alert System), which is managed by the Commission (Article 50).

Some new psychoactive substances can be treated as food, since any substance meant to be ingested orally is considered as food and therefore subject to food safety legislation (Article 2).

- **Directive 2000/13/EC[29] of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.**

The Directive sets out conditions for food labelling (name, ingredient, quantity) and defines and prohibits misleading clauses. Controls are implemented by national authorities, which also impose sanctions.

- **Regulation (EC) No 1925/2006[30] of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.**

The Regulation on food supplements enables the Commission to ban, limit or subject to a four-year monitoring process substances that pose or are likely to pose a risk to human health (Article 8). The relevant clause has never been applied.

- **Regulation (EC) No 1907/2006[31] of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.**

Within the framework of REACH, the most relevant provisions for the purpose of this document concern the restriction process. Under REACH, either a Member State or the European Chemicals Agency (the latter at the request of the Commission) carries out the assessment of the hazard and risk of substances on their own, in mixtures or articles, where it is considered that they pose a risk to human health or environment that is not adequately controlled and which needs to be addressed on a EU-wide basis. On this basis, and also taking into account the socio-economic consequences, a restriction report is prepared and submitted for review to the Committee for Risk Assessment and the Committee for Socio-economic Analysis in the European Chemicals Agency. Following the receipt of the Committees opinions, the Commission decides under the comitology procedure whether it restricts the manufacture, use or placing on the market, either completely or under specific conditions. In implementing REACH, Member States have to lay down penalties that are effective, proportionate and dissuasive, as well as to maintain a system of official controls and other activities as appropriate to the circumstances.

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28 Article 53 and following.
29 OJ L 109, 6.5.2000, p. 29–42.
30 OJ L 404, 30.12.2006, p. 26–38.
31 OJ L 396, 30.12.2006, p. 1–849.

6. FUNCTIONING OF THE COUNCIL DECISION ON NEW PSYCHOACTIVE SUBSTANCES

The Council Decision has three main stages, namely: information exchange covering the Early Warning System and the Joint Report, risk assessment and decision-making. There are clear criteria for triggering these phases and timeframes for implementation.

Table 6.1 Overview of mechanisms and timeframe of the Council Decision

Step	What	Who	Timeframe	Output	Article
1.	Notification on new psychoactive substances; data on manufacture, trade, use	Member States via Reitox National Focal Points and Eurpopol National Units	**Ongoing**	Information is transmitted through Early Warning System to Member States, Commission and EMA	4
	Assessment of information on a specific new psychoactive substance	EMCDDA and Europol		Decision to develop EMCDDA-Europol Joint Report[32]	
	Joint Report: data collection	Member States EMCDDA/ Europol/ EMA	**6 weeks**	Data from all Member States and available data at EU level; preliminary scientific data	5(1) to 5(4)
	Presentation of Joint Report	EMCDDA/ Europol	**4 weeks**	Joint Report is presented to Council and European Commission	5(5)
	Decision on need for and possibility of Risk Assessment	Council (at request of Commission or at least 1/4th Member States)	**4 weeks** after reception of Joint Report by Commission or Council	Decision by Council	6(1)
2.	Risk Assessment[33]	Scientific Committee of the EMCDDA (extended with Commission, Europol, EMA and external experts)	**12 weeks** after notification by Council Secretariat of Council Decision to conduct a Risk Assessment	Risk Assessment Report	6(2)-6(3) 7

[32] The criteria used to make this decision include: quantity of substance seized, evidence of international trafficking and organised crime involvement, toxico-pharmacological properties of the substance, evidence for potential further (rapid) spread, of intoxications or fatalities.

[33] The risk assessment report shall include a physical and chemical description of the substance, including medical value; health and social risks; involvement of organised crime, information on seizures and manufacture; information on any assessment of the substance in the UN system; a description of control measures applicable to the substance in the Member States; options for control and possible consequences of control measures.

	Proposal on making specific new psychoactive substance subject to control measures	European Commission	**6 weeks** after receipt of Risk Assessment Report	Proposal for a Council Decision OR report by the Commission why control is not deemed necessary	8(1)
3.	Decision on Commission's proposal	Council	**Unspecified**	Decision to control or not to control the specific new psychoactive substance	8(2), 8(3)
	Implementation of possible Council Decision to control the new psychoactive substance	Member States	**52 weeks** after publication of the Council Decision in the Official Journal	Member States submit substance to control measures and criminal penalties as provided under their laws by virtue of their obligations under the UN Drug Conventions	9

7. FINDINGS OF THE SURVEY AMONG MEMBER STATES

In October 2010, the European Commission invited the Member States to answer a questionnaire on the functioning of the Council Decision – its formulation, scope and instruments. Member States were also asked, more broadly, how they had tackled new psychoactive substances over the previous five years. Twenty-five Member States returned their answers to the Commission. A summary of these answers is presented in this section.

7.1. Assessment of the Council Decision

Of the Member States that responded, 18[34] find that the **overall formulation** of the Council Decision is sufficiently clear. Greece comments that the text is not up to date. Fifteen Member States[35] indicate that the provisions on **information exchange** are clearly formulated and the other 15 Member States[36] believe that this is the case for the **risk-assessment stage**. Portugal comments that the formulation could be improved, but does not indicate in which parts. Twelve Member States[37] are satisfied with the formulation of the Council Decision with regard to the **decision-making stage**. Ireland points out that the formulation should be improved to enable better adherence to timelines. Portugal comments that it could be improved. Sweden is unclear as to whether other national control options are acceptable.

Fourteen Member States[38] find that the **scope** of the Council Decision, defined by analogy with the UN Drugs Conventions, is appropriate as regards the substances included. Ireland

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34 Belgium, Bulgaria, Czech Republic, Germany, Greece, Spain, Estonia, Hungary, Ireland, Italy, Lithuania, Latvia, Malta, Netherlands, Poland, Portugal, Sweden, Slovenia.

35 Belgium, Bulgaria, Germany, Estonia, Hungary, Ireland, Italy, Lithuania, Latvia, Malta, the Netherlands, Poland, Portugal, Sweden, Slovenia.

36 Belgium, Bulgaria, Germany, Estonia, France, Hungary, Ireland, Italy, Lithuania, Latvia, Malta, the Netherlands, Poland, Sweden, Slovenia.

37 Belgium, Bulgaria, Germany, Estonia, Hungary, Italy, Lithuania, Latvia, Malta, the Netherlands, Poland, Slovenia.

38 Belgium, Bulgaria, Germany, Greece, Spain, Estonia, Hungary, Italy, Lithuania, Malta, the Netherlands, Poland, Romania, Slovenia.

suggests that the scope should be widened and notes that the Council Decision does not take into account the fact that some substances are both "drugs precursors" and "end products". It points out that substances used in medicinal products are exempted from control, but does not indicate why this is a problem. France suggests that the scope could be expanded to include substances used for the production of medicines. Portugal comments that the scope could be optimised. Sweden suggests widening the scope to include substances used for doping (not related to sports) as well as substances used in smoking mixtures (such as Spice). Latvia comments that Article 2 should include a reference to the legislation on drugs precursors[39].

Ten Member States[40] take the view that **the control option** provided by the Council Decision is appropriate. Bulgaria suggests considering the possibility of a generic approach (banning several chemically related substances simultaneously). Lithuania, the Netherlands, the UK, Portugal, Latvia and Ireland point out that alternative risk management options should be available to deal with these substances. Ireland adds that particular attention should be paid to the supply of new psychoactive substances over the internet.

7.2. Stages in the functioning of the Council Decision

Information exchange (EWS and Joint Report)

Most Member States are satisfied with the **rapidity and outputs of the EWS**. However, certain Member States[41] note that a long time elapses between the detection of substances and reporting on them via the EWS. Most Member States are satisfied with the way in which the EWS facilitates the sharing of information, although three[42] would like more information to be provided in the early warning reports.

Although most Member States find the **effectiveness and efficiency of the EWS** satisfactory, three[43] point out that more information should be disseminated[44]. The Netherlands finds that too much information is provided, and Belgium says that the system is too slow and ineffective. France contends that the information exchanged through the EWS reflects the capacity and efficiency of individual Member States. All Member States find the **EWS useful not only as an EU-level instrument**, but also at national level because it alerts national authorities to the emergence of new substances in neighbouring Member States.

Most Member States are satisfied with the **Joint Report, although** some argue that it should be completed sooner. Nearly all Member States think that substances that have been subject to a Joint Report, but are not submitted to risk assessment, should be actively monitored. Poland suggests that substances subjected to Joint Reports should be temporarily controlled until a decision on conducting a risk assessment is taken and the assessment is completed.

There is no consensus on the need to build **EU research capacity to provide toxicological and forensic analysis**. Sixteen Member States state that the EU's forensic capacity should be

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39 Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug Precursors [OJ L22, 26.1.2005, p.1-10].

40 Belgium, Germany, Greece, Spain, Estonia, Hungary, Italy, Malta, Poland, Slovenia.

41 Cyprus, Italy and to a lesser extent, Germany.

42 Slovakia, Sweden, and the United Kingdom.

43 Bulgaria, Italy, Lithuania.

44 These three countries find that the EWS facilitates the information sharing in a satisfactory manner.

enhanced[45], while three take the view that it is adequate[46]. Three Member States are in favour of building a centralised forensic capacity[47], while ten believe that it should be improved through enhanced cooperation between national laboratories or by subcontracting national laboratories to conduct forensic analysis.

Risk Assessment

Most Member States consider that the **time-frame** in which the **risk assessment** is carried out is satisfactory. Five Member States[48] consider the process to be too long and one Member State (the Netherlands) considers it to be too short to reach any valid conclusions. The UK considers the process too long for a quick response, but too short for a robust assessment. All Member States consider the information and criteria used to complete the risk assessment to be satisfactory.

Most Member States find the **role and composition of the EMCDDA's Scientific Committee** to be satisfactory[49]. Greece points out that the Balkan countries should be better represented in the Scientific Committee, while Ireland believes that experts from all Member States should be included, since decisions to ban substances across the EU will be taken on the basis of risk assessment. Bulgaria calls for the Scientific Committee to be given decision-making powers, but does not explain how these powers could be implemented within the current EU institutional framework.

Most Member States find the content and **structure of the risk assessment report** satisfactory. Portugal points out that the report should include toxicological and forensic analysis, as well as the results of questionnaires addressed to drug users, while Bulgaria has requested more scientific information. Ireland points out that the scope of the risk assessment is too limited.

All Member States except France are in favour of **increasing the EU research capacity** on new psychoactive substances, either because of a lack of national research capacity in this field or because they think that decisions to impose control measures on substances should be backed up by enhanced scientific evidence. France is planning to increase its own capacity to detect new psychoactive substances and to evaluate their availability, use and toxicity.

Two Member States[50] suggest that the risk assessment report should be **translated into all official EU languages**. Spain thinks that the Council Decision should enable monitoring of substances that are not subject to control. Ireland, Finland and France suggest that several substances of the same chemical family should be submitted to a risk assessment at the same time. The Netherlands notes that the risk assessment reports have so far provided insufficient evidence to justify the control of substances (in particular in the case of BZP) and contends that this undermines the objectives of the Council Decision. All Member States consider that

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45 Belgium, Bulgaria, Cyprus, France, Germany, Greece, Ireland, Italy, Malta, Lithuania, Poland, Portugal, Romania, Spain, Sweden and UK.

46 Latvia, Netherlands and Slovenia.

47 Bulgaria, Romania and UK.

48 Spain, Estonia, France, Poland, Slovenia.

49 The composition of the Scientific Committee was changed in 2008. From a body representing all Member States, it became an independent body of experts nominated on the basis of their scientific background.

50 Belgium and Cyprus.

the risk assessment report is useful at national level, either as a complementary source of information or when considering national control measures.

Decision making

Eight Member States[51] find the **decision-making** procedure adequate, whereas 17 Member States[52] believe it is too slow. Belgium thinks that the Commission is too slow in deciding on its position. Denmark suggests that Member States should decide directly on the basis of the risk assessment, without awaiting the Commission's position. Four Member States[53] point out that several countries had already introduced control measures by the time a decision was made at EU level, but they do not elaborate on whether that is a problem and, if so, why.

Eighteen Member States[54] are in favour of **fast-track/emergency control measures**. Lithuania mentions that it has no experience of temporary control measures. Bulgaria notes that temporary control measures are not necessary in the current structure, but if the risk assessment includes more thorough research, which takes more time, such measures might be needed. Portugal suggests that the EWS should play a more proactive role in detecting new substances, monitoring the market and identifying new trends. Spain suggests a Standing Committee, which will include the relevant EU institutions and agencies and all the Member States, to decide on temporary control measures. France is cautious about emergency measures, because substances that do not pose risks would also be controlled under such measures.

Fourteen Member States[55] agree that a **wider range of control options** should be considered, including temporary controls and regulation, in respect of substances that are found to pose little or no risk to health. Greece notes that it already applies other control measures (e.g. consumer protection and food safety legislation) and suggests that such options should also be viable at EU level. Finland, Ireland and the UK are in favour of using a generic approach to new psychoactive substances (simultaneous assessment and control of several related compounds), to avoid the emergence of similar versions of the same substance. The Netherlands suggests increasing the monitoring of substances and the introduction of education and prevention programmes, while Malta considers that control options should reflect the overall risks of a substance – on the basis of scientific evidence - to the individual and society. France proposes that the time between risk assessment and decision should be shortened.

7.3. National responses to new psychoactive substances

Fourteen Member States report that the decision to subject BZP to control measures has had no **measurable effect** – either because the situation has remained unchanged[56] or because there is no information on the presence of the substance on the market after it was subjected

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51 Bulgaria, Lithuania, Italy, Germany, Cyprus, Greece, the Netherlands and the Czech Republic.

52 Belgium, Denmark, Romania, Portugal, Poland, Ireland, Hungary, Latvia, Estonia, Spain, Slovakia, Finland, the United Kingdom, Sweden, Malta, Slovenia and France.

53 Denmark, Lithuania, Sweden and United Kingdom.

54 Bulgaria, Cyprus, Denmark, Estonia, Finland, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Malta, Poland, Romania, Spain, Slovakia, Sweden and UK.

55 Belgium, Cyprus, Finland, Greece, Ireland, Lithuania, Malta, Latvia, Netherlands, Portugal, Poland, Romania, Sweden and UK.

56 France, Germany, Hungary, Netherlands, Poland, Portugal, Slovakia, Spain, Sweden and UK.

to control[57]. Six Member States[58] report a decrease in seizures after the introduction of the ban.

Six Member States[59] report that they have specialised shops selling drugs on their territory and that, when specific substances are prohibited, they are no longer found in these shops. Eight Member States[60] have forbidden headshops, either by controlling the substances they sold or by tightening health and food legislation. Seven Member States[61] have no legislation on headshops. Six Member States[62] have taken specific measures to **tackle the sale of new psychoactive substances online**. Six Member States[63] have not taken any action, but do not indicate whether online sales are a problem. Eight Member States[64] use existing legislation for illicit drugs control, health or food and consumer protection to regulate online shops, which sometimes means that no action is taken.

Six Member States[65] use **medicines legislation** to regulate these substances until they become prohibited under illicit drug legislation. Three[66] of them use consumer protection or public health laws to control new psychoactive substances. Italy confirms that it has implemented emergency measures. Six Member States[67] have enforced measures available under **other types of legislation** because they enable a faster and more flexible response. Four of these[68] believe that the alternative options mentioned have a deterrent effect. Three[69] indicate that they use such alternative options as temporary measures, until drug control legislation is in place.

57 Belgium, Bulgaria, Latvia and Slovenia.
58 Cyprus, Denmark, Estonia, Greece, Ireland and Malta.
59 Italy, Netherlands, Portugal, Spain, Romania and UK.
60 Bulgaria, Finland, Greece, Ireland, Latvia, Lithuania, Poland and Slovakia.
61 Cyprus, Estonia, Germany, Hungary, Malta, Sweden and Slovenia.
62 Ireland, Italy, Poland, Romania, Spain and the UK.
63 Bulgaria, Cyprus, Greece, Hungary, Malta and the Netherlands.
64 Estonia, Finland, France, Germany, Latvia, Lithuania, Portugal and Sweden.
65 Estonia, Finland, Germany, Italy, Netherlands and Lithuania.
66 France, Lithuania and Spain.
67 Germany, Ireland, Italy, Lithuania, Malta and the Netherlands.
68 Germany, Ireland, Lithuania and the Netherlands.
69 Italy, Lithuania and Malta.

7.3.1. List of new psychoactive substances first notified by year

2005			
	January – May (under the terms of the Joint Action		
Nr	**Common/code name**	**Chemical Name**	**First notification**
1	***m*CPP**	1-(3-chlorophenyl)piperazin/CPP (chlor-phenyl-piperazine)	February, France
2	**4-HO-DIPT**	4-hydroxy-N,N-diisopropyltryptamine	March 2005
3	**methylone**	3,4-methylenedioxymethcathinone	March, Netherlands;
4	**4-HO-DET**	4-hydroxy-N,N-diethyltryptamine	April, Sweden
5	**DIPT**	Diisopropyltryptamine	April, Sweden
6	**MeOPP**	1-(4-methoxyphenyl)-piperazine	April, Sweden
	May-December(under the terms of the Council Decision		
7	**MDHOET**	3,4-methylenedioxy-N-(2-hydroxyethyl)amphetamine	May, France
8	**2C-P**	2,5-dimethoxy-4-(n)-propylphenethylamine	August, UK
9	**5MeO-AMT**	5-Methoxy-α-methyltryptamine	August, UK[70]
10	**MIPT**	*N*-Methyl-*N*-isopropyltryptamine	August, UK
11	**2C-T-4**	2,5-dimethoxy-4-isopropylthiophenethylamine	August, UK
12	**4-AcO-DIPT**	4-acetoxy-N,N-diisopropyltryptamin	September, Sweden
13	**DPIA**	Di-(β-phenylisopropyl)amine	October, Malta
2006			
Nr	**Common/code name**	**Chemical Name**	**First notification**

[70] Substance not included in the count – previously notified in 2004.

1	**pFPP**	p-Fluorophenylpiperazine	19 April 2006, UK
2	**pCPP**	1-4 chloro phenyl piperazine	6 November 2006, France
3	**DBZP**	1, 4-Dibenzylpiperazine	9 November 2006, UK
4	**2,4-DMA**	2,4-dimethoxy-alpha-methylbenzeneethanamine (or 2,5-DMA (2,5-dimethoxy-alpha-methylbenzeneethanamine)	20 November 2006, Finland
5	**2-aminoindan**	1H-Inden-2-amine, 2,3-dihydro; or 1-aminoindan (1H-Inden-1-amine, 2,3-dihydro	21 November 2006, Finland
6	**Bromo-Dragonfly**	Bromo-benzodifuranyl-isoprophylamine	21 November 2006, Sweden
7	**DOI**	4-iodo-2,5-dimethoxyamphetamine	21 November 2006, Sweden
2007			
Nr	**Common/code name**	**Chemical Name**	**First notification**
1	**2C-B-Fly**	(8-bromo-2,3,6,7-benzo-dihydro-difuran-ethylamine)	15 February 2007, Finland
2	**5-MeO-Dalt**	N,N-diallyl-5-methoxytryptamine	15 February 2007, Finland
3	**N-ethyl-2C-B**	N-ethyl- 4-Bromo-2,5-dimethoxybenzeneethanamine	22 February 2007, Finland
4	**Vanoxerine**	1-[2-[bis(4-fluorophenyl)methoxy]ethyl]-4-(3-phenylpropyl)piperazine	3 May 2007, Belgium
5	**D2PM (**proposed code name)	(S)-(-)-α,α-Diphenyl-2-pyrrolidinylmethanol	11 May 2007, UK
6	**N-Acetyl-DOB**	N-Acetyl-4-bromo-2,5-dimethoxyamphetamine	11 June 2007, UK
7	**1-PEA**	1-Phenylethylamine	1st half of 2007, UK
8	**Gelbes** (working name)	1-(3-chlorophenyl)-4-(3Chloropropyl)piperazine hydrochloride	24 September 2007, Austria
9	**NMPEA** (proposed code name)	N methyl Phenylethylamine	6 December 2007, France
10	**Glaucine** (International non-proprietary name)	(6aS)-1,2,9,10-tetramethoxyaporphine)	2 July 2007, UK
11	**Fenazepam**	7-brom-5/o-chlorphenyl/1,2-dihydro-3H-1,4-benzodiazepin-2-on	1st half of 2007, Finland

12	**Nimetazepam**	2-methyl-9-nitro-6-phenyl-2,5-diazabicyclo[5.4.0]undeca-5,8,10,12-tetraen-3-one	1st half of 2007, UK
13	**N-desmethylsibutramine**	14 December 2007, Poland	14 December 2007, Poland
14	**Bufotenine**	3-(2-dimethylaminoethyl)-1H-indol-5-ol	1st half of 2007, UK
15	**Harmine**	7-Methoxy-1-methyl-9H-pyrido[3,4-b]indole	1st half of 2007, Finland
16	**Salvia Divinorum**		1st half of 2007, UK
2008			
Nr	**Common/code name**	**Chemical Name**	**First notification**
1	**bk-MBDB**	2-methylamino-1-(3,4-methylenedioxyphenyl)butan-1-one	29 January 2008, UK
2	**Ethylcathinone/Subcoca I**	2-Ethylamino-1-phenylpropan-1-one	7 March 2008, Finland
3	**Mephedrone/Subcoca II**	2-Methylamino-1-p-tolylpropan-1-one	7 March 2008, Finland
4	**Kratom**	Mitragynin/7α-Hydroxy-7H-mitragynin/Paynanthein	19 March 2008, Austria
5	**4-HO-MET**	4-hydroxy-N-methyl-N-ethyltryptamin	4 June 2008, Sweden
6	**Kava**	Piper methysticum	22 July 2008, UK
7	**Flephedrone**	p-fluormethcathinone	30 September 2008, Denmark
8	**3-Fluoromethcathinone**		20 October 2008, UK
9	**LSA**	(8β)-9,10-didehydro-6-methyl-ergoline-8-carboxamide	29 October 2008, Bulgaria
10	**pFBT**	3-pseudotropyl-4-fluorobenzoate	1 December 2008, Finland
11	**MDPV**	1-(3,4-methylenedioxyphenyl)-2-pyrrolidinyl-pentan-1-one	5 December 2008, Finland
12	**p-Fluoramphetamine**	1-(4-fluorophenyl)propan-2-amine	5 December 2008, Denmark
13	**JWH-018**	Naphthalen-1-yl-(1-pentylindol-3-yl)methanon	19 December 2008, Áustria
2009			

Nr	Common/code name	Chemical Name	First notification
1	**-**	2- or 3-fluoroamphetamine	8 January 2009, Belgium
2	**PPP**	α-pyrrolidinopropiophenone	27 January 2009, Denmark
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, UK
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, UK
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
2010			
Nr	**Common/code name**	**Chemical Name**	**First notification**
1	**2C-B-BZP**	1-(4-bromo-2,5-dimethoxybenzyl)piperazine	18 January 2010, Germany
2	**MDAI**	5,6-methylenedioxy-2-aminoindane	26 February 2010, Sweden
3	**β-Me-PEA**	2-phenylpropan-1-amine	26 February 2010, Norway
4	**-**	N-benzyl-1-phenethylamine	26 February 2010, Norway
5	**-**	N,N-dimethylphenethylamine	26 February 2010, Norway
6	**4-FMA**	4-fluoromethamphetamine	24 March 2010, Norway
7		(4-methoxyphenyl)(1-pentyl-1H-indol-3-yl)methanone	25 May 2010, Hungary
8	**JWH-081**	1-pentyl-3-(4-methoxy-1-naphthoyl)indole	2 June 2010, Latvia
9	**Naphyrone**	naphthylpyrovalerone	11 June 2010, Sweden
10	**Iso-ethcathinone**	1-ethylamino-1-phenyl-propan-2-one	18 June 2010, Ireland
11	**DMAA**	1,3-dimethylamylamine	21 June 2010, Ireland
12	**Dimethocaine**	(3-diethylamino-2,2-dimethylpropyl)-4-aminobenzoate	21 June 2010, Ireland
13	**JWH-073 methyl derivative**	1-Butyl-3-(1-(4-methyl)naphthoyl)indole)	30 June 2010, Germany
14	**Buphedrone**	(2-(methylamino)-1-phenylbutan-1-one	5 July 2010, Finland
15	**4-methylethcathinone**	2-Ethylamino-1-(4-methylphenyl)-1-propanone	July 2010, UK
16	**AM-694**	1-[(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophenyl)methanone	19 July 2010, Ireland
17	**JWH-122**	1-pentyl-3-(4-methyl-1-naphthoyl)indole)	23 July 2010, Latvia
18	**MPBP**	4'-methyl-α-pyrrolidinobutyrophenone	27 July 2010, Bulgaria
19	**JWH-015**	1-propyl-2-methyl-3-(1-naphthoyl)indole)	27 July 2010, Austria

20	**4-MBC**	4-methyl-N-benzylcathinone	16 August 2010, UK
21	**MPPP**	4'-Methyl-α-pyrrolidinopropiophenone	16 August 2010, UK
22	**CP 47,497 (C8 + C2) variant**		17 August 2010, UK
23	**-**	1-naphthalen-1-yl-2-pyrrolidin-1-yl-pentan-1-one	18 August 2010, UK
24	**Pentylone**	2-Methylamino-1-(3,4-methylenedioxyphenyl)pentan-1-one	3 September 2010, UK
25	**M-ALPHA**	1-methylamino-1-(3,4-methylenedioxy-phenyl)propane	3 September 2010, UK
26	**5-MeO-DPT**	5-methoxy-N,N-dipropyltryptamine	13 September 2010, Finland
27	**β-Ethyl-Methcathinone**	2-methylamino-1-phenyl-1-pentanone	17 September 2010, Austria
28	**JWH- 210**	4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone	22 September 2010, Germany
29	**3,4-Dimethylmethcathinone**	1-(3,4-dimethylphenyl)-2-(methylamino)propan-1-one	13 October 2010, Hungary
30	**JWH-203**	2-(2-chlorophenyl)-1-(1-pentylindol-3-yl)ethanone	14 October 2010, Latvia
31	**JWH-019**	1-hexyl-3-(1-naphthoyl)indole	26 October 2010, Finland
32	**Methoxetamine**	2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone	9 November 2010, UK
33	**-**	3-(4-Hydroxymethylbenzoyl)-1-pentylindole	9 November 2010, UK
34	**MDPBP**	3',4'-methylenedioxy-α-pyrrolidinobutyrophenone	17 November 2010, UK
35	**3-MeO-PCE**	3-methoxyeticyclidine	17 November 2010, UK
36	**DiButylone or bk-MMBDB**	2-dimethylamino-1-(3,4-methylenedioxyphenyl)-butan-1-one	18 November 2010, Finland
37	**Arecoline**	methyl methyl-1,2,5,6-tetrahydropyridine-3-carboxylate	22 November 2010, UK
38	**BMDP**	2-benzylamino-1-(3,4-methylenedioxyphenyl)propan-1-one	9 December 2010, UK
39	**BMDB**	2-benzylamino-1-(3,4-methylenedioxyphenyl)butan-1-one	9 December 2010, UK
40	**5-APB**	5-(2-aminopropyl)benzofuran	14 December 2010, UK
41	**Desoxy-D2PM**	2-(diphenylmethyl)pyrrolidine	23 December 2010, UK