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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

New psychoactive substances[1] are becoming widely available at an unprecedented pace. The speed at which they appear and the way they can be distributed challenge the established procedures for monitoring, responding to and controlling the use of new psychoactive substances, according to a 2010 report of Europol and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).[2]

Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances adopted on 10 May 2005[3] ('the Council Decision') sets up an EU-wide system for dealing with these new narcotic drugs and psychotropic substances entering the European market. It involves the exchange of information (early warning system) between Member States on such substances, their risk assessment and, if necessary, their submission to control measures and criminal sanctions[4] across the EU.

The present assessment is a follow-up to the recommendation of the EU Drugs Action Plan 2009-2012,[5] which requires the Commission to '*assess the functioning'* of this Council Decision '*and amend it, if necessary'*. The Commission has done this with the support of EMCDDA, its Scientific Committee and Europol. Member States provided input through a survey ('the Survey')[6].

The assessment highlights the fact that the market for new psychoactive substances has changed dramatically in the past three years: there has been a significant increase in the number of substances detected, their variety and the diversification of their distribution

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1 Under the definitions of the Council Decision (Article 3), '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.

2 EMCDDA-Europol 2010 Annual Report on the implementation of Council Decision 2005/387/JHA, p.15.

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

4 Member States should take the necessary measures by virtue of their obligations under the UN 1971 Convention on Psychotropic Substances and the 1961 UN Single Convention on Narcotic Drugs (Article 9 of the Council Decision). These obligations are stated under Article 3 of the 1988 UN Convention against illicit traffic in narcotic drugs and psychotropic substances: 'Each Party shall adopt such measures as may be necessary to establish as criminal offences under its domestic law, when committed intentionally' the production, manufacture, distribution, sale, delivery, transport, importation or exportation, the possession or purchase of any narcotic drug or any psychotropic substance.

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

6 See Annex (section 7) for a summary report of the findings of the survey.

channels. It concludes that the Council Decision is not an adequate instrument to address these new challenges. The Commission therefore invites the European Parliament and the Council to contribute to a debate on ways of reinforcing the EU legislation. This is with a view to possible Commission legislative proposals in 2012.

2. NEW PSYCHOACTIVE SUBSTANCES IN THE EU: EVOLUTION AND CHALLENGES

In the past five years, Member States have notified 115 psychoactive substances[7] through the information exchange mechanism[8] set up by the Council Decision. While in the period 2005-2008 the number of new substances notified was stable at 10-15 a year, from 2009 there was a large increase in the number of notifications.

Many new psychoactive substances are in fact variations within a specific group of chemicals and are similar to substances controlled at national level. Some are products containing herbal and synthetic compounds that appear in various mixtures in different Member States. One example is Spice, a mixture containing herbs and synthetic cannabinoids that mimic the effects of cannabis[9]. They are difficult to identify and regulate because of their diversity and the speed with which they are developed to replace those that are controlled.

Many of these substances are manufactured in commercial laboratories, probably in Asia[10], and are often cheaper than illicit drugs. Despite their status as licit substances ('legal highs')[11] — which could make users believe that they are safe — they may pose a threat to public health comparable with the illicit drugs listed in the so-called schedules to the United Nations Conventions on Narcotic Drugs and on Psychotropic Substances. Their constituent compounds and the effects they have are often unclear. Hence, they can be toxic, addictive and have long-term adverse effects. For users, the main sources of information on their potential effects and risks are websites and messages posted on the internet by drug user communities. They are marketed and sold mainly through specialised shops, illicit drug sellers and over the internet.

For many years specialised shops selling new psychoactive substances existed in only a few Member States. In the past two years, however, such shops have opened up at a rapid pace in several countries, including Poland, Ireland and Romania. There is no common approach across the EU to the regulation of the specialised shops. Nevertheless, national decisions on these shops can have knock-on effects on other Member States' policies[12].

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7 See Annex (section 4 and 7) for a breakdown of notified substances, types and trends.

8 The EMCDDA/ Europol Early Warning System, in which all Member States participate.

9 Spice first appeared in Europe in 2006 and gained popularity in 2008. None of the Spice compounds have developed as a drug in its own rights; www.emcdda.europa.eu/publications/thematic-papers/spice

10 In particular in China and India.

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

12 For instance, recent interventions by the Polish authorities on over 1,300 head shops in the country has resulted in traders opening similar shops in neighbouring Czech Republic.

The EMCDDA's 2010 snapshot survey[13] identified 136 online shops selling new psychoactive substances. Most of these shops were based in the Netherlands, the UK and Germany, but at least five were found in Poland, France and Hungary.

The Member States have been affected by new psychoactive substances in different ways. They have used different laws to control or regulate the manufacture, sale and possession of new psychoactive substances, in particular drugs control and medicines legislation. They can also use legislation based on several directives and regulations[14] that tackle food safety,[15] consumer protection, dangerous substances and products at EU level.[16] However, some new psychoactive substances are sold – for example - with the label *'not for human consumption'*, to circumvent drugs legislation[17].

3. OBJECTIVES AND SCOPE OF THE COUNCIL DECISION

The Council Decision of 10 May 2005 was adopted on the basis of ex-articles 29, 31(1)(e) and 34(2)(c)[18] of the Treaty on European Union (third pillar). Its rationale was to enable Member States to tackle the emergence of psychoactive substances effectively by submitting them to EU-wide control measures.

There are six steps in the procedure established by the Council Decision for submitting a new psychoactive substance to control measures: 1) a Member State provides information on a new substance on its market; 2) Europol and the EMCDDA, in collaboration with the European Medicines Agency (EMA) prepare a Joint Report and submit it to the Council; 3) the Council requests a Risk Assessment from the EMCDDA; 4) the EMCDDA submits the risk assessment to the Council and the Commission; 5) the Commission presents an initiative for control measures to the Council; 6) the Council decides on the submission of the substance to control measures and on the obligation to introduce criminal law measures. This procedure has been used only twice since 2005. In 2007 the Council decided to submit BZP[19] to control measures and in 2010 it submitted mephedrone.[20]

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13 EMCDDA, Annual Report 2010 on the State of the Drug Problem in Europe; p. 92-93.

14 See Annex (section 5) for an overview of these EU instruments.

15 Some new psychoactive substances can be treated as food, since any substance meant to be ingested orally is considered to be food and subject to food safety legislation (Article 2 of Regulation (EC) No 178/2002 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).

16 Possession for personal use is not a criminal offence under medicines legislation, but is often so under drug control laws. Food safety and consumer protection legislation requires producers to prove the safety of their products.

17 Mephedrone, which was submitted to control measures across the EU on 2 December 2010 (OJ L 322, 20.12.2010, p. 44), was marketed as 'plant food', other products are e.g. sold as 'bath salts' or 'room odorisers'.

18 These articles deal with police and judicial cooperation in criminal matters and the adoption of measures establishing minimum rules relating to the constituent elements of criminal acts and to penalties in the field of illicit drug trafficking. The Lisbon Treaty challenges the legal rationale of the Council Decision as it repealed ex-Article 34(2)(c) TEU, on the basis of which the decision to submit a substance to control measures could be taken. The decision to submit mephedrone to control measures could only be taken pursuant to the principle of preservation of the third pillar *acquis*.

19 1-Benzylpiperazine.

20 4-methylmethcathinone.

The scope of the Council Decision is defined by analogy with that of the drug control system as foreseen in the UN Conventions on drugs, which it seeks to reproduce at EU level.[21] It covers substances that are not scheduled under these Conventions and which may pose a comparable threat to public health. It does not cover drugs precursors[22] or substances that are used in the manufacturing of medicinal products[23]. The Council Decision does not intend to replace Member States' legislation on new psychoactive substances, but rather to address those substances that are, or could become, a problem across the EU.

4. FUNCTIONING OF THE COUNCIL DECISION

A record number of new substances (41) were reported in 2010, more than a third of all substances notified since 2005. This increase in the number of notifications illustrates not only the rapid rise in the number of substances available in the EU but also improved reporting capacities in some Member States. Five countries accounted for 75% of all first notifications, with the UK reporting one third of new substances, which reflects the UK's high level reporting and identification capabilities.[24]

Since not all Member States adopt a proactive approach (through controlled test purchases on the internet and from specialised shops) the number of new substances on the market may be higher than reported.

Until now notifications from Member States have led to the publication of three Joint Reports: on *m*CPP[25] (2006), BZP (2007) and mephedrone (2010). The Joint Reports on BZP and mephedrone were followed by risk assessment.[26]

The risk assessments on BZP and mephedrone provided arguments for submitting the substances to control measures. Both concluded that the substances posed risks for health and society but acknowledged that there was limited scientific evidence on the acute and long-term effects on health and fatalities, on consumption patterns and on prevalence.

The Council Decision stipulates that, based on the findings of the risk assessment, the Council may decide on the submission of the substance to control measures and on the obligation to introduce criminal law measures. The lack of alternatives (i.e. measures other than criminal ones) mirrors the mechanism of the UN Conventions on illicit drugs. In both cases (BZP and mephedrone) when a substance was assessed, the Commission proposed — and the Council

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21 Article 3(b) and (c).

22 Chemicals used to manufacture drugs.

23 Article 7(3).

24 See Annex (section 4).

25 1-(3-chlorophenyl) piperazine.

26 *m*CPP was not assessed because the substance is used in the manufacture of medicinal products. It could not be followed up under the pharmacovigilance system either. The Council Decision does not foresee monitoring of substances not submitted to risk assessment, but reports from third sources indicate that *m*CPP continued to be present in the market, as such or in ecstasy tablets. The pharmacovigilance system is 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, p. 1-32.

agreed[27] — to submit it to control measures, requiring Member States to introduce criminal sanctions[28]. In the case of BZP, the Council Decision[29] acknowledged that the risk assessment lacked conclusive evidence on the overall risks of the substance but it stated '*following the precautionary principle'* that it was necessary to take measures because of its risk to health.

5. RESULTS OF THE SURVEY

The survey conducted among the Member States[30] shows that the information exchange mechanism is a useful tool for alerting them to new substances detected in neighbouring countries. However, a number of countries point out that additional information should be provided, in particular toxicology or forensic information. Most Member States indicate that substances that are not submitted to risk assessment following a Joint Report should nevertheless be actively monitored.

While the Scientific Committee acknowledges that risk assessments are inherently based on partial knowledge, given the scarcity of information on these new substances, it points out that additional resources should be made available to support the risk assessment process, for instance for conducting toxicology tests. Several Member States back this view.

Numerous Member States are concerned that the Council Decision can only address one psychoactive substance at a time. They argue that this approach prevents a comprehensive response, because as soon as a substance is submitted to control measures, a new one may be developed and easily marketed to replace it. It also makes it difficult to take action on drugs that are composed of several substances, in various combinations, each of which should be studied individually. This is why no action was taken at EU level on Spice.

A number of Member States have tried addressing several substances at a time, adopting a generic approach,[31] but not all Member States use this method. While simultaneous control measures for a group of chemically related substances is one way of dealing with the problem which deserves a thorough discussion, to assess different substances simultaneously is difficult in practice and scientifically less robust, as the effects and potential harm vary widely between substances included in any generic group. The Scientific Committee of EMCDDA indicated that a broader discussion on chemically similar compounds could be included in risk assessments to provide better insights into related substances that could be launched in the market.

The survey showed that a large number of Member States see the current lack of alternatives to criminal control as inadequate and point out that a wider range of options should be considered, in particular temporary control and risk management measures.

As far as the timing for decision-making is concerned, all the Member States stress that swift action is necessary to tackle new psychoactive substances. According to the survey the majority of Member States believe that the decision-making process is too slow: BZP was

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27 Member States must take national measures to implement, within one year, Council decisions to this effect (Article 9(1)).

28 COM (2007) 430 final, 17.7.2007; COM (2010) 583 final; 2010/0293 (NLE), 20.10.2010.

29 OJ L 63, 7.3.2008, p.45 — recital 8.

30 See Annex (section 7) for a summary report of the findings of the survey.

31 Simultaneous assessment and/or control of a group of chemically-related compounds.

submitted to control 15 months after the launch of the Joint Report, and mephedrone 12 months after.

Seventeen Member States would be in favour of a fast-track/emergency procedure, in particular when a substance is raising considerable concern and more time is required for conducting further scientific research. Certain Member States already use this emergency approach — an accelerated procedure to restrict the sale of new substances for a limited period of time. One Member State suggested that a standing committee could be set up so that EU institutions and agencies can decide on temporary measures. Another Member State recommended caution with respect to emergency measures, pointing to the risk that the ban might not be lifted, even if the risk assessment fails to provide evidence of the harms caused by a substance.

6. NEED FOR A COMPREHENSIVE APPROACH

Although the public threat from new psychoactive substances might appear to be lower than that of traditional illicit drugs,[32] the duty to protect public health leaves no room for complacency. Therefore, a firm and comprehensive response should be developed at EU level to the frequent emergence and rising popularity of these substances. The key challenge is that they are manufactured and traded in a regulatory grey area, somewhere between drugs control, food safety, consumer protection, medicines and chemicals legislation. Authorities in many Member States are often unsure what legislation would tackle these substances most effectively.

The Council Decision may be regarded both as a tool designed to protect public health as well as a criminal justice instrument, aimed at addressing new psychoactive substances through enhanced law enforcement and judicial cooperation among the Member States. Nevertheless, it has been extensively applied over the past five years, mostly as a public health tool, enabling authorities to exchange information about new substances and to understand and anticipate trends in this rapidly changing market. It has been used as a criminal justice instrument only twice: to submit two substances to control measures and subsequently to criminal sanctions.

Many substances that were notified by the Member States were not of EU-wide concern and were therefore dealt with at national level. Certain products, for instance Spice, raised concerns across several EU Member States, but were not dealt with at EU level because of the limited scope for action under the Council Decision to address such mixtures of substances. Several other substances that have raised public health concerns could probably have been tackled at EU level had the Council Decision offered 'lighter' risk-management options, in addition to criminal control measures.

Mirroring the UN Conventions on drugs, the scope of the current Council Decision limits the options for addressing these substances, thus reducing the number of substances that can effectively be tackled at EU level. Although there seems to be a consensus among Member

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[32] The risk assessment reports on BZP and mephedrone identified two deaths in which these substances appeared to be the sole cause of death, although in the meantime more cases were confirmed. The EMCDDA estimates that 7,500 to 8,000 individuals die every year in the EU as a result of opiate and cocaine overdose. 10458/07, CORDROGUE 35, 5.6.2007; 12658/10, CORDROGUE 67, 29.7.2010. EMCDDA 2010 Annual Report on the State of the Drug Problem in Europe, p.16.

States that criminal law should be part of the answer to new psychoactive substances at EU level, most seem to agree that it is not always a sustainable option for tackling the spread of new psychoactive substances and at any rate should not be the only option. Member States agree that the ultimate goal of control is to protect citizens from the unknown risks surrounding these substances.

The information exchange and risk assessment phases allowed Member States to swap information and provided them with relevant and timely feedback on trends and developments in this rapidly evolving market. Risk assessment provides an indispensable pooling of EU-wide research, but it needs to be stepped up, so that decisions are based on evidence. According to the Survey, in order to address the inherent constraints of assessing new substances on which there is little information, resources should be made available, in particular to support toxicology, forensic analysis and pharmacological studies.

On the question of decision-making, the Survey makes it clear that a rapid EU response is crucial. According to some Member States quicker action could be taken using instruments that work well in the fields of food and product safety and of dangerous chemicals. In some cases these could be intermediary steps, pending a decision on criminal control measures. These systems have a notification and information exchange mechanism, as well as emergency procedures in the event of imminent health threats (including temporary bans). They also have classification systems that enable authorities to act proportionately to the risk of the product assessed. Such mechanisms could give the Member States greater flexibility when deciding on the most appropriate way to tackle specific substances while enabling them to act faster.

7. CONCLUSIONS — THE WAY FORWARD

The Council Decision on new psychoactive substances is certainly a useful instrument for tackling new substances at the EU level, in particular as it allows for an exchange of information among the Member States (early warning system). However, it appears from this assessment that it has three major shortcomings when it comes to submitting these substances to Europe-wide control measures:

- It is not able to tackle the large increase in the number of new psychoactive substances on the market, because it addresses substances one by one, through a lengthy process.

- It is reactive, as substances submitted to control measures are quickly replaced with new ones with similar effects, often through small modifications of their chemical composition.

- It lacks options for control measures.

Therefore, subject to a further Impact Assessment, the Commission will examine the need for a more effective legal instrument. It will examine how to reconcile the need for a rapid response with enhanced risk assessment of substances. It will assess measures to extend the support for collecting toxicological and forensic information.

The Commission sees the need for a comprehensive response at EU level, closing gaps between drugs control and other types of legislation, including food or product safety. In

addition to criminal justice control measures, alternative risk management options would need to be assessed with a view to a faster response, at EU level, to the emergence of substances that raise concerns.

To improve understanding of the rapidly evolving market for new psychoactive substances, the Commission will examine ways of monitoring substances that are not submitted to risk assessment but that cause concern[33] as well as those subjected to control measures.

Any legislative proposals on new psychoactive substances should be based on thorough and comprehensive analysis and debate. Therefore, the European Parliament and the Council are invited to take part in the debate on how EU legislation in this field could be made more effective. In the autumn, the Commission intends to present to the European Parliament and the Council, the main objectives and options for revising Council Decision 2005/387/JHA.

As legislation alone will not provide the complete answer to the complex challenge posed by new psychoactive substances, the Commission invites Member States to step up their efforts to improve the efficiency of drug information and prevention programmes,[34] which should take into account the rising popularity of new psychoactive substances.

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33 E.g. *m*CPP and SPICE.

34 The development of integrated and innovative approaches to identify, monitor and respond to trends in the consumption of new psychoactive substances is a priority under the Commission's Drug Prevention and Information Programme. Decision No 1150/2007/EC of the European Parliament and of the Council of 25 September 2007 establishing for the period 2007-2013 the Specific Programme 'Drug prevention and information' as part of the General Programme 'Fundamental Rights and Justice'; OJ L 257, 03.10.2007, p. 23.