Procedure file

Basic information

CNS - Consultation procedure Decision	2003/0215(CNS)	Procedure completed
Combatting drugs: information exchange, risk-assessment and control of new psychoactive substances See also 2013/0021(NLE) See also 2013/0207(NLE) Repealed by 2013/0304(COD) See also 2014/0183(NLE) See also 2014/0340(NLE) Subject 7.30.05 Police cooperation 7.30.30.04 Action to combat drugs and drug-trafficking		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	LIBE Citizens' Freedoms and Rights, Justice and Home Affairs	PPE-DE PIRKER Hubert	17/11/2003
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health, Consumer Policy	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Competitiveness (Internal Market, Industry, Research and Space)	2658	10/05/2005
European Commission	Commission DG	Commissioner	
	Justice and Consumers		

Key events

03/10/2003	Legislative proposal published	COM(2003)0560	Summary
05/11/2003	Committee referral announced in Parliament		
16/12/2003	Vote in committee		Summary
16/12/2003	Committee report tabled for plenary, 1st reading/single reading	A5-0483/2003	
13/01/2004	Decision by Parliament	T5-0004/2004	Summary
10/05/2005	Act adopted by Council after consultation of Parliament		
10/05/2005	End of procedure in Parliament		

20/05/2005	Final act published in Official Journal		

Technical information

Procedure reference	2003/0215(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Decision
	See also 2013/0021(NLE) See also 2013/0207(NLE) Repealed by 2013/0304(COD) See also 2014/0183(NLE) See also 2014/0340(NLE)
Legal basis	EC Treaty (after Amsterdam) EC 034-p1; EC Treaty (after Amsterdam) EC 029
Stage reached in procedure	Procedure completed
Committee dossier	LIBE/5/20158

Documentation gateway

Legislative proposal		COM(2003)0560	03/10/2003	EC	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0483/2003	16/12/2003	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0004/2004 OJ C 092 16.04.2004, p. 0018-0068 E	13/01/2004	EP	Summary
Follow-up document		COM(2011)0430	11/07/2011	EC	Summary
Follow-up document		SEC(2011)0912	11/07/2011	EC	

Additional information

European Commission	EUR-Lex

Final act

Decision 2005/387
OJ L 127 20.05.2005, p. 0032-0037 Summary

Combatting drugs: information exchange, risk-assessment and control of new psychoactive substances

PURPOSE: to establish a mechanism for a rapid exchange of information on new narcotic drugs and new synthetic drugs that are being used illicitly, and provide for a risk assessment of the drugs.

PROPOSED ACT: Council Decision.

CONTENT: this Council Decision aims at updating and extending the Joint Action on New Synthetic Drugs of 16 June 1997. The mechanism as created by the Joint Action on New Synthetic Drugs is being adapted significantly, but its established basic structure remains unaffected.

The Decision consists of the three consecutive but independent phases created by the Joint Action on New Synthetic Drugs:

- an early warning system (EWS) to exchange rapidly all information available on substances notified to Europol and the EMCDDA;

- a risk-assessment by a scientific committee in order to assess the social, health and other risks associated with a notified substance;

- an EU-level procedure for bringing notified substances under control in the Member States.

The following points must be noted:

The most important innovation is that this Council Decision includes under its scope all new synthetic drugs and all new narcotic drugs alike, including those drugs that could be defined as medicinal products. This extended scope, which will permit the notification of a wider range of substances than under the former Joint Action on New Synthetic Drugs, will not lead to an enhanced use of the risk-assessment and the control-measures (the second and third phase). The phases of risk assessment and control are restricted to a small number of the substances that come within the scope of the Council Decision. Most notably, medicinal products and substances already under assessment by the United Nations are excluded from these phases. Thus, a sharper separation between the early warning system and the procedures of risk-assessment and control will be created.

The proposal also makes a distinction between notified substances that demand prompt measures at EU level, and substances that do not demand prompt measures. This distinction has been made operational by the inclusion of two specific provisions: 1) The inclusion of a deadline by which the Joint Report by Europol and the EMCDDA must be submitted to the Member States, the EMEA and the Commission. In case no Joint Report by Europol/EMCDDA has been submitted by this deadline the phases of risk-assessment and control remain closed. 2) The provision of some discretion to Europol and the EMCDDA whether or not to draw up a Joint Report. Though in principle a notification of a new narcotic drug or a new synthetic drug should be followed up by a Joint Report, it can be assumed that not all notifications would merit such a follow-up. A prudent judgment is required to be exercised by both bodies, but Europol and the EMCDDA are also invited to develop policy guidelines which could be used to select those notifications that would demand a risk-assessment.

The introduction of a majority threshold with respect to the start of a risk-assessment on a notified substance. Only where more than half of the Member States have indicated to be infavour of a risk-assessment on a notified new narcotic or new synthetic substance will the risk assessment will be carried out. Member States have 30 working days to come to a decision.

A final change concerns the composition of the EMCDDA-Scientific Committee. The extended Scientific Committee will be composed of the members of the EMCDDA Scientific Committee and representatives from the Commission, the EMEA, and Europol. To this body will be added at most five experts from scientific fields not (sufficiently) represented in the Scientific Committee, but whose contribution is necessary for the balanced and adequate assessment of the risks associated with the assessed substance, including health and social risks.

This proposal has no financial implications.

Combatting drugs: information exchange, risk-assessment and control of new psychoactive substances

The committee adopted the report by Hubert PIRKER (EPP-ED, A) broadly approving the proposal under the consultation procedure, subject to a number of mainly technical and drafting amendments seeking to simplify the procedures for the exchange of information and risk assessment and streamline the text. MEPs also said that a Joint Report should be a precondition for the carrying out of a risk assessment and that a written request from one-third (as opposed to one-half) of the Member States should be sufficient to have a risk assessment carried out. Other amendments sought to ensure that Parliament is notified about the measures taken by the Member States and about the impact of the Decision. Lastly, the committee added a new clause stipulating that the EMCDDA and Europol should report on their experiences relating to coordination between the early-warning system and the pharmacovigilance system.

Combatting drugs: information exchange, risk-assessment and control of new psychoactive substances

The European Parliament adopted a resolution drafted by Hubert PIRKER (EPP-ED, Austria), making mainly procedural amendments to the Commission's proposals. (Please see the summary of 16/12/03.) A Joint Report should be a precondition for the carrying-out of a risk-assessment. Accordingly, this should be laid down as the next step in the procedure. No risk-assessment will be carried out in instances where Europol and the EMCDDA have not drawn up a Joint Report. Parliament also deleted a clause giving the Commission power to decide whether a new drug should be submitted to control measures and to submit its views to the Council. Finally, Parliament reduced from one year to ten months the period within which national measures are to be taken.

Combatting drugs: information exchange, risk-assessment and control of new psychoactive substances

LEGISLATIVE ACT: Council Decision 2005/387/JHA on the exchange, risk-assessment and control of new psychoactive substances.

CONTENT: The Council has approved a legal instrument that broadens the scope of EU action on new substances appearing on the drug scene in the Member States. The Decision establishes a mechanism for a rapid exchange of information on new psychoactive substances and provides for an assessment of the risks by a Scientific Committee and a European procedure for bringing the substances notified under control. The Decision on information exchange, risk assessment and control of new psychoactive substances, replaces the 1997 Joint action, which was devoted exclusively to new synthetic drugs. The new instrument maintains the three-step procedure of the Joint action.

It allows the EU to act on all new psychoactive substances (narcotic, psychotropic) which appear in the Member States and which may pose similar health or social risks to those listed in the Schedules to the 1961 UN Single Convention on Narcotic Drugs and the 1971 UN Convention on Psychotropic Substances.

The instrument not only covers a wider range of substances than before but also promises fast and more transparent results. The introduction of deadlines into every phase of the procedure established by the Decision should guarantee that the instrument can react swiftly and enhances its ability to provide a quick-response mechanism.

The EMCDDA (European Monitoring Centre for Drugs and Drug Addiction) and Europol are required to report annually to the Council, Parliament and the Commission on the efficacy and achievements of the system. Another innovation of the new instrument is that, unlike the Joint action, it also provides for the collection and exchange (but not control) of information on medicinal products diverted from their legitimate use. Here, the European Medicines Agency (EMEA) is set to play a more active role by assessing with the European Commission, and in close cooperation with the EMCDDA, the need for further action on these products.

ENTRY INTO FORCE: 21/05/2005.

Combatting drugs: information exchange, risk-assessment and control of new psychoactive substances

The Commission presents a report on the assessment of the functioning of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances. The assessment is a follow-up to the recommendation of the EU Drugs Action Plan 2009-2012 which requires the Commission to assess the functioning of this Council Decision and amend it, if necessary.

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 channels.

Whilst 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), it appears from the assessment that it has three major shortcomings when it comes to submitting these substances to Europe-wide control measures:

Increase in new substances: the Decision 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. In the past five years, Member States have notified 115 psychoactive substances through the information exchange mechanism 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. 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.

Decision is reactive: substances submitted to control measures are quickly replaced with new ones with similar effects, often through small modifications of their chemical composition. Several Member States argue that the Decision 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.

Lack of alternative control measures: 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. 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. In both cases the Council agreed to submit it to control measures, requiring Member States to introduce criminal sanctions. In the case of BZP, the Council 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.

A more effective instrument: 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 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.

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.

The report stresses the importance of 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 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, which should take into account the rising popularity of new psychoactive substances.