Basic information

2016/0261(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
New psychoactive substances: information exchange, early warning system and risk assessment procedure Amending Regulation (EC) No 1920/2006 2005/0166(COD) **Subject** 7.30.30.04 Action to combat drugs and drug-trafficking 8.40.08 Agencies and bodies of the EU	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
LIBE Civil Liberties, Justice and Home Affairs	BONI Michał (PPE)	03/10/2016

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	BUŞOI Cristian-Silviu (PPE)	10/10/2016

Council of the European Union

Council configuration	Meetings	Date
Foreign Affairs	3573	2017-11-10

European Commission

Commission DG	Commissioner
Migration and Home Affairs	AVRAMOPOULOS Dimitris

European Economic and Social Committee

European Committee of the Regions

Key events

Date	Event	Reference	Summary
29/08/2016	Legislative proposal published	COM(2016)0547	Summary
12/09/2016	Committee referral announced in Parliament, 1st reading		
17/11/2016	Vote in committee, 1st reading		

17/11/2016	Committee decision to open interinstitutional negotiations with report adopted in committee		
30/11/2016	Committee report tabled for plenary, 1st reading	A8-0359/2016	Summary
23/10/2017	Debate in Parliament		
24/10/2017	Decision by Parliament, 1st reading	T8-0393/2017	Summary
24/10/2017	Results of vote in Parliament		
10/11/2017	Act adopted by Council after Parliament's 1st reading		
15/11/2017	Final act signed		
15/11/2017	End of procedure in Parliament		
21/11/2017	Final act published in Official Journal		

Technical information

Procedure reference	2016/0261(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amending Regulation (EC) No 1920/2006 2005/0166(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 168-p5
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	LIBE/8/07650

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE589.454	30/09/2016	
Amendments tabled in committee		PE593.828	28/10/2016	
Committee opinion	ENVI	PE592.081	09/11/2016	
Committee report tabled for plenary, 1st reading/single reading		A8-0359/2016	30/11/2016	Summary
Text adopted by Parliament, 1st reading/single reading		T8-0393/2017	24/10/2017	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00026/2017/LEX	15/11/2017	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2016)0547	29/08/2016	Summary
Commission response to text adopted in plenary	SP(2017)766	06/12/2017	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	IT_SENATE	COM(2016)0547	20/10/2016	
Contribution	PT_PARLIAMENT	COM(2016)0547	11/11/2016	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Regulation 2017/2101
OJ L 305 21.11.2017, p. 0001 Summary

New psychoactive substances: information exchange, early warning system and risk assessment procedure

2016/0261(COD) - 30/11/2016 - Committee report tabled for plenary, 1st reading/single reading

The Committee on Civil Liberties, Justice and Home Affairs adopted the report by Michal BONI (EPP, PL) on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances.

The committee recommended that Parliament's position adopted in first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

Improve monitoring: bearing in mind the rapid growth of the market of those novel products, which continues to be challenging, the amended text stressed the need to enhance **monitoring and early warning systems**, to assess their health, safety and social risks in order to develop responses such as risk reduction measures in order to combat those threats.

The Regulation should take into account the fact that **vulnerable groups**, and especially young people, are particularly exposed to the public health, safety and social risks arising from new psychoactive substances.

Exchange of information, early warning system and risk assessment: Members proposed that provisions on **new trends** in the use of existing psychoactive substances should be maintained. Information provided to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and to Europol should also include **distribution channels, trafficking and smuggling**. The Centre, in cooperation with Europol, shall collect, analyse, assess, and communicate this information in a timely manner to Member States and to the Commission.

The **initial report** on the new psychoactive substance should also give a first indication of **safety risks**. As one of the reasons of this report is to make the procedures limiting the dangerous new psychoactive substances shorter and more efficient, the information should be provided **without undue delay** to the Centre by the European Medicines Agency.

Risk assessment report: this must contain:

- an analysis of the health risks associated with the new psychoactive substance, including **contraindications** for use with other substances, where available;
- an analysis of the social risks associated with the new psychoactive substance, in particular the involvement of **criminal groups** in the development, manufacture, distribution and distribution channels, trafficking and smuggling of the new psychoactive substance.

The Scientific Committee assessing the risks posed by the new psychoactive substance may include a **psychologist** specialising in addiction.

Exclusion from risk assessment: a substance not assumed dangerous on the international level could pose serious threats in the EU. Accordingly, if the data indicates this is needed, Members consider that it should be possible to conduct a risk assessment at Union level.

New psychoactive substances: information exchange, early warning system and risk assessment procedure

2016/0261(COD) - 24/10/2017 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 609 votes to 19, with 29 abstentions, a resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Improving monitoring: given the rapidly growing market for these new products, which remains challenging, the amended text stressed the need to **enhance monitoring and early warning systems** and to assess their health and social risks.

Vulnerable groups, especially young people, are particularly exposed to the health and social risks associated with new psychoactive substances.

Exchange of information, early warning system and risk assessment: the European Monitoring Center for Drugs and Drug Addiction (EMCDDA) in cooperation with Europol shall collect, collate, analyse and assess the information and **communicate it in a timely manner to the national focal points and the Europol national units** as well as to the Commission with a view to providing them with any information required for the purposes of early warning and for the purposes of allowing the Centre to draw up the initial report or the combined initial report.

Initial report: an initial report shall be drawn up on a new psychoactive substance where information provided by the Member States on that new psychoactive substance gives rise to concerns that it might pose health or social risks at Union level. The initial report shall allow the Commission to **make an informed decision** regarding the launch of the risk assessment procedure. The risk assessment procedure at Union level should be undertaken rapidly.

Where the a **majority of the Member States** considers that information shared on a new psychoactive substance gives rise to concerns that the new psychoactive substance may pose health or social risks at Union level, the Centre shall draw up an initial report on the new psychoactive substance.

The amended text stated that the initial report shall contain a first indication of the nature, number and scale of **incidents showing health and social problems** in which the new psychoactive substance may potentially be involved, and the patterns of use of the new psychoactive substance.

The initial report shall also contain information:

- on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or in a veterinary medicinal product;
- on the **commercial and industrial use** of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes.

The **Scientific Committee** may be extended as deemed necessary by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks posed by the new psychoactive substance.

Following the risk assessment procedure, the Commission shall determine whether the new psychoactive substance in question **should be included in the definition of 'drug'** in accordance with the procedure provided for in Council Framework Decision 2004/757/JHA.

Exclusion from risk assessment: in principle, no risk assessment shall be carried out on a new psychoactive substance if it is subject to an assessment **under international law**, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report. In addition, no risk assessment shall be carried out on a new psychoactive substance if it is an active substance in a **medicinal product for human use** or in a veterinary medicinal product.

New psychoactive substances: information exchange, early warning system and risk assessment procedure

2016/0261(COD) - 29/08/2016 - Legislative proposal

PURPOSE: to amend Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances (NPS).

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: new psychoactive substances can pose serious cross border threats to health which makes necessary to enhance monitoring, early warning and combating of those threats.

In 2015, 100 new substances were reported for the first time to the EU Early Warning System (EWS), bringing the total number of new substances monitored to **more than 560 – with more than 380 (70%) of these detected in the last five years** alone.

On 17 September 2013, the Commission put forward a package of two legislative proposals on new psychoactive substances: (i) a proposal for a Regulation on new psychoactive substances and; (ii) a proposed Directive amending Council Framework Decision 2004/757/JHA laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug.

Inter-institutional negotiations of this legislative package have been ongoing for more than two years. The European Parliament adopted its legislative resolutions on 17 April 2014. The Council did not adopt a general approach on the proposals; during the examination of the proposals Member States expressed doubts concerning the choice of Article 114 of the Treaty on the Functioning of the European Union (TFEU) as the legal basis for the proposed Regulation.

In response to the **agreement by COREPER** on 6 April 2016 on a compromise approach proposed by the Netherlands Presidency of the Council to achieve the same objective of a swifter, more effective EU action on NPS, the Commission proposes targeted amendments of Regulation 1920/2006 integrating the draft provisions on early warning system and risk assessment procedure that were part of the 2013 Commission proposal for a Regulation on new psychoactive substances into the founding Regulation of the EMCDDA.

The proposal reflects the priorities set out by the European Agenda on Security adopted on 28 April 2015.

CONTENT: this proposal - based on Article 168(5) TFEU - seeks to amend Regulation (EC) No 1920/2006 in order to **strengthen the EU early warning system and the risk assessment** and streamline procedures to ensure more effective and fast action.

In order to speed up the process, **deadlines are substantially shortened** compared to the current system based on Council Decision 2005/387/JHA.

For the purpose of swift and effective collection of information on NPS, the EMCDDA should conclude working arrangements with Europol, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority without undue delay following the publication of the Regulation in the Official Journal.

This proposal also ensures a **participation of EUROPOL** in the early warning system and risk assessment procedure, in particular as input on the involvement of criminal groups in the manufacture and distribution of new psychoactive substances is concerned.

According to Article 23 of Regulation 1920/2006 the Commission may propose, if appropriate, and in the light of developments in respect of regulatory agencies on the basis of the next evaluation of the Centre further amendments to the EMCDDA founding Regulation

The following amendments to Regulation 1920/2006 seek to:

- clarify that tasks of the EMCDDA are information exchange and early warning on new psychoactive substances as well as risk assessment. The Centre also monitors all new psychoactive substances that have been reported by Member States;
- establish the respective roles of Member States, the EMCDDA and Europol in the process of exchange of information and early warning on new psychoactive substances;
- lay down the contents and the procedures for the drawing up and the transmission by the EMCDDA of an initial report on a new psychoactive substance. Europol, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority are associated to the collection of information for an initial report;
- empower the Commission to request the EMCDDA to assess the risks of a new psychoactive substance on which an initial report has been drawn up. The proposal lays down the procedures for the risk assessment, which is to be conducted by the Scientific Committee of the EMCDDA, and for the drawing up and the transmission of a risk assessment report;
- detail circumstances in which no risk assessment is to be conducted on a new psychoactive substance.

BUDGETARY IMPLICATIONS: the subsidy for the Centre forms already part of the Union's budget. However, for the Centre to adequately deal with the growing number of requests related to information exchange on new psychoactive substances as well as with the proposed streamlined procedures for the EU early warning system and risk assessment procedure, an amount of **EUR 676 000 in total for the period 2017-2020** for the system development and an amount of **EUR 100 000 per year** to finance three additional contract agents will need to be added to the Centre's budget.

New psychoactive substances: information exchange, early warning system and risk assessment procedure

2016/0261(COD) - 15/11/2017 - Final act

PURPOSE: to strengthen the EU's early warning system and risk assessment procedure for new psychoactive substances (NPS).

LEGISLATIVE ACT: Regulation (EU) 2017/2101 of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances.

CONTENT: this Regulation amends Regulation (EC) No 1920/2006 in order to **strengthen surveillance** and improve the early warning system and to assess the health and social risks associated with new psychoactive substances. The Regulation shall take into account that **vulnerable groups**, especially young people, are particularly exposed to the risks associated with these new substances.

The main amendments adopted concern the following points:

Exchange of information, early warning system and risk assessment: each Member State shall ensure that its national focal point and Europol national units provide the **European Monitoring Centre for Drugs and Drug Addiction** (EMCDDA) with the necessary information they have on the NSPs.

The Centre, in cooperation with Europol, shall collect, collate, analyse and assess the information and communicate it in a timely manner to the national focal points and the Europol national units as well as to the Commission with a view to providing them with any information required for the purposes of early warning and for the purposes of allowing the Centre to draw up the initial report.

Initial report: where the Centre, the Commission or a majority of the Member States considers that information shared on a new psychoactive substance collected in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks at Union level, the Centre shall draw up an initial report on the new psychoactive substance.

The initial report shall allow the Commission to make an informed decision regarding the launch of the risk assessment procedure. Europol, the European Medicines Agency, the European Centre for Disease Prevention and Control, the European Chemicals Agency and the European Food Safety Authority shall be involved in collecting information for the preparation of the initial reports.

Risk assessment procedure and report: within **two weeks** of receipt of an initial report, the Commission may request the Centre to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report. The Centre shall submit the risk assessment report or the combined risk assessment report to the Commission and the Member States within **six weeks** of receipt of the request from the Commission to draw up a risk assessment report. Following the risk assessment procedure, the Commission shall determine whether the new psychoactive substance in question should be included in the definition of ‘drug’ in accordance with the procedure provided for in Council Framework Decision 2004/757/JHA.

Exclusion from risk assessment: no risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system.

No risk assessment shall be carried out where the new psychoactive substance is an active substance in a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation.

ENTRY INTO FORCE: 22.11.2017.

APPLICATION: from 23.11.2018.