Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2013/0305(COD)	Procedure lapsed or withdrawn
New psychoactive substances See also 2013/0304(COD) Subject 4.20.03 Drug addiction, alcoholism, smoking 7.30.30.04 Action to combat drugs and drug-trafficking		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	LIBE Civil Liberties, Justice and Home Affairs		
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		
Council of the European Union	Council configuration	Meeting	Date
	Justice and Home Affairs (JHA)	3508	09/12/2016
	Justice and Home Affairs (JHA)	3415	09/10/2015
	Competitiveness (Internal Market, Industry, Research and Space)	3333	26/09/2014
	Economic and Financial Affairs ECOFIN	3324	20/06/2014
	Economic and Financial Affairs ECOFIN	3290	28/01/2014
	Justice and Home Affairs (JHA)	3260	07/10/2013
European Commission	Commission DG	Commissioner	
	Justice and Consumers	REDING Viviane	
European Economic and Social Committee			

Key events

17/09/2013	Legislative proposal published	COM(2013)0619	Summary
08/10/2013	Committee referral announced in Parliament, 1st reading		
28/01/2014	Debate in Council	3290	
10/03/2014	Vote in committee, 1st reading		
13/03/2014	Committee report tabled for plenary, 1st reading	A7-0172/2014	Summary
17/04/2014	Results of vote in Parliament		

17/04/2014	Decision by Parliament, 1st reading	T7-0453/2014	Summary
20/06/2014	Debate in Council	3324	
05/02/2015	Committee decision to open interinstitutional negotiations after 1st reading in Parliament		
14/09/2015	Debate in Council		
20/05/2017	Proposal withdrawn by Commission		

Technical information

Procedure reference	2013/0305(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	See also 2013/0304(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure lapsed or withdrawn
Committee dossier	LIBE/7/13824

Documentation gateway

Legislative proposal		COM(2013)0619	17/09/2013	EC	Summary
Document attached to the procedure		SWD(2013)0319	17/09/2013	EC	
Document attached to the procedure		SWD(2013)0320	17/09/2013	EC	
Committee draft report		PE519.611	23/12/2013	EP	
Amendments tabled in committee		PE519.808	29/01/2014	EP	
Committee opinion	ENVI	PE524.592	31/01/2014	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0172/2014	13/03/2014	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0453/2014	17/04/2014	EP	Summary
Commission response to text adopted in plenary		SP(2014)471	09/07/2014	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

New psychoactive substances

PURPOSE: to approximate the rules relating to new psychoactive substances that are of concern at Union level whilst ensuring a high level of health, safety and consumer protection.

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, which may have numerous commercial and industrial uses, as well as scientific uses, can pose health, social and safety risks when consumed by humans. Consumption of new psychoactive substances appears to be increasing in Europe and use is predominant among young people. According to the 2011 Eurobarometer "Youth attitudes on drugs", 5% of young people in the EU have used such substances at least once in their life, with a peak of 16% in Ireland, and close to 10% in Poland, Latvia and the UK.

During the past years, Member States have notified an increasing number of new psychoactive substances to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). National restriction measures, which can vary depending on the Member State and on the substance, lead to obstacles to trade in licit uses, fragmentation, an uneven level playing field and legal uncertainties for economic operators, and make it difficult for companies to operate across the internal market. They make research more cumbersome, hampering the development of new uses for these substances.

In this context, the case for swifter, more effective and more proportionate action on new psychoactive substances at EU level is compelling, considering the rapid changes in this market, which put national authorities under pressure to act.

The Commission Communication "Towards a stronger European response to drugs", adopted in October 2011, identified the spread of new psychoactive substances as one of the most challenging developments in drugs policy requiring a firmer EU response.

IMPACT ASSESSMENT: taking into account the results of impact assessment, the following solutions are preferred: (i) a more graduated and better targeted set of restriction measures on new psychoactive substances, which should not hinder the industrial use of substances; (ii) restriction measures should be introduced earlier; (iii) substances suspected to pose immediate public health risks should be subjected to temporary restrictions; (iv) restriction measures should be proportionate to a better determined level of risk of substances; (v) restriction measures should be introduced through a quicker procedure.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union.

CONTENT: this proposed Regulation which is intended to replace Council Decision 2005/387/JHA - aims at ensuring that trade in new psychoactive substances having industrial and commercial uses is not hindered and that the functioning of this market is improved, while the health and safety of individuals are protected from harmful substances, which cause concern at the EU level.

The proposal is accompanied by a proposal for a 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.

The main elements of the proposal are as follows:

Exchange of information and temporary consumer market restrictions: this proposal sets up a robust system: (i) for exchanging rapidly information on new psychoactive substances emerging on the market, including on their commercial and industrial uses, for assessing the risks of substances that cause EU-wide concern and; (ii) for withdrawing from the market those substances that pose risks.

The substances suspected to pose immediate public health risk will be withdrawn from the consumer market temporarily, pending their risk assessment. Once the risk assessment is completed, measures will be taken proportionate to the risks of substances.

The proposal establishes the respective roles of Member States, the EMCDDA and Europol in the process of exchange of information on new psychoactive substances.

Low and moderate risks: according to the proposal, no restriction measures shall be introduced on new psychoactive substances posing low health, social and safety risks and provides a definition of low risks.

For substances posing moderate risks and permanent consumer market restrictions, they cannot be sold to consumers (except for uses specifically authorised, for instance by medicines legislation) but their trade is allowed for commercial and industrial purposes as well as for scientific research and development.

Severe risks: the proposal empowers the Commission to prohibit the production, manufacture, making available on the market, transport, importation or exportation of new psychoactive substances which pose severe health, social and safety risks, and provides a definition of severe risks.

New psychoactive substances posing severe risks will be subjected to permanent market restriction, covering both the consumer and commercial markets, and their use will only be possible for specifically authorised industrial and commercial purposes, as well as for scientific research and development. In addition, these substances will be subjected to EU criminal law provisions.

Sanctions: the proposal establishes the obligation for the Member States to lay down the rules on administrative sanctions applicable to infringements to market restriction, and to ensure that they are effective, proportionate and dissuasive.

BUDGETARY IMPLICATION: the proposal has no direct impact on the EU budget and does not create new tasks for the EMCDDA, Europol, the European Medicines Agencies, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).

New psychoactive substances

The Committee on Civil Liberties, Justice and Home Affairs adopted the report by Jacek PROTASIEWICZ (EPP, PL) on the proposal for a regulation of the European Parliament and of the Council on new psychoactive substances.

The committee recommended that Parliaments position in first reading following the ordinary legislative procedure should amend the Commission position as follows:

Information exchange: to enable a more effective response to the rapid emergence and spread of new psychoactive substances across the Union, Members considered that the information exchange mechanism (the 'Early Warning System') should be maintained and further developed, in particular as regards to the collection and management of data on the detection and identification of new psychoactive substances.

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) should issue health alerts to all Member States, through the system for rapid exchange of information on new psychoactive substances if, on the basis of information received on a new psychoactive substances, this seemed to cause public health concerns. Those health alerts should also contain information regarding prevention, treatment and harm reduction measures that could be taken to address the risk of the substance.

Immediate risks to public health, and market restrictions: the proposal provided that the Commission should, by means of a Decision, prohibit the making available on the market to consumers of the new psychoactive substance if, based on existing information, it poses immediate risks to public health. The market restriction should not exceed a period of twelve months.

Members proposed that if the level of health, social and safety risks posed by the new psychoactive substance justified the introduction of permanent restriction measures, the duration of the temporary market restriction may be extended by a further 12 months, in the absence of permanent market restriction.

Low risks at Union level: the Commission should not adopt restriction measures on a new psychoactive substance if, based on the existing evidence and on prescribed criteria, it posed, overall, low health, social and safety risks at Union level.

However, where the decision to not adopt restriction measures on a new psychoactive substance that was considered to pose overall low health, social and safety risk at Union level was based on a partial or total lack of evidence, it should include an appropriate reference in the justification.

The report also stressed that Members States should not be prohibited from introducing or maintaining the more stringent measures regarding the specific risks the new psychoactive substance posed within their territory, independently of the classification of the substance by the Commission as posing low or moderate risks on the EU level. The relevant laws, regulations or administrative provisions should be communicated to the Commission and the other Member States should be informed.

Authorised use: decisions prohibiting the marketing of new psychoactive substance presenting a serious risk should not impede the free movement in the Union and the production, manufacture, making available on the market of new psychoactive substances for scientific research and development purposes, by duly authorised persons in establishments which were directly under the control of Member States' authorities or specifically approved by them.

For all of authorised uses, new psychoactive substances and products containing new psychoactive substances should include directions for use, including cautions, warnings and contraindications with other substances, to be either indicated on the label or included in the accompanying leaflet for the safety of the user.

Furthermore, Member States should take any appropriate measures to prevent the diversion to the illicit market of new psychoactive substances used for research and development purposes or for any other authorised uses.

Research, analysis, prevention and funding: the amended text provided that financial support and the necessary resources should be provided at Union and national level for the development, sharing and dissemination of information and knowledge on new psychoactive substances.

Moreover, the Commission and the Member States should promote the research into new psychoactive substances and ensure cooperation and coordination between networks at national and Union level in order to strengthen understanding of the phenomenon.

Prevention schemes as well as measures to raise awareness of the risks posed by psychoactive substances, such as educational information campaigns should be promoted.

Evaluation: five years after the entry into force of the Regulation and every five years thereafter, the Commission should:

- assess the implementation, application and effectiveness of this Regulation and publish a report. In this respect, the Commission, the EMCDDA and Europol should conduct post-risk assessments of new psychoactive substances;
- evaluate and if appropriate present a proposal for possible classification of groups of the new psychoactive substances in order to counteract the practise of bypassing the legislation in force by slight modifications of the chemical structure of the psychoactive substances.

New psychoactive substances

The European Parliament adopted by 507 votes 37 with 33 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on new psychoactive substances.

Parliaments position in first reading following the ordinary legislative procedure amended the Commission position as follows:

Information exchange: to enable a more effective response to the rapid emergence and spread of new psychoactive substances across the Union, Parliament considered that the information exchange mechanism (the 'Early Warning System') should be maintained and further developed, in particular as regards to the collection and management of data on the detection and identification of new psychoactive substances.

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) should issue health alerts to all Member States, through the system for rapid exchange of information on new psychoactive substances if, on the basis of information received on a new psychoactive substances, this seemed to cause public health concerns. Those health alerts should also contain information regarding prevention, treatment and harm reduction measures that could be taken to address the risk of the substance. Information should include consumption and its patterns, serious intoxication or deaths, possible risks as well as the toxicity level, and data concerning manufacture.

Risk assessment: a risk assessment should be conducted if there were sufficient data available at Union level to suggest the need for a joint report of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol.

Immediate risks to public health, and market restrictions: the proposal provided that the Commission should, by means of a Decision, prohibit the making available on the market to consumers of the new psychoactive substance if, based on existing information, it poses immediate risks to public health. The market restriction should not exceed a period of twelve months.

Members proposed that if the level of health, social and safety risks posed by the new psychoactive substance justified the introduction of permanent restriction measures, the duration of the temporary market restriction may be extended by a further 12 months, in the absence of permanent market restriction.

Low risks at Union level: the Commission should not adopt restriction measures on a new psychoactive substance if, based on the existing evidence and on prescribed criteria, it posed, overall, low health, social and safety risks at Union level.

However, where the decision to not adopt restriction measures on a new psychoactive substance that was considered to pose overall low health, social and safety risk at Union level was based on a partial or total lack of evidence, it should include an appropriate reference in the justification.

Parliament also stressed that Members States should not be prohibited from introducing or maintaining the more stringent measures regarding the specific risks the new psychoactive substance posed within their territory, independently of the classification of the substance by the Commission as posing low or moderate risks on the EU level.

A Member State willing to introduce a more stringent measure concerning the new psychoactive should immediately communicate the relevant draft laws, regulations or administrative provisions to the Commission and shall inform the other Member States.

Authorised use: decisions prohibiting the marketing of new psychoactive substance presenting a serious risk should not impede the free movement in the Union and the production, manufacture, making available on the market of new psychoactive substances for scientific research and development purposes, by duly authorised persons in establishments which were directly under the control of Member States' authorities or specifically approved by them.

For all of authorised uses, new psychoactive substances and products containing new psychoactive substances should include directions for use, including cautions, warnings and contraindications with other substances, to be either indicated on the label or included in the accompanying leaflet for the safety of the user.

Furthermore, Member States should take any appropriate measures to prevent the diversion to the illicit market of new psychoactive substances used for research and development purposes or for any other authorised uses.

Research, analysis, prevention and funding: the amended text provided that financial support and the necessary resources should be provided at Union and national level for the development, sharing and dissemination of information and knowledge on new psychoactive substances.

Moreover, the Commission and the Member States should promote the research into new psychoactive substances and ensure cooperation and coordination between networks at national and Union level in order to strengthen understanding of the phenomenon.

Prevention schemes as well as measures to raise awareness of the risks posed by psychoactive substances, such as educational information campaigns should be promoted.

Evaluation: the EMCDDA and Europol should report annually to the European Parliament, the Commission and Member States on the implementation of the Regulation. Five years after the entry into force of the Regulation and every five years thereafter, the Commission should:

- assess the implementation, application and effectiveness of this Regulation and publish a report. In this respect, the Commission, the EMCDDA and Europol should conduct post-risk assessments of new psychoactive substances;
- evaluate and if appropriate present a proposal for possible classification of groups of the new psychoactive substances in order to counteract the practise of bypassing the legislation in force by slight modifications of the chemical structure of the psychoactive substances.

The implementation reports should be published on a website and made publicly available.