European Parliament
2014-2019

Committee on the Environment, Public Health and Food Safety

2016/0261(COD)

9.11.2016

OPINION

of the Committee on the Environment, Public Health and Food Safety

for the Committee on Civil Liberties, Justice and Home Affairs

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
(COM(2016)0547 – C8-0351/2016 – 2016/0261(COD))

Rapporteur: Cristian-Silviu Buşoi

SHORT JUSTIFICATION

Psychoactive substance use is becoming commonly known for compromising health and resulting in the death of millions of individuals every year. WHO states that new psychoactive substances are substances that, when taken in or administered into one's system, affect mental processes, e.g. cognition or affect. This term and its equivalent, psychotropic drug, is the most neutral and descriptive term for the whole class of substances, licit and illicit, of interest to drug policy. 'Psychoactive' does not necessarily imply dependence-producing, and in common parlance, the term is often left unstated, as in 'drug use' or 'substance abuse'.[1]

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is the reference point for collecting, analysing and disseminating information on the European drug situation in the Union. A central task for the agency is to produce an annual report of the latest data available on drug use in Europe, based on a set of standardized reporting tools, which have been refined during the 20 years in which the system has been operational.

Substance use and substance use among youth is a significant public health concern worldwide, yet, little is known on the prevalence. The proposal of the Commission comes at a time when in the last few years, there has been a rapid increase in the number of NPS available and launched on the European drugs market, more than 450 substances being monitored by the EMCDDA, close to twice the number controlled under the UN International drug control conventions.[2]

The rapporteur acknowledges that over the past five years an unprecedented increase tendency in the number, type and availability of NPS at the Union level has been reported, with a total number of 101 substances identified for the first time reported through the early warning system during the year 2014, according to their last report.

The presence of some of these new substances has been detected through the European reporting system that incorporates multiple indicators alongside an early warning system (EWS) on uncontrolled new psychoactive substances. The European reporting system formally covers all 28 European Union (EU) Member States, Norway and Turkey.

The new proposal as the previous ones aims at strengthening the EU early warning system and the risk assessment and at streamlining procedures to ensure more effective and fast action.

The rapporteur appreciates that while much has been done to improve data quality and comparability, to overcome difficulties in monitoring drug use and in generating cross-national comparisons, the phenomenon of NPS use is continuously increasing which makes is challenging.

Understanding the nature and magnitude of NPS use as well as the factors that contribute to it should allow developing effective intervention strategies or action plans on the long term. Structured information is now available on patterns and trends in drug consumption in

[1] http://www.who.int/substance_abuse/terminology/psychoactive_substances/en/
[2] New psychoactive substances in Europe: Innovative legal responses, EMCDDA Publication, Lisbon, June 2015, page 4

Europe, however, the pattern of factors affecting NPS use, is not yet well known. Findings of the EMCDDA report state that more frequent NPS self-reported or detected are synthetic cannabinoids and cathinones, and that a combination of different NPS and also mixed with other drugs, mainly cannabis and ecstasy, is usual among experienced drug users.

Estimating the prevalence of NPS use is challenging also due to methodological and theoretical inconsistencies. The rapporteur considers that public health risks should also take into account information concerning toxicity of the NPS and relevant evidence on the interaction with other substances and pre-existing health conditions. The rapid increase of NPSs is a growing concern and sets new challenges not only for societies in drug prevention and delivering policy to combat the substance use, but also in clinical and forensic toxicology.

The rapporteur reflects that in the process it should also be assessed the safety risks associated with the new psychoactive substance.

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Civil Liberties, Justice and Home Affairs, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) New psychoactive substances can pose serious cross border threats to health ***which makes*** necessary to enhance monitoring***,*** early warning ***and combating of*** those threats.	(1) New psychoactive substances***, which may have numerous commercial and industrial uses, as well as scientific uses,*** can pose serious cross border threats to health***, in particular due to their diversity and the speed with which they have been appearing. The rapid growth of the market of those novel products continues to be challenging, making it*** necessary 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.

Amendment 2

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) The term "psychoactive substances" refers to a broad category of unregulated psychoactive compounds or products containing them that are marketed as legal alternatives to well-known controlled drugs, usually sold via the internet or in "smart shops" or "head shops".

Amendment 3

Proposal for a regulation
Recital 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) Psychoactive substances could be advertised with aggressive and sophisticated marketing strategies and could be sold to consumers with intentional mislabelling and with declared ingredients differing from the actual composition. It is therefore necessary to take rapid action at Union level.

Amendment 4

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) During the past years, Member States have notified an increasing number of new psychoactive substances via the mechanism for rapid exchange of information which was established by Joint Action 97/396/JHA adopted by the Council on the basis of Article K.3 of the Treaty on European Union concerning the	(2) During the past years, Member States have notified an increasing number of new psychoactive substances via the mechanism for rapid exchange of information which was established by Joint Action 97/396/JHA adopted by the Council on the basis of Article K.3 of the Treaty on European Union concerning the

information exchange, risk assessment and the control of new synthetic drugs[13] and was further strengthened by Council Decision 2005/387/JHA[14].

information exchange, risk assessment and the control of new synthetic drugs[13] and was further strengthened by Council Decision 2005/387/JHA[14]. ***According to the European Medicine Centre for Drugs and Drug addiction ("the Centre"), Member States notified 101 new psychoactive substances, which had not been reported previously, via that mechanism during the year 2014.***

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[13] Council Joint Action 97/396/JHA of 16 June 1997 concerning the information exchange, risk assessment and control of new synthetic drugs (OJ L 167, 25.6.1997, p. 1).

[14] Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances (OJ L 127, 20.5.2005, p. 32).

[13] Council Joint Action 97/396/JHA of 16 June 1997 concerning the information exchange, risk assessment and control of new synthetic drugs (OJ L 167, 25.6.1997, p. 1).

[14] Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances (OJ L 127, 20.5.2005, p. 32).

Amendment 5

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) Europol, in its interim Serious and Organised Crime Threat Assessment for 2015[1a], warns against the fact that organised criminal groups are able to react quickly to changes in legislation and respond to the prohibition of certain substances by creating new formulas that are not covered by Union or national law.

[1a] Interim SOCTA 2015: An update on Serious and Organised Crime in the EU.

Amendment 6

Proposal for a regulation

Recital 2 b (new)

Text proposed by the Commission	*Amendment*
	(2b) This 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.

Amendment 7

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) New psychoactive substances that pose health and social risks across the Union should be addressed at the Union level. This Regulation has therefore to be read in conjunction with Council Framework Decision 2004/757/JHA[15] [as amended by Directive (EU) …/…] since both acts are designed to replace the mechanism established by Council Decision 2005/387/JHA.	(3) New psychoactive substances that pose health***, safety*** and social risks across the Union should be addressed at the Union level. This Regulation has therefore to be read in conjunction with Council Framework Decision 2004/757/JHA[15] [as amended by Directive (EU) …/…] since both acts are designed to replace the mechanism established by Council Decision 2005/387/JHA.
[15] Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8).	[15] Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8).

Amendment 8

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Any Union action on new	(5) Any Union action on new

psychoactive substances should be based on scientific evidence.	psychoactive substances should be based on scientific evidence ***or on sufficient data on the risks that the new psychoactive substances pose***. ***Given that in some cases new psychoactive substances could be so novel to the field that, at least initially, there would be very limited evidence from scientific research on public health risks, it is necessary to undertake rapid risk assessment procedures at Union level.***

Amendment 9

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) No risk assessment should be conducted on a new psychoactive substance if it is subject to an assessment under international law, or if it is an active substance in a medicinal product or in a veterinary medicinal product.	(7) No risk assessment should be conducted on a new psychoactive substance if it is subject to an assessment under international law, or if it is an active substance in a medicinal product or in a veterinary medicinal product***, unless there is sufficient scientific evidence, data or studies available at Union level to suggest the need of such assessment***.

Amendment 10

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 1920/2006
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
(2) In Article 5 (2) the second ***and third subparagraphs are*** deleted.	(2) In Article 5 (2) the second ***subparagraph is*** deleted.

Justification

The third subparagraph of Article 5 (2) of Regulation (EC) No 1920/2006 concerns new trend in the use of existing psychoactive substances and should thus be maintained.

Amendment 11

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5a – paragraph 1

Text proposed by the Commission	*Amendment*
Each Member State shall ensure that its Reitox National Focal Points and the Europol National ***Unit*** provide timely and without any undue delay to the Centre and Europol the available information on new psychoactive substances. The information shall be related to the detection and identification, use and patterns of use**,** potential and identified risks, manufacture, extraction, distribution, trafficking, commercial, as well as medical and scientific use of these substances.	Each Member State shall ensure that its National Focal Points ***within the European Information Network on Drugs and Drug Addiction ("Reitox")*** and the Europol National ***Units*** provide timely and without any undue delay to the Centre and Europol the available information on ***what appears to be a*** new psychoactive substance ***or mixture***. The information shall be related to the detection and identification, use and patterns of use, ***prevalence of use,*** potential and identified risks, manufacture, extraction, distribution ***and distribution channels***, trafficking ***and cross-border global supply chains,*** commercial, as well as medical and scientific use of these substances.

Amendment 12

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5a – paragraph 2

Text proposed by the Commission	*Amendment*
The Centre, in cooperation with Europol, shall collect, analyse, assess, and communicate this information in a timely manner to Member States ***with a view*** to providing Member States 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 pursuant to Article 5b.	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, with the purpose*** to providing Member States ***and the Commission*** with any information required for ***developing*** early warning ***models*** and for the purposes of allowing the Centre to draw up the initial report or the combined initial report pursuant to Article 5b.

Amendment 13

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5b – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where the Centre, the Commission or the Council, acting by a simple majority of Member States, consider that the information shared on a new psychoactive substance collected pursuant to Article 5a in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks at the Union level, the Centre shall draw up an initial report on the new psychoactive substance.	1. Where the Centre, the Commission or the Council, acting by a simple majority of Member States, consider that the information shared on a new psychoactive substance collected pursuant to Article 5a in one or more Member States gives rise to concerns that the new psychoactive substance may pose health***, safety*** or social risks at the Union level, the Centre shall draw up ***without undue delay*** an initial report on the new psychoactive substance.

Amendment 14

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5b – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) a first indication of the nature or scale of health and social risks associated with the new psychoactive substance;	(a) a first indication of the nature or scale of health***, safety*** and social risks associated with the new psychoactive substance***, including contraindications for use with other substances when available***;

Amendment 15

Proposal for a regulation
Article 1 – paragraph 1 – point 3

Regulation (EC) No 1920/2006
Article 5b – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) information on the toxicity of the new psychoactive substance and relevant evidence on its interaction with other substances or pre-existing health conditions;

Amendment 16

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5b – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) information on the involvement of criminal groups in the manufacture and distribution of the new psychoactive substance;	(d) information on the involvement of criminal groups in the ***development,*** manufacture and distribution of the new psychoactive substance;

Amendment 17

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5b – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) information on similarities to, and differences from, other substances with similar chemical structure or pharmacological properties;

Amendment 18

Proposal for a regulation
Article 1 – paragraph 1 – point 3

Regulation (EC) No 1920/2006
Article 5b – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Centre shall request the European Medicines Agency to provide information on whether, in the Union or in any Member State, the new psychoactive substance is:	5. The Centre shall request the European Medicines Agency to provide***, without undue delay,*** information on whether, in the Union or in any Member State, the new psychoactive substance is:

Amendment 19

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5b – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Centre shall request Europol to provide information on the involvement of criminal groups in the manufacture and distribution of the new psychoactive substance, and in any use of the new psychoactive substance.	6. The Centre shall request Europol to provide***, without undue delay,*** information on the involvement of criminal groups in the ***development,*** manufacture***,*** distribution ***and supply*** of the new psychoactive substance, and in any use of the new psychoactive substance.

Amendment 20

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5b – paragraph 7

Text proposed by the Commission	*Amendment*
7. The Centre shall request the European Chemicals Agency ***and*** the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance.	7. The Centre shall request the European Chemicals Agency***,*** the European Food Safety Authority ***and the European Centre for Disease Prevention and Control*** to provide the information and data at their disposal on the new

psychoactive substance.

Amendment 21

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5b – paragraph 11

Text proposed by the Commission	*Amendment*
11. When the Centre collects information on several new psychoactive substances ***with*** similar chemical structure, it shall submit to the Commission and the Council individual initial reports or combined reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks from the launch of the initial report.	11. When the Centre collects information on several new psychoactive substances ***that it considers to be of*** similar chemical structure, it shall submit to the Commission and the Council individual initial reports or combined reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks from the launch of the initial report.

Justification

This paragraph is a positive addition to the Regulation as it will allow the Centre to do more at once, however, the level of similarity between chemical structures of new psychoactive substances can sometimes be difficult to determine, so it should be up to the Centre to determine whether substances can be considered similar enough to be dealt with under a combined report.

Amendment 22

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5c – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and its physical, mental and behavioural effects;	(c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and its physical, mental and behavioural effects**,**

	and also relevant evidence on the interaction of new psychoactive substances with other substances or pre-existing health conditions;

Amendment 23

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5c – paragraph 3 – point d

Text proposed by the Commission	*Amendment*
(d) an analysis of the social risks associated with the new psychoactive substance, in particular its impact on social functioning, public order and criminal activities, the involvement of criminal groups in the manufacture and distribution of the new psychoactive substance;	(d) an analysis of the social risks associated with the new psychoactive substance, in particular its impact on social functioning, public order and criminal activities, the involvement of criminal groups in the ***development,*** manufacture and distribution of the new psychoactive substance;

Amendment 24

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5c – paragraph 3 – point e

Text proposed by the Commission	*Amendment*
(e) information on the prevalence and patterns of the use of the new psychoactive substance, its availability and potential for diffusion within the Union;	(e) information on the prevalence and patterns of the use of the new psychoactive substance, its availability and potential for diffusion within the Union***, considering all possible distribution channels, as well as information on the rationale of its consumption***;

Amendment 25

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5c – paragraph 3 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) an analysis of the safety risks associated with the new psychoactive substance, in particular with regard to its manufacture, its manufacturing conditions and the ingredients which make up that new psychoactive substance;

Amendment 26

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5c – paragraph 3 – point f

Text proposed by the Commission	*Amendment*
(f) information on the commercial and industrial use of the new psychoactive substance, the extent of such use(s), as well as its use for scientific research and development purposes.	(f) information on the commercial and industrial use of the new psychoactive substance, the extent of such use(s), as well as its use for scientific research and development purposes***, including information on the potential for misuse of the substance authorised for legitimate purposes***.

Amendment 27

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5c – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Scientific Committee shall assess the risks posed by the new psychoactive substance or group of new psychoactive	The Scientific Committee ***of the Centre*** shall assess the risks posed by the new psychoactive substance or group of new

substances. The Committee may be extended as deemed necessary by the Director, acting on the advice of the chairperson of the Scientific Committee, by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks of the new psychoactive substance. The Director shall designate them from a list of experts. The Management Board shall approve the list of experts every three years.	psychoactive substances. The Committee may be extended as deemed necessary by the Director, acting on the advice of the chairperson of the Scientific Committee, by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks of the new psychoactive substance. The Director shall designate them from a list of experts. The Management Board shall approve the list of experts every three years.

Amendment 28

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5c – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Scientific Committee shall carry out the risk assessment on the basis of the available information and of any other relevant scientific evidence. It shall take into account all opinions held by its members. The Centre shall organise the risk assessment process, including identifying future information needs and relevant studies.	5. The Scientific Committee ***of the Centre*** shall carry out the risk assessment on the basis of the available information and of any other relevant scientific evidence. It shall take into account all opinions held by its members. The Centre shall organise the risk assessment process, including identifying future information needs and relevant studies.

Amendment 29

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5d – paragraph 1

Text proposed by the Commission	*Amendment*
1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation expert	1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation expert

committee on drug dependence has published its critical review together with a written recommendation, except where there is ***significant information that is new or of particular relevance for the*** Union and that has not been taken into account by the United Nations system.

committee on drug dependence has published its critical review together with a written recommendation, except where there is ***relevant new evidence that suggests the need for a risk assessment report at*** Union ***level,*** and that has not been taken into account by the United Nations system.

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Information exchange, early warning system and risk assessment procedure on new psychoactive substances
References	COM(2016)0547 – C8-0351/2016 – 2016/0261(COD)
Committee responsible Date announced in plenary	LIBE 12.9.2016
Opinion by Date announced in plenary	ENVI 12.9.2016
Rapporteur Date appointed	Cristian-Silviu Buşoi 10.10.2016
Discussed in committee	12.10.2016
Date adopted	8.11.2016
Result of final vote	+: 54 –: 2 0: 0
Members present for the final vote	Marco Affronte, Margrete Auken, Pilar Ayuso, Zoltán Balczó, Ivo Belet, Biljana Borzan, Paul Brannen, Cristian-Silviu Buşoi, Soledad Cabezón Ruiz, Nessa Childers, Mireille D'Ornano, Miriam Dalli, Seb Dance, Angélique Delahaye, Jørn Dohrmann, Stefan Eck, Bas Eickhout, José Inácio Faria, Karl-Heinz Florenz, Francesc Gambús, Elisabetta Gardini, Gerben-Jan Gerbrandy, Jens Gieseke, Françoise Grossetête, György Hölvényi, Anneli Jäätteenmäki, Jean-François Jalkh, Benedek Jávor, Karin Kadenbach, Kateřina Konečná, Giovanni La Via, Peter Liese, Norbert Lins, Valentinas Mazuronis, Susanne Melior, Miroslav Mikolášik, Massimo Paolucci, Piernicola Pedicini, Bolesław G. Piecha, Pavel Poc, Annie Schreijer-Pierik, Davor Škrlec, Renate Sommer, Estefanía Torres Martínez, Jadwiga Wiśniewska, Damiano Zoffoli
Substitutes present for the final vote	Nicola Caputo, Michel Dantin, Christofer Fjellner, Elena Gentile, Peter Jahr, James Nicholson, Jasenko Selimovic, Bart Staes
Substitutes under Rule 200(2) present for the final vote	Jens Nilsson, Marco Valli