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DRAFT 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

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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 can pose serious cross border threats to health***. The rapid growth in the market of new psychoactive substances, which continues to be challenging, coupled with the threats they may pose make it*** necessary to enhance monitoring ***and*** early warning ***systems and to assess the health, safety and social risks associated with such substances in order to develop responses and combat*** those threats.

Or. en

Amendment 2

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).

Or. en

Amendment 3

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Any Union action on new psychoactive substances should be based on scientific evidence.	(5) Any Union action on new psychoactive substances should be based on scientific evidence ***or on sufficient data on the risks that the new psychoactive substances pose***.

Or. en

Amendment 4

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***.

Or. en

Amendment 5

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 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**,** patterns of use ***and prevalence of use,*** potential and identified risks, manufacture, extraction, distribution ***channels***, trafficking ***and supply chains***, commercial, as well as medical and scientific use of these substances.

Or. en

Amendment 6

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.

Or. en

Amendment 7

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.

Or. en

Amendment 8

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;

Or. en

Amendment 9

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;

Or. en

Amendment 10

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;

Or. en

Amendment 11

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:

Or. en

Amendment 12

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 manufacture***,*** distribution ***and supply*** of the new psychoactive substance, and in any use of the new psychoactive substance.

Or. en

Amendment 13

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.

Or. en

Amendment 14

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***;

Or. en

Amendment 15

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***, as well as information on the rationale of its consumption***;

Or. en

Amendment 16

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;

Or. en

Amendment 17

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 substances. The Committee may be extended as deemed necessary by the Director, acting on the advice of the	The Scientific Committee ***of the Centre*** shall assess the risks posed by the new psychoactive substance or group of new 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.	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.

Or. en

Amendment 18

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.

Or. en

Amendment 19

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	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.	once the World Health Organisation expert 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.

Or. en