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Committee on the Environment, Public Health and Food Safety

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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 on new psychoactive substances
(COM(2013)0619 – C7-0272/2013 – 2013/0305(COD))

Rapporteur: Elena Oana Antonescu

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SHORT JUSTIFICATION

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 United Kingdom.

The consumption of new psychoactive substances can cause harms to the health and safety of individuals and can pose risks and burdens on society, as it may lead to violent behaviour and crime. The rapid emergence and spread of these substances, have led national authorities to subject them to various restriction measures. Hundreds such substances or mixtures of substances have been subjected to different restriction measures in the Member States in the past years.

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.
The rising number of new psychoactive substances available in the EU internal market, their growing diversity, both in type and risk level, the speed with which they emerge and the growing number of individuals who consume them, challenge the capacity of public authorities to provide effective responses to protect public health and safety without hampering legitimate trade.

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 proposed Regulation is intended to replace Council Decision 2005/387/JHA. It 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 for a Regulation are as follows:
•Exchange of information and temporary consumer market restrictions: this proposal sets up a robust system 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 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 carried out by the scientific committee of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Once the risk assessment is completed, measures will be taken proportionate to the risks of substances.

•No restriction measures would be introduced on new psychoactive substances posing low health, social and safety risks.
•For substances posing moderate risks, the Commission shall prohibit the making available on the market to consumers of these substances. They cannot be sold to consumers (except for uses specifically authorised, for instance by medicines legislation) but their trade would be allowed for commercial and industrial purposes as well as for scientific research and development.
•For substances posing severe risks: the Commission shall prohibit the production, manufacture, making available on the market including the transport, importation or exportation of new psychoactive substances which pose severe health, social and safety risks. The 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.

The rapporteur considers that regulatory interventions are very important and that they should be complemented by other activities including research and monitoring psychoactive substances.
In order to address the growing use of new psychoactive substances and their potential risks, Member States should improve the availability and effectiveness of prevention programmes and raise awareness about the risk of the use of these substances and the related consequences.

With regard to the information exchange process described in Article 5 of the proposal, the rapporteur considers that the information which will be provided by the National Focal Points and Europol National Units to the EMCDDA and Europol, should also refer to the detection and identification of the substances that appear to be new psychoactive substances or mixtures, consumption patterns, information on non-fatal intoxication and deaths caused by the consumption of such substances.

The rapporteur considers that besides the European Chemicals Agency and the European Food Safety Authority, the European Centre for Disease Prevention and Control should also be involved in the collection of the data and information on new psychoactive substances.
The determination of the level of the health, social and safety risks posed by the new psychoactive substance on which a risk assessment report was drafted shall be done by the Commission without undue delay.

Contraindications with other substances should also be taken into account by the Commission when determining the level of the health, social and safety risks posed by the new psychoactive substances on which a risk assessment report was drafted.

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 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) The 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 seems to cause public health concerns. These health alerts should also contain information regarding prevention, treatment and harm reduction measures that could be taken to address the risk of the substance.

Or. en

Amendment 2

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) Prevention, treatment and harm reduction measures are important for addressing the growing use of new psychoactive substances and their potential risks. The internet, which is one of the important distribution channels through which new psychoactive substances are sold, should be used for disseminating information on the health, social and safety risks that they pose.	(29) Prevention, ***early detection and intervention,*** treatment, ***risk*** and harm reduction measures are important for addressing the growing use of new psychoactive substances and their potential risks. ***Member States should improve the availability and effectiveness of prevention programmes and raise awareness about the risk of the use of the new psychoactive substances and related consequences. To this end, prevention measures should include early detection and intervention, promotion of healthy lifestyles and targeted prevention directed also at families and communities.*** The

internet, which is one of the important distribution channels through which new psychoactive substances are sold, should be used for disseminating information on the health, social and safety risks that they pose.

Or. en

Amendment 3

Proposal for a regulation
Recital 30 a (new)

Text proposed by the Commission	*Amendment*
	(30a) Primary health care still plays a limited role in the early identification, treatment and counselling for people with substance abuse problems. Member States should provide an integrated response by targeting users of new psychoactive substances in their health care and social protection systems.

Or. en

Amendment 4

Proposal for a regulation
Article 2 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) 'new psychoactive substance' means a natural or synthetic substance that, when consumed by a human, has the capacity to produce central nervous system stimulation or depression, resulting in hallucinations, alterations in motor function, thinking, behaviour, perception, awareness or mood, ***which*** is intended for human consumption	(a) 'new psychoactive substance' means a natural or synthetic substance that, when consumed by a human, has the capacity to produce central nervous system stimulation or depression, resulting in hallucinations, alterations in motor function, thinking, behaviour, perception, awareness or mood, ***whether it*** is intended ***or not*** for human

or is likely to be consumed by humans even if not intended for them with the purpose of inducing one or more of the effects mentioned above, which is neither controlled under the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, nor the 1971 United Nations Convention on Psychotropic Substances; it excludes alcohol, caffeine and tobacco, as well as tobacco products within the meaning of Council Directive 2001/37/EC of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products[24] ;	consumption, with the purpose of inducing one or more of the effects mentioned above, which is intended for human consumption or is likely to be consumed by humans even if not intended for them with the purpose of inducing one or more of the effects mentioned above, which is neither controlled under the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, nor the 1971 United Nations Convention on Psychotropic Substances; it excludes alcohol, caffeine and tobacco, as well as tobacco products within the meaning of Council Directive 2001/37/EC of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products[24];
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[24]OJ L 194, 18.7.2001, p. 26.	[24]OJ L 194, 18.7.2001, p. 26.

Or. en

Amendment 5

Proposal for a regulation
Article 5

Text proposed by the Commission	*Amendment*
National Focal Points within the European Information Network on Drugs and Drug Addiction ("Reitox") and Europol National Units shall provide to the EMCDDA and Europol the available information on the consumption, possible risks, manufacture, extraction, importation, trade, distribution, trafficking, commercial and scientific use of substances that appear to be new psychoactive substances or mixtures.	National Focal Points within the European Information Network on Drugs and Drug Addiction ("Reitox") and Europol National Units shall provide ***in a timely manner*** to the EMCDDA and Europol the available information on the ***detection and identification***, consumption ***patterns***, possible risks, ***including information on non-fatal intoxication and deaths***, manufacture, extraction, importation, trade, distribution, trafficking, commercial and scientific use of substances that appear to

	be new psychoactive substances or mixtures.
The EMCDDA and Europol shall communicate that information immediately to Reitox ***and*** the Europol National Units.	The EMCDDA and Europol shall communicate that information immediately to Reitox, and the Europol National Units, ***the Commission and to the European Medicines Agency***.

Or. en

Amendment 6

Proposal for a regulation
Article 6 – paragraph 4 – point c

Text proposed by the Commission	*Amendment*
(c) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation, but the marketing authorisation has been suspended by the competent authority;	(c) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation, but the marketing authorisation has been suspended, ***revoked or withdrawn*** by the competent authority;

Or. en

Amendment 7

Proposal for a regulation
Article 6 – paragraph 5

Text proposed by the Commission	*Amendment*
The EMCDDA 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. The EMCDDA shall respect the conditions on use of the information, which are communicated to the EMCDDA by the European Chemicals Agency and the European Food Safety	The EMCDDA shall request the European Chemicals Agency, ***the European Centre for Disease Prevention and Control (ECDC)*** and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance. The EMCDDA shall respect the conditions on use of the information, which are communicated to

Authority, including conditions on information and data security and protection of confidential business information.	the EMCDDA by the European Chemicals Agency, ***the European Centre for Disease Prevention and Control*** and the European Food Safety Authority, including conditions on information and data security and protection of confidential business information.
The European Chemicals Agency and the European Food Safety Authority shall provide the information and data at their disposal within four weeks from receipt of the request.	The European Chemicals Agency, ***the European Centre for Disease Prevention and Control*** and the European Food Safety Authority shall provide the information and data at their disposal within four weeks from receipt of the request.

Or. en

Amendment 8

Proposal for a regulation
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Scientific Committee of the EMCDDA shall carry out the risk assessment on the basis of information on the risks of the substance and on its uses, including commercial and industrial uses, provided by the Member States, the Commission, the EMCDDA, Europol, the European Medicines Agency, the European Chemicals Agency, the European Food Safety Authority and on the basis of any other relevant scientific evidence. It shall take into consideration all opinions held by its members. The EMCDDA shall support the risk assessment and shall identify information needs, including targeted studies or tests.	4. The Scientific Committee of the EMCDDA shall carry out the risk assessment on the basis of information on the risks of the substance and on its uses, including commercial and industrial uses, provided by the Member States, the Commission, the EMCDDA, Europol***,*** the European Medicines Agency, the European Chemicals Agency, ***the European Centre for Disease Prevention and Control***, the European Food Safety Authority and on the basis of any other relevant scientific evidence. It shall take into consideration all opinions held by its members. The EMCDDA shall support the risk assessment and shall identify information needs, including targeted studies or tests.

Or. en

Amendment 9

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall determine the level of the health, social and safety risks posed by the new psychoactive substance on which a risk assessment report was drafted. It shall do so on the basis of all available evidence, in particular the risk assessment report.	1. The Commission shall determine ***without undue delay*** the level of the health, social and safety risks posed by the new psychoactive substance on which a risk assessment report was drafted. It shall do so on the basis of all available evidence, in particular the risk assessment report.

Or. en

Amendment 10

Proposal for a regulation
Article 10 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, in particular injury, disease, and physical and mental impairment;	(a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, ***contraindications with other substances,*** abuse liability and dependence-producing potential, in particular injury, disease, and physical and mental impairment;

Or. en

Amendment 11

Proposal for a regulation
Article 11 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is ***limited, as it provokes minor injury and disease, and minor physical or mental impairment;***	(a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is ***insignificant.***

Or. en

Amendment 12

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall, by means of a Decision, without undue delay, prohibit the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of the new psychoactive substance if, based on existing evidence, it poses, overall, severe health, social ***and*** safety risks, in particular:	1. The Commission shall, by means of a Decision, without undue delay, prohibit the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of the new psychoactive substance if, based on existing evidence, it poses, overall, severe health, social ***or*** safety risks, in particular:

Or. en

Amendment 13

Proposal for a regulation
Article 20

Text proposed by the Commission	*Amendment*
The Commission and the Member States shall support the development, sharing and	The Commission and the Member States shall support the development, sharing and

dissemination of information and knowledge on new psychoactive substances. They shall do so by facilitating cooperation between the EMCDDA, other Union agencies, and scientific and research centres.	dissemination of information and knowledge on new psychoactive substances. They shall do so by facilitating cooperation between the EMCDDA, other Union agencies ***(in particular European Medicines Agency, European Chemicals Agency, European Centre for Disease and Prevention Control)*** and scientific and research centres. ***The Commission and the Member States shall also promote and support the research, including applied research into new psychoactive substances and ensure cooperation and coordination between networks at national and EU level in order to strenghten the understanding of the phenomenon. They shall do so by facilitating cooperation between the EMCDDA, other Union agencies (in particular European Medicines Agency, European Chemicals Agency, European Centre for Disease and Prevention Control) and scientific and research centres. In particular, emphasis should be placed on developing forensic and toxicological capacity as well as on improving the availability of epidemiological information.***

Or. en