COUNCIL OF THE EUROPEAN UNION

Brussels, 7 May 2014

9045/14

Interinstitutional File: 2013/0305 (COD)

CODEC 1130
CORDROGUE 28
SAN 184
DROIPEN 59
PE 299

INFORMATION NOTE

from:	General Secretariat of the Council
to:	Permanent Representatives Committee/Council
Subject:	Proposal for a Regulation of the European Parliament and of the Council on new psychoactive substances - Outcome of the European Parliament's first reading (Strasbourg, 14 to 17 April 2014)

I. INTRODUCTION

The Rapporteur, Mr Jacek PROTASIEWICZ (EPP-PL), presented a report consisting of 51 amendments (amendment 1-51) to the proposal for a Regulation, on behalf of the Committee on Civil Liberties, Justice and Home Affairs.

II. DEBATE

No debate took place.

III. VOTE

When it voted on 17 April 2014, the plenary adopted the 51 amendments in the report of the Committee on Civil Liberties, Justice and Home Affairs.

The Commission's proposal, as thus amended, and the legislative resolution constitute the Parliament's position at first reading. The text of the amendments adopted and the European Parliament's legislative resolution are set out in the Annex to this note

ANNEX
(17.4.2014)

New psychoactive substances ***I

European Parliament legislative resolution of 17 April 2014 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))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2013)0619),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0272/2013),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the United Kingdom House of Commons and the United Kingdom House of Lords, asserting that the draft legislative act does not comply with the principle of subsidiarity,

– having regard to the opinion of the European Economic and Social Committee of 21 January 2014 [1],

– having regard to Rule 55 of its Rules of Procedure,

– having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs and the opinion of the Committee on the Environment, Public Health and Food Safety (A7-0172/2014),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a regulation
Recital 3

[1] Not yet published in the Official Journal.

Text proposed by the Commission	*Amendment*
(3) Member States' competent public authorities introduce various restriction measures on these new psychoactive substances to address the risks that they pose or may pose when consumed. As new psychoactive substances are often used in the production of various goods or of other substances which are used for manufacturing goods, such as medicines, industrial solvents, cleaning agents, goods in the hi-tech industry, restricting their access for this use can have an important impact on economic operators, potentially disrupting their business activities in the internal market.	(3) Member States' competent public authorities introduce various restriction measures on these new psychoactive substances to address the risks that they pose or may pose when consumed. As new psychoactive substances are often used ***for scientific research and development purposes and*** in the production of various goods or of other substances which are used for manufacturing goods, such as medicines, industrial solvents, cleaning agents, goods in the hi-tech industry, restricting their access for this use can have an important impact on economic operators, potentially disrupting their business activities in the internal market ***and can also impede sustainable scientific research and development***.

Amendment 2

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) The increasing number of new psychoactive substances available in the internal market, their growing diversity, the speed with which they emerge on the market, the different risks that they may pose when consumed by humans ***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 the functioning of the internal market.	(4) The increasing number of new psychoactive substances available in the internal market, their growing diversity, the speed with which they emerge on the market, the different risks that they may pose when consumed by humans***,*** the growing number of individuals who consume them ***and the lack of general public knowledge and awareness about the risks associated with their consumption***, challenge the capacity of public authorities to provide effective responses to protect public health and safety without hampering the functioning of the internal market.

Amendment 3

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) ***Restriction*** measures vary ***significantly*** in different Member States, meaning that economic operators that use them in the production of various goods must comply, in the case of the same new psychoactive substance, with different requirements, such as pre-export notification, export authorisation, or import and export licences. Consequently, the differences between the Member States' laws, regulations and administrative provisions on new psychoactive substances hinder the functioning of the internal market, by causing obstacles to trade, market fragmentation, lack of legal clarity and of an even level playing field for economic operators, making it difficult for companies to operate across the internal market.	(5) ***As conditions and circumstances differ in Member States with regard to psychoactive substances, restriction*** measures vary ***accordingly*** in different Member States, meaning that economic operators that use them in the production of various goods must comply, in the case of the same new psychoactive substance, with different requirements, such as pre-export notification, export authorisation, or import and export licences. Consequently, the differences between the Member States' laws, regulations and administrative provisions on new psychoactive substances ***could potentially*** hinder ***to some extent*** the functioning of the internal market, by causing obstacles to trade, market fragmentation, lack of legal clarity and of an even level playing field for economic operators, making it ***more*** difficult for companies to operate across the internal market.

Amendment 4

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) Restriction measures not only cause barriers to trade in the case of new psychoactive substances that already have commercial, industrial or scientific uses, but ***can*** also impede the development of such uses, and are likely to cause obstacles to trade for economic operators that seek to develop such uses, by making access to those new psychoactive substances more difficult.	(6) Restriction measures ***could*** not only cause barriers to trade in the case of new psychoactive substances that already have commercial, industrial or scientific uses, but ***could*** also impede the development of such uses, and are likely to cause obstacles to trade for economic operators that seek to develop such uses, by making access to those new psychoactive substances more difficult.

Amendment 5

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) The disparities between the various restriction measures applied to new psychoactive substances ***can*** also lead to displacement of harmful new psychoactive substances between the Member States, hampering efforts to restrict their availability to consumers and undermining consumer protection across the Union.	(7) The disparities between the various restriction measures applied to new psychoactive substances***, while they are legitimate since they respond to each Member State's particularities with regard to psychoactive substances, could*** also lead to displacement of harmful new psychoactive substances between the Member States, hampering efforts to restrict their availability to consumers and undermining consumer protection across the Union, ***if efficient information exchange and coordination among Member States is not strengthened***.

Amendment 6

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) Such disparities facilitate illegal trafficking of such substances by criminals, in particular organised criminal gangs.

Amendment 7

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) Such disparities are expected to ***increase*** as Member States ***continue to pursue*** divergent approaches to addressing new psychoactive substances. Therefore, the obstacles to trade and market fragmentation, and the lack of legal clarity and of a level playing field are expected to ***increase***, further hindering the functioning of the internal market.	(8) Such disparities are expected to ***continue*** as Member States ***adopt*** divergent approaches to addressing ***challenges with regard to*** new psychoactive substances. Therefore, the obstacles to trade and market fragmentation, and the lack of legal clarity and of a level playing field are expected to ***continue***, further hindering the functioning of the internal market ***if Member States do not coordinate and cooperate more efficiently***.

Amendment 8

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) ***Those*** distortions to the functioning of the internal market should be ***eliminated*** and, to that end, the rules relating to new psychoactive substances that are of concern at Union level should be approximated, while, at the same time, ensuring a high level of health, safety and consumer protection.	(9) ***Where*** distortions to the functioning of the internal market ***are identified they*** should be ***addressed*** and, to that end, the rules relating to new psychoactive substances that are of concern at Union level should be approximated, while, at the same time, ensuring a high level of health, safety and consumer protection ***and flexibility for Member States to respond to local situations***.

Amendment 9

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) New psychoactive substances and mixtures should be able to move freely in the Union when intended for commercial and industrial use, as well as for scientific research and development***. This Regulation should establish rules for introducing restrictions to this free movement***.	(10) New psychoactive substances and mixtures should be able to move freely in the Union when intended for commercial and industrial use, as well as for scientific research and development***, by duly authorised persons in establishments which are directly under the control of Member States' authorities or specifically approved by them***.

Amendment 10

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) No risk assessment should be conducted under this Regulation 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.	(14) No risk assessment should be conducted under this Regulation 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 are 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.

Amendment 11

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Certain new psychoactive substances pose immediate public health risks, requiring urgent action. Therefore, their availability to consumers should be restricted for a ***limited*** time, pending their risk assessment.	(17) Certain new psychoactive substances pose immediate public health risks, requiring urgent action. Therefore, their availability to consumers should be restricted for a ***sufficient period of*** time, pending their risk assessment ***and until the level of risk posed by a new psychoactive substance has been determined and, if justified, a decision introducing permanent market measures has entered into force***.

Amendment 12

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) ***No*** restriction measures should be introduced at Union level on new psychoactive substances which pose low health, social and safety risks.	(18) ***On the basis of existing evidence and on predefined criteria, no*** restriction measures should be introduced at Union level on new psychoactive substances which pose low health, social and safety risks, ***but Member States may introduce further measures that are deemed appropriate or necessary depending on the specific risks that the substance poses in their territories taking into account national circumstances and any social, economic, legal, administrative or other factor they may consider relevant***.

Amendment 13

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) ***Those*** new psychoactive substances which pose moderate health, social and safety risks should not be made available to consumers.	(19) ***On the basis of the existing evidence and on predefined criteria, those*** new psychoactive substances which pose moderate health, social and safety risks should not be made available to consumers.

Amendment 14

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) ***Those*** new psychoactive substances which pose severe health, social and safety risks should not be made available on the market.	(20) ***On the basis of the existing evidence and on predefined criteria, those*** new psychoactive substances which pose severe health, social and safety risks should not be made available on the market.

Amendment 15

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) This Regulation should provide for exceptions in order to ensure the protection of human and animal health, to facilitate scientific research and development, and to allow the use of new psychoactive substances in industry, provided that they cannot be abused or recovered.	(21) This Regulation should provide for exceptions in order to ensure the protection of human and animal health, to facilitate scientific research and development, and to allow the use of new psychoactive substances in industry, provided that they ***are not liable to have ill effects and that they*** cannot be abused or recovered.

Amendment 16

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) Member States should take 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.

Amendment 17

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(23) The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) established by Regulation 1920/2006/EC of the European Parliament and of the Council of 12 December 2006[18] should have a central role in the exchange of information on new psychoactive substances and in the assessment of the health, social and safety risks that they pose.	(23) The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) established by Regulation 1920/2006/EC of the European Parliament and of the Council of 12 December 2006[18] should have a central role in the exchange ***and coordination*** of information on new psychoactive substances and in the assessment of the health, social and safety risks that they pose. ***Given that within the scope of this Regulation there is an increase in the amount of information expected to be collected and managed by EMCDDA, specific support should be envisaged and provided.***
[18] OJ L 376, 27.12.2006, p. 1.	[18] OJ L 376, 27.12.2006, p. 1.

Amendment 18

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) The mechanism for rapid exchange of information on new psychoactive substances has proved to be a useful channel for sharing information on new psychoactive substances, on new trends in the use of controlled psychoactive substances and on related public health warnings. ***That mechanism should be further strengthened to*** enable a more effective response to the rapid emergence and spread of new psychoactive substances across the Union.	(24) The mechanism for rapid exchange of information on new psychoactive substances ***(the 'European Union Early Warning System on New Psychoactive Substances' ('EWS'))*** has proved to be a useful channel for sharing information on new psychoactive substances, on new trends in the use of controlled psychoactive substances and on related public health warnings. ***To*** enable a more effective response to the rapid emergence and spread of new psychoactive substances across the Union***, the mechanism 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, adverse events associated with their use, and the involvement of criminal groups in the market through the Union new psychoactive substances database (the 'European Database on New Drugs'). The media, particularly scientific and medical literature, can be an important source of information on adverse event case reports. In order to enhance the efficiency of reporting, the EMCDDA should monitor all new psychoactive substances and enter this information in the European Database on New Drugs. Data sets essential to the functioning of this Regulation include data on the detection and identification of new psychoactive substances, adverse events associated with their use, and the involvement of criminal groups in the market. A core data set should be defined. The core data set should be reviewed on a regular basis to ensure that it reflects the information required for the effective functioning of the Regulation. Suspected serious adverse events, including fatal adverse events, should be subject to expedited reporting.

Amendment 19

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) In order to allow Member States to receive, access simultaneously and share information on new psychoactive substances in the Union, the European Database on New Drugs should be fully and permanently accessible to the Member States, the EMCDDA, Europol and the Commission.

Amendment 20

Proposal for a regulation
Recital 24 b (new)

Text proposed by the Commission	*Amendment*
	(24b) 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. 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.

Amendment 21

Proposal for a regulation
Recital 24 c (new)

Text proposed by the Commission	*Amendment*
	(24c) In order to protect public health, the EWS activities of EMCDDA and Europol should be adequately funded.

Amendment 22

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) Information from Member States is crucial for the effective functioning of the procedures leading to decision on market restriction of new psychoactive substances. Therefore, Member States should collect, on a regular basis, data on the use of new psychoactive substances, related health, safety and social problems and policy responses, in accordance with the EMCDDA framework for data collection for the key epidemiological indicators and other relevant data. They should share ***this***	(25) Information from Member States is crucial for the effective functioning of the procedures leading to ***a*** decision on market restriction of new psychoactive substances. Therefore, Member States should ***monitor and*** collect, on a regular basis, data on the ***emergence and*** use of ***any*** new psychoactive substances, related health, safety and social problems and policy responses, in accordance with the EMCDDA framework for data collection for the key epidemiological indicators and other relevant data. They should share

data.	***those*** data ***notably with the EMCDDA, Europol and the Commission***.

Amendment 23

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission	*Amendment*
	(25a) Information on new psychoactive substances provided by and exchanged among Member States is crucial for their national health policies, both in terms of drug prevention and of the treatment for psychoactive drug users in recovery services. Member States should make use of all the available information in an effective manner and monitor the relevant developments.

Amendment 24

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) A lack of capacity to identify and anticipate the emergence and spread of new psychoactive substances and a lack of evidence about their health, social and safety risks hamper the provision of an effective response. Therefore, support should be provided, including at Union level, to facilitate cooperation between the EMCDDA, research institutes and forensic laboratories with relevant expertise, in order to increase the capacity to assess and address effectively new psychoactive substances.	(26) A lack of capacity to identify and anticipate the emergence and spread of new psychoactive substances and a lack of evidence about their health, social and safety risks hamper the provision of an effective response. Therefore, support ***and the necessary resources*** should be provided, at Union ***and national*** level, to facilitate ***regular and systematic*** cooperation between the EMCDDA, ***National Focal Points, health care and law enforcement representatives at national and regional level,*** research institutes and forensic laboratories with relevant expertise, in order to increase the capacity to assess and address effectively new psychoactive substances.

Amendment 25

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26a) Appropriate safeguards, such as data anonymisation, should be put in place in order to ensure a high level of protection of personal data, in particular when sensitive data are collected and shared.

Amendment 26

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28a) Children and adolescents are particularly vulnerable to the dangers presented by such substances, the risks of which are still largely unknown.

Amendment 27

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 new psychoactive substances and related consequences. To that 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 ***and rapidly developing*** distribution channels through which new psychoactive

substances are ***advertised and*** sold, should be used for disseminating information on the health, social and safety risks that they pose ***, and for the prevention of misuse and abuse***. ***It is essential for children, adolescents and young adults to be made aware of those risks, including by means of information campaigns in schools and other educational environments.***

Amendment 28

Proposal for a regulation
Recital 29 a (new)

Text proposed by the Commission	*Amendment*
	(29a) The Commission and the Member States should also promote educational and awareness-raising activities, initiatives and campaigns, targeting the health, social and safety risks associated with the misuse and abuse of new psychoactive substances.

Amendment 29

Proposal for a regulation
Recital 30 a (new)

Text proposed by the Commission	*Amendment*
	(30a) The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the criteria regarding low, moderate and severe risks substances. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Amendment 30

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to a rapid increase in the number of reported fatalities in several Member States associated with the consumption of the new psychoactive substance concerned, imperative grounds of urgency so require.	(32) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to a rapid increase in the number of reported fatalities ***and severe health consequences or incidents posing a grave threat to health*** in several Member States associated with the consumption of the new psychoactive substance concerned, imperative grounds of urgency so require.

Amendment 31

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) In the application of this Regulation, the Commission should consult Member States' experts, relevant Union agencies, civil society ***and*** economic operators.	(33) In the application of this Regulation, the Commission should consult Member States' experts, relevant Union agencies, ***in particular the EMCDDA,*** civil society***,*** economic operators ***and any other relevant stakeholder***.

Amendment 32

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, including the freedom to conduct a business, the right to property and the right to ***an effective remedy***,	(36) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union ***and of the European Convention for the Protection of Human Rights and Fundamental Freedoms***, including the freedom to conduct a business, the right to property***, the right of access to preventive healthcare*** and the right to ***benefit from medical treatment***,

Amendment 33

Proposal for a regulation
Article 2 – 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 ***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];	(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 or not it*** is intended for human consumption 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[24];
[24] OJ L 194, 18.7.2001, p. 26.	[24] ***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 (***OJ L 194, 18.7.2001, p. 26***)***.

Amendment 34

Proposal for a regulation
Article 4

Text proposed by the Commission	*Amendment*
Insofar as the Union has not adopted	Insofar as the Union has not adopted

measures to subject a new psychoactive substance to market restriction under this Regulation, Member States may adopt technical regulations on such new psychoactive substance in accordance with Directive 98/34/EC.	measures to subject a new psychoactive substance to market restriction under this Regulation, ***or when the Commission has not adopted a restriction measure pursuant to Article 11,*** Member States may adopt technical regulations on such new psychoactive substance in accordance with Directive 98/34/EC.
Member States shall immediately communicate to the Commission any such draft technical regulation on new psychoactive substances, in accordance with Directive 98/34/EC.	Member States shall immediately communicate to the Commission any such draft technical regulation on new psychoactive substances, in accordance with Directive 98/34/EC.

Amendment 35

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.	***If a Member State has information relating to what appears to be a new psychoactive substance or mixture, its*** National Focal Points within the European Information Network on Drugs and Drug Addiction ("Reitox") and Europol National Units shall ***collect and*** provide ***in a timely manner*** to the EMCDDA and Europol the available information on the ***detection and identification***, consumption ***and its patterns***, ***serious intoxication or deaths***, possible risks ***as well as the toxicity level***, ***data concerning*** manufacture, extraction, importation, trade, distribution ***and its channels***, 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, the Europol National Units ***and the European Medicines Agency***. ***To enable a more effective response to the rapid emergence and spread of new psychoactive substances across the Union, the information exchange mechanism (the 'Early Warning System') shall 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.

Amendment 36

Proposal for a regulation
Article 6

Text proposed by the Commission	*Amendment*
1. Where the EMCDDA and Europol, or the Commission, consider that the information shared on a new psychoactive substance notified by several Member States gives rise to concerns across the Union because of the health, social and safety risks that the new psychoactive substance may pose, the EMCDDA and Europol shall draw up a joint report on the new psychoactive substance.	1. Where the EMCDDA and Europol, or the Commission, consider that the information shared on a new psychoactive substance notified by several Member States gives rise to concerns across the Union because of the health, social and safety risks that the new psychoactive substance may pose, ***or in response to a reasoned request from more than one Member State,*** the EMCDDA and Europol shall draw up a joint report on the new psychoactive substance.
2. The joint report shall contain the following information:	2. The joint report shall contain the following information:
(a) the nature of the risks that the new psychoactive substance poses when consumed by humans and the scale of the risk to public health, as referred to in Article 9(1);	(a) the nature of the risks that the new psychoactive substance poses when consumed by humans, ***including contraindications with other substances when available*** and the scale of the risk to public health, as referred to in Article 9(1);
(b) the chemical and physical identity of the new psychoactive substance, the methods and, if known, the chemical precursors used for its manufacture or extraction, and other new psychoactive substances with a similar chemical structure that have emerged;	(b) the chemical and physical identity of the new psychoactive substance, the methods and, if known, the chemical precursors used for its manufacture or extraction, and other new psychoactive substances with a similar chemical structure that have emerged ***or which may reasonably be expected to emerge, based on scientific assessment***;
(c) the commercial and industrial use of the new psychoactive substance, as well as its use for scientific research and development purposes;	(c) the commercial and industrial use of the new psychoactive substance, as well as its use for scientific research and development purposes;
(d) the human and veterinary medical use of the new psychoactive substance, including as an active substance in a	(d) the human and veterinary medical use of the new psychoactive substance, including as an active substance in a

medicinal product or veterinary medicinal product;	medicinal product or veterinary medicinal product;
(e) the involvement of criminal groups in the manufacture, distribution or trade in the new psychoactive substance, and any use of the new psychoactive substance in the manufacture of narcotic drugs or psychotropic substances;	(e) the involvement of criminal groups in the manufacture, distribution or trade in the new psychoactive substance, and any use of the new psychoactive substance in the manufacture of narcotic drugs or psychotropic substances;
(f) whether the new psychoactive substance is currently under assessment, or has been under assessment, by the United Nations system;	(f) whether the new psychoactive substance is currently under assessment, or has been under assessment, by the United Nations system;
(g) whether the new psychoactive substance is subject to any restriction measures in the Member States;	(g) whether the new psychoactive substance is subject to any restriction measures in the Member States;
(h) any existing prevention and treatment measure in place to address the consequences of the use of the new psychoactive substance.	(h) any existing prevention and treatment measure in place to address the consequences of the use of the new psychoactive substance.
3. The EMCDDA and Europol shall request the National Focal Points and the Europol National Units to provide additional information on the new psychoactive substance. They shall provide that information within four weeks from receipt of the request.	3. The EMCDDA and Europol shall request the National Focal Points and the Europol National Units to provide additional information on the new psychoactive substance. They shall provide that information within four weeks from receipt of the request.
4. The EMCDDA and Europol shall request the European Medicines Agency to provide information on whether, in the Union or in any Member State, the new psychoactive substance is:	4. The EMCDDA and Europol shall request the European Medicines Agency, ***which should consult the competent authorities for medicines of Member States,*** to provide information on whether, in the Union or in any Member State, the new psychoactive substance is:
(a) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation;	(a) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation;
(b) an active substance in a medicinal product or a veterinary medicinal product that is the subject of an application for a marketing authorisation;	(b) an active substance in a medicinal product or a veterinary medicinal product that is the subject of an application for a marketing authorisation;
(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	(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;	competent authority;
(d) an active substance in an unauthorised medicinal product in accordance with Article 5 of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with Article 10(c) of Directive 2001/82/EC.	(d) an active substance in an unauthorised medicinal product in accordance with Article 5 of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with Article 10(c) of Directive 2001/82/EC.
Member States shall provide the European Medicines Agency with the above information, if so requested by it.	Member States shall provide the European Medicines Agency with the above information ***without undue delay***, if so requested by it.
The European Medicines Agency shall provide the information at its disposal within four weeks from receipt of the request from the EMCDDA.	The European Medicines Agency shall provide the information at its disposal within four weeks from receipt of the request from the EMCDDA.
5. 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 Authority, including conditions on information and data security and protection of confidential business information.	5. 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 the EMCDDA by the European Chemicals Agency, ***ECDC*** and the European Food Safety Authority, including conditions on information and data security and protection of confidential ***data, including sensitive data or*** 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, ***ECDC*** and the European Food Safety Authority shall provide the information and data at their disposal within four weeks from receipt of the request.
6. The EMCDDA and Europol shall submit the joint report to the Commission within eight weeks from the request for additional information referred to in paragraph 3.	6. The EMCDDA and Europol shall submit the joint report to the Commission within eight weeks from the request for additional information referred to in paragraph 3.
When the EMCDDA and Europol collect information on mixtures or on several new psychoactive substances with similar chemical structure, they shall submit individual joint reports to the Commission within ten weeks from the request for	When the EMCDDA and Europol collect information on mixtures or on several new psychoactive substances with similar chemical structure, they shall submit individual joint reports to the Commission within ten weeks from the request for

additional information referred to in paragraph 3.	additional information referred to in paragraph 3.

Amendment 37

Proposal for a regulation
Article 7

Text proposed by the Commission	*Amendment*
1. Within four weeks from the receipt of the joint report referred to in Article 6, the Commission may request the EMCDDA to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report. The risk assessment shall be conducted by the Scientific Committee of the EMCDDA.	1. Within four weeks from the receipt of the joint report referred to in Article 6 the Commission may request the EMCDDA to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report. The risk assessment shall be conducted by the Scientific Committee of the EMCDDA.
2. The risk assessment report shall include an analysis of the criteria and of the information referred to in Article 10(2) to enable the Commission to determine the level of health, social and safety risks that the new psychoactive substance poses.	2. The risk assessment report shall include an analysis of the criteria and of the information referred to in Article 10(2) to enable the Commission to determine the level of health, social and safety risks that the new psychoactive substance poses.
3. The Scientific Committee of the EMCDDA shall assess the risks during a special meeting. The Committee may be extended by not more than five experts, representing the scientific fields relevant for ensuring a balanced assessment of the risks of the new psychoactive substance. The Director of the EMCDDA shall designate them from a list of experts. The Management Board of the EMCDDA shall approve the list of experts every three years. The Commission, the EMCDDA, Europol and the European Medicines Agency shall each have the right to nominate two observers.	3. The Scientific Committee of the EMCDDA shall assess the risks during a special meeting. The Committee may be extended by not more than five experts, ***including a psychologist specialising in addiction,*** representing the scientific fields relevant for ensuring a balanced assessment of the risks of the new psychoactive substance. The Director of the EMCDDA shall designate them from a list of experts. The Management Board of the EMCDDA shall approve the list of experts every three years. The ***European Parliament, the Council***, ***the*** Commission, the EMCDDA, Europol and the European Medicines Agency shall each have the right to nominate two observers.
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	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, ***such as its patterns and dosage,*** including commercial and industrial uses, provided by the Member States, the Commission, the EMCDDA, Europol, 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.	Medicines Agency, the European Chemicals Agency, ***the ECDC***, 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.
5. The EMCDDA shall submit the risk assessment report to the Commission within twelve weeks from the date when it received the request from the Commission.	5. The EMCDDA shall submit the risk assessment report to the Commission within twelve weeks from the date when it received the request from the Commission.
6. Upon request of the EMCDDA, the Commission may extend the period to complete the risk assessment by no more than twelve weeks to allow for additional research and data collection to take place. The EMCDDA shall submit such a request to the Commission within six weeks from the launch of the risk assessment. If within two weeks of such request being made the Commission has not objected to such request, the risk assessment shall be so extended.	6. Upon request of the EMCDDA, the Commission may extend the period to complete the risk assessment by no more than twelve weeks to allow for additional research and data collection to take place. The EMCDDA shall submit such a request to the Commission within six weeks from the launch of the risk assessment. If within two weeks of such request being made the Commission has not objected to such request, the risk assessment shall be so extended.

Amendment 38

Proposal for a regulation
Article 8 – 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 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.	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 ***and concrete*** information that is new or of particular relevance for the Union and that has not been taken into account by the United Nations system***, which is to be mentioned in the assessment report***.

Amendment 39

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. No risk assessment shall be carried out where the new psychoactive substance has been assessed within the United Nations system, but it has been decided not to schedule it under the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or the 1971 Convention on Psychotropic Substances, except where there is significant information that is new or of particular relevance for the Union.	2. No risk assessment shall be carried out where the new psychoactive substance has been assessed within the United Nations system, but it has been decided not to schedule it under the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or the 1971 Convention on Psychotropic Substances, except where there is significant ***and concrete*** information that is new or of particular relevance for the Union***, the reasons for which shall be indicated in the assessment report***.

Amendment 40

Proposal for a regulation
Article 8 – paragraph 4 (new)

Text proposed by the Commission	*Amendment*
	4. However, the risk assessment shall be carried out if at Union level there are sufficient data available to suggest the need for a joint report of the EMCDDA and Europol.

Amendment 41

Proposal for a regulation
Article 9

Text proposed by the Commission	*Amendment*
1. Where it requests a risk assessment of a new psychoactive substance pursuant to Article 7(1), the Commission shall, 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, evidenced by:	1. Where it requests a risk assessment of a new psychoactive substance pursuant to Article 7(1), the Commission shall, 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, evidenced by:
(a) reported fatalities and severe health	(a) reported fatalities and severe health

consequences associated with the consumption of the new psychoactive substance in ***several*** Member States, related to the ***serious acute*** toxicity of the new psychoactive substance;	consequences associated with the consumption of the new psychoactive substance ***including contraindications with other substances when available,*** in Member States, related to the toxicity of the new psychoactive substance;
(b) the prevalence and patterns of use of the new psychoactive substance in the general population and in specific groups, in particular frequency, quantities and modality of use, its availability to consumers and the potential for diffusion, which indicate that the scale of the risk is considerable.	(b) the prevalence and patterns of use of the new psychoactive substance in the general population and in specific groups, in particular frequency, quantities and modality of use, its availability to consumers and the potential for diffusion, which indicate that the scale of the risk is considerable.
2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).	2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).
On duly justified imperative grounds of urgency relating to a rapid increase in the number of reported fatalities in several Member States associated with the consumption of the new psychoactive substance concerned, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure laid down in Article 19(3).	On duly justified imperative grounds of urgency relating to a rapid increase in the number of reported fatalities in several Member States associated with the consumption of the new psychoactive substance concerned, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure laid down in Article 19(3).
3. The market restriction contained in the Decision referred to in paragraph 1 shall not exceed a period of twelve months.	3. The market restriction contained in the Decision referred to in paragraph 1 shall not exceed a period of twelve months. ***If the level of health, social and safety risks posed by the new psychoactive substance justifies 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.***

Amendment 42

Proposal for a regulation
Article 10

Text proposed by the Commission	*Amendment*
1. The Commission shall determine the level of the health, social and safety risks	1. The Commission shall, ***without undue delay,*** determine the level of the health,

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.	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.
2. The Commission shall take the following criteria into account when determining the level of risk of a new psychoactive substance:	2. The Commission shall take the following criteria into account when determining the level of risk of a new psychoactive substance:
(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 when available,*** abuse liability and dependence-producing potential, in particular injury, disease, ***aggression, as well as*** physical and mental impairment;
(b) the social harm caused to individuals and to society, in particular its impact on social functioning, public order and criminal activities, organised crime activity associated with the new psychoactive substance, illicit profits generated by the production, trade and distribution of the new psychoactive substance, and associated economic costs of the social harm;	(b) the social harm caused to individuals and to society, in particular ***based on*** its impact on social functioning, public order and criminal activities, organised crime activity associated with the new psychoactive substance, illicit profits generated by the production, trade and distribution of the new psychoactive substance, and associated economic costs of the social harm;
(c) the risks to safety, in particular the spread of diseases, including transmission of blood borne viruses, the consequences of physical and mental impairment on the ability to drive, the impact of the manufacture, transport and disposal of the new psychoactive substance and associated waste materials on the environment.	(c) the risks to ***public*** safety, in particular ***based on*** the spread of diseases, including transmission of blood borne viruses, the consequences of physical and mental impairment on the ability to drive, the impact of the manufacture, transport and disposal of the new psychoactive substance and associated waste materials on the environment.
The Commission shall also take into account the prevalence and patterns of use of the new psychoactive substance in the general population and in specific groups, its availability to consumers, its potential for diffusion, the number of Member States where it poses health, social and safety risks, the extent of its commercial and industrial use, and its use for scientific research and development purposes.	The Commission shall also take into account the prevalence and patterns of use of the new psychoactive substance in the general population and in specific groups, its availability to consumers, its potential for diffusion, the number of Member States where it poses health, social and safety risks, the extent of its commercial and industrial use, and its use for scientific research and development purposes.

Amendment 43

Proposal for a regulation
Article 11

Text proposed by the Commission	*Amendment*
Low risks	Low risks ***at Union level***
The Commission shall not adopt restriction measures on a new psychoactive substance if, based on existing evidence, it poses, overall, low health, social and safety risks***, in particular***:	The Commission shall not adopt restriction measures on a new psychoactive substance if, based on ***the*** existing evidence ***and on the following criteria***, it poses, overall, low health, social and safety risks ***at Union level***:
(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***;
(b) the social harm caused to individuals and to society is limited, in particular ***regarding*** its impact on social functioning and public order, criminal activities associated with the new psychoactive substance is low, illicit profits generated by the production, trade and distribution of the new psychoactive substance and associated economic costs are non-existent or negligible;	(b) the social harm caused to individuals and to society is limited, in particular ***based on*** its impact on social functioning and public order, criminal activities associated with the new psychoactive substance is low, illicit profits generated by the production, trade and distribution of the new psychoactive substance and associated economic costs are non-existent or negligible;
(c) the risks to safety are limited, in particular low risk of spread of diseases, including transmission of blood borne viruses, non-existent or low consequences of physical and mental impairment on the ability to drive, and the impact of the manufacture, transport and disposal of the new psychoactive substance and associated waste materials on the environment is low.	(c) the risks to ***public*** safety are limited, in particular ***based on a*** low risk of spread of diseases, including transmission of blood borne viruses, non-existent or low consequences of physical and mental impairment on the ability to drive, and the impact of the manufacture, transport and disposal of the new psychoactive substance and associated waste materials on the environment is low.
	Where the decision to not adopt restriction measures on a new psychoactive substance that is considered to pose overall low health, social and safety risk at Union level was based on a partial or total lack of evidence, it shall include an appropriate reference in the

justification.

Amendment 44

Proposal for a regulation
Article 12

Text proposed by the Commission	*Amendment*
Moderate risks and permanent consumer market restriction	Moderate risks and permanent consumer market restriction ***at Union level***
1. The Commission shall, by means of a Decision, without undue delay, prohibit the making available on the market to consumers of the new psychoactive substance if, based on existing evidence, it poses, overall, moderate health, social and safety risks***, in particular***:	1. The Commission shall, by means of a Decision, without undue delay, prohibit the making available on the market to consumers of the new psychoactive substance if, based on ***the*** existing evidence ***and on the following criteria***, it poses, overall, moderate health, social and safety risks:
(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 moderate, as it generally provokes non-lethal injury and disease, and moderate physical or mental impairment;	(a) 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 moderate, as it generally provokes non-lethal injury and disease, and moderate physical or mental impairment;
(b) the social harm caused to individuals and to society is moderate, in particular ***regarding*** its impact on social functioning and public order, producing public nuisance; criminal activities and organised crime activity associated with the substance are sporadic, illicit profits and economic costs are moderate;	(b) the social harm caused to individuals and to society is moderate, in particular ***based on*** its impact on social functioning and public order, producing public nuisance; criminal activities and organised crime activity associated with the substance are sporadic, illicit profits and economic costs are moderate;
(c) the risks to safety are moderate, in particular sporadic spread of diseases, including transmission of blood borne viruses, moderate consequences of physical and mental impairment on the ability to drive, and the manufacture, transport and disposal of the new psychoactive substance and associated waste materials results in environmental nuisance.	(c) the risks to ***public*** safety are moderate, in particular ***based on a*** sporadic spread of diseases, including transmission of blood borne viruses, moderate consequences of physical and mental impairment on the ability to drive, and the manufacture, transport and disposal of the new psychoactive substance and associated waste materials results in environmental nuisance.
2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in	2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in

accordance with the examination procedure referred to in Article 19(2).	accordance with the examination procedure referred to in Article 19(2).
	3. Where the information or evidence available shows that the new psychoactive substance subject to the Decision referred to in paragraph 1 poses a higher level of health, social and safety risks in a given Member State, in particular because of the modalities or scale of consumption of that substance or given the specific risks that the substance poses in its territory taking into account national circumstances and any social, economic, legal, administrative or other factor, Member States may maintain or introduce more stringent measures to ensure a high level of protection of public health.
	4. A Member State willing to maintain a more stringent measure concerning the new psychoactive substance in accordance with paragraph 3 shall immediately communicate the relevant laws, regulations or administrative provisions to the Commission and shall inform the other Member States thereof.
	5. A Member State willing to introduce a more stringent measure concerning the new psychoactive substance in accordance with paragraph 3 shall immediately communicate the relevant draft laws, regulations or administrative provisions to the Commission and shall inform the other Member States thereof.

Amendment 45

Proposal for a regulation
Article 13

Text proposed by the Commission	*Amendment*
Severe risks and permanent market restriction	Severe risks and permanent market restriction ***at Union level***
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	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

if, ***based on existing evidence, it poses, overall, severe health, social and safety risks, in particular:***	***it poses severe health, social and safety risks, based on the existing evidence and on the following criteria:***
(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 ***life threatening***, as it generally provokes death or lethal injury, severe disease, and severe 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 ***severe***, as it generally provokes death or lethal injury, severe disease, and severe physical or mental impairment;
(b) the social harm caused to individuals and to society is severe, in particular ***regarding*** its impact on social functioning and public order, resulting in public order disruption, violent and anti-social behaviour causing damage to the user, to others and to property; criminal activities and organised crime activity associated with the new psychoactive substance are systematic, ***illicit profits, and economic costs are high***;	(b) the social harm caused to individuals and to society is severe, in particular ***based on*** its impact on social functioning and public order, resulting in public order disruption, violent and anti-social behaviour causing damage to the user, to others and to property; criminal activities and organised crime activity associated with the new psychoactive substance are systematic;
(c) the risks to safety are severe, in particular significant spread of diseases, including transmission of blood borne viruses, severe consequences of physical and mental impairment on the ability to drive, and the manufacture, transport and disposal of the new psychoactive substance and associated waste materials result in environmental harm.	(c) the risks to ***public*** safety are severe, in particular ***based on a*** significant spread of diseases, including transmission of blood borne viruses, severe consequences of physical and mental impairment on the ability to drive, and the manufacture, transport and disposal of the new psychoactive substance and associated waste materials result in environmental harm.
2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).	2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

Amendment 46

Proposal for a regulation
Article 13 a (new)

Text proposed by the Commission	*Amendment*
	Article 13a
	Delegation of power

	The Commission shall be empowered to adopt delegated acts in accordance with Article 20a to amend the criteria listed in Articles 11, 12 and 13.

Amendment 47

Proposal for a regulation
Article 14

Text proposed by the Commission	*Amendment*
1. The Decisions referred to in Article 9(1) and Article 12(1) shall not impede the free movement in the Union and the making available on the market to consumers of new psychoactive substances that are active substances in medicinal products or veterinary medicinal products that have obtained a marketing authorisation.	1. The Decisions referred to in Article 9(1) and Article 12(1) shall not impede the free movement in the Union and the making available on the market to consumers of new psychoactive substances that are active substances in medicinal products or veterinary medicinal products that have obtained a marketing authorisation.
2. The Decisions referred to in Article 13(1) shall not impede the free movement in the Union and the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances:	2. The Decisions referred to in Article 13(1) shall not impede the free movement in the Union and the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances:
(a) for scientific research and development purposes;	(a) for scientific research and development purposes, ***by duly authorised persons in establishments which are directly under the control of Member States' authorities or specifically approved by them***;
(b) for uses authorised under Union legislation;	(b) for uses authorised under Union legislation;
(c) that are active substances in medicinal products or veterinary medicinal products that have obtained a marketing authorisation;	(c) that are active substances in medicinal products or veterinary medicinal products that have obtained a marketing authorisation;
(d) for use in the manufacture of substances and products provided that the new psychoactive substances are transformed in such a condition that they cannot be abused or recovered.	(d) for use in the manufacture of substances and products provided that the new psychoactive substances are transformed in such a condition that they cannot be abused or recovered, ***that the amount of each substance used is included in the information about the substance or the product***.
	2a. For all of authorised uses, new psychoactive substances and products

	containing new psychoactive substances shall 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.
3. The Decisions referred to in Article 13(1) may set requirements and conditions for the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances posing severe health, social and safety risks for the uses listed in paragraph 2.	3. The Decisions referred to in Article 13(1) may set requirements and conditions for the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances posing severe health, social and safety risks for the uses listed in paragraph 2.
	4. Member States shall 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.

Amendment 48

Proposal for a regulation
Article 20

Text proposed by the Commission	*Amendment*
Research ***and*** analysis	Research, analysis, ***prevention and funding***
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.	***1. Financial support and the necessary resources shall be provided at Union and national level for*** the development, sharing and dissemination of information and knowledge on new psychoactive substances. ***The Commission and the Member States*** shall do so by facilitating cooperation between the EMCDDA, other Union agencies, scientific and research centres ***and other bodies with relevant expertise, and by regularly providing those bodies with up to date information on such substances***.
	2. 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 Union level in order to strengthen understanding of the phenomenon. They shall do so by facilitating cooperation between the EMCDDA, other Union agencies (in particular European Medicines Agency and European Chemicals Agency) and scientific and research centres. Emphasis shall be placed on developing forensic and toxicological capacity as well as on improving the availability of epidemiological information.
	3. The Member States shall promote prevention schemes as well as, together with the Commission, measures to raise awareness of the risks posed by psychoactive substances, such as educational information campaigns.

Amendment 49

Proposal for a regulation
Article 20 a (new)

Text proposed by the Commission	*Amendment*
	Article 20a
	Exercise of the delegation
	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
	2. The power to adopt delegated acts referred to in Article 13a shall be conferred on the Commission for a period of ten years from (the entry into force of this Regulation). The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the ten year period. The delegation of powers shall be tacitly extended for a further period of ten years, unless the European Parliament or the Council opposes such extension not later than three months before the end of this period.
	3. The delegation of powers referred to in Article 13a may be revoked at any time by the European Parliament or by the

Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 13a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Amendment 50

Proposal for a regulation
Article 21

Text proposed by the Commission	*Amendment*
The EMCDDA and Europol shall report annually on the implementation of this Regulation.	***1.*** The EMCDDA and Europol shall report annually ***to the European Parliament, the Commission and Member States*** on the implementation of this Regulation. ***The implementation reports shall be published on a website and made publicly available.***
	2. The Commission shall [five years after entry into force of this Regulation] present to the European Parliament and Member States a report and if justified followed by a proposal for closing any identified loop-holes between Regulation (EC) No 1907/2006 of the European Parliament and of the Council [1a], Directive 2001/83/EC of the European

Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and this Regulation in order to make sure that psychotropic substances are properly regulated.

[1a] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Amendment 51

Proposal for a regulation
Article 22

Text proposed by the Commission	*Amendment*
By [five years after the entry into force of this Regulation] at the latest and every five years thereafter, the Commission shall assess the implementation, application and effectiveness of this Regulation and publish a report.	By [five years after the entry into force of this Regulation] at the latest and every five years thereafter, the Commission shall assess the implementation, application and effectiveness of this Regulation and publish a report. ***In this respect, the Commission, the EMCDDA and Europol shall conduct post-risk assessments of new psychoactive substances.***
	By [five years after entry into force of this Regulation] the Commission shall evaluate and if appropriate present a proposal for possible classification of groups of the new psychoactive substances in order to counteract the practice of bypassing the legislation in force by slight modifications of the chemical structure of the psychoactive substances.