P7_TA(2014)0453

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.

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[1] OJ C 177, 11.6.2014, p. 52.

P7_TC1-COD(2013)0305

Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on new psychoactive substances

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure[2],

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1 OJ C 177, 11.6.2014, p. 52.

2 Position of the European Parliament of 17 April 2014.

Whereas:

(1) 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.

(2) During the past years, Member States have notified an increasing number of new psychoactive substances via the mechanism for rapid exchange of information which was established by Joint Action 97/396/JHA[1] and was further strengthened by the Council Decision 2005/387/JHA[2]. A large majority of these new psychoactive substances were reported by more than one Member State. Many such new psychoactive substances were sold to consumers without appropriate labelling and instructions of use.

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[1] Joint Action 97/396/JHA of 16 June 1997 adopted by the Council on the basis of Article K.3 of the Treaty on European Union, concerning the information exchange, risk assessment and the control of new synthetic drugs (OJ L 167, 25.6.1997, p. 1).

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

(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***. **[Am. 1]**

(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 ***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. **[Am. 2]**

(5) ~~Restriction~~ ***As conditions and circumstances differ in Member States with regard to psychoactive substances, restriction*** measures vary ~~significantly~~ ***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. **[Am. 3]**

(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 ~~can~~ ***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. **[Am. 4]**

(7) The disparities between the various restriction measures applied to new psychoactive substances ~~can~~***, 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***. **[Am. 5]**

(7a) Such disparities facilitate illegal trafficking in such substances by criminals, in particular organised criminal gangs. **[Am. 6]**

(8) Such disparities are expected to ~~increase~~ ***continue*** as Member States ~~continue to pursue~~ ***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 ~~increase~~ ***continue***, further hindering the functioning of the internal market ***if Member States do not coordinate and cooperate more efficiently***. **[Am. 7]**

(9) ~~Those~~ ***Where*** distortions to the functioning of the internal market ***are identified they*** should be ~~eliminated~~ ***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***. **[Am. 8]**

(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***. ~~This Regulation should establish rules for introducing restrictions to this free movement.~~ **[Am. 9]**

(11) New psychoactive substances that pose health, social and safety risks across the Union should be addressed at the Union level. Action on new psychoactive substances under this Regulation should contribute to a high level of protection of human health and safety, as enshrined in the Charter of Fundamental Rights of the European Union.

(12) This Regulation should not apply to drug precursors because the diversion of those chemical substances for the purpose of manufacturing narcotic drugs or psychotropic substances is addressed under Regulation (EC) No 273/2004 of the European Parliament and of the Council[1] and Council Regulation (EC) No 111/2005[2].

(13) Any Union action on new psychoactive substances should be based on scientific evidence and subject to a specific procedure. Based on the information notified by Member States, a report should be drawn up on new psychoactive substances that give rise to concerns across the Union. The report should indicate whether it is necessary to carry out a risk assessment. Following the risk assessment, the Commission should determine whether the new psychoactive substances should be subjected to any restriction measures. In case of immediate public health concerns, the Commission should subject them to temporary consumer market restriction before the conclusion of the risk assessment. In case new information emerges on a new psychoactive substance, the Commission should re-assess the level of risks that it poses. Reports on new psychoactive substances should be made publicly available.

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1 Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).

2 Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).

(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***. **[Am. 10]**

(15) Where the new psychoactive substance on which a report is drawn up is an active substance in a medicinal product or in a veterinary medicinal product, the Commission should assess with the European Medicines Agency the need for further action.

(16) The measures taken on new psychoactive substances at Union level should be proportionate to the health, social and safety risks that they pose.

(17) Certain new psychoactive substances pose immediate public health risks, requiring urgent action. Therefore, their availability to consumers should be restricted for a ~~limited~~ ***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***. **[Am. 11]**

(18) ~~No~~ ***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 a substance poses in their territories taking into account national circumstances and any social, economic, legal, administrative or other factor they may consider relevant***. **[Am. 12]**

(19) ~~Those~~ ***On the basis of the existing evidence and of predefined criteria, those*** new psychoactive substances which pose moderate health, social and safety risks should not be made available to consumers. **[Am. 13]**

(20) ~~Those~~ ***On the basis of the existing evidence and of predefined criteria, those*** new psychoactive substances which pose severe health, social and safety risks should not be made available on the market. **[Am. 14]**

(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 adverse effects and that they*** cannot be abused or recovered. **[Am. 15]**

(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. **[Am. 16]**

(22) In order to ensure the efficient implementation of this Regulation, the Member States should lay down rules on the sanctions applicable to infringements of restriction measures. Those sanctions should be effective, proportionate and dissuasive.

(23) The EMCDDA established by Regulation (EC) No 1920/2006 of the European Parliament and of the Council[1] 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.*** **[Am. 17]**

[1] Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (OJ L 376, 27.12.2006, p. 1).

(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. ~~That mechanism should be further strengthened to~~ ***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 this Regulation. Suspected serious adverse events, including fatal adverse events, should be subject to expedited reporting***. **[Am. 18]**

(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. **[Am. 19]**

(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 substance, that substance 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 risks associated with the substance. **[Am. 20]**

(24c) In order to protect public health, the EWS activities of EMCDDA and Europol should be adequately funded. **[Am. 21]**

(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 ***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 ~~this~~ ***those*** data ***notably with the EMCDDA, Europol and the Commission***. **[Am. 22]**

(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. **[Am. 23]**

(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, including 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. **[Am. 24]**

(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. **[Am. 25]**

(27) The procedures for information exchange, risk assessment and adoption of temporary and permanent restriction measures on new psychoactive substances established by this Regulation should enable swift action. Market restriction measures should be adopted without undue delay, not later than eight weeks from receipt of the joint report or risk assessment report.

(28) As long 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 that new psychoactive substance in compliance with the provisions of Directive 98/34/EC of the European Parliament and of the Council[1]. In order to preserve the unity of the Union's internal market and to prevent the emergence of unjustified barriers to trade, Member States should immediately communicate to the Commission any draft technical regulation on new psychoactive substances, in accordance with the procedure established by Directive 98/34/EC.

(28a) Children and adolescents are particularly vulnerable to the dangers presented by such substances, the risks of which are still largely unknown. **[Am. 26]**

[1] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society Services (OJ L 204, 21.7.1998. p. 37).

(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***. **[Am. 27]**

(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. **[Am. 28]**

(30) Medicinal products and veterinary medicinal products are addressed under Directive 2001/82/EC of the European Parliament and of the Council[1], Directive 2001/83/EC of the European Parliament and of the Council[2] and Regulation (EC) No 726/2004 of the European Parliament and of the Council[3]. Their abuse or misuse should, therefore, not be covered by this Regulation.

(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 risk 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. **[Am. 29]**

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1 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 67).

2 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 1).

3 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

(31) In order to ensure uniform conditions for the implementation of temporary and permanent market restrictions, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1].

(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. **[Am. 30]**

(33) In the application of this Regulation, the Commission should consult Member States' experts, relevant Union agencies, ***in particular the EMCDDA,*** civil society ~~and~~***,*** economic operators ***and any other relevant stakeholder***. **[Am. 31]**

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[1] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).

(34) Since the objectives of the proposed action cannot be sufficiently achieved by the Member States, but can rather, by reason of the effects of the envisaged action, be better achieved at the Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(35) In order to establish uniform rules and ensure clarity of concepts and procedures, as well as to provide legal certainty for economic operators, it is appropriate to adopt this act in the form of a Regulation.

(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 ~~an effective remedy~~ ***benefit from medical treatment***, **[Am. 32]**

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE, DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation establishes rules for restrictions to the free movement of new psychoactive substances in the internal market. For that purpose it sets up a mechanism for information exchange on, risk assessment and submission to market restriction measures of new psychoactive substances at Union level.

2. This Regulation shall not apply to scheduled substances as defined in Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005.

Article 2

Definitions

For the purpose of this Regulation, the following definitions apply:

(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~~ ***whether or not it*** 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 Directive 2001/37/EC of the European Parliament and of the Council~~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~~ [1]; **[Am. 33]**

(b) ‘mixture’ means a mixture or solution containing one or more new psychoactive substances;

[1] ***Directive 2001/37/EC of the European Parliament and of the Council 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).

(c) ‘medicinal product’ means a product as defined in point 2 of Article 1 of Directive 2001/83/EC;

(d) ‘veterinary medicinal product’ means a product as defined in point 2 of Article 1 of Directive 2001/82/EC;

(e) ‘marketing authorisation’ means an authorisation to place a medicinal product or a veterinary medicinal product on the market, in accordance with Directive 2001/83/EC, Directive 2001/82/EC or Regulation (EC) No 726/2004;

(f) ‘making available on the market’ means any supply of a new psychoactive substance for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(g) ‘consumer’ means any natural person who is acting for purposes which are outside his/her trade, business or profession;

(h) ‘commercial and industrial use’ means any manufacture, processing, formulation, storage, mixing, production and sale to natural and legal persons other than consumers;

(i) ‘scientific research and development’ means any scientific experimentation, analysis or research carried out under strictly controlled conditions, in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[1];

(j) ‘United Nations system’ means the World Health Organisation, the Commission on Narcotic Drugs and the Economic and Social Committee acting in accordance with their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances.

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[1] 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.)

CHAPTER II

FREE MOVEMENT

Article 3

Free movement

New psychoactive substances and mixtures shall move freely in the Union for commercial and industrial use, as well as for scientific research and development purposes.

Article 4

Prevention of barriers to free movement

Insofar as the Union has not adopted measures to subject a new psychoactive substance to market restriction under this Regulation, ***or when the Commission pursuant to Article 11 has not adopted a restriction measure,*** 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. **[Am. 34]**

CHAPTER III

EXCHANGE AND COLLECTION OF INFORMATION

Article 5

Information exchange

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 ***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 ('EWS') 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. **[Am. 35]**

Article 6

Joint report

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:

(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 ***or which may reasonably be expected to emerge, on the basis of scientific assessment***;

(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 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;

(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;

(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.

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;

(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 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 point (c) of Article 10 of Directive 2001/82/EC.

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.

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, ***the 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, ***the 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.

   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. **[Am. 36]**

CHAPTER IV

RISK ASSESSMENT

Article 7

Risk assessment procedure and report

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.

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, ***such as its patterns and dosage,*** including commercial and industrial uses, provided by the Member States, the Commission, the EMCDDA, Europol, the European 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.

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. **[Am. 37]**

Article 8

Exclusion from risk assessment

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***. **[Am. 38]**

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***. **[Am. 39]**

3. No risk assessment shall be carried out where the new psychoactive substance is:

(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;

(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.

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.

[Am. 40]

CHAPTER V

MARKET RESTRICTIONS

Article 9

Immediate risks to public health and temporary consumer market restriction

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 consequences associated with the consumption of the new psychoactive substance***, including contraindications with other substances when available,*** in ~~several~~ Member States, related to the ~~serious acute~~ 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.

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).

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.*** **[Am. 41]**

Article 10

Determination of the level of health, social and safety risks following the risk assessment

1. The Commission shall, ***without undue delay,*** 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.

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, ***contraindications with other substances when available,*** abuse liability and dependence-producing potential, in particular injury, disease, ~~and~~ ***aggression, as well as*** physical and mental impairment;

(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 ***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. **[Am. 42]**

Article 11

Low risks ***at Union level***

The Commission shall not adopt restriction measures on a new psychoactive substance if, on the basis of ***the*** existing evidence ***and of the following criteria***, it poses, overall, low health, social and safety risks~~, in particular~~ ***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~~ ***insignificant***;

(b) the social harm caused to individuals and to society is limited, in particular ~~regarding~~ ***on the basis of*** its impact on social functioning and public order, criminal activities associated with the new psychoactive substance are 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 ***public*** safety are limited, in particular ***on the basis of 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 in relation to 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.
[Am. 43]

Article 12

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, on ***the*** basis of existing evidence ***and of the following criteria***, it poses, overall, moderate health, social and safety risks~~, in particular~~:

(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;

(b) the social harm caused to individuals and to society is moderate, in particular ~~regarding~~ ***on the basis of*** 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 ***public*** safety are moderate, in particular ***on the basis of 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 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 intending 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.*** **[Am. 44]**

Article 13

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 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~~ ***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~~ ***on the basis of*** 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~~;

(c) the risks to ***public*** safety are severe, in particular ***on the basis of 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). **[Am. 45]**

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. **[Am. 46]**

Article 14

Authorised uses

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:

(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;

(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, ***that the amount of each substance used is included in the information about the substance or the product***.

2a. For all 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.

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. **[Am. 47]**

CHAPTER VI

MONITORING AND RE-EXAMINATION

Article 15

Monitoring

The EMCDDA and Europol, with the support of Reitox, shall monitor all new psychoactive substances on which a joint report has been drawn up.

Article 16

Re-examination of level of risks

Where new information and evidence is available on the risks posed by a new psychoactive substance the health, social and safety risks of which have already been determined in accordance with Article 10, the Commission shall request the EMCDDA to update the risk assessment report drafted on the new psychoactive substance and shall re-examine the level of risks that the new psychoactive substance poses.

CHAPTER VII

SANCTIONS AND REMEDY

Article 17

Sanctions

Member States shall lay down the rules on sanctions applicable to infringements of the Decisions referred to in Article 9(1), Article 12(1) and Article 13(1) and shall take all necessary measures to ensure that they are implemented. The sanctions provided for shall be effective, proportionate and dissuasive. Member States shall notify those rules on sanctions and any subsequent amendment affecting those provisions to the Commission without delay.

Article 18

Remedy

Any person whose rights are affected by the implementation of a sanction taken by a Member State in accordance with Article 17 shall have the right to an effective remedy before a tribunal in that Member State.

CHAPTER VIII

PROCEDURES

Article 19

Committee

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

CHAPTER IX

FINAL PROVISIONS

Article 20

Research ~~and,~~ analysis, ***prevention and funding***

1. ~~The Commission and the Member States shall support~~***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. ~~They~~ ***The Commission and the Member States*** shall do so by facilitating cooperation between the EMCDDA, other Union agencies, ~~and~~ 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 Union and national 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. **[Am. 48]**

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 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 each 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.*

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* OJ: Please insert the date of the entry into force of this Regulation.

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.*** **[Am. 49]**

Article 21

Reporting

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 by ...[*] 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, Directive 2001/83/EC, Regulation (EC) No 726/2004 and this Regulation in order to make sure that psychotropic substances are properly regulated. **[Am. 50]**

[*] *OJ: Please insert the date: five years after entry into force of this Regulation.*

Article 22

Evaluation

By ...* at the latest and every five years thereafter, the Commission shall assess the implementation, application and effectiveness of this Regulation and shall publish a report. ***In this respect, the Commission, the EMCDDA and Europol shall conduct post-risk assessments of new psychoactive substances.***

By ...* the Commission shall evaluate and, if appropriate, present a proposal for a possible classification of groups of 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. **[Am. 51]**

Article 23

Replacement of Decision 2005/387/JHA

Decision 2005/387/JHA is hereby repealed and replaced, without prejudice to the obligations of the Member States relating to the time limit for transposition of that Decision into national law. References to Decision 2005/387/JHA shall be construed as reference to this Regulation.

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* ***OJ: Please insert the date: five years after entry into force of this Regulation.***

Article 24

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at …,

For the European Parliament	*For the Council*
The President	*The President*