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Committee on the Environment, Public Health and Food Safety

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AMENDMENTS

14 - 56

Draft opinion
Elena Oana Antonescu
(PE524.592v01-00)

on the proposal for a regulation of the European Parliament and of the Council
on new psychoactive substances

Proposal for a regulation
(COM(2013)0619 – C7-0272/2013 – 2013/0305(COD))

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United in diversity

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Amendment 14
James Nicholson

Proposal for a regulation
Citation 1

Text proposed by the Commission

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

Amendment

Having regard to the Treaty on the Functioning of the European Union, and in particular **Title V** thereof,

Or. en

Justification

Title V (Area of Freedom, Security and Justice) is the more appropriate legal base particularly in light of the huge levels of illicit trade of NPS.

Amendment 15
Marusya Lyubcheva

Proposal for a regulation
Recital 3

Text proposed by the Commission

(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.

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 **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 16
Marusya Lyubcheva

Proposal for a regulation
Recital 4

Text proposed by the Commission

(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.

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, 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 17
Jacek Olgierd Kurski

Proposal for a regulation
Recital 5

Text proposed by the Commission

(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

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.

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 **and violating the principle of equality**.

Or. pl

Amendment 18
Zbigniew Ziobro

Proposal for a regulation
Recital 7

Text proposed by the Commission

(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.***

Amendment

(7) The disparities ***in the provisions governing restrictions on the trade in psychoactive substances significantly increase the risk of illegal smuggling channels arising for these substances and lead to laws being circumvented in order to obtain the necessary permits.***

Or. pl

Amendment 19
Marusya Lyubcheva

Proposal for a regulation
Recital 7

Text proposed by the Commission

(7) The disparities between the various restriction measures applied to new

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.

psychoactive substances can also lead to displacement of harmful new psychoactive substances between the Member States, hampering efforts to restrict their availability to consumers, undermining consumer protection across the Union *and the efforts to combat potential criminal activities and organised crime activity associated with their distribution.*

Or. en

Amendment 20
Jacek Olgierd Kurski

Proposal for a regulation
Recital 7

Text proposed by the Commission

(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.

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. *The disparities in the provisions governing restrictions on the trade in psychoactive substances significantly increase the risk of illegal smuggling channels arising for these substances and lead to laws being circumvented in order to obtain the necessary permits.*

Or. pl

Amendment 21
Marusya Lyubcheva

Proposal for a regulation
Recital 8

Text proposed by the Commission

(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.

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 ***and the protection of public health and safety.***

Or. en

Amendment 22
Zbigniew Ziobro

Proposal for a regulation
Recital 10

Text proposed by the Commission

(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.

Amendment

deleted

Or. pl

Amendment 23
Radvilė Morkūnaitė-Mikulėnienė

Proposal for a regulation
Recital 10

Text proposed by the Commission

(10) New psychoactive substances and

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.

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. ***In addition, however, illicit distribution of these substances and mixtures should be prevented.***

Or. It

Amendment 24
Zbigniew Ziobro

Proposal for a regulation
Recital 13

Text proposed by the Commission

(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.

Amendment

(13) Any Union action on new psychoactive substances should be based on scientific evidence, ***as well as on Member States' wide experience in this area***, 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 ***shall include an assessment of the dangers posed by the relevant psychoactive substances***. Following the risk assessment, the Commission should determine ***what restriction measures the relevant substances*** should be subjected to. 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 ***and re-impose market restrictions***. Reports on new psychoactive substances should be made publicly available.

available.

Or. pl

Amendment 25
Nikos Chrysogelos

Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission

Amendment

(13a) Taking into consideration international developments regarding drug policy reform and control of illicit substances, an objective impact assessment based upon scientific evidence is required to evaluate the effectiveness of different control and regulatory options, including current restricting policies, in order to safeguard public health, consumer safety and human rights of individual users.

Or. en

Amendment 26
Marusya Lyubcheva

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.

Or. en

Amendment 27
Zbigniew Ziobro

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) No restriction measures should be introduced at Union level on new psychoactive substances which pose low health, social and safety risks.

Amendment

deleted

Or. pl

Amendment 28
Marusya Lyubcheva

Proposal for a regulation
Recital 24

Text proposed by the Commission

(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.

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, *as well as to raise the level of public awareness about the risks associated with their use for any purposes, other than commercial, industrial or scientific.*

Or. en

Amendment 29
Marusya Lyubcheva

Proposal for a regulation
Recital 29

Text proposed by the Commission

(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.

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 ***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.***

Or. en

Amendment 30
Marusya Lyubcheva

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-rising activities, initiatives and campaigns, targeting the health, social and safety risks associated with the misuse and abuse of new psychoactive substances.

Or. en

Amendment 31
Zbigniew Ziobro

Proposal for a regulation
Recital 32

Text proposed by the Commission

(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.

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 ***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.

Or. pl

Amendment 32
Marusya Lyubcheva

Proposal for a regulation
Recital 32

Text proposed by the Commission

(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.

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 ***and severe health consequences*** in several Member States associated with the consumption of the new psychoactive substance concerned, imperative grounds of urgency so require.

Or. en

Amendment 33
Radvilė Morkūnaitė-Mikulėnienė

Proposal for a regulation
Article 3 – paragraph 1

Text proposed by the Commission

New psychoactive substances and mixtures shall move freely in the Union for commercial and industrial use, as well as

Amendment

New psychoactive substances and mixtures shall move freely in the Union for commercial and industrial use ***only***, as well

for scientific research and development purposes.

as for scientific research and development purposes.

Or. It

Amendment 34
James Nicholson

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

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.

Amendment

1. Where the EMCDDA and Europol, **the Member States** 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.

Or. en

Justification

The Member States may call on the EMCDDA to draw up a report.

Amendment 35
Rebecca Taylor

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Where the EMCDDA and Europol, or the Commission, consider that the information shared on a new psychoactive substance notified by **three or more** Member States gives rise to concerns

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.

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.

Or. en

Justification

The word 'several' is ambiguous. For clarity, the EU should act only when a substance has been identified in three or more Member States.

Amendment 36
Rebecca Taylor

Proposal for a regulation
Article 6 – paragraph 2 – point b

Text proposed by the Commission

(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;

Amendment

(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 **any** other new psychoactive **substance or groups of** substances with a similar chemical structure that have emerged;

Or. en

Amendment 37
James Nicholson

Proposal for a regulation
Article 6 – paragraph 2 – point c

Text proposed by the Commission

(c) the commercial and industrial use of the new psychoactive substance, as well as its use for scientific research and development

Amendment

(c) the commercial and industrial use of the new psychoactive substance, as well as its use for scientific research and development

purposes;

purposes *or any other known use*;

Or. en

Amendment 38
James Nicholson

Proposal for a regulation
Article 6 – paragraph 2 – point d

Text proposed by the Commission

(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;

Amendment

(d) the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal, veterinary medicinal *or similar* product;

Or. en

Amendment 39
James Nicholson

Proposal for a regulation
Article 6 – paragraph 6 – subparagraph 1

Text proposed by the Commission

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.

Amendment

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 *and* 4.

Or. en

Amendment 40
James Nicholson

Proposal for a regulation
Article 9 – paragraph 1 – point a

Text proposed by the Commission

(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;

Amendment

(a) reported fatalities and severe health consequences associated with the consumption of the new psychoactive substance in several Member States, related to the toxicity of the new psychoactive substance;

Or. en

Justification

The new psychoactive substances may cause fatalities and severe health consequences even without having acute toxicity.

Amendment 41
Marusya Lyubcheva

Proposal for a regulation
Article 9 – paragraph 1 – point b

Text proposed by the Commission

(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.

Amendment

(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 *moderate or* considerable.

Or. en

Amendment 42
James Nicholson

Proposal for a regulation
Article 9 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Amendment

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).

deleted

Or. en

Justification

The Member States should have the possibility to object the immediate ban on new psychoactive substances, therefore procedure in Article 19(2) should be used for all cases.

Amendment 43

Marusya Lyubcheva

Proposal for a regulation

Article 10 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission

Amendment

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

Or. en

Amendment 44

Rebecca Taylor

Proposal for a regulation

Article 10 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission

(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.

Amendment

(c) the risks to **public** 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.

Or. en

Amendment 45
Marusya Lyubcheva

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

Text proposed by the Commission

(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;

Amendment

(a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is **non-existent or negligible**, as it **does not provoke** injury and disease, **aggression** and physical or mental impairment;

Or. en

Amendment 46
Rebecca Taylor

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

Text proposed by the Commission

(c) the risks to safety are limited, in particular low risk of spread of diseases,

Amendment

(c) the risks to **public** 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.

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.

Or. en

Amendment 47
Rebecca Taylor

Proposal for a regulation
Article 12 – paragraph 1 – point c

Text proposed by the Commission

(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.

Amendment

(c) the risks to **public** 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.

Or. en

Amendment 48
Rebecca Taylor

Proposal for a regulation
Article 13 – paragraph 1 – point a

Text proposed by the Commission

(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

Amendment

(a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is **severe and significant**, as it generally provokes

or lethal injury, severe disease, and severe physical or mental impairment;

death or lethal injury, severe disease, and severe physical or mental impairment;

Or. en

Justification

Severe disease and severe physical or mental impairment are not necessarily life threatening, but substances having such consequences should be considered as high risk.

Amendment 49
Rebecca Taylor

Proposal for a regulation
Article 13 – paragraph 1 – point c

Text proposed by the Commission

(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.

Amendment

(c) the risks to **public** 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.

Or. en

Amendment 50
Jolanta Emilia Hibner

Proposal for a regulation
Article 13 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The Commission shall not adopt the draft implementing act where no opinion is delivered by the committee referred to in the Article 19(1).

Or. en

Amendment 51
Nikos Chrysogelos

Proposal for a regulation
Article 13 a (new)

Text proposed by the Commission

Amendment

Article 13a

Information to individual consumers

(a) The Commission shall make readily available to the public, especially youth, science-based information on health, social and safety risks of the new psychoactive substances as referred to in articles 11, 12.1 and 13.1.

(b) With regard to new psychoactive substances of low risk as referred to in article 11, the Commission shall also make widely available to the public, especially youth, information on usage effects and safe usage, as well as, harm reduction guidelines.

(c) With regard to new psychoactive substances of moderate or severe risks as referred to in articles 12.1 and 13.1, the Commission shall also make widely available to the public, especially youth, information on identification and early warning, prevention, treatment and harm reduction measures.

(d) The Commission shall collaborate with National Focal Points within the European Information network on Drugs and Drug Addiction ("Reitox") and other harm reduction and addiction treatment associations for providing accurate and timely information to individual users.

Or. en

Justification

Necessary in order to safeguard public health of users and consumer safety

Amendment 52
James Nicholson

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

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.

Amendment

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 **or the Member States** 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.

Or. en

Justification

Member States should have the right to ask for re-examine the level of risk as well.

Amendment 53
Radvilė Morkūnaitė-Mikulėnienė

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission

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

Amendment

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 to illicit distribution of new psychoactive substances or mixtures**, 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 provisions to the Commission without delay.

those rules on sanctions and any subsequent amendment affecting those provisions to the Commission without delay.

Or. It

Amendment 54
Rebecca Taylor

Proposal for a regulation
Article -20 (new)

Text proposed by the Commission

Amendment

Article -20

National scope

Where the EU has not acted, or the Commission has decided not to adopt any restriction measures based on the EMCDDA risk assessment of a new psychoactive substance, individual Member States may maintain or introduce in their territory restrictions on the making available of the new psychoactive substance on the market to consumers, without prejudice to legitimate trade in industry, or to medicinal products or veterinary medicinal products that have obtained a marketing authorisation.

Member States shall ensure that such restrictions are immediately communicated to the Commission, the EMCDDA and Europol.

Or. en

Justification

As the effects of certain new psychoactive substances can be extremely localised, Member States should be free to introduce consumer bans on substances within their own territories where the EU has not acted, or has decided that a substance poses a low risk at European level and therefore requires no Union action. However, in respect to the principle of free movement of goods and the internal market, legitimate Union trade in such substances, where it exists, should not be compromised.

Amendment 55
Rebecca Taylor

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

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.

Amendment

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, **and by regularly providing these bodies with up to date information on such substances wherever possible.**

Or. en

Justification

The nature of new psychoactive substances can change rapidly, and therefore Union agencies and scientific and research centres need to be kept as up to date as possible in order to monitor any emerging threats to public health.

Amendment 56
Rebecca Taylor

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission

The EMCDDA and Europol shall report annually on the implementation of this Regulation.

Amendment

The EMCDDA and Europol shall report annually **to the Commission and Member States** on the implementation of this Regulation, **and such reports will be published on a website and made public.**

Or. en