



**2016/0261(COD)**

19.10.2016

# **AMENDMENTS**

## **20 - 42**

**Draft opinion**  
**Cristian-Silviu Buşoi**  
(PE592.081v01-00)

on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances

Proposal for a regulation  
(COM(2016)0547 – C8-0351/2016 – 2016/0261(COD))



**Amendment 20**  
**Notis Marias**

**Proposal for a regulation**  
**Citation 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***Having regard to Protocol No 1 of the Treaty on the Functioning of the European Union on the role of national parliaments in the European Union,***

Or. en

**Amendment 21**  
**Notis Marias**

**Proposal for a regulation**  
**Citation 1 b (new)**

*Text proposed by the Commission*

*Amendment*

***Having regard to Protocol No 2 of the Treaty on the Functioning of the European Union on the application of the principles of subsidiarity and proportionality,***

Or. en

**Amendment 22**  
**Jasenko Selimovic, Frédérique Ries, José Inácio Faria**

**Proposal for a regulation**  
**Recital 1**

*Text proposed by the Commission*

*Amendment*

(1) New psychoactive substances can pose serious cross border threats to health which makes necessary to enhance monitoring, early warning and combating of those threats.

(1) New psychoactive substances can pose serious cross border threats to health, ***in particular due to their diversity and the speed with which they have been appearing,*** which makes necessary to

enhance monitoring, early warning and combating of those threats.

Or. en

### **Amendment 23**

**Bas Eickhout**

#### **Proposal for a regulation**

##### **Recital 1**

*Text proposed by the Commission*

(1) New psychoactive substances can pose serious cross border threats to health which makes necessary to enhance monitoring, early warning and combating of those threats.

*Amendment*

(1) New psychoactive substances can pose serious cross border threats to health which makes necessary to enhance monitoring, early warning, **risk reduction measures** and combating of those threats.

Or. en

### **Amendment 24**

**Nicola Caputo**

#### **Proposal for a regulation**

##### **Recital 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***(1a) 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.***

Or. en

### **Amendment 25**

**Jasenko Selimovic, Frédérique Ries, José Inácio Faria**

#### **Proposal for a regulation**

##### **Recital 1 a (new)**

*Text proposed by the Commission*

*Amendment*

**(1a)** *The term "psychoactive substances" refers to a broad category of unregulated psychoactive compounds or products containing them that are marketed as legal alternatives to well-known controlled drugs, usually sold via the internet or in "smart shops" or "head shops".*

Or. en

#### **Amendment 26**

**Jasenko Selimovic, Frédérique Ries, José Inácio Faria, Cristian-Silviu Buşoi**

#### **Proposal for a regulation**

#### **Recital 1 b (new)**

*Text proposed by the Commission*

*Amendment*

**(1b)** *It is possible that psychoactive substances are advertised with aggressive and sophisticated marketing strategies and are intentionally mislabelled, with declared ingredients differing from the actual composition. It is therefore necessary to take rapid action at Union level.*

Or. en

#### **Amendment 27**

**Jasenko Selimovic, Frédérique Ries, José Inácio Faria**

#### **Proposal for a regulation**

#### **Recital 2**

*Text proposed by the Commission*

*Amendment*

(2) During the past years, Member States have notified an increasing number of new psychoactive substances via the mechanism for rapid exchange of

(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 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<sup>13</sup> and was further strengthened by Council Decision 2005/387/JHA<sup>14</sup>.

information which was established by Joint Action 97/396/JHA 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<sup>13</sup> and was further strengthened by Council Decision 2005/387/JHA<sup>14</sup>. ***According to the European Medicine Centre for Drugs and Drug addiction ("the Centre"), Member States notified 101 new psychoactive substances, which had not been reported previously, via that mechanism during the year 2014.***

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<sup>13</sup> Council Joint Action 97/396/JHA of 16 June 1997 concerning the information exchange, risk assessment and control of new synthetic drugs (OJ L 167, 25.6.1997, p. 1).

<sup>14</sup> 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).

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<sup>13</sup> Council Joint Action 97/396/JHA of 16 June 1997 concerning the information exchange, risk assessment and control of new synthetic drugs (OJ L 167, 25.6.1997, p. 1).

<sup>14</sup> 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).

Or. en

## **Amendment 28**

### **Nicola Caputo**

#### **Proposal for a regulation**

##### **Recital 2**

###### *Text proposed by the Commission*

(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 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<sup>13</sup> and

###### *Amendment*

(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 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<sup>13</sup> and

was further strengthened by Council Decision 2005/387/JHA<sup>14</sup>.

was further strengthened by Council Decision 2005/387/JHA<sup>14</sup>. ***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 for use.***

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<sup>13</sup> Council Joint Action 97/396/JHA of 16 June 1997 concerning the information exchange, risk assessment and control of new synthetic drugs (OJ L 167, 25.6.1997, p. 1).

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<sup>13</sup> Council Joint Action 97/396/JHA of 16 June 1997 concerning the information exchange, risk assessment and control of new synthetic drugs (OJ L 167, 25.6.1997, p. 1).

<sup>14</sup> 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).

<sup>14</sup> 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).

Or. en

**Amendment 29**  
**Frédérique Ries, Jasenko Selimovic**

**Proposal for a regulation**  
**Recital 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***(2a) Europol, in its interim Serious and Organised Crime Threat Assessment for 2015<sup>1a</sup>, warns against the fact that organised criminal groups are able to react quickly to changes in legislation and respond to the prohibition of certain substances by creating new formulas that are not covered by Union or national law.***

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***<sup>1a</sup> Interim SOCTA 2015: An update on Serious and Organised Crime in the EU.***

Or. en

**Amendment 30**  
**Jasenko Selimovic, Frédérique Ries, José Inácio Faria**

**Proposal for a regulation**  
**Recital 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**(2a) This Regulation should take into account the fact that vulnerable groups, and especially young people, are particularly exposed to the public health, safety and social risks arising from new psychoactive substances.**

Or. en

**Amendment 31**  
**Jasenko Selimovic, Frédérique Ries, José Inácio Faria**

**Proposal for a regulation**  
**Recital 5**

*Text proposed by the Commission*

*Amendment*

(5) Any Union action on new psychoactive substances should be based on scientific evidence.

(5) Any Union action on new psychoactive substances should be based on scientific evidence. ***Given that in some cases new psychoactive substances could be so novel to the field that, at least initially, there would be very limited evidence from scientific research on public health risks, it is necessary to undertake rapid risk assessment procedures at Union level.***

Or. en

**Amendment 32**  
**Elena Gentile**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 2**  
Regulation (EC) No 1920/2006  
Article 5 – paragraph 2 – subparagraphs 2 and 3



*Text proposed by the Commission*

*Amendment*

(2) In Article 5 (2) the second ***and third subparagraphs are*** deleted.

(2) In Article 5 (2) the second ***subparagraph is*** deleted.

Or. en

*Justification*

*The third subparagraph of Article 5 (2) of Regulation (EC) No 1920/2006 concerns new trend in the use of existing psychoactive substances and should thus be maintained.*

**Amendment 33**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 3**  
Regulation (EC) No 1920/2006  
Article 5a – paragraph 1

*Text proposed by the Commission*

*Amendment*

***Each*** Member State ***shall ensure that its Reitox National Focal Points and the Europol National Unit provide timely and without any undue delay to the Centre and Europol the available information on new psychoactive substances. The information shall be related to the detection and identification, use and patterns of use, potential and identified risks, manufacture, extraction, distribution, trafficking, commercial, as well as medical and scientific use of these substances.***

***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 consumption patterns, serious intoxication or deaths as a result of, possible risks as well as the toxicity level, data concerning manufacture, extraction, importation, trade, distribution and distribution channels, trafficking and commercial and scientific use of substances that appear to be new psychoactive substances or mixtures.***

Or. en

## Amendment 34

Jasenko Selimovic, Frédérique Ries, José Inácio Faria

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 3

Regulation (EC) No 1920/2006

Article 5a – paragraph 1

#### *Text proposed by the Commission*

Each Member State shall ensure that its Reitox National Focal Points and the Europol National Unit provide timely and without any undue delay to the Centre and Europol the available information on new psychoactive substances. The information shall be related to the detection and identification, use and patterns of use, potential and identified risks, manufacture, extraction, distribution, trafficking, commercial, as well as medical and scientific use of these substances.

#### *Amendment*

Each Member State shall ensure that its Reitox National Focal Points and the Europol National Unit provide timely and without any undue delay to the Centre and Europol the available information on new psychoactive substances. The information shall be related to the detection and identification, use and patterns of use, potential and identified risks, manufacture, extraction, distribution, trafficking, **cross-border global supply chains**, commercial, as well as medical and scientific use of these substances.

Or. en

## Amendment 35

Daciana Octavia Sârbu

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 3

Regulation (EC) No 1920/2006

Article 5b – paragraph 1

#### *Text proposed by the Commission*

1. Where the Centre, the Commission or the Council, acting by a simple majority of Member States, consider that the information shared on a new psychoactive substance collected pursuant to Article 5a in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks **at the Union level**, the Centre shall draw up an initial report on the new psychoactive substance.

#### *Amendment*

1. Where the Centre, the Commission or the Council, acting by a simple majority of Member States, consider that the information shared on a new psychoactive substance collected pursuant to Article 5a in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks, the Centre shall draw up an initial report on the new psychoactive substance.

*Justification*

*The level of risk should be determined at the risk assessment stage and based on the information in the initial report.*

**Amendment 36**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 3**  
Regulation (EC) No 1920/2006  
Article 5b – paragraph 2 – point a

*Text proposed by the Commission*

(a) a first indication of the nature or scale of health and social risks associated with the new psychoactive substance;

*Amendment*

(a) a first indication of the nature or scale of health and social risks associated with the new psychoactive substance, ***including contraindications for use with other substances when available;***

Or. en

**Amendment 37**  
**Elena Gentile**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 3**  
Regulation (EC) No 1920/2006  
Article 5b – paragraph 2 – point d

*Text proposed by the Commission*

(d) information on the involvement of criminal groups in the manufacture and distribution of the new psychoactive substance;

*Amendment*

(d) information on the involvement of criminal groups in the ***development,*** manufacture and distribution of the new psychoactive substance;

Or. en

**Amendment 38**  
**Elena Gentile**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 3**  
Regulation (EC) No 1920/2006  
Article 5b – paragraph 6

*Text proposed by the Commission*

6. The Centre shall request Europol to provide information on the involvement of criminal groups in the manufacture and distribution of the new psychoactive substance, and in any use of the new psychoactive substance.

*Amendment*

6. The Centre shall request Europol to provide information on the involvement of criminal groups in the **development**, manufacture and distribution of the new psychoactive substance, and in any use of the new psychoactive substance.

Or. en

**Amendment 39**  
**Elena Gentile**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 3**  
Regulation (EC) No 1920/2006  
Article 5b – paragraph 11

*Text proposed by the Commission*

11. When the Centre collects information on several new psychoactive substances **with** similar chemical structure, it shall submit to the Commission and the Council individual initial reports or combined reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks from the launch of the initial report.

*Amendment*

11. When the Centre collects information on several new psychoactive substances **that it considers to be of** similar chemical structure, it shall submit to the Commission and the Council individual initial reports or combined reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks from the launch of the initial report.

Or. en

*Justification*

*This paragraph is a positive addition to the Regulation as it will allow the Centre to do more*

*at once, however, the level of similarity between chemical structures of new psychoactive substances can sometimes be difficult to determine, so it should be up to the Centre to determine whether substances can be considered similar enough to be dealt with under a combined report.*

#### **Amendment 40**

**Elena Gentile**

##### **Proposal for a regulation**

##### **Article 1 – paragraph 1 – point 3**

Regulation (EC) No 1920/2006

Article 5c – paragraph 3 – point d

##### *Text proposed by the Commission*

(d) an analysis of the social risks associated with the new psychoactive substance, in particular its impact on social functioning, public order and criminal activities, the involvement of criminal groups in the manufacture and distribution of the new psychoactive substance;

##### *Amendment*

(d) an analysis of the social risks associated with the new psychoactive substance, in particular its impact on social functioning, public order and criminal activities, the involvement of criminal groups in the ***development***, manufacture and distribution of the new psychoactive substance;

Or. en

#### **Amendment 41**

**Elena Gentile**

##### **Proposal for a regulation**

##### **Article 1 – paragraph 1 – point 3**

Regulation (EC) No 1920/2006

Article 5c – paragraph 3 – point e

##### *Text proposed by the Commission*

(e) information on the prevalence and patterns of the use of the new psychoactive substance, its availability and potential for diffusion within the Union;

##### *Amendment*

(e) information on the prevalence and patterns of the use of the new psychoactive substance, its availability and potential for diffusion within the Union, ***considering all possible distribution channels***;

Or. en

**Amendment 42**  
**Elena Gentile**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 3**

Regulation (EC) No 1920/2006

Article 5c – paragraph 3 – point f

*Text proposed by the Commission*

(f) information on the commercial and industrial use of the new psychoactive substance, the extent of such use(s), as well as its use for scientific research and development purposes.

*Amendment*

(f) information on the commercial and industrial use of the new psychoactive substance, the extent of such use(s), as well as its use for scientific research and development purposes, ***including information on the potential for misuse of the substance authorised for legitimate purposes.***

Or. en