



2016/0261(COD)

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AMENDMENTS

16 - 38

Draft report

Michal Boni

(PE589.454v01-00)

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 16
Eleftherios Synadinos

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 **risks** to health **and result in life-threatening consequences**, which makes **it** necessary to enhance **identification**, monitoring, early warning and combating of those threats.

Or. en

Amendment 17
Eleftherios Synadinos

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission

Amendment

(1 a) A new psychoactive substance should be defined as a new narcotic or psychotropic drug, in pure form or in preparation, that is not covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and the 1971 United Nations Convention on Psychotropic Substances, but which may pose a public health threat comparable to that posed by substances listed in those Conventions. A psychoactive substance should be defined as any substance which affects a person's mental functioning, emotional state, or behavioural output when there is intention that it will be consumed for its psychoactive effects.

Or. en

Amendment 18

Eleftherios Synadinos

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 drugs¹³ and was further strengthened by Council Decision 2005/387/JHA¹⁴.

¹³ 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).

¹⁴ 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).

Amendment

(2) During the past years, Member States have notified **a progressively** 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 drugs¹³ and was further strengthened by Council Decision 2005/387/JHA¹⁴.

¹³ 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).

¹⁴ 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 19

Eleftherios Synadinos

Proposal for a regulation

Recital 3

Text proposed by the Commission

(3) New psychoactive substances that pose health and social risks across the Union **should** be addressed at the Union level. This Regulation has therefore to be read in conjunction with Council Framework Decision 2004/757/JHA¹⁵ [as PE593.828v01-00

Amendment

(3) New psychoactive substances that pose health and social risks across the Union **could** be addressed at the Union level **within the scope of synergistic provisions and by tackling common threats to public health and public order.**

amended by Directive (EU) .../...] since both acts are designed to replace the mechanism established by Council Decision 2005/387/JHA.

This Regulation has therefore to be read in conjunction with Council Framework Decision 2004/757/JHA¹⁵ [as amended by Directive (EU) .../...] since both acts are designed to replace the mechanism established by Council Decision 2005/387/JHA.

¹⁵ Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8).

¹⁵ Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8).

Or. en

Amendment 20 **Eleftherios Synadinos**

Proposal for a regulation **Recital 5**

Text proposed by the Commission

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

Amendment

(5) Any Union action on new psychoactive substances should be based on ***sound, unbiased and well-founded*** scientific evidence.

Or. en

Amendment 21 **Eleftherios Synadinos**

Proposal for a regulation **Recital 7**

Text proposed by the Commission

(7) ***No risk assessment should*** be conducted 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.

Amendment

(7) ***A framework should be adopted for targeted risk assessments that could*** be conducted on a new psychoactive substance ***even where*** it is subject to an assessment under international law, or ***where*** it is an active substance in a

medicinal product or in a veterinary medicinal product, *based on scientific evidence, reporting from Member States and needs across the Union.*

Or. en

Amendment 22

Maite Pagazaurtundúa Ruiz

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 *and smuggling*, commercial, as well as medical and scientific use of these substances.

Or. en

Amendment 23

Eleftherios Synadinos

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

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 *all* 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.

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.

Or. en

Amendment 24
Eleftherios Synadinos

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

Text proposed by the Commission

Amendment

The Reitox National Focal Points may also provide information on new trends in the use of existing substances and/or new combinations of psychoactive substances.

Or. en

Amendment 25
Maite Pagazaurtundúa Ruiz

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

Text proposed by the Commission

Amendment

The Centre, in cooperation with Europol, shall collect, analyse, assess, and communicate this information in a timely manner to Member States with a view to providing Member States with any information required for the purposes of early warning and for the purposes of allowing the Centre to draw up the initial report or the combined initial report pursuant to Article 5b.

The Centre, in cooperation with Europol, shall collect, analyse, assess, and communicate this information in a timely manner to Member States ***and to the Commission*** with a view to providing Member States ***and the Commission*** with any information required for the purposes of early warning and for the purposes of allowing the Centre to draw up the initial report or the combined initial report

pursuant to Article 5b.

Or. en

Amendment 26
Maite Pagazaurtundúa Ruiz

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

Text proposed by the Commission

Amendment

The Centre shall communicate to the European Parliament, to the Council and to the Commission an annual summary report on the functioning of the information exchange and early warning system on new psychoactive substances.

Or. en

Amendment 27
Eleftherios Synadinos

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

Amendment

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

(a) a first indication of the nature or scale of health and social risks associated with the new psychoactive substance, *newly misused on the market*;

Or. en

Amendment 28
Maite Pagazaurtundúa Ruiz

Proposal for a regulation
Article 1 – paragraph 1 – point 3

PE593.828v01-00

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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 manufacture, **distribution, trafficking and smuggling** of the new psychoactive substance, and in any use of the new psychoactive substance.

Or. en

Amendment 29
Maite Pagazaurtundúa Ruiz

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5b – paragraph 7

Text proposed by the Commission

7. The Centre shall request the European Chemicals Agency and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance.

Amendment

7. The Centre shall request the European Chemicals Agency, **the European Centre for Disease Prevention and Control**, and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance.

Or. en

Amendment 30
Eleftherios Synadinos

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1920/2006
Article 5b – paragraph 9

Text proposed by the Commission

9. The Centre shall respect the conditions on use of the information, which are communicated to the Centre, including

Amendment

9. The Centre shall respect the conditions on use of the information, which are communicated to the Centre, including

conditions on information and data security **and** protection of confidential business information.

conditions on information and data security, protection of confidential business information, **and provisions on intellectual property**.

Or. en

Amendment 31

Maite Pagazaurtundúa Ruiz

Proposal for a regulation

Article 1 – paragraph 1 – point 3

Regulation (EC) No 1920/2006

Article 5b – paragraph 9

Text proposed by the Commission

9. The Centre shall respect the conditions on use of the information, which are communicated to the Centre, including conditions on information and data security and protection of confidential business information.

Amendment

9. The Centre shall respect the conditions on use of the information, which are communicated to the Centre, including conditions on **access to documents**, information and data security and protection of confidential business information.

Or. en

Amendment 32

Eleftherios Synadinos

Proposal for a regulation

Article 1 – paragraph 1 – point 3

Regulation (EC) No 1920/2006

Article 5c – paragraph 3 – point a

Text proposed by the Commission

(a) information on the chemical and physical properties of the new psychoactive substance, the methods and the precursors used for its manufacture or extraction;

Amendment

(a) information on the chemical and physical properties of the new psychoactive substance, the methods and the precursors used for its manufacture or extraction, **and derivatives**;

Or. en

Amendment 33
Eleftherios Synadinos

Proposal for a regulation

Article 1 – paragraph 1 – point 3

Regulation (EC) No 1920/2006

Article 5c – paragraph 3 – point b

Text proposed by the Commission

(b) information on the pharmacological and toxicological properties of the new psychoactive substance;

Amendment

(b) information on the pharmacological and toxicological properties of the new psychoactive substance **and a reference to known analogues, similar in pharmacological activity and similar in chemical structure;**

Or. en

Amendment 34
Eleftherios Synadinos

Proposal for a regulation

Article 1 – paragraph 1 – point 3

Regulation (EC) No 1920/2006

Article 5c – paragraph 3 – point c

Text proposed by the Commission

(c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and its physical, mental and behavioural effects;

Amendment

(c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and its physical, mental, **emotional** and behavioural effects;

Or. en

Amendment 35
Eleftherios Synadinos

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, ***groups of the population targeted or particularly affected***, public order and criminal activities, the involvement of criminal groups in the manufacture and distribution of the new psychoactive substance;

Or. en

Amendment 36

Maite Pagazaurtundúa Ruiz

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 manufacture, ***distribution, trafficking and smuggling*** of the new psychoactive substance;

Or. en

Amendment 37

Eleftherios Synadinos

Proposal for a regulation

Article 1 – paragraph 1 – point 3

Regulation (EC) No 1920/2006

Article 5c – paragraph 4 – subparagraph 2

Text proposed by the Commission

The Commission, the Centre, Europol and the European Medicines Agency shall each

Amendment

The European Parliament, the Commission, the Centre, Europol and the

have the right to nominate two observers.

European Medicines Agency shall each have the right to nominate two observers.

Or. en

Amendment 38
Eleftherios Synadinos

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

Text proposed by the Commission

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

Amendment

3. ***Unless there is a strong indication that there are significant health and/or social risks or a major potential impact on public order,*** no risk assessment shall be carried out where the new psychoactive substance is:

Or. en