European Parliament
2014-2019

Committee on Civil Liberties, Justice and Home Affairs

2016/0261(COD)

30.9.2016

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DRAFT REPORT

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
(COM(2016)0547 – C8-0351/2016 – 2016/0261(COD))

Committee on Civil Liberties, Justice and Home Affairs

Rapporteur: Michał Boni

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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 (COM(2016)0547 – C8-0351/2016 – 2016/0261(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2016)0547),

– having regard to Article 294(2) and Article 168(5) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0351/2016),

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

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

– having regard to the opinion of the Committee of Regions of […][2],

– having regard to Rule 59 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 (A8-0000/2016),

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

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

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

Amendment 1

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) No risk assessment should be	(7) No risk assessment should be

[1] [OJ C 0, 0.0.0000, p.0 / Not yet published in the Official Journal].
[2] [OJ C 0, 0.0.0000, p.0 / Not yet published in the Official Journal].

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.	conducted on a new psychoactive substance if it is subject to an assessment under international law, ***unless there are sufficient data available at Union level to suggest the need for a risk assessment report. No risk assessment should be conducted on a new psychoactive substance*** if it is an active substance in a medicinal product or in a veterinary medicinal product.

Or. en

Justification

Even if the substance is under assessment under international law, there might be cases that there are special conditions in the EU and the substance not assumed dangerous on the international level could pose serious threats in the EU, for that reason and if there are data suggesting so, it should be possible to prepare a risk assessment report. The same logic was applied by the Parliament position adopted in 2014 on the regulation on new psychoactive substances.

Amendment 2

Proposal for a regulation
Article 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.	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 ***and distribution channels***, trafficking, commercial, as well as medical and scientific use of these substances.

Or. en

Justification

As the Commission also can initiate preparation of the initial report according to Article 5a, it should receive information from the Centre that should be basis of initiating this report.

Amendment 3

Proposal for a regulation
Article 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

Justification

As the Commission also can initiate preparation of the initial report according to Article 5a, it should receive information from the Centre that should be basis of initiating this report.

Amendment 4

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

Text proposed by the Commission	*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	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.	in one or more Member States gives rise to concerns that the new psychoactive substance may pose health***,*** social ***or safety*** risks at the Union level, the Centre shall draw up an initial report on the new psychoactive substance.

Or. en

Justification

The amendment is following the Parliament position on the Regulation on new psychoactive substances adopted in 2014.

Amendment 5

Proposal for a regulation
Article 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***,*** social ***or safety*** risks associated with the new psychoactive substance;

Or. en

Amendment 6

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

Text proposed by the Commission	*Amendment*
5. The Centre shall request the European Medicines Agency to provide information on whether, in the Union or in any Member State, the new psychoactive substance is:	5. The Centre shall request the European Medicines Agency to provide***,*** ***without undue delay,*** information on whether, in the Union or in any Member State, the new psychoactive substance is:

Or. en

Justification

As one of the reasons of this report is to make the procedures limiting the dangerous new psychoactive substances shorter and more efficient, the information should be provided without undue delay. According to Article 5b paragraph 8, the detail cooperation will be included in the working agreements between the Centre and European Medicines Agency.

Amendment 7

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

Text proposed by the Commission	*Amendment*
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.	6. The Centre shall request Europol to provide***, without undue delay,*** information on the involvement of criminal groups in the manufacture***,*** distribution and ***distribution channels*** of the new psychoactive substance, and in any use of the new psychoactive substance ***and other relevant information on the new psychoactive substance***.

Or. en

Justification

As one of the reasons of this report is to make the procedures limiting the dangerous new psychoactive substances shorter and more efficient, the information should be provided without undue delay. According to Article 5b paragraph 8, the detail cooperation will be included in the working agreements between the Centre and Europol.

Amendment 8

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

Text proposed by the Commission	*Amendment*
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.	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 ***without undue delay*** the information and data at their disposal on the new psychoactive substance.

Or. en

Justification

Adding the European Centre for Disease Prevention and Control is following the Parliament position on the Regulation on new psychoactive substances adopted in 2014. As one of the reasons of this report is to make the procedures limiting the dangerous new psychoactive substances shorter and more efficient, the information should be provided without undue delay. According to Article 5b paragraph 8, the detail cooperation will be included in the working agreements between the Centre and these agencies and bodies.

Amendment 9

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

Text proposed by the Commission	*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.	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 ***data, including sensitive data or confidential*** business information.

Or. en

Justification

This amendment is following the Parliament position on the Regulation on new psychoactive substances adopted in 2014.

Amendment 10

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

Text proposed by the Commission	*Amendment*
2. Within two weeks from the receipt of the combined initial report referred to in Article 5b(11), the Commission may request the Centre to assess the potential risks posed by several new psychoactive substances with similar chemical structure and to draw up a combined risk assessment report. The combined risk assessment shall be conducted by the Scientific Committee ***of the Centre***.	2. Within two weeks from the receipt of the combined initial report referred to in Article 5b(11), the Commission may request the Centre to assess the potential risks posed by several new psychoactive substances with similar chemical structure and to draw up a combined risk assessment report. The combined risk assessment shall be conducted by the Scientific Committee.

Or. en

Justification

This amendment is following the logic of the Article 5c paragraph 2.

Amendment 11

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

Text proposed by the Commission	*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 and behavioural effects;	(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, ***including contraindications for use with other substances, where available;***

Or. en

Justification

This amendment is following the Parliament position on the Regulation on new psychoactive substances adopted in 2014.

Amendment 12

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

Text proposed by the Commission	*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 and distribution of the new psychoactive substance;	(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 ***and distribution channels*** of the new psychoactive substance;

Or. en

Amendment 13

Proposal for a regulation
Article 1 – point 3
Regulation (EC) No 1920/2006
Article 5c – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Scientific Committee shall assess the risks posed by the new psychoactive substance or group of new psychoactive substances. The Committee may be extended as deemed necessary by the Director, acting on the advice of the chairperson of the Scientific Committee, by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks of the new psychoactive substance. The Director shall designate them from a list of experts. The Management Board shall approve the list	The Scientific Committee shall assess the risks posed by the new psychoactive substance or group of new psychoactive substances. The Committee may be extended as deemed necessary by the Director, acting on the advice of the chairperson of the Scientific Committee, by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks of the new psychoactive substance***, including a psychologist specialising in addiction***. The Director shall designate them from a list of

of experts every three years.	experts. The Management Board shall approve the list of experts every three years.

Or. en

Justification

This amendment is following the Parliament position on the Regulation on new psychoactive substances adopted in 2014.

Amendment 14

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

Text proposed by the Commission	*Amendment*
1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation expert committee on drug dependence has published its critical review together with a written recommendation, except where there ***is significant*** information ***that is new or of particular relevance for the Union and that has not been taken into account by the United Nations system.***	1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation expert committee on drug dependence has published its critical review together with a written recommendation, except where there ***are sufficient data and*** information ***available to suggest the need for a risk assessment report at the Union level, the reasons for which shall be indicated in the initial report.***

Or. en

Justification

This amendment is following the Parliament position on the Regulation on new psychoactive substances adopted in 2014.

Amendment 15

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

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

Or. en

Justification

Even if the substance is under assessment under international law, there might be cases that there are special conditions in the EU and the substance not assumed dangerous on the international level could pose serious threats in the EU, for that reason and if there are data suggesting so, it should be possible to prepare a risk assessment report. The same logic was applied by the Parliament position adopted in 2014 on the regulation on new psychoactive substances.