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From:	Presidency
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Subject:	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

Delegations will find below the above-mentioned text including, to the extent possible, the latest comments from the delegations of the Horizontal Working Party on Drugs (HDG) provided at the HDG meeting on 9 November 2016 and through the written procedures by 22 November 2016.

ANNEX

2016/0261 (COD)

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof,

Having regard to the proposal from the European Commission,

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

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

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

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

[1] OJ C , , p.
[2] OJ C , , p. .

(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[3] and was further strengthened by Council Decision 2005/387/JHA[4].

(3) New psychoactive substances that pose public health risks or public 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/JHA[5] [as amended by Directive (EU) …/…] since both acts are designed to replace the mechanism established by Council Decision 2005/387/JHA.

(4) It is necessary to insert provisions concerning the information exchange and early warning system on new psychoactive substances as well as the risk assessment procedure into Regulation (EC) 1920/2006 of the European Parliament and of the Council.[6] In particular provisions concerning the early warning on new psychoactive substances should be strengthened and the procedures for drawing up an initial report and organising the risk assessment procedure should be made more efficient. Substantially shortened deadlines for all stages of the procedure should be set.

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

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3 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).

4 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).

5 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).

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

(6) Following the risk assessment procedure, the Commission should determine whether the new psychoactive substances should be included in the definition of drug in line with the procedure provided for in Council Framework Decision 2004/757/JHA [as amended by Directive (EU) …/…]. With the view to ensuring the countinuous functioning of the mechanism of exchange of information and of the procedures of reporting and of risk assessment, as set out in Council Decision 2005/387/JHA and in this Regulation,this Regulation shouldenter into force on the same day as the day for transposition of the Directive [(EU) …/…], which is also the day on which Council Decision 2005/387/JHA is repealed,since both acts are designed to replace the mechanism established by Council Decision 2005/387/JHA.

(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 for human use or in a veterinary medicinal product.

(8) Regulation (EC) 1920/2006 should therefore be amended accordingly.

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1920/2006

Regulation (EC) No 1920/2006 is amended as follows:

(1) In Article 2 the following point (f) is added:

"(f) ***Exchange of information, early warning system and risk assessment on new psychoactive substances***

(i) collecting, collating, analysing, and assessing the available information from the Reitox National Focal Points and the Europol National Units on new psychoactive substances as defined in Article […] of Council Framework Decision 2004/757/JHA [as amended by Directive (EU) …/…] and communicating this information to the Reitox National Focal Points and the Europol National Units as well as to the Commission without undue delay;

(ii) drawing up the initial report or combined initial report in accordance with Article 5b;

(iii) organising the risk assessment procedure in accordance with Articles 5c and 5d;

(iv) monitoring, in cooperation with Europol and with the support of the Reitox National Focal Points and the Europol National Units, all new psychoactive substances that have been reported by Member States."

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

(3) The following Articles 5a, 5b, 5c and 5d are inserted:

"*Article 5a*

Information exchange and early warning system on new psychoactive 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 taking into account the respective mandates of the two bodies. 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.

The Centre, in cooperation with Europol, shall collect, analyse, assess, and communicate this information in a timely manner to Reitox National Focal Points and the Europol National Units as well as to the Commission with a view to providing them 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.

Article 5b

Initial report

1. Where the Centre, the Commission or 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.

   For the purpose of the application of this paragraph, Member States shall inform the Commission and other Member States on their wish to prepare an initial report. Where the required majority is reached, the Commission shall instruct the Centre accordingly and shall inform the Member States thereof.

2. The initial report shall contain a first indication of:

   (a) the nature and scale of incidents showing health and social problems in which the new psychoactive substance may potentially be involved, including the number of incidents and patterns of use;

   (b) chemical and physical description of the new psychoactive substance, the methods and the precursors used for its manufacture or extraction;

   (c) pharmacological and toxicological description of the new psychoactive substance;

   (d) the involvement of criminal groups in the manufacture or distribution of the new psychoactive substance;

The initial report shall also contain:

(e) information on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or veterinary medicinal product;

(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.

(g) information on whether the new psychoactive substance is subject to any restrictive measures in the Member States;

(h) information on whether the new psychoactive substance is currently under assessment, or has been under assessment, within the system established by the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or the 1971 Convention on Psychotropic Substances (United Nations system);

(i) other relevant information if available.

3. For the purpose of the initial report, the Centre shall use information which is already at its disposal.

4. Where the Centre considers it necessary, it shall request the Reitox National Focal Points to provide additional information on the new psychoactive substance. The Reitox National Focal Points shall provide that information within two weeks of the receipt of the request.

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

(a) an active substance in a medicinal product for human use or a veterinary medicinal product that has obtained a marketing authorisation, in accordance with Directive 2001/83/EC of the European Parliament and of the Council[7], Directive 2001/82/EC of the European Parliament and of the Council[8] or Regulation (EC) No 726/2004 of the European Parliament and of the Council[9];

(b) an active substance in a medicinal product for human use or a veterinary medicinal product that is the subject of an application for a marketing authorisation;

(c) an active substance in a medicinal product for human use or a veterinary medicinal product that has obtained a marketing authorisation, but the marketing authorisation has been suspended by the competent authority;

(d) an active substance in an unauthorised medicinal product for human use in accordance with Article 5 of Directive 2001/83/EC of the European Parliament and of the Council or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with Article 10(1)(c) of Directive 2001/82/EC of the European Parliament and of the Council;

(e) an active substance in investigational medicinal products for human use as defined by Article 2(d) of Directive 2001/20/EC of the European Parliament and of the Council[10].

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7 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

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

9 Regulation 726/2004 of the European Parliament and of the Council of 31 March 2004 (as amended) laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

10 Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

Where this information relates to marketing authorisations granted by Member States, these Member States shall provide the European Medicines Agency with this information if so requested by it.

6. The Centre shall request without undue delayEuropol 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.

7. The Centre shall request without undue delay the European Chemicals Agency and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance.

8. The details of the cooperation between the Centre and the bodies and agencies referred to in paragraphs 5, 6 and 7 shall be governed by working arrangements. Such working arrangements shall be concluded in accordance with the second paragraph of Article 20.

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.

10. The Centre shall submit the initial report to the Commission and the Member States within five weeks from the requests for information referred to in paragraphs 5, 6 and 7.

11. When the Centre collects information on several new psychoactive substances with similar chemical structure, it shall submit to the Commission and the Member States individual initial reports or combined initial reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks from the requests for information referred to in paragraphs 5, 6 and 7.

Article 5c

Risk assessment procedure and report

1. Within two weeks from the receipt of the initial report referred to in Article 5b(10) the Commission may request the Centre to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report, where the initial report gives indications to believe that this substance may pose severe public health risks or public health and social risks. The risk assessment shall be conducted by the Scientific Committee.

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.

3. The risk assessment report or combined risk assessment report shall contain:

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

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

(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;

(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;

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

(f) available 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.

(g) other relevant information if available.

4. The Scientific Committee shall assess the risks posed by the new psychoactive substance or group of new psychoactive substances. The Scientific 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 of experts every three years.

The Commission, the Centre, Europol and the European Medicines Agency shall each have the right to nominate two observers.

5. The Scientific Committee shall carry out the risk assessment on the basis of the available information and of any other relevant scientific evidence. It shall take into account all opinions held by its members. The Centre shall organise the risk assessment process, including identifying future information needs and relevant studies.

6. The Centre shall submit the risk assessment report to the Commission and the Member States within six weeks from the receipt of the request from the Commission.

7. Upon duly motivated request of the Centre, the Commission may extend the period to complete the risk assessment or combined risk assessment to allow for additional research and data collection to take place. The request of the Centre shall contain information on the period of time needed to complete the risk assessment or combined risk assessment.

Article 5d

Exclusion from risk assessment

1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation Expert Committee on Drug Dependence has published its critical review together with a written recommendation, except where there is significant information that is new or of particular relevance for the Union and that has not been taken into account by the United Nations system.

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.

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

(a) an active substance in a medicinal product for human use or a veterinary medicinal product that has obtained a marketing authorisation;

(b) an active substance in a medicinal product for human use or a veterinary medicinal product that is the subject of an application for a marketing authorisation;

(c) an active substance in a medicinal product for human use or a veterinary medicinal product that has obtained a marketing authorisation, but the marketing authorisation has been suspended, but has not yet been withdrawn, by the competent authority;

(d) an active substance involved in investigational medicinal products for human use."

(4) In Article 13 (2) the fourth subparagraph is replaced by the following:

"For the purpose of assessing the risks posed by the psychoactive substance or group of new psychoactive substances, the Scientific Committee may be extended following the procedure laid down in Article 5c(4)."

Article 2

Entry into force

This Regulation shall enter into force on [the same day as the day for transposition of Directive (EU) …/ … [amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provision on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking].

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

Done at Brussels,

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