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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

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Over the past decade there has been a massive growth in new psychoactive substances (NPS), at global level and in Europe as well, and there are no signs of a slowdown. In 2015, 100 new substances were reported for the first time to the EU Early Warning System (EWS), bringing the total number of new substances monitored to more than 560 – with more than 380 (70%) of these detected in the last five years alone.[1]

The United Nations General Assembly at the Special Session on the world drug problem (UNGASS, 19-21 April 2016) adopted the outcome document "Our joint commitment to effectively addressing and countering the world drug problem"[2]. A specific section deals with addressing emerging and persistent challenges and threats including NPS. The joint commitment calls for strengthening action to address the challenge of NPS as well as for enhancing information-sharing and early warning networks.

On 17 September 2013, the Commission put forward a package of two legislative proposals on new psychoactive substances: a proposal for a Regulation on new psychoactive substances[3] and a Directive amending 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, as regards the definition of drug[4]. The objective was to reduce the availability of new psychoactive substances that pose risk through swifter, more effective action on Union level compared to the currently applicable system based on Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances[5].

Inter-institutional negotiations of this legislative package have been ongoing for more than two years. The European Parliament adopted its legislative resolutions on 17 April 2014[6]. The Council did not adopt a general approach on the proposals; during the examination of the proposals Member States expressed doubts concerning the choice of Article 114 of the Treaty on the Functioning of the European Union (TFEU) as the legal basis for the proposed Regulation.

To achieve the same objective of a swifter, more effective EU action on NPS, the Permanent Representatives Committee (COREPER) on 6 April 2016[7] agreed to the approach proposed by the Netherlands Presidency in its discussion paper, including amendments of the draft Directive based on Article 83 TFEU that will in particular contain a definition of new psychoactive substances and provisions on swift Union level decision making in order to criminalise harmful new psychoactive substances in all Member States. COREPER also invited the Commission to present a proposal on amending the founding Regulation of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), Regulation

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1 EU Drugs Market Report 2016, p. 28.
2 General Assembly Resolution A/RES/S-30/1.
3 COM(2013) 619 final.
4 COM(2013) 618 final.
5 OJ L 127, 10.5.2005, p. 32. The different policy options have been analysed in the impact assessment accompanying both proposals, SWD(2013) 319 final.
6 European Parliament Document P7_TA(2014)0453.
7 Summary record, Council document 7908/1/16 REV 1 of 27 May 2016.

1920/2006. According to the Summary Record of the 2580th meeting of COREPER this decision triggers the start of the 3 months' opt-in deadline for the Member States concerned by Protocol 21 and has consequences under Protocol 22 annexed to the TEU. The European Parliament is informed about this change by a letter from the Council.

Given that the decision of COREPER aims to achieve the same objectives as proposed by the package of 2013, the Commission proposes targeted amendments of Regulation 1920/2006 integrating the draft provisions on early warning system and risk assessment procedure that were part of the 2013 Commission proposal for a Regulation on new psychoactive substances into the founding Regulation of the EMCDDA. The Commission will consider the withdrawal of the proposal on a Regulation on new psychoactive substances in preparing Commission's Work Programme for 2017.

The new proposal as the previous one aims at strengthening the EU early warning system and the risk assessment and at streamlining procedures to ensure more effective and fast action. Therefore, in order to speed up the process, deadlines are substantially shortened compared to the current system based on Council Decision 2005/387/JHA. For the purpose of swift and effective collection of information on NPS, the EMCDDA should conclude working arrangements with Europol, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority without undue delay following the publication of the Regulation in the Official Journal.

This proposal also ensures a participation of EUROPOL in the early warning system and risk assessment procedure, in particular as input on the involvement of criminal groups in the manufacture and distribution of new psychoactive substances is concerned.

According to Article 23 of Regulation 1920/2006 the Commission may propose, if appropriate, and in the light of developments in respect of regulatory agencies on the basis of the next evaluation of the Centre further amendments to the EMCDDA founding Regulation.

- **Consistency with existing policy provisions in the policy area**

The proposal reflects the priorities set out by the European Agenda on Security[8] adopted on 28 April 2015. The European Agenda of Security stresses that the market for illicit drugs remains the most dynamic of criminal markets, with a recent trend being the proliferation of new psychoactive substances. It also states that the production of these substances is increasingly taking place in the Union thus pointing to the urgency of adopting a new legislative framework.

This proposal has to be read in conjunction with Directive (EU) …/ … [amending 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[9]]. Both instruments are designed to replace the mechanism established by Council Decision 2005/387/JHA.

[8] COM(2015) 185 final.

[9] OJ L 335, 11.11.2004, p.8.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Article 168(5) TFEU, which empowers the European Parliament and the Council to adopt measures concerning monitoring, early warning of and combating serious cross border threats to health whilst excluding any harmonisation of the laws and regulations of the Member States.

• Subsidiarity

There is a clear need for EU action on new psychoactive substances. Member States alone cannot reduce the problems caused by the spread of harmful new psychoactive substances. Uncoordinated national action in this area can produce adverse knock-on effects, for instance displacement of harmful substances from one Member State to another. Criminal groups may exploit this situation.

Consequently, EU-level action is necessary to ensure that potentially harmful new psychoactive substances, which cause EU-wide concern, can be identified, assessed and, if they pose risks, incriminated in all Member States. This Regulation has therefore to be read in conjunction with Directive (EU) …/ … [amending 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] since both acts are designed to replace the mechanism established by Council Decision 2005/387/JHA.

• Proportionality

The proposal is proportionate and does not go beyond what is necessary to achieve the objectives because it only addresses new psychoactive substances that are a concern at the EU level.

• Choice of the instrument

The proposal concerns the amendment of a Regulation. There are no indications that a different instrument than a Regulation would be appropriate.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

• Stakeholder consultations

This proposal follows an agreement by COREPER on 6 April 2016 on a compromise approach proposed by the Netherlands Presidency of the Council. In the meeting of the Committee on Civil Liberties, Justice and Home Affairs (LIBE) of the European Parliament of 15 June 2016, the Rapporteurs and the Shadow Rapporteurs announced that they have taken the decision to pursue this new approach as a package and work together with the Council and the Commissions to reach agreement. As the content reflects this agreement, this new proposal does not require further stakeholder consultations.

• Impact assessment

The Commission conducted an impact assessment of policy alternatives in the context of the package of two proposals put forward on 17 September of 2013. The impact assessment in particular concluded that the quality and quantity of information available at EU level and shared by Member States as well as the capacity to rapidly identify and assess new

psychoactive substances needs to be improved.[10] Therefore, no new impact assessment is required for this proposal.

4. BUDGETARY IMPLICATIONS

The EMCDDA is tasked with the exchange of information, the early warning system and the risk assessment procedure on new psychoactive substances. The subsidy for the Centre forms already part of the Union's budget.

However, for the Centre to adequately deal with the growing number of requests related to information exchange on new psychoactive substances as well as with the proposed streamlined procedures for the EU early warning system and risk assessment procedure, an amount of EUR 676.000 in total for the period 2017-2020 for the system development and an amount of EUR 100.000 per year to finance three additional contract agents will need to be added to the Centre's budget.

5. OTHER ELEMENTS

- **Monitoring, evaluation and reporting arrangements**

The EMCDDA is on a regular basis evaluated according to Article 23 of Regulation 1920/2006. According to this article, the Commission shall initiate an external evaluation of the EMCDDA every six years to coincide with the completion of two of the Centre's three-year programmes.

- **Detailed explanation of the specific provisions of the proposal**

Article 1 provides for the following amendments to Regulation 1920/2006:

New point (f) in Article 2 (Tasks) – this provision clarifies that tasks of the EMCDDA are information exchange and early warning on new psychoactive substances as well as risk assessment. The Centre also monitors all new psychoactive substances that have been reported by Member States.

New Article 5a (Exchange of information, early warning system and risk assessment on new psychoactive substances) – this provision establishes the respective roles of Member States, the EMCDDA and Europol in the process of exchange of information and early warning on new psychoactive substances.

New Article 5b (Initial report) – this provision lays down the contents and the procedures for the drawing up and the transmission by the EMCDDA of an initial report on a new psychoactive substance. Europol, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority are associated to the collection of information for an initial report.

New Article 5c (Risk assessment procedure and report) – this provision empowers the Commission to request the EMCDDA to assess the risks of a new psychoactive substance on which an initial report has been drawn up. It lays down the procedures for the risk assessment, which is to be conducted by the Scientific Committee of the EMCDDA, and for the drawing up and the transmission of a risk assessment report.

New Article 5d (Exclusion from risk assessment) – this provision details such circumstances in which no risk assessment is to be conducted on a new psychoactive substance.

[10] SWD(2013) 319 final, p. 46-75.

Article 2 establishes when the Regulation shall enter into force.

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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 combating of those threats.

(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 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

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1 OJ C , , p.

2 OJ C , , p. .

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).

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 action on new psychoactive substances should be based on scientific evidence.

(6) Following the risk assessment procedure, the Commission should determine whether the new psychoactive substances should be incriminated, in line with the procedure provided for in Council Framework Decision 2004/757/JHA [as amended by Directive (EU) …/…]. This Regulation will enter into force on the same day as the day for transposition of the Directive 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 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;

[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).

(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 and third subparagraphs are 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. 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 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.

Article 5b

Initial report

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.

2. The initial report shall contain:

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

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

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

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

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

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

(g) 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).

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 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 or a veterinary medicinal product that has obtained a marketing authorisation;

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

(c) an active substance in a medicinal product 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 in accordance with Article 5 of Directive 2001/83/EC of the European Parliament and of the Council[7] 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[8];

(e) an active substance in authorised clinical trials and in investigational medicinal products in accordance with Article 2(d) of Directive 2001/20/EC of the European Parliament and of the Council[9].

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.

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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 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).

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.

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 Council 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 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.

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. 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 of the Centre.

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

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

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

(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.

4. 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 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 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 or a veterinary medicinal product that has obtained a marketing authorisation;

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

(c) an active substance in a medicinal product 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 authorised clinical trials and in investigational medicinal products."

(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

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*

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

   1.1. Title of the proposal/initiative

   1.2. Policy area(s) concerned in the ABM/ABB structure

   1.3. Nature of the proposal/initiative

   1.4. Objective(s)

   1.5. Grounds for the proposal/initiative

   1.6. Duration and financial impact

   1.7. Management mode(s) planned

2. MANAGEMENT MEASURES

   2.1. Monitoring and reporting rules

   2.2. Management and control system

   2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

   3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

   3.2. Estimated impact on expenditure

   3.2.1. Summary of estimated impact on expenditure

   3.2.2. Estimated impact on operational appropriations

   3.2.3. Estimated impact on appropriations of an administrative nature

   3.2.4. Compatibility with the current multiannual financial framework

   3.2.5. Third-party contributions

   3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances

1.2. Policy area(s) concerned in the ABM/ABB structure[20]

18 – Migration and Home Affairs

1.3. Nature of the proposal/initiative

☒ The proposal/initiative relates to **a new action in the mandate of the Agency (exponential growth)**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[21]

☐ The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objective(s)

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

The Commission Work Programme 2016, title "An area of justice and fundamental rights based on mutual trust" refers to the implementation of the European Agenda on Security (COM(2015) 185 final adopted on 28.4.2015. The European Agenda on Security states:

"The market for illicit drugs remains the most dynamic of criminal markets, with a recent trend being the proliferation of new psychoactive substances (NPS). The production of NPS increasingly takes place in the EU and points to the urgency of adopting a new legislative framework."

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Relevant general objective:

Contribute to ensuring a high level of security in the European Union while facilitating legitimate travel, through a uniform and high level of control at the external borders and the effective processing of Schengen visas, in compliance with the Union's commitment to fundamental freedoms and human rights.

Specific objective 6:

To support initiatives in the field of drugs policy as regards judicial cooperation and crime prevention aspects closely linked to the general objective of the Justice Programme, insofar as they are not covered by the ISF of by the Health for Growth programme.

[20] ABM: activity-based management; ABB: activity-based budgeting.

[21] As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

Specific objective 7:

To contribute to reducing drug use and trafficking, and the harms that drugs cause to individuals and to society, through measures to reduce the availability of new drugs, to improve the quality of drug-demand reduction services and the understanding of drug supply, by supporting actions to raise awareness about the risks of drugs, enhance the effectiveness of treatment and support cross-border operational cooperation against drug

ABM/ABB activity(ies) concerned

Anti-drugs

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

Providing for an effective and efficient early warning system and risk assessment procedure on new psychoactive substances in order to proactively protect, identify, validate, respond and prevent serious harms caused by new psychoactive substances, and to ensure that harmful new psychoactive can be incriminated in all Member States on the basis of Council Framework Decision 2004/757/JHA [as amended by Directive (EU) …/…]

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

Result indicator 1 (objective 6):

Number of new psychoactive substances assessed (including through testing, if necessary) to enable the EU or the Member States to take appropriate action to protect consumers, depending on the type and level of risk that may pose when consumed by humans.

Result indicator 3 (objective 7):

Degree to which new psychoactive substances which are notified by several Member States and which seem to pose risks are subjected to risk assessment (including to testing, if necessary) to enable the EU or the Member States to take appropriate action to protect consumers.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

- To protect the health of individuals from the risks posed by harmful new psychoactive substances
- To provide a basis for decision-making on Union level concerning incrimination of harmful new psychoactive substances on the basis of Council Framework Decision 2004/757/JHA [as amended by Directive (EU) …/…]
- To improve the capacity to rapidly identify and assess new psychoactive substances

1.5.2. Added value of EU involvement

A strengthened early warning system would boost the exchange of information among Member States, with the clear added value of alerting Member States to potentially harmful substances that have emerged in other Member States, to help them anticipate a potential public health threat. The assessment of risk of new psychoactive substances at EU level has the added value of pooling scientific resources and analytical capacities from across the Union and to provide the best evidence available on a substance, thus forming a solid basis of decision making on Union level on new psychoactive substances based on Council Framework Decision 2004/757/JHA [as amended by Directive (EU) …/…]

1.5.3. Lessons learned from similar experiences in the past

The current system based on Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances is too slow to address effectively the fast growing number of new psychoactive substances.

1.5.4. Compatibility and possible synergy with other appropriate instruments

Action in the field of new psychoactive substances is in compliance with Union strategic policy documents, in particular the European Agenda on Security[22] and the EU Drugs Strategy 2013-2020. EU action in the field of new psychoactive substances is also fully consistent with action at the United Nation's level.

1.6. Duration and financial impact

☐ Proposal/initiative of limited duration

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

☒ Proposal/initiative of **unlimited duration**

– ☐ Implementation with a start-up period from 2017 to 2020,

– ☐ followed by full-scale operation.

1.7. Management mode(s) planned[23]

☐ **Direct management** by the Commission

[22] COM(2015) 185 final.

[23] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

– ☐ by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

☒ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated;

– ☐ international organisations and their agencies (to be specified);

– ☐the EIB and the European Investment Fund;

– ☒ bodies referred to in Articles 208 and 209 of the Financial Regulation;

– ☐ public law bodies;

– ☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

– ☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

– If more than one management mode is indicated, please provide details in the 'Comments' section.

Comments

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

According to Article 23 of Regulation No 1920/2006 establishing the European Monitoring Centre for Drugs and Drug Addiction an external evaluation of the Centre takes place every six years which coincide with the completion of two subsequent 3-year working programmes of the Centre. According to Article 9(7) of Regulation No 1920/2006 establishing the European Monitoring Centre for Drugs and Drug Addiction "The Management Board shall adopt the annual report on the Centre's activities and forward it by 15 June to the European Parliament, the Council, the Commission, the Court of Auditors and the Member States."

2.2. Management and control system

2.2.1. Risk(s) identified

Possible delays in implementation to be mitigated by regular monitoring

2.2.2. Information concerning the internal control system set up

Standard Commission control/infringment procedures concerning the application of the amended Regulation

2.2.3. Estimate of the costs and benefits of the controls and assessment of the expected level of risk of error

Not relevant as no risks identified

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

According to Article 16 of Regulation No 1920/2006 establishing the European Monitoring Centre for Drugs and Drug Addiction, in order to combat fraud, corruption and any other illegal activies affecting the Communities financial interests, the provisions of Regulation 1073/1999 shall apply without restrictions to the Centre.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number Heading 3	Diff./Non-diff.[24]	from EFTA countries[25]	from candidate countries[26]	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
	European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 18 06 02	Diff.	NO	NO	NO	NO

- New budget lines requested - NA

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number […][Heading……]	Diff./Non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
	[…][XX.YY.YY.YY]		YES/NO	YES/NO	YES/NO	YES/NO

[24] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

[25] EFTA: European Free Trade Association.

[26] Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	Heading 3

EMCDDA			Year **2017**[27]	Year **2018**	Year **2019**	Year **2020**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
• Operational appropriations										
Number of budget line **18 06 02**	Commitments	(1)	15,1356	15,1356	15,2866	15,5886				**61,1464**
	Payments	(2)	15,1356	15,1356	15,2866	15,5886				**61,1464**
Number of budget line	Commitments	(1a)								
	Payments	(2a)								
Appropriations of an administrative nature financed from the envelope of specific programmes[28]										
Number of budget line		(3)	1	1	1	1				
TOTAL appropriations for EMCDDA	Commitments	=1+1a +3	15,1356	15,1356	15,2866	15,5886				**61,1464**
	Payments	=2+2a +3	15,1356	15,1356	15,2866	15,5886				**61,1464**
• TOTAL operational appropriations	Commitments	(4)	15,1356	15,1356	15,2866	15,5886				**61,1464**
	Payments	(5)	15,1356	15,1356	15,2866	15,5886				**61,1464**

[27] Year N is the year in which implementation of the proposal/initiative starts.

[28] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
TOTAL appropriations under HEADING 3 of the multiannual financial framework	Commitments	=4+ 6	15,1356	15,1356	15,2866	15,5886				**61,1464**
	Payments	=5+ 6	15,1356	15,1356	15,2866	15,5886				**61,1464**

If more than one heading is affected by the proposal / initiative: NA

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)	Commitments	=4+ 6								
	Payments	=5+ 6								

Heading of multiannual financial framework	**5**	'Administrative expenditure'

EUR million (to three decimal places)

		Year **2017**	Year **2018**	Year **2019**	Year **2020**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
DG: HOME									
• Human resources		0,402	0,402	0,402	0,402				**1,6080**
• Other administrative expenditure									
TOTAL DG HOME	Appropriations	0,402	0,402	0,402	0,402				**1,6080**

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	0,402	0,402	0,402	0,402				**1,6080**

EUR million (to three decimal places)

		Year[29] **2017**	Year **2018**	Year **2019**	Year **2020**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	15,5376	15,5376	15,6886	15,9906				**62,7544**
	Payments	15,5376	15,5376	15,6886	15,9906				**62,7544**

[29] Year N is the year in which implementation of the proposal/initiative starts.

3.2.2. Estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of additional operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs* ⇩			Year **2017**		Year **2018**		Year **2019**		Year **2020**		Enter as many years as necessary to show the duration of the impact (see point 1.6)						**TOTAL**	
	OUTPUTS																	
	Type[30]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVES No 6 & 7[31]																		
- Output	System development		1	0,2416	1	0,2416	1	0,0966	1	0,0966								0,676
- Output																		
Subtotal for specific objectives No 6 & 7			1	0,2416	1	0,2416	1	0,0966	1	0,0966								0,676
TOTAL COST			1	0,2416	1	0,2416	1	0,0966	1	0,0966								0,676

* The output presented only covers the new task linked to the NPS.

30 Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

31 As described in point 1.4.2. 'Specific objective(s)…'

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	2017 [32]	2018	2019	2020	Enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
HEADING 5 of the multiannual financial framework	2017	2018	2019	2020				
Human resources (FTE DG HOME)	0,402	0,402	0,402	0,402				**1,6080**
Other administrative expenditure								
Total HEADING 5 of the multiannual financial framework	0,402	0,402	0,402	0,402				**1,6080**

TOTAL	0,402	0,402	0,402	0,402				**1,6080**

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

3.2.3.2. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources.

– ☒ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full time equivalent units

	Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)

[32] Year N is the year in which implementation of the proposal/initiative starts.

• Establishment plan posts (officials and temporary staff)								
18 01 01 01 (Headquarters and Commission's Representation Offices)		3	3	3	3			
XX 01 01 02 (Delegations)								
XX 01 05 01 (Indirect research)								
10 01 05 01 (Direct research)								
• External staff (in Full Time Equivalent unit: FTE)[33]								
XX 01 02 01 (AC, END, INT from the 'global envelope')								
XX 01 02 02 (AC, AL, END, INT and JED in the delegations)								
XX 01 04 **yy**[34]	- at Headquarters							
	- in Delegations							
XX 01 05 02 (AC, END, INT – Indirect research)								
10 01 05 02 (AC, END, INT – Direct research)								
Other budget lines (specify)								
TOTAL		**3**	**3**	**3**	**3**			

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	Represent the Commission in the Management Board of the Agency. Draw up Commissin opinion on the annual work programme and monitor its implementation. Supervise the preparation of the Agency's budget and monitor implementation of the budget. Assist the Agency in developing its activities in line with EU policies including by participating in experts meetings.
External staff	

3.2.4. Compatibility with the current multiannual financial framework

– ☒ The proposal/initiative is compatible with the current multiannual financial framework.

– ☐ The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

– ☐ The proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. Third-party contributions

[33] AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JED= Junior Experts in Delegations.

[34] Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

– ☒ The proposal/initiative does not provide for co-financing by third parties.

– The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to three decimal places)

	Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

3.3. Estimated impact on revenue

– ☒ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

– ☐ on own resources

– ☐ on miscellaneous revenue

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[35]						
		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
Article …….								

For miscellaneous 'assigned' revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

[35] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25 % for collection costs.