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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on new psychoactive substances

(Text with EEA relevance)

{SWD(2013) 319 final}

{SWD(2013) 320 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. General context

A growing number of new psychoactive substances, which imitate the effects of substances controlled under the UN Conventions on Drugs and are marketed as legal alternatives to them ('legal highs'), are emerging and spreading fast in the internal market. These substances, which act on the central nervous system, modifying mental functions, also have uses in industry or research - as active substances for medicines, for instance. A rising number of individuals, in particular young people, consume new psychoactive substances, despite the risks that they may pose, which may be comparable to those posed by UN-controlled drugs.

During the past years, one new psychoactive substance was reported every week in the EU, and the rapid pace of notification is expected to continue in the coming years. These substances are sold freely, unless public authorities subject them to various restriction measures, underpinned by administrative or criminal sanctions, because of the risks that they pose when consumed by humans. Such national restriction measures, which may differ depending on the Member State and on the substance, can hamper trade in the internal market and hinder the development of future industrial or commercial uses.

New psychoactive substances are not subjected to control measures under the UN Conventions on Drugs, unlike psychoactive substances such as cocaine or amphetamines, although they could be considered for UN-level control on the basis of a risk assessment conducted by the World Health Organisation at the request of at least one UN Member State.

The Commission Communication "Towards a stronger European response to drugs"¹, adopted in October 2011, identified the spread of new psychoactive substances as one of the most challenging developments in drugs policy requiring a firmer EU response. The Communication set the ground for new EU legislative proposals on new psychoactive substances, building on the Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances². In December 2011³, the Council requested the Commission to table a legislative proposal revising Council Decision 2005/387/JHA. A legislative proposal on new psychoactive substances is foreseen in the Commission's 2013 Work Programme⁴.

¹ COM(2011) 689 final.

² OJ L 127, 10.5.2005, p.32.

³ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/jha/126879.pdf

⁴ COM(2012) 629 final.

This proposal for a Regulation aims at improving the functioning of the internal market regarding licit uses of new psychoactive substances, by reducing obstacles to trade, preventing the emergence of such obstacles and increasing legal certainty for economic operators, while reducing the availability of substances that pose risks through swifter, more effective and more proportionate EU action. It is accompanied by a proposal for 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 trafficking⁵. This aims at expanding the scope of application of the Framework Decision to cover the most harmful new psychoactive substances, which pose severe risks. This means that substances that pose severe health, social and safety risks and are, therefore, submitted to permanent market restriction under this proposed Regulation, are also covered, through the proposed amended Framework Decision, by the criminal law provisions applying to controlled drugs.

The case for swifter, more effective and more proportionate action on new psychoactive substances at EU level is compelling, considering the rapid changes in this market, which put national authorities under pressure to act. During the past years, Member States have notified an increasing number of new psychoactive substances to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Between 1997 and 2012 they reported around 290 substances. The number of notified substances tripled between 2009 and 2012 (from 24 to 73). Around 80% of these substances were reported by more than one Member State. The number of substances that can emerge may run into the thousands because many variations of existing or new, still unexploited substances, can be manufactured at relatively low cost. The issue has been further highlighted in the 2012⁶ and 2013⁷ EMCDDA annual reports, as well as in the EMCDDA-Europol "EU drug markets report: a strategic analysis"⁸, published in January 2013.

Consumption of new psychoactive substances appears to be increasing in Europe and use is predominant among young people. According to the 2011 Eurobarometer "Youth attitudes on drugs", 5% of young people in the EU have used such substances at least once in their life, with a peak of 16% in Ireland, and close to 10% in Poland, Latvia and the UK. According to the results of snapshot surveys conducted by the EMCDDA, the number of online shops selling new psychoactive substances increased four-fold between 2010 and 2012, to 690.

The consumption of new psychoactive substances can cause harms to individuals' health and safety, resulting in deaths, injury or disease, and can pose risks to and burdens on society, as it may lead to violent behaviour and crime. These risks are amplified by the fact that many such substances are sold to consumers without appropriate labelling and instructions of use. In some cases they are sold on the black market alongside, or instead of, controlled drugs.

⁵ OJ L 335, 11.11.2004, p. 8.

⁶ EMCDDA, *2012 Annual report on the state of the drugs problem in Europe*; available at: <http://www.emcdda.europa.eu/publications/annual-report/2012>

⁷ EMCDDA, *European Drug Report 2013*; available at: <http://www.emcdda.europa.eu/edr2013>.

⁸ Available at: <http://www.emcdda.europa.eu/publications/joint-publications/drug-markets>

The rapid emergence and spread of these substances, and the potential risks that they pose, have led national authorities to subject them to various restriction measures. Hundreds such substances or mixtures of substances have been subjected to different restriction measures in the Member States in the past years. Such national measures disrupt trade in licit uses of these substances. Around a fifth of the substances notified by the Member States have other uses (but information on such uses is not collected systematically across the EU).

National restriction measures, which can vary depending on the Member State and on the substance, lead to obstacles to trade in licit uses, fragmentation, an uneven level playing field and legal uncertainties for economic operators, and make it difficult for companies to operate across the internal market. They make research more cumbersome, hampering the development of new uses for these substances. They have a chain-reaction impact on operators in different markets, because such substances are used in the production of other substances or mixtures, which in turn are used for manufacturing various goods. As the market for new psychoactive substances is likely to grow, so will these obstacles to licit trade.

In order to facilitate the functioning of the internal market while protecting consumers from harmful new psychoactive substances, EU-level action shall ensure the free movement of new psychoactive substances for commercial and industrial use, and for scientific research and development, and provide for a graduated set of restriction measures for substances posing risks, proportionate to their level of risk.

This proposal, therefore, sets up a robust system for exchanging rapidly information on new psychoactive substances emerging on the market, including on their commercial and industrial uses, for assessing the risks of substances that cause EU-wide concern and for withdrawing from the market those substances that pose risks.

The substances suspected to pose immediate public health risk will be withdrawn from the consumer market temporarily, pending their risk assessment. Once the risk assessment is completed, measures will be taken proportionate to the risks of substances. While no restrictions will be introduced at the EU level on substances posing low health, social and safety risks, substances posing moderate risks will be subjected to consumer market restriction, which means that they cannot be sold to consumers (except for uses specifically authorised, for instance by medicines legislation) but their trade is allowed for commercial and industrial purposes as well as for scientific research and development.

New psychoactive substances posing severe risks will be subjected to permanent market restriction, covering both the consumer and commercial markets, and their use will only be possible for specifically authorised industrial and commercial purposes, as well as for scientific research and development. In addition, as explained above, these substances will be subjected to EU criminal law provisions under the accompanying proposal for a Directive amending the Framework Decision on illicit drug trafficking.

In relation to new psychoactive substances on which the EU has not acted, Member States may introduce national technical regulations, in full compliance with the EU provisions preventing the emergence of unjustified barriers to trade⁹.

1.2. Legal context

Soon after a borderless internal market was created, and following the emergence and rapid spread of synthetic drugs, such as amphetamines and ecstasy, it became clear that the effectiveness of national actions is limited and that EU action was necessary to contain the spread of harmful substances. The EU Joint Action 97/396/JHA concerning the information exchange, risk assessment and the control of new synthetic drugs¹⁰ was adopted in 1997 to address this problem.

Council Decision 2005/387/JHA, which repealed Joint Action 97/396/JHA, established an EU-wide system for tackling new psychoactive substances (synthetic and natural) that raise concern at EU level. It lays down rules on the exchange of information on these substances between Member States, coordinated by the EMCDDA and Europol, on the assessment of their risks and the submission to control and criminal penalties across the EU of those substances that pose risks.

The Commission's assessment report¹¹ of July 2011, concluded that, while Council Decision 2005/387/JHA is a useful instrument, it is inadequate, considering the scale and complexity of the problem, and it, therefore, requires revision. This is because it involves a lengthy process, it is reactive and it lacks options to the submission to control and criminal penalties.

This Regulation replaces Council Decision 2005/387/JHA.

⁹ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society Services, OJ L 204, 21.7.1998, p. 37.

¹⁰ OJ L 167, 25.6.1997, p.1.

¹¹ COM(2011) 430 final and SEC(2011) 912 final.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT

2.1. Consultations with interested parties

Broad stakeholder and expert consultations together with a web-based public consultation and an external study have informed the preparatory work for this proposal. The Commission involved all Member States in the assessment of the functioning of Council Decision 2005/387/JHA, through written consultation. In the context of the external study, the Commission collected and examined the views of a host of national authorities (responsible for drug legislation, justice and health ministries, health institutes and law enforcement agencies) and of EU agencies involved in the implementation of Council Decision 2005/387/JHA. It also collected and examined the views of international organisations (including the World Health Organisation), civil society organisations, economic operators in various markets, research institutes and academic experts.

The survey conducted among Member States in the context of the assessment report showed that a large number of Member States view the lack of alternatives to control and criminal penalties in the current instrument as inadequate and suggest that a wider range of options should be considered, backed by administrative law. Moreover, all Member States agreed that swifter action is necessary to address new psychoactive substances (including temporary measures) and that the current decision-making process is too slow.

During the two experts' meetings organised by the Commission on 15 December 2011 and 1 March 2012, academic experts and practitioners stressed that the Council Decision and product safety legislation are inadequate to tackle the large number of new psychoactive substances emerging on the market, whose effects and risks are mostly unknown. They pointed out that new legislation on new psychoactive substances should be calibrated to the different levels of risks posed by these substances. Certain participants expressed concern that too rigorous policy responses (such as blanket restrictions on entire groups of substances or a wide recourse to criminal penalties) could have adverse effects. Such adverse effects include a displacement of substances from the licit to the illicit market, a replacement of the substances withdrawn from the market with other substances, possibly even more harmful, and rendering such substances inaccessible for research.

Surveys and interviews were conducted with economic operators which manufacture such substances for various industrial uses, and with their trade associations, as well as with those who produce or distribute new psychoactive substances for recreational use. Recreational users of new psychoactive substances were also interviewed.

The views of young people (15-24 years' old) were collected through the 2011 Eurobarometer "Youth attitudes on drugs". Almost half of respondents (47%) thought that only those substances which are proved to pose risks to health should be restricted, while 34% held that all substances which imitate the effects of controlled drugs should be restricted.

The Commission run a public consultation on drugs policy from 28 October 2011 to 3 February 2012. It included a question on regulatory measures that the EU should develop to contain the spread of new psychoactive substances. Among the 134 replies, most stressed the need for more rapid action on new psychoactive substances and warned against imposing criminal sanctions indiscriminately. The European Economic and Social Committee has urged¹² the Commission to explore options that avoid making the personal use of such substances a criminal offence.

2.2. Impact Assessment

The Commission conducted an impact assessment of policy alternatives, taking into account the consultation of interested parties and the results of external studies. The impact assessment concluded that the following solution would be preferred:

- a more graduated and better targeted set of restriction measures on new psychoactive substances, which should not hinder the industrial use of substances.
- restriction measures should be introduced earlier and substances suspected to pose immediate public health risks should be subjected to temporary restrictions.
- restriction measures should be proportionate to a better determined level of risk of substances, with substances posing moderate risks subjected to restrictions on the consumer market (covered by administrative law), while substances posing severe risks should be subjected to a wider market restriction, as well as being covered by criminal law.
- restriction measures should be introduced through a quicker procedure.

The impact assessment concluded that the most effective way to keep harmful new psychoactive substances out of the market is to apply the EU provisions on illicit drug trafficking to new psychoactive substances that pose severe risks. Applying the same criminal law provisions to controlled drugs and to equally harmful new psychoactive substances, posing severe risks, will help deter trafficking in such substances and the involvement of criminal groups, while streamlining and clarifying the EU legal framework on drugs.

¹² OJ C 229, 31.7.2012, p. 85.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. The legal base

The proposal aims at ensuring that trade in new psychoactive substances having industrial and commercial uses is not hindered and that the functioning of this market is improved, while the health and safety of individuals are protected from harmful substances, which cause concern at the EU level.

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU), which empowers the European Parliament and the Council to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in the Member States which have as their object the establishment and functioning of the internal market. Article 114(3) TFEU requires the Commission to ensure a high level of health, safety and consumer protection in its proposals envisaged in paragraph 1 of Article 114 TFEU. This proposal falls within the scope of action to improve the functioning of the internal market for the following reasons:

- it addresses obstacles to trade in new psychoactive substances having dual uses, while enabling the adoption of measures to restrict the availability to consumers of substances posing risks.
- it addresses the lack of legal certainty for economic operators by harmonising the response given to substances causing concern across the EU.
- it connects the market for industrial uses of new psychoactive substances to the wider internal market.

3.2. Subsidiarity, proportionality and the respect for fundamental rights

There is a clear need for EU action on new psychoactive substances. This is because Member States alone cannot reduce the problems caused by the spread in the internal market of harmful new psychoactive substances and by the proliferation of divergent national responses. Uncoordinated national action in this area can produce adverse knock-on effects, for instance hindrance to the operation of the internal market as far as licit trade in these substances is concerned or displacement of harmful substances from one Member State to another.

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, withdrawn from the market rapidly in all Member States.

The proposal is relevant for the following rights and principles enshrined in the EU Charter of Fundamental Rights: the right to health care (notably to a high level of human health protection, Article 35) and to consumer protection (Article 38), the respect of the freedom to conduct a business (Article 16), the right to property (Article 17), the right to an effective remedy and to a fair trial (Article 47), the presumption of innocence and right to defence (Article 48). These rights and freedoms can be subject to limitations, but only under the limits and requirements set by Article 52(1) of the EU Charter.

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 and because it sets out a calibrated, graduated approach, under which measures are proportionate to the actual risks of substances.

Explicit safeguards laid down in the instrument itself guarantee that any person whose rights are affected by the implementation of any administrative measures or sanctions pursuant to the Regulation shall have the right to an effective remedy before a tribunal.

3.3. Choice of instrument

In order to establish uniform rules, ensure clarity of concepts and procedures, and provide legal certainty for market operators, while ensuring that restriction measures are directly applicable in all Member States, a Regulation is the appropriate instrument.

3.4 Specific provisions

Article 1: Subject matter and scope – this provision sets out the purpose and scope of the proposal, and in particular that it establishes rules for restrictions to the free movement of new psychoactive substances in the internal market.

Article 2: Definitions – this provision sets out definitions which apply throughout the instrument.

Article 3: Free movement – this provision lays down the principle of free movement of new psychoactive substances for industrial and commercial uses, and for research and development.

Article 4: Prevention of barriers to free movement – this provision clarifies under what conditions Member States may introduce restrictions on new psychoactive substances.

Article 5: Information exchange – this provision establishes the respective roles of Member States, the EMCDDA and Europol in the process of exchange of information on new psychoactive substances.

Article 6: Joint report – this provision lays down the contents and the procedures for the drawing up and the transmission by the EMCDDA and Europol of a joint report on a new psychoactive substance. The Commission, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority are associated to the collection of information for a joint report.

Article 7: 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 a joint report was 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.

Article 8: Exclusion from risk assessment – this provision details such circumstances in which no risk assessment is to be conducted on a new psychoactive substance.

Article 9: Immediate risks to public health and temporary consumer market restriction – this provision lays down the criteria on the basis of which the Commission determines whether a new psychoactive substance poses immediate risks to public health, and empowers the Commission to prohibit, temporarily, the making available of this substance on the consumer market, if it poses such immediate risks to public health.

Article 10: Determination of the level of health, social and safety risks following the risk assessment – this provision lays down the criteria on the basis of which the Commission determines the level of health, social and safety risks posed by a new psychoactive substance.

Article 11: Low risks – this provision sets out that the Commission shall introduce no restriction measures on new psychoactive substances posing low health, social and safety risks and provides a definition of low risks.

Article 12: Moderate risks and permanent consumer market restriction – this provision empowers the Commission to prohibit the making available on the consumer market of new psychoactive substances which pose moderate health, social and safety risks, and provides a definition of moderate risks.

Article 13: Severe risks and permanent market restriction – this provision empowers the Commission to prohibit the production, manufacture, making available on the market, transport, importation or exportation of new psychoactive substances which pose severe health, social and safety risks, and provides a definition of severe risks.

Article 14: Authorised uses – this provision sets out the exceptions to the market restrictions introduced under the Regulation.

Article 15: Monitoring – this provision lays down monitoring obligations with regard to substances on which a joint report has been drawn up.

Article 16: Re-examination of the level of risks – this provision sets out the procedure for re-examining the level of risks posed by a new psychoactive substance in the light of new information and evidence on the substance.

Article 17: Sanctions – this provision establishes the obligation for the Member States to lay down the rules on administrative sanctions applicable to infringements to market restriction, and to ensure that they are effective, proportionate and dissuasive.

Article 18: Remedy – this provision sets out the right to an effective judicial remedy enshrined in Article 47 of the Charter of Fundamental Rights.

Articles 19: Committee – this provision lays down the standard rules for the exercise of implementing powers in line with Article 291 TFEU.

Article 20: Research and analysis – this provision describes the ways in which the EU shall support the development, sharing and dissemination of information and knowledge on new psychoactive substances, to support the rapid exchange of information on and risk assessment of new psychoactive substances.

Article 21: Reporting – this provision requests the EMCDDA and Europol to report annually on the implementation of certain aspects of the Regulation.

Article 22: Evaluation – this provision sets out an obligation for the Commission to regularly assess the implementation, application and effectiveness of this Regulation and to report to the European Parliament and Council.

Article 23: Replacement of Decision 2005/387/JHA – this provision sets out that this Regulation replaces Council Decision 2005/387/JHA.

Article 24: Entry into force – this establishes when the Regulation shall enter into force.

4. BUDGETARY IMPLICATION

The proposal has no direct impact on the EU budget and does not create new tasks for the EMCDDA, Europol, the European Medicines Agencies, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA). For the purpose of this Regulation, the ECHA and the EFSA are only required to share the information at their disposal, on a limited number of substances, and are not requested to produce new information.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on new psychoactive substances

(Text with EEA relevance)

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 114 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 Committee¹³,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) New psychoactive substances, which may have numerous commercial and industrial uses, as well as scientific uses, can pose health, social and safety risks when consumed by humans.

¹³ 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 of 16 June 1997 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 drugs¹⁴ and was further strengthened by the Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances¹⁵. A large majority of these new psychoactive substances were reported by more than one Member State. Many such new psychoactive substances were sold to consumers without appropriate labelling and instructions of use.
- (3) Member States' competent public authorities introduce various restriction measures on these new psychoactive substances to address the risks that they pose or may pose when consumed. As new psychoactive substances are often used in the production of various goods or of other substances which are used for manufacturing goods, such as medicines, industrial solvents, cleaning agents, goods in the hi-tech industry, restricting their access for this use can have an important impact on economic operators, potentially disrupting their business activities in the internal market.
- (4) The increasing number of new psychoactive substances available in the internal market, their growing diversity, the speed with which they emerge on the market, the different risks that they may pose when consumed by humans and the growing number of individuals who consume them, challenge the capacity of public authorities to provide effective responses to protect public health and safety without hampering the functioning of the internal market.
- (5) Restriction measures vary significantly in different Member States, meaning that economic operators that use them in the production of various goods must comply, in the case of the same new psychoactive substance, with different requirements, such as pre-export notification, export authorisation, or import and export licences. Consequently, the differences between the Member States' laws, regulations and administrative provisions on new psychoactive substances hinder the functioning of the internal market, by causing obstacles to trade, market fragmentation, lack of legal clarity and of an even level playing field for economic operators, making it difficult for companies to operate across the internal market.

¹⁴ OJ L 167, 25.6.1997, p. 1.

¹⁵ OJ L 127, 20.5.2005, p. 32.

- (6) Restriction measures not only cause barriers to trade in the case of new psychoactive substances that already have commercial, industrial or scientific uses, but can also impede the development of such uses, and are likely to cause obstacles to trade for economic operators that seek to develop such uses, by making access to those new psychoactive substances more difficult.
- (7) The disparities between the various restriction measures applied to new psychoactive substances can also lead to displacement of harmful new psychoactive substances between the Member States, hampering efforts to restrict their availability to consumers and undermining consumer protection across the Union.
- (8) Such disparities are expected to increase as Member States continue to pursue divergent approaches to addressing new psychoactive substances. Therefore, the obstacles to trade and market fragmentation, and the lack of legal clarity and of a level playing field are expected to increase, further hindering the functioning of the internal market.
- (9) Those distortions to the functioning of the internal market should be eliminated and, to that end, the rules relating to new psychoactive substances that are of concern at Union level should be approximated, while, at the same time, ensuring a high level of health, safety and consumer protection.
- (10) New psychoactive substances and mixtures should be able to move freely in the Union when intended for commercial and industrial use, as well as for scientific research and development. This Regulation should establish rules for introducing restrictions to this free movement.
- (11) New psychoactive substances that pose health, social and safety risks across the Union should be addressed at the Union level. Action on new psychoactive substances under this Regulation should contribute to a high level of protection of human health and safety, as enshrined in the Charter of Fundamental Rights of the European Union.

- (12) This Regulation should not apply to drug precursors because the diversion of those chemical substances for the purpose of manufacturing narcotic drugs or psychotropic substances is addressed under Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors¹⁶ and Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors¹⁷.
- (13) Any Union action on new psychoactive substances should be based on scientific evidence and subject to a specific procedure. Based on the information notified by Member States, a report should be drawn up on new psychoactive substances that give rise to concerns across the Union. The report should indicate whether it is necessary to carry out a risk assessment. Following the risk assessment, the Commission should determine whether the new psychoactive substances should be subjected to any restriction measures. In case of immediate public health concerns, the Commission should subject them to temporary consumer market restriction before the conclusion of the risk assessment. In case new information emerges on a new psychoactive substance, the Commission should re-assess the level of risks that it poses. Reports on new psychoactive substances should be made publicly available.
- (14) No risk assessment should be conducted under this Regulation 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.
- (15) Where the new psychoactive substance on which a report is drawn up is an active substance in a medicinal product or in a veterinary medicinal product, the Commission should assess with the European Medicines Agency the need for further action.
- (16) The measures taken on new psychoactive substances at Union level should be proportionate to the health, social and safety risks that they pose.
- (17) Certain new psychoactive substances pose immediate public health risks, requiring urgent action. Therefore, their availability to consumers should be restricted for a limited time, pending their risk assessment.
- (18) No restriction measures should be introduced at Union level on new psychoactive substances which pose low health, social and safety risks.

¹⁶ OJ L 47, 18.2.2004, p. 1.

¹⁷ OJ L 22, 26.1.2005, p. 1.

- (19) Those new psychoactive substances which pose moderate health, social and safety risks should not be made available to consumers.
- (20) Those new psychoactive substances which pose severe health, social and safety risks should not be made available on the market.
- (21) This Regulation should provide for exceptions in order to ensure the protection of human and animal health, to facilitate scientific research and development, and to allow the use of new psychoactive substances in industry, provided that they cannot be abused or recovered.
- (22) In order to ensure the efficient implementation of this Regulation, the Member States should lay down rules on the sanctions applicable to infringements of restriction measures. Those sanctions should be effective, proportionate and dissuasive.
- (23) The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) established by Regulation 1920/2006/EC of the European Parliament and of the Council of 12 December 2006¹⁸ should have a central role in the exchange of information on new psychoactive substances and in the assessment of the health, social and safety risks that they pose.
- (24) The mechanism for rapid exchange of information on new psychoactive substances has proved to be a useful channel for sharing information on new psychoactive substances, on new trends in the use of controlled psychoactive substances and on related public health warnings. That mechanism should be further strengthened to enable a more effective response to the rapid emergence and spread of new psychoactive substances across the Union.
- (25) Information from Member States is crucial for the effective functioning of the procedures leading to decision on market restriction of new psychoactive substances. Therefore, Member States should collect, on a regular basis, data on the use of new psychoactive substances, related health, safety and social problems and policy responses, in accordance with the EMCDDA framework for data collection for the key epidemiological indicators and other relevant data. They should share this data.

¹⁸ OJ L 376, 27.12.2006, p. 1.

- (26) A lack of capacity to identify and anticipate the emergence and spread of new psychoactive substances and a lack of evidence about their health, social and safety risks hamper the provision of an effective response. Therefore, support should be provided, including at Union level, to facilitate cooperation between the EMCDDA, research institutes and forensic laboratories with relevant expertise, in order to increase the capacity to assess and address effectively new psychoactive substances.
- (27) The procedures for information exchange, risk assessment and adoption of temporary and permanent restriction measures on new psychoactive substances established by this Regulation should enable swift action. Market restriction measures should be adopted without undue delay, not later than eight weeks from receipt of the joint report or risk assessment report.
- (28) As long as the Union has not adopted measures to subject a new psychoactive substance to market restriction under this Regulation, Member States may adopt technical regulations on that new psychoactive substance in compliance with the provisions of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society Services¹⁹. In order to preserve the unity of the Union's internal market and to prevent the emergence of unjustified barriers to trade, Member States should immediately communicate to the Commission any draft technical regulation on new psychoactive substances, in accordance with the procedure established by Directive 98/34/EC.
- (29) Prevention, treatment and harm reduction measures are important for addressing the growing use of new psychoactive substances and their potential risks. The internet, which is one of the important distribution channels through which new psychoactive substances are sold, should be used for disseminating information on the health, social and safety risks that they pose.

¹⁹ OJ L 204, 21.7.1998. p. 37.

- (30) Medicinal products and veterinary medicinal products are addressed under Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products²⁰, 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 use²¹ and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²². Their abuse or misuse should, therefore, not be covered by this Regulation.
- (31) In order to ensure uniform conditions for the implementation of temporary and permanent market restrictions, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers²³.
- (32) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to a rapid increase in the number of reported fatalities in several Member States associated with the consumption of the new psychoactive substance concerned, imperative grounds of urgency so require.
- (33) In the application of this Regulation, the Commission should consult Member States' experts, relevant Union agencies, civil society and economic operators.
- (34) Since the objectives of the proposed action cannot be sufficiently achieved by the Member States, and can therefore, by reason of the effects of the envisaged action, be better achieved at the Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

²⁰ OJ L 311, 28.11.2001, p. 67.

²¹ OJ L 311, 28.11.2001, p. 1.

²² OJ L 136, 30.4.2004, p. 1.

²³ OJ L 55, 28.02.2011, p.13.

- (35) In order to establish uniform rules and ensure clarity of concepts and procedures, as well as to provide legal certainty for economic operators, it is appropriate to adopt this act in the form of a Regulation.
- (36) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, including the freedom to conduct a business, the right to property and the right to an effective remedy,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER - SCOPE - DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation establishes rules for restrictions to the free movement of new psychoactive substances in the internal market. For that purpose it sets up a mechanism for information exchange on, risk assessment and submission to market restriction measures of new psychoactive substances at Union level.
2. This Regulation shall not apply to scheduled substances as defined in Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005.

Article 2

Definitions

For the purpose of this Regulation, the following definitions apply:

- (a) ‘new psychoactive substance’ means a natural or synthetic substance that, when consumed by a human, has the capacity to produce central nervous system stimulation or depression, resulting in hallucinations, alterations in motor function, thinking, behaviour, perception, awareness or mood, which is intended for human consumption or is likely to be consumed by humans even if not intended for them with the purpose of inducing one or more of the effects mentioned above, which is neither controlled under the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, nor the 1971 United Nations Convention on Psychotropic Substances; it excludes alcohol, caffeine and tobacco, as well as tobacco products within the meaning of Council Directive 2001/37/EC of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products²⁴;
- (b) ‘mixture’ means a mixture or solution containing one or more new psychoactive substances;
- (c) ‘medicinal product’ means a product as defined in point 2 of Article 1 of Directive 2001/83/EC;
- (d) ‘veterinary medicinal product’ means a product as defined in point 2 of Article 1 of Directive 2001/82/EC;
- (e) ‘marketing authorisation’ means an authorisation to place a medicinal product or a veterinary medicinal product on the market, in accordance with Directive 2001/83/EC, Directive 2001/82/EC or Regulation (EC) No 726/2004;
- (f) ‘making available on the market’ means any supply of a new psychoactive substance for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

²⁴ OJ L 194, 18.7.2001, p. 26.

- (g) ‘consumer’ means any natural person who is acting for purposes which are outside his/her trade, business or profession;
- (h) ‘commercial and industrial use’ means any manufacture, processing, formulation, storage, mixing, production and sale to natural and legal persons other than consumers;
- (i) ‘scientific research and development’ means any scientific experimentation, analysis or research carried out under strictly controlled conditions, in accordance with Regulation (EC) No 1907/2006;
- (j) ‘United Nations system’ means the World Health Organisation, the Commission on Narcotic Drugs and the Economic and Social Committee acting in accordance with their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances.

CHAPTER II

FREE MOVEMENT

Article 3

Free movement

New psychoactive substances and mixtures shall move freely in the Union for commercial and industrial use, as well as for scientific research and development purposes.

Article 4

Prevention of barriers to free movement

Insofar as the Union has not adopted measures to subject a new psychoactive substance to market restriction under this Regulation, Member States may adopt technical regulations on such new psychoactive substance in accordance with Directive 98/34/EC.

Member States shall immediately communicate to the Commission any such draft technical regulation on new psychoactive substances, in accordance with Directive 98/34/EC.

CHAPTER III

EXCHANGE AND COLLECTION OF INFORMATION

Article 5

Information exchange

National Focal Points within the European Information Network on Drugs and Drug Addiction ("Reitox") and Europol National Units shall provide to the EMCDDA and Europol the available information on the consumption, possible risks, manufacture, extraction, importation, trade, distribution, trafficking, commercial and scientific use of substances that appear to be new psychoactive substances or mixtures.

The EMCDDA and Europol shall communicate that information immediately to Reitox and the Europol National Units.

Article 6

Joint report

1. Where the EMCDDA and Europol, or the Commission, consider that the information shared on a new psychoactive substance notified by several Member States gives rise to concerns across the Union because of the health, social and safety risks that the new psychoactive substance may pose, the EMCDDA and Europol shall draw up a joint report on the new psychoactive substance.
2. The joint report shall contain the following information:
 - (a) the nature of the risks that the new psychoactive substance poses when consumed by humans and the scale of the risk to public health, as referred to in Article 9(1);
 - (b) the chemical and physical identity of the new psychoactive substance, the methods and, if known, the chemical precursors used for its manufacture or extraction, and other new psychoactive substances with a similar chemical structure that have emerged;

- (c) the commercial and industrial use of the new psychoactive substance, as well as its use for scientific research and development purposes;
 - (d) the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product or veterinary medicinal product;
 - (e) the involvement of criminal groups in the manufacture, distribution or trade in the new psychoactive substance, and any use of the new psychoactive substance in the manufacture of narcotic drugs or psychotropic substances;
 - (f) whether the new psychoactive substance is currently under assessment, or has been under assessment, by the United Nations system;
 - (g) whether the new psychoactive substance is subject to any restriction measures in the Member States;
 - (h) any existing prevention and treatment measure in place to address the consequences of the use of the new psychoactive substance.
3. The EMCDDA and Europol shall request the National Focal Points and the Europol National Units to provide additional information on the new psychoactive substance. They shall provide that information within four weeks from receipt of the request.
4. The EMCDDA and Europol 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 or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with Article 10(c) of Directive 2001/82/EC.

Member States shall provide the European Medicines Agency with the above information, if so requested by it.

The European Medicines Agency shall provide the information at its disposal within four weeks from receipt of the request from the EMCDDA.

5. The EMCDDA 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. The EMCDDA shall respect the conditions on use of the information, which are communicated to the EMCDDA by the European Chemicals Agency and the European Food Safety Authority, including conditions on information and data security and protection of confidential business information.

The European Chemicals Agency and the European Food Safety Authority shall provide the information and data at their disposal within four weeks from receipt of the request.

6. The EMCDDA and Europol shall submit the joint report to the Commission within eight weeks from the request for additional information referred to in paragraph 3.

When the EMCDDA and Europol collect information on mixtures or on several new psychoactive substances with similar chemical structure, they shall submit individual joint reports to the Commission within ten weeks from the request for additional information referred to in paragraph 3.

CHAPTER IV

RISK ASSESSMENT

Article 7

Risk assessment procedure and report

1. Within four weeks from the receipt of the joint report referred to in Article 6, the Commission may request the EMCDDA 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 of the EMCDDA.
2. The risk assessment report shall include an analysis of the criteria and of the information referred to in Article 10(2) to enable the Commission to determine the level of health, social and safety risks that the new psychoactive substance poses.

3. The Scientific Committee of the EMCDDA shall assess the risks during a special meeting. The Committee may be extended by not more than five experts, representing the scientific fields relevant for ensuring a balanced assessment of the risks of the new psychoactive substance. The Director of the EMCDDA shall designate them from a list of experts. The Management Board of the EMCDDA shall approve the list of experts every three years. The Commission, the EMCDDA, Europol and the European Medicines Agency shall each have the right to nominate two observers.
4. The Scientific Committee of the EMCDDA shall carry out the risk assessment on the basis of information on the risks of the substance and on its uses, including commercial and industrial uses, provided by the Member States, the Commission, the EMCDDA, Europol, the European Medicines Agency, the European Chemicals Agency, the European Food Safety Authority and on the basis of any other relevant scientific evidence. It shall take into consideration all opinions held by its members. The EMCDDA shall support the risk assessment and shall identify information needs, including targeted studies or tests.
5. The EMCDDA shall submit the risk assessment report to the Commission within twelve weeks from the date when it received the request from the Commission.
6. Upon request of the EMCDDA, the Commission may extend the period to complete the risk assessment by no more than twelve weeks to allow for additional research and data collection to take place. The EMCDDA shall submit such a request to the Commission within six weeks from the launch of the risk assessment. If within two weeks of such request being made the Commission has not objected to such request, the risk assessment shall be so extended.

Article 8

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 by the competent authority.

CHAPTER V

MARKET RESTRICTIONS

Article 9

Immediate risks to public health and temporary consumer market restriction

1. Where it requests a risk assessment of a new psychoactive substance pursuant to Article 7(1), the Commission shall, by means of a Decision, prohibit the making available on the market to consumers of the new psychoactive substance if, based on existing information, it poses immediate risks to public health, evidenced by:
 - (a) reported fatalities and severe health consequences associated with the consumption of the new psychoactive substance in several Member States, related to the serious acute toxicity of the new psychoactive substance;
 - (b) the prevalence and patterns of use of the new psychoactive substance in the general population and in specific groups, in particular frequency, quantities and modality of use, its availability to consumers and the potential for diffusion, which indicate that the scale of the risk is considerable.

2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

On duly justified imperative grounds of urgency relating to a rapid increase in the number of reported fatalities in several Member States associated with the consumption of the new psychoactive substance concerned, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure laid down in Article 19(3).

3. The market restriction contained in the Decision referred to in paragraph 1 shall not exceed a period of twelve months.

Article 10

Determination of the level of health, social and safety risks following the risk assessment

1. The Commission shall determine the level of the health, social and safety risks posed by the new psychoactive substance on which a risk assessment report was drafted. It shall do so on the basis of all available evidence, in particular the risk assessment report.
2. The Commission shall take the following criteria into account when determining the level of risk of a new psychoactive substance:
 - (a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, in particular injury, disease, and physical and mental impairment;
 - (b) the social harm caused to individuals and to society, in particular its impact on social functioning, public order and criminal activities, organised crime activity associated with the new psychoactive substance, illicit profits generated by the production, trade and distribution of the new psychoactive substance, and associated economic costs of the social harm;
 - (c) the risks to safety, in particular the spread of diseases, including transmission of blood borne viruses, the consequences of physical and mental impairment on the ability to drive, the impact of the manufacture, transport and disposal of the new psychoactive substance and associated waste materials on the environment.

The Commission shall also take into account the prevalence and patterns of use of the new psychoactive substance in the general population and in specific groups, its availability to consumers, its potential for diffusion, the number of Member States where it poses health, social and safety risks, the extent of its commercial and industrial use, and its use for scientific research and development purposes.

Article 11

Low risks

The Commission shall not adopt restriction measures on a new psychoactive substance if, based on existing evidence, it poses, overall, low health, social and safety risks, in particular:

- (a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is limited, as it provokes minor injury and disease, and minor physical or mental impairment;
- (b) the social harm caused to individuals and to society is limited, in particular regarding its impact on social functioning and public order, criminal activities associated with the new psychoactive substance is low, illicit profits generated by the production, trade and distribution of the new psychoactive substance and associated economic costs are non-existent or negligible;
- (c) the risks to safety are limited, in particular low risk of spread of diseases, including transmission of blood borne viruses, non-existent or low consequences of physical and mental impairment on the ability to drive, and the impact of the manufacture, transport and disposal of the new psychoactive substance and associated waste materials on the environment is low.

Article 12

Moderate risks and permanent consumer market restriction

1. The Commission shall, by means of a Decision, without undue delay, prohibit the making available on the market to consumers of the new psychoactive substance if, based on existing evidence, it poses, overall, moderate health, social and safety risks, in particular:
 - (a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is moderate, as it generally provokes non-lethal injury and disease, and moderate physical or mental impairment;

- (b) the social harm caused to individuals and to society is moderate, in particular regarding its impact on social functioning and public order, producing public nuisance; criminal activities and organised crime activity associated with the substance are sporadic, illicit profits and economic costs are moderate;
 - (c) the risks to safety are moderate, in particular sporadic spread of diseases, including transmission of blood borne viruses, moderate consequences of physical and mental impairment on the ability to drive, and the manufacture, transport and disposal of the new psychoactive substance and associated waste materials results in environmental nuisance.
2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

Article 13

Severe risks and permanent market restriction

1. The Commission shall, by means of a Decision, without undue delay, prohibit the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of the new psychoactive substance if, based on existing evidence, it poses, overall, severe health, social and safety risks, in particular:
- (a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is life threatening, as it generally provokes death or lethal injury, severe disease, and severe physical or mental impairment;
 - (b) the social harm caused to individuals and to society is severe, in particular regarding its impact on social functioning and public order, resulting in public order disruption, violent and anti-social behaviour causing damage to the user, to others and to property; criminal activities and organised crime activity associated with the new psychoactive substance are systematic, illicit profits, and economic costs are high;
 - (c) the risks to safety are severe, in particular significant spread of diseases, including transmission of blood borne viruses, severe consequences of physical and mental impairment on the ability to drive, and the manufacture, transport and disposal of the new psychoactive substance and associated waste materials result in environmental harm.

2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

Article 14

Authorised uses

1. The Decisions referred to in Article 9(1) and Article 12(1) shall not impede the free movement in the Union and the making available on the market to consumers of new psychoactive substances that are active substances in medicinal products or veterinary medicinal products that have obtained a marketing authorisation.
2. The Decisions referred to in Article 13(1) shall not impede the free movement in the Union and the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances:
 - (a) for scientific research and development purposes;
 - (b) for uses authorised under Union legislation;
 - (c) that are active substances in medicinal products or veterinary medicinal products that have obtained a marketing authorisation;
 - (d) for use in the manufacture of substances and products provided that the new psychoactive substances are transformed in such a condition that they cannot be abused or recovered.
3. The Decisions referred to in Article 13(1) may set requirements and conditions for the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances posing severe health, social and safety risks for the uses listed in paragraph 2.

CHAPTER VI

MONITORING AND RE-EXAMINATION

Article 15

Monitoring

The EMCDDA and Europol, with the support of Reitox, shall monitor all new psychoactive substances on which a joint report has been drawn up.

Article 16

Re-examination of level of risks

Where new information and evidence is available on the risks posed by a new psychoactive substance the health, social and safety risks of which have already been determined in accordance with Article 10, the Commission shall request the EMCDDA to update the risk assessment report drafted on the new psychoactive substance and shall re-examine the level of risks that the new psychoactive substance poses.

CHAPTER VII

SANCTIONS AND REMEDY

Article 17

Sanctions

Member States shall lay down the rules on sanctions applicable to infringements of the Decisions referred to in Article 9(1), Article 12(1) and Article 13(1) and shall take all necessary measures to ensure that they are implemented. The sanctions provided for shall be effective, proportionate and dissuasive. Member States shall notify those rules on sanctions and any subsequent amendment affecting those provisions to the Commission without delay.

Article 18

Remedy

Any person whose rights are affected by the implementation of a sanction taken by a Member State in accordance with Article 17 shall have the right to an effective remedy before a tribunal in that Member State.

CHAPTER VIII

PROCEDURES

Article 19

Committee

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

CHAPTER IX

FINAL PROVISIONS

Article 20

Research and analysis

The Commission and the Member States shall support the development, sharing and dissemination of information and knowledge on new psychoactive substances. They shall do so by facilitating cooperation between the EMCDDA, other Union agencies, and scientific and research centres.

Article 21

Reporting

The EMCDDA and Europol shall report annually on the implementation of this Regulation.

Article 22

Evaluation

By [*five years after the entry into force of this Regulation*] at the latest and every five years thereafter, the Commission shall assess the implementation, application and effectiveness of this Regulation and publish a report.

Article 23

Replacement of Decision 2005/387/JHA

Decision 2005/387/JHA is hereby repealed and replaced, without prejudice to the obligations of the Member States relating to the time limit for transposition of that Decision into national law. References to Decision 2005/387/JHA shall be construed as reference to this Regulation.

Article 24

Entry into force

This Regulation shall enter into force on the [*twentieth*] day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Regulation of the European Parliament and of the Council on new psychoactive substances

1.2. Policy area(s) concerned in the ABM/ABB structure²⁵

Title 33: Justice

1.3. Nature of the proposal/initiative

- The proposal/initiative relates to **a new action**
- The proposal/initiative relates to **a new action following a pilot project/preparatory action**²⁶
- 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*

Building a safe and secure Europe: to improve the capacity to detect, assess and respond rapidly and effectively to the emergence of new psychoactive substances

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

Specific objective No:

Prevent and reduce drug use, drug dependence and drug-related harm

ABM/ABB activity(ies) concerned

²⁵ ABM: activity-based management – ABB: activity-based budgeting.

²⁶ As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

1.4.3. Expected result(s) and impact

To reduce the availability in the EU internal market of new psychoactive substances that pose health, social and safety risks, and to prevent the emergence of obstacles to legitimate trade and increase legal certainty for economic operators.

1.4.4. Indicators of results and impact

- Number of new psychoactive substances notified, of Member States that notified it.
- Known commercial and industrial uses of new psychoactive substances.
- Characteristics and availability (including on the internet) of the substances.
- Number of joint reports and risk assessments conducted.
- Number and type of restriction measures on new psychoactive substances at the EU and national level.
- Number of health alerts issued on new psychoactive substances and follow-up given by responsible authorities.

1.5. Grounds for the proposal/initiative

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

- To reduce obstacles to legitimate trade in new psychoactive substances and prevent the emergence of such obstacles.
- To protect the health and safety of consumers from the risks posed by harmful new psychoactive substances.
- To address substances that pose health, social and safety risks, and that raise immediate public health concerns.
- To improve the capacity to rapidly identify and assess new psychoactive substances, and to address them depending on their risks.
- To facilitate legitimate trade in such substances within the internal market.
- To improve consistency between national responses to harmful new psychoactive substances which raise cross-border concerns and to reduce the risk of their displacement between the Member States.

1.5.2. Added value of EU involvement

EU action on new psychoactive substances would boost the exchange of information among the 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 risks of substances at the EU level has the added value of pooling scientific resources and analytical capacities from across the EU, to provide the best evidence available on a substance and help develop effective responses to it. EU-level decisions on restricting the availability of harmful substances would increase legal certainty and reduce obstacles for economic operators in the market for legitimate uses, while improving consumer protection across the EU.

1.5.3. Lessons learned from similar experiences in the past

The 2011 Commission's assessment report²⁷ on the implementing of the current Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances, based on an extensive consultation of Member State stakeholders, concluded that the Council Decision is a useful instrument for tackling new substances at the EU level, but that it has several major shortcomings, including:

- (1) It is slow and reactive, and it is therefore not able to address effectively the increase in the number of new psychoactive substances.
- (2) Insufficient evidence is available to take appropriate and sustainable decisions under this instrument.
- (3) It lacks options for restriction measures.

1.5.4. Compatibility and possible synergy with other appropriate instruments

Action in the field of new psychoactive substances is in compliance with the existing rules on the functioning of the internal market, as well as with EU strategic policy documents, including the EU Drugs Strategy 2013-2020, the Stockholm Programme and the Commission Communication "Towards a stronger European response to drugs". EU action in the field of new psychoactive substances is also fully consistent with action at the United Nations' level.

²⁷ COM(2011) 430 final and SEC(2011) 912.

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 YYYY to YYYY,

– followed by full-scale operation.

1.7. Management mode(s) planned²⁸

From the 2014 budget

Direct management by the Commission

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

– by the executive agencies;

Shared management with the Member States

Indirect management by delegating 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;

²⁸ 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

- 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:

The only minor costs expected for the EU budget relate to the evaluation of the legislative instrument and meetings of the committee of Member States.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

The Commission will evaluate the implementation, functioning, effectiveness, efficiency, utility and added value of the future mechanism on new psychoactive substances every five years, publish the results and propose amendments, if necessary.

2.2. Management and control system

2.2.1. Risk(s) identified

None identified.

2.2.2. Information concerning the internal control system set up

Standard Commission control/infringement procedures concerning the application of the future Regulation and Directive.

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 specific risk identified.

2.3. Measures to prevent fraud and irregularities

In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 apply.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

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

- Existing expenditure 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.....]	Diff./non-diff. ⁽²⁹⁾	from EFTA countries ³⁰	from candidate countries ³¹	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
3	[33 03 03]	Diff.	NO	NO	NO	NO

- New budget lines requested

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

²⁹ Diff. = Differentiated appropriations / Non-Diff. = Non-differentiated appropriations.

³⁰ EFTA: European Free Trade Association.

³¹ 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: Security and Citizenship]
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DG JUST			Year 2014	Year 2015	Year 2016	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
• Operational appropriations											
33 03 03	Commitments	(1)						0,150			0,150
	Payments	(2)						0,150			0,150
Number of budget line	Commitments	(1a)									
	Payments	(2a)									
Appropriations of an administrative nature financed from the envelope of specific programmes ³²											
Number of budget line		(3)									
TOTAL appropriations for DG JUST	Commitments	=1+1a +3						0,150			0,150
	Payments	=2+2a +3						0,150			0,150

³² 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 operational appropriations	Commitments	(4)						0,150					0,150
	Payments	(5)						0,150					0,150
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)											
TOTAL appropriations for HEADING 3 of the multiannual financial framework	Commitments	=4+ 6						0,150					0,150
	Payments	=5+ 6						0,150					0,150

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

• 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"
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EUR million (to three decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	TOTAL
DG JUST									
• Human resources		0,013	0,013	0,013	0,013	0,013	0,065	0,013	0,143
• Other administrative expenditure		0,025	0,025	0,025	0,025	0,025	0,025	0,025	0,175
TOTAL DG JUST	Appropriations								
TOTAL appropriations for HEADING 5 of the multiannual financial framework	Total commitments = Total payments	0,038	0,038	0,038	0,038	0,038	0,09	0,038	0,318

EUR million (to three decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	TOTAL
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	0,038	0,038	0,038	0,038	0,038	0,240	0,038	0,468
	Payments	0,038	0,038	0,038	0,038	0,038	0,240	0,038	0,468

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 operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ↓			Year 2014		Year 2015		Year 2016		Year 2017		Year 2018		Year 2019		Year 2020		TOTAL		
	OUTPUTS																		
	Type ³³	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No total	Total cost	
SPECIFIC OBJECTIVE No 1 Prevent and reduce drug use, drug dependence and drug-related harm																			
- Output	Evaluation	0,158												1	0,150			1	0,150
- Output																			
- Output																			
Subtotal for specific objective No 1														1	0,150			1	0,150

³³ Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

SPECIFIC OBJECTIVE NO 2 ...																	
- Output																	
Subtotal for specific objective No 2																	
TOTAL COST												1	0,150			1	0,150

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)

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	TOTAL
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HEADING 5 of the multiannual financial framework								
Human resources	0,013	0,013	0,013	0,013	0,013	0,065	0,013	0,143
Other administrative expenditure	0,025	0,025	0,025	0,025	0,025	0,025	0,025	0,175
Subtotal HEADING 5 of the multiannual financial framework	0,038	0,038	0,038	0,038	0,038	0,090	0,038	0,318

Outside HEADING 5³⁴ of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 5 of the multiannual financial framework								

TOTAL	0,038	0,038	0,038	0,038	0,038	0,090	0,038	0,318
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The human resources appropriations required 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.

³⁴ 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.

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 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	TOTAL
• Establishment plan posts (officials and temporary staff)								
33 01 01 01 (Headquarters and Commission's Representation Offices)	0,1	0,1	0,1	0,1	0,1	0,5	0,1	1,1
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)³⁵								
XX 01 02 01 (CA, SNE, INT from the "global envelope")								
XX 01 02 02 (CA, LA, SNE, INT and JED in the delegations)								
XX 01 04 yy ³⁶	- at Headquarters							
	- Delegations							
XX 01 05 02 (CA, SNE, INT - Indirect research)								
10 01 05 02 (CA, INT, SNE - Direct research)								
Other budget lines (specify)								
TOTAL	0,1	0,1	0,1	0,1	0,1	0,5	0,1	1,1

33 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	Preparation of one committee meeting of Member States per year. Coordination of an external study for the evaluation of the instrument every five years.
External staff	

³⁵ CA= Contract Staff; LA = Local Staff; SNE= Seconded National Expert; INT = agency staff; JED= Junior Experts in Delegations).

³⁶ Sub-ceiling for external staff covered by operational appropriations (former "BA" lines).

3.2.4. *Compatibility with the current multiannual financial framework*

- Proposal/initiative is compatible with the current multiannual financial framework.
- 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.

- Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework³⁷.

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

3.2.5. *Third-party contributions*

- 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 3 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 cofinanced								

³⁷ See points 19 and 24 of the Interinstitutional Agreement (for the period 2007-2013).

3.3. Estimated impact on revenue

- Proposal/initiative has no financial impact on revenue.
- 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 ³⁸						
		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.

³⁸ 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.