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EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2017/2101 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 15 November 2017****amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) New psychoactive substances can pose serious cross-border threats to health, in particular due to the large number and diversity of those substances and the speed with which they appear. In order to develop responses for addressing those threats, it is necessary to enhance monitoring and the early warning system and to assess the health and social risks associated with new psychoactive substances.
- (2) Vulnerable groups, especially young people, are particularly exposed to the health and social risks associated with new psychoactive substances.
- (3) In recent years, Member States have notified an increasing number of new psychoactive substances via the mechanism for rapid exchange of information on such substances, which was established by Council Joint Action 97/396/JHA ⁽³⁾ and further strengthened by Council Decision 2005/387/JHA ⁽⁴⁾.
- (4) New psychoactive substances that pose public health and, where applicable, social risks across the Union should be addressed at Union level. This Regulation should therefore be read in conjunction with Directive (EU) 2017/2103 of the European Parliament and of the Council ⁽⁵⁾ because both acts are designed to replace the mechanism established by Decision 2005/387/JHA.

⁽¹⁾ OJ C 34, 2.2.2017, p. 182.

⁽²⁾ Position of the European Parliament of 24 October 2017 (not yet published in the Official Journal) and decision of the Council of 10 November 2017.

⁽³⁾ 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 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⁾ Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA (see page 12 of this Official Journal).

- (5) A small number of new psychoactive substances can have commercial and industrial uses and can be used for scientific research and development.
- (6) Provisions concerning information exchange on, and the early warning system and risk assessment procedure for, new psychoactive substances should be included in Regulation (EC) No 1920/2006 of the European Parliament and of the Council ⁽¹⁾. Provisions concerning the early warning of new psychoactive substances should, in particular, be strengthened and the procedures for drawing up an initial report and organising the risk assessment should be made more efficient. Substantially shortened deadlines for all stages of those procedures should be set.
- (7) Any Union action on new psychoactive substances should be based on scientific evidence and be subject to a specific procedure.
- (8) An initial report should be drawn up on a new psychoactive substance where information provided by the Member States on that new psychoactive substance gives rise to concerns that it might pose health or social risks at Union level. The initial report should allow the Commission to make an informed decision regarding the launch of the risk assessment procedure. The risk assessment procedure at Union level should be undertaken rapidly.
- (9) Following the risk assessment procedure, the Commission should determine whether the new psychoactive substance in question should be included in the definition of 'drug' in accordance with the procedure provided for in Council Framework Decision 2004/757/JHA ⁽²⁾. With a view to ensuring the continuous functioning of the mechanism for information exchange and of the reporting and risk assessment procedures set out in Decision 2005/387/JHA and in this Regulation, this Regulation should apply from the same date as the deadline for transposition of Directive (EU) 2017/2103, which is also the date on which Decision 2005/387/JHA is to be repealed.
- (10) In principle, no risk assessment should be carried out on a new psychoactive substance if it is subject to an assessment under international law. No risk assessment should be carried out on a new psychoactive substance if it is an active substance in a medicinal product for human use or in a veterinary medicinal product.
- (11) Regulation (EC) No 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 is added:

- '(f) Exchange of information on, early warning system for, and risk assessment of, new psychoactive substances
 - (i) collecting, collating, analysing and assessing the available information from the national focal points referred to in Article 5 and the Europol national units on new psychoactive substances as defined in point 4 of Article 1 of Council Framework Decision 2004/757/JHA ^(*) and communicating that information to the 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;

⁽¹⁾ 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).

⁽²⁾ 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).

- (iv) monitoring, in cooperation with Europol and with the support of the national focal points referred to in Article 5 and the Europol national units, all new psychoactive substances that have been reported by Member States.

(*) 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).;

(2) in Article 5(2), the second subparagraph is deleted;

(3) the following Articles are inserted:

'Article 5a

Information exchange on, and early warning system for, new psychoactive substances

Each Member State shall ensure that its national focal point, as referred to in Article 5, and its Europol national unit provide the Centre and Europol, taking into account their respective mandates, with the available information on new psychoactive substances in a timely manner and without undue delay. The information shall be related to the detection and identification, use and patterns of use, manufacture, extraction, distribution and distribution methods, trafficking, and commercial, medical and scientific use of, and potential and identified risks posed by, those substances.

The Centre, in cooperation with Europol, shall collect, collate, analyse and assess the information and communicate it in a timely manner to the national focal points and the Europol national units as well as to the Commission with a view to providing them with any information required for the purposes of early warning and for the purposes of allowing the Centre to draw up the initial report or the combined initial report pursuant to Article 5b.

Article 5b

Initial report

1. Where the Centre, the Commission or a majority of the Member States considers that 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 Union level, the Centre shall draw up an initial report on the new psychoactive substance.

For the purpose of this paragraph, Member States shall inform the Commission and other Member States of their wish that an initial report be drawn up. Where the majority of Member States is reached, the Commission shall instruct the Centre accordingly and shall inform the Member States thereof.

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

- (a) the nature, number and scale of incidents showing health and social problems in which the new psychoactive substance may potentially be involved, and the patterns of use of the new psychoactive substance;
- (b) the chemical and physical description of the new psychoactive substance and the methods and precursors used for its manufacture or extraction;
- (c) the pharmacological and toxicological description of the new psychoactive substance;
- (d) the involvement of criminal groups in the manufacture or distribution of the new psychoactive substance.

The initial report shall also contain:

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

- (b) information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;
- (c) information on whether the new psychoactive substance is subject to any restrictive measures in the Member States;
- (d) information on whether the new psychoactive substance is currently or has been under assessment within the system established by the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and the 1971 Convention on Psychotropic Substances ('United Nations system');
- (e) other relevant information, where available.

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

4. Where the Centre considers it necessary, it shall request the national focal points referred to in Article 5 to provide additional information on the new psychoactive substance. The national focal points shall provide that information within two weeks of receipt of the request.

5. The Centre shall, without undue delay, request the European Medicines Agency to provide information on whether, at Union or national level, the new psychoactive substance is an active substance in:

- (a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC of the European Parliament and of the Council (*), Directive 2001/82/EC of the European Parliament and of the Council (**) or Regulation (EC) No 726/2004 of the European Parliament and of the Council (***);
- (b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;
- (c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;
- (d) an unauthorised medicinal product for human use 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 law in accordance with point (c) of Article 10(1) of Directive 2001/82/EC;
- (e) an investigational medicinal product as defined in point (d) of Article 2 of Directive 2001/20/EC of the European Parliament and of the Council (****).

Where the information relates to marketing authorisations granted by Member States, the Member States concerned shall provide the European Medicines Agency with such information upon its request.

6. The Centre shall, without undue delay, request Europol to provide information on the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance, and in any use of the new psychoactive substance.

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

8. The details of the cooperation between the Centre and the bodies and agencies referred to in paragraphs 5, 6 and 7 of this Article 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 access to documents, information and data security and protection of confidential data, including sensitive data and confidential business information.

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

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

Article 5c

Risk assessment procedure and report

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

2. Within two weeks of receipt of a combined initial report as referred to in Article 5b(11), the Commission may request the Centre to assess the potential risks posed by several new psychoactive substances with a similar chemical structure and to draw up a combined risk assessment report, where there are indications in the combined initial report to believe that the substances may pose severe public health risks and, where applicable, severe social risks. The combined risk assessment shall be carried out by the Scientific Committee.

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

- (a) available information on the chemical and physical properties of the new psychoactive substance and the methods and the precursors used for its manufacture or extraction;
- (b) available information on the pharmacological and toxicological properties of the new psychoactive substance;
- (c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and 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, and the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance;
- (e) available information on the extent and patterns of use of the new psychoactive substance, its availability and potential for diffusion within the Union;
- (f) available information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;
- (g) other relevant information, where available.

4. The Scientific Committee shall assess the risks posed by the new psychoactive substance or group of new psychoactive substances. The Scientific Committee may be extended as deemed necessary by the Director, acting on the advice of the chairperson of the Scientific Committee, by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks posed by the new psychoactive substance. The Director shall designate those experts 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 procedure, including identifying future information needs and relevant studies.

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

7. Upon receipt of a duly reasoned request of the Centre, the Commission may extend the period for completion of the risk assessment or combined risk assessment to allow for additional research and data collection to take place. That request 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 are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.

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

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

- (a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation;
- (b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;
- (c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;
- (d) an investigational medicinal product as defined in point (d) of Article 2 of Directive 2001/20/EC.

(*) 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).

(**) 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).

(***) 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 Agency (OJ L 136, 30.4.2004, p. 1).

(****) 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).;

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

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

Article 2

Entry into force

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

It shall apply from 23 November 2018.

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

Done at Strasbourg, 15 November 2017.

For the European Parliament

The President

A. TAJANI

For the Council

The President

M. MAASIKAS

DIRECTIVES

DIRECTIVE (EU) 2017/2102 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 November 2017

amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

(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 Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Directive 2011/65/EU of the European Parliament and of the Council ⁽³⁾ on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) contains a request that the Commission examine the need to amend the scope of that Directive in respect of the EEE covered therein and, if appropriate, present a legislative proposal with respect to any additional exclusions related to that EEE.
- (2) Secondary market operations for EEE, which involve repair, replacement of spare parts, refurbishment and reuse, and retrofitting, should be facilitated to promote a circular economy in the Union. A high level of protection of human health and the environment should be ensured, including through the environmentally sound recovery and disposal of waste EEE. Any unnecessary administrative burden on market operators should be avoided. Directive 2011/65/EU allows EEE that fell outside the scope of the previous Directive 2002/95/EC of the European Parliament and of the Council ⁽⁴⁾, but which would not comply with Directive 2011/65/EU, to continue to be made available on the market until 22 July 2019. After that date, however, both the first placing on the market and secondary market operations of non-compliant EEE are prohibited. Such prohibition of secondary market operations is inconsistent with the general principles underlying Union measures for the approximation of laws relating to products and should therefore be removed.
- (3) Certain niche product groups should be excluded from the scope of Directive 2011/65/EU as their inclusion would bring negligible environmental or health benefits and introduce unresolvable compliance problems or market distortions that cannot effectively be addressed through the exemption mechanism provided for in that Directive.
- (4) Pipes in organs are built using a specific type of lead-based alloy, for which no alternative has been found so far. Most pipe organs are kept in the same place for centuries and their turnover rate is negligible. Pipe organs should therefore be excluded from the scope of Directive 2011/65/EU as their inclusion would bring negligible benefit in terms of the substitution of lead.

⁽¹⁾ OJ C 345, 13.10.2017, p. 110.

⁽²⁾ Position of the European Parliament of 3 October 2017 (not yet published in the Official Journal) and decision of the Council of 23 October 2017.

⁽³⁾ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

⁽⁴⁾ Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 37, 13.2.2003, p. 19).

- (5) Directive 2011/65/EU does not apply to non-road mobile machinery with an on-board power source, which is made available exclusively for professional use. However, for certain types of non-road mobile machinery, two versions are produced in the same production line, with the power source (either on-board or external) being the only difference. Those versions should be treated in the same way under that Directive. Non-road mobile machinery with a traction drive powered by an external power source should therefore also be excluded from the scope of Directive 2011/65/EU.
- (6) For all relevant EEE categories, as set out in Annex I to Directive 2011/65/EU, the conditions for the exemption of reused spare parts, recovered from EEE, should be clearly specified. Likewise, since exemptions from the restriction of the use of certain hazardous substances should have a limited duration, the maximum validity period for existing exemptions should also be clearly specified for all relevant EEE categories, including for category 11.
- (7) When an application for renewal of an exemption is submitted, the Commission is required to take a decision no later than 6 months before the expiry date of the existing exemption, unless specific circumstances justify a different deadline. No deadline is specified for the Commission to take a decision on applications for new exemptions. According to the report of 18 April 2016 from the Commission to the European Parliament and the Council on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Directive 2011/65/EU, that deadline has proven to be unfeasible in practice, due to the need to follow several mandatory procedural steps for the evaluation of an application for renewal of an exemption. While the deadline brings no additional value to the existing procedure for the evaluation of applications for renewal, it entails uncertainties for businesses and other stakeholders due to its impracticability. On the other hand, business continuity is ensured since market operators are able to rely on an existing exemption remaining valid until a decision is taken on the application for renewal. Therefore, the provision related to the deadline should be removed. However, the Commission should provide to the applicant, the Member States and the European Parliament, shortly after the receipt of an application, a timeline for the adoption of its decision on the application. Furthermore, the general review of Directive 2011/65/EU to be carried out by the Commission no later than 22 July 2021 should include the specification of a realistic deadline for a decision by the Commission on an application for renewal of an exemption before the expiry of the relevant exemption.
- (8) Since the objectives of this Directive, which are to contribute to the protection of human health and the environmentally sound recovery and disposal of waste EEE by means of the restriction of the use of hazardous substances in EEE, cannot be sufficiently achieved by the Member States because disparities between the laws or administrative measures adopted by the Member States could create barriers to trade and distort competition in the Union and thus have a direct impact on the internal market, but can rather, by reason of the scale of the problem and its implications in respect of other Union legislation on recovery and disposal of waste and areas of common interest, such as human health protection, be better achieved at 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 Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2011/65/EU is amended as follows:

(1) Article 2 is amended as follows:

- (a) paragraph 2 is deleted;
- (b) in paragraph 4, the following point is added:
'(k) pipe organs.');

(2) in Article 3, point (28) is replaced by the following:

- '(28) "non-road mobile machinery made available exclusively for professional use" means machinery, with an on-board power source or with a traction drive powered by an external power source, the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working, and which is made available exclusively for professional use.');

(3) Article 4 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. Paragraph 1 shall apply to medical devices and monitoring and control instruments which are placed on the market from 22 July 2014, to in vitro diagnostic medical devices which are placed on the market from 22 July 2016, to industrial monitoring and control instruments which are placed on the market from 22 July 2017, and to all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market from 22 July 2019.’;

(b) in paragraph 4, the following point is inserted:

‘(ea) all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market before 22 July 2019.’;

(c) paragraph 5 is replaced by the following:

‘5. Provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of spare parts is notified to the consumer, paragraph 1 shall not apply to reused spare parts:

- (a) recovered from EEE placed on the market before 1 July 2006 and used in EEE placed on the market before 1 July 2016;
- (b) recovered from medical devices or monitoring and control instruments placed on the market before 22 July 2014 and used in EEE placed on the market before 22 July 2024;
- (c) recovered from in vitro diagnostic medical devices placed on the market before 22 July 2016 and used in EEE placed on the market before 22 July 2026;
- (d) recovered from industrial monitoring and control instruments placed on the market before 22 July 2017 and used in EEE placed on the market before 22 July 2027;
- (e) recovered from all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market before 22 July 2019, and used in EEE placed on the market before 22 July 2029.’;

(4) Article 5 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘For the exemptions listed in Annex III as at 21 July 2011, unless a shorter period is specified, the maximum validity period, which may be renewed, shall be:

- (a) for categories 1 to 7 and category 10 of Annex I, 5 years from 21 July 2011;
- (b) for categories 8 and 9 of Annex I, 7 years from the relevant dates laid down in Article 4(3); and
- (c) for category 11 of Annex I, 5 years from 22 July 2019.’;

(b) in paragraph 4, the following point is inserted:

‘(ba) within 1 month of receipt of an application, provide to the applicant, the Member States and the European Parliament a timeline for the adoption of its decision on the application.’;

(c) in paragraph 5, the first sentence of the second subparagraph is deleted.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 12 June 2019. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Strasbourg, 15 November 2017.

For the European Parliament

The President

A. TAJANI

For the Council

The President

M. MAASIKAS

DIRECTIVE (EU) 2017/2103 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 15 November 2017****amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of ‘drug’ and repealing Council Decision 2005/387/JHA**

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 83(1) 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⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Council Framework Decision 2004/757/JHA ⁽³⁾ provides for a common approach to tackle illicit drug trafficking, which poses a threat to the health, safety and quality of life of citizens of the Union, to the legal economy and to the stability and security of the Member States. Framework Decision 2004/757/JHA sets out minimum common rules on the definition of drug trafficking offences and penalties in order to avoid problems arising in the cooperation between the judicial authorities and law enforcement agencies of Member States owing to the fact that the offence or offences in question are not punishable under the laws of both the requesting and the requested Member State.
- (2) Framework Decision 2004/757/JHA applies to the substances covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and to the substances covered by the 1971 United Nations Convention on Psychotropic Substances (‘UN Conventions’), as well as to the synthetic drugs subjected to control measures across the Union pursuant to Council Joint Action 97/396/JHA ⁽⁴⁾, which pose public health risks comparable to those posed by the substances scheduled under the UN Conventions.
- (3) Framework Decision 2004/757/JHA should also apply to the substances subjected to control measures and criminal penalties pursuant to Council Decision 2005/387/JHA ⁽⁵⁾, which pose public health risks comparable to those posed by the substances scheduled under the UN Conventions.
- (4) New psychoactive substances, which imitate the effects of substances scheduled under the UN Conventions, are emerging frequently and are spreading rapidly in the Union. Certain new psychoactive substances pose severe public health and social risks. Regulation (EU) 2017/2101 of the European Parliament and of the Council ⁽⁶⁾ provides the framework for the exchange of information on new psychoactive substances and for a risk assessment procedure based on an initial report and risk assessment report drawn up to evaluate whether a new psychoactive substance poses severe public health and social risks. To effectively reduce the availability of new psychoactive substances that pose severe public health risks and, where applicable, severe social risks, and to deter trafficking in those substances across the Union, as well as the involvement of criminal organisations, those substances should be included in the definition of ‘drug’ in accordance with the provisions of this Directive and underpinned by proportionate criminal law provisions.

⁽¹⁾ OJ C 177, 11.6.2014, p. 52.

⁽²⁾ Position of the European Parliament of 17 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 25 September 2017 (not yet published in the Official Journal). Position of the European Parliament of 24 October 2017 (not yet published in the Official Journal).

⁽³⁾ 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).

⁽⁴⁾ 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 drugs (OJ L 167, 25.6.1997, p. 1).

⁽⁵⁾ 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).

⁽⁶⁾ Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances (see page 1 of this Official Journal).

- (5) The new psychoactive substances included in the definition of 'drug' should therefore be covered by the Union criminal law provisions on illicit drug trafficking. This would also help streamline and clarify the Union legal framework, as the same criminal law provisions would apply to substances covered by the UN Conventions and to the most harmful new psychoactive substances. The definition of 'drug' in Framework Decision 2004/757/JHA should therefore be amended.
- (6) This Directive should establish the essential elements of the definition of 'drug', as well as the procedure and the criteria for the inclusion of new psychoactive substances in that definition. Furthermore, in order to include in the definition of 'drug' psychoactive substances which are already subject to control measures by Council decisions adopted in accordance with Joint Action 97/396/JHA and Decision 2005/387/JHA, an Annex containing a list of those psychoactive substances should be added to Framework Decision 2004/757/JHA.
- (7) However, in order to swiftly address the emergence and spread of harmful new psychoactive substances in the Union, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in respect of amending that Annex to include new psychoactive substances in the definition of 'drug'. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ⁽¹⁾. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (8) In order to swiftly address the emergence and spread of harmful new psychoactive substances in the Union, Member States should apply the provisions of Framework Decision 2004/757/JHA to new psychoactive substances which pose severe public health risks and, where applicable, severe social risks, as soon as possible but no later than six months from the entry into force of a delegated act amending the Annex to include them in the definition of 'drug'. Member States should, to the extent possible, make every effort to shorten that deadline.
- (9) Since the objective of this Directive, namely to extend the application of the Union criminal law provisions that apply to illicit drug trafficking to new psychoactive substances posing severe public health risks and, where applicable, severe social risks, cannot be sufficiently achieved by the Member States acting alone, but can rather be better achieved at 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 (TEU). In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (10) This Directive respects the fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, and in particular the right to an effective remedy and to a fair trial, the presumption of innocence and the right of defence, the right not to be tried or punished twice in criminal proceedings for the same criminal offence and the principles of legality and proportionality of criminal offences and penalties.
- (11) As this Directive together with Regulation (EU) 2017/2101, is designed to replace the mechanism established by Decision 2005/387/JHA, that Decision should be repealed.
- (12) In accordance with Article 3 of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, annexed to the TEU and to the TFEU, Ireland has notified its wish to take part in the adoption and application of this Directive.
- (13) In accordance with Articles 1 and 2 of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, annexed to the TEU and to the TFEU, and without prejudice to Article 4 of that Protocol, the United Kingdom is not taking part in the adoption of this Directive and is not bound by it or subject to its application.
- (14) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the TEU and to the TFEU, Denmark is not taking part in the adoption of this Directive and is not bound by it or subject to its application.

⁽¹⁾ OJ L 123, 12.5.2016, p. 1.

(15) Framework Decision 2004/757/JHA should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Framework Decision 2004/757/JHA

Framework Decision 2004/757/JHA is amended as follows:

(1) Article 1 is amended as follows:

(a) point 1 is replaced by the following:

‘1. “drug” means any of the following:

(a) a substance covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances;

(b) any of the substances listed in the Annex;’;

(b) the following points are added:

‘4. “new psychoactive substance” means a substance in pure form or in a preparation that is not covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances but may pose health or social risks similar to those posed by the substances covered by those Conventions;

5. “preparation” means a mixture containing one or more new psychoactive substances.’;

(2) the following Articles are inserted:

‘Article 1a

Procedure for including new psychoactive substances in the definition of “drug”

1. Based on a risk assessment or combined risk assessment carried out pursuant to Article 5c of Regulation (EC) No 1920/2006 of the European Parliament and of the Council (*), and in accordance with the criteria set out in paragraph 2 of this Article, the Commission shall, without undue delay, adopt a delegated act in accordance with Article 8a amending the Annex to this Framework Decision in order to add the new psychoactive substance or substances to it and provide that the new psychoactive substance or substances pose severe public health risks and, where applicable, severe social risks at Union level, and that it is or they are included in the definition of “drug”.

2. When considering whether to adopt a delegated act as referred to in paragraph 1, the Commission shall take into account whether the extent or patterns of use of the new psychoactive substance and its availability and potential for diffusion within the Union are significant, and whether the harm to health caused by the consumption of the new psychoactive substance, associated with its acute or chronic toxicity and abuse liability or dependence-producing potential, is life-threatening. The harm to health is considered life-threatening if the new psychoactive substance is likely to cause death or lethal injury, severe disease, severe physical or mental impairment or a significant spread of diseases, including the transmission of blood-borne viruses.

In addition, the Commission shall take into account whether the social harm caused by the new psychoactive substance to individuals and to society is severe, and, in particular, whether the impact of the new psychoactive substance on social functioning and public order is such as to disrupt public order, or cause violent or anti-social behaviour, resulting in harm to the user or to other persons or damage to property, or whether criminal activities, including organised crime, associated with the new psychoactive substance are systematic, involve significant illicit profits or entail significant economic costs.

3. If, within six weeks of the date of receipt of the risk assessment report or the combined risk assessment report in accordance with Article 5c(6) of Regulation (EC) No 1920/2006, the Commission considers that it is not necessary to adopt a delegated act to include the new psychoactive substance or substances in the definition of “drug”, it shall present a report to the European Parliament and to the Council explaining the reasons for not doing so.

4. As regards new psychoactive substances added to the Annex to this Framework Decision, Member States which have not yet done so shall bring into force the laws, regulations and administrative provisions necessary to apply the provisions of this Framework Decision to those new psychoactive substances as soon as possible but no later than six months after the entry into force of the delegated act amending the Annex. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Framework Decision or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Article 1b

National control measures

Without prejudice to the obligations imposed on the Member States under this Framework Decision, Member States may maintain or introduce in their territories, with regard to new psychoactive substances, any national control measures that they consider appropriate.

(*) 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).;

(3) the following Article is inserted:

‘Article 8a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 1a shall be conferred on the Commission for a period of five years from 22 November 2017. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 1a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making (*).

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 1a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

(*) OJ L 123, 12.5.2016, p. 1.;

(4) an Annex, as set out in the Annex to this Directive, is added.

Article 2

Transposition of this Directive

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 23 November 2018. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Article 3

Repeal of Decision 2005/387/JHA

1. Decision 2005/387/JHA is repealed with effect from 23 November 2018.
2. Notwithstanding paragraph 1, Decision 2005/387/JHA shall continue to apply to new psychoactive substances in respect of which a joint report, as referred to in Article 5 of that Decision, has been submitted before 23 November 2018.
3. The Commission shall adopt delegated acts in accordance with paragraphs 4 to 8 of this Article amending the Annex to Framework Decision 2004/757/JHA in order to add to it new psychoactive substances as referred to in paragraph 2 of this Article.
4. The power to adopt delegated acts referred to in paragraph 3 shall be conferred on the Commission for a period of two years from 22 November 2017.
5. The delegation of power referred to in paragraph 3 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
6. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
7. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
8. A delegated act adopted pursuant to paragraph 3 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 4

Entry into force

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

*Article 5***Addressees**

This Directive is addressed to the Member States in accordance with the Treaties.

Done at Strasbourg, 15 November 2017.

For the European Parliament

The President

A. TAJANI

For the Council

The President

M. MAASIKAS

ANNEX

‘ANNEX

List of substances referred to in point (b) of point 1 of Article 1

1. P-Methylthioamphetamine or 4-Methylthioamphetamine, as referred to in Council Decision 1999/615/JHA ⁽¹⁾.
2. Paramethoxymethylamphetamine or N-methyl-1-(4-methoxyphenyl)-2-aminopropane, as referred to in Council Decision 2002/188/JHA ⁽²⁾.
3. 2,5-dimethoxy-4-iodophenethylamine, 2,5-dimethoxy-4-ethylthiophenethylamine, 2,5-dimethoxy-4-(n)-propylthiophenethylamine and 2,4,5-trimethoxyamphetamine, as referred to in Council Decision 2003/847/JHA ⁽³⁾.
4. 1-benzylpiperazine or 1-benzyl-1,4-diazacyclohexane or N-benzylpiperazine or benzylpiperazine, as referred to in Council Decision 2008/206/JHA ⁽⁴⁾.
5. 4-methylmethcathinone, as referred to in Council Decision 2010/759/EU ⁽⁵⁾.
6. 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4'-DMAR) and 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45), as referred to in Council Implementing Decision (EU) 2015/1873 ⁽⁶⁾.
7. 4-methylamphetamine, as referred to in Council Implementing Decision (EU) 2015/1874 ⁽⁷⁾.
8. 4-iodo-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25I-NBOMe), 3,4-dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]benzamide (AH-7921), 3,4-methylenedioxypyrovalerone (MDPV) and 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone (methoxetamine), as referred to in Council Implementing Decision (EU) 2015/1875 ⁽⁸⁾.
9. 5-(2-aminopropyl)indole, as referred to in Council Implementing Decision (EU) 2015/1876 ⁽⁹⁾.
10. 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (α-pyrrolidinovalerophenone, α-PVP), as referred to in Council Implementing Decision (EU) 2016/1070 ⁽¹⁰⁾.
11. Methyl 2-[[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA), as referred to in Council Implementing Decision (EU) 2017/369 ⁽¹¹⁾.
12. N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryloylfentanyl), as referred to in Council Implementing Decision (EU) 2017/1774 ⁽¹²⁾.

⁽¹⁾ Council Decision 1999/615/JHA of 13 September 1999 defining 4-MTA as a new synthetic drug which is to be made subject to control measures and criminal penalties (OJ L 244, 16.9.1999, p. 1).

⁽²⁾ Council Decision 2002/188/JHA of 28 February 2002 concerning control measures and criminal sanctions in respect of the new synthetic drug PMMA (OJ L 63, 6.3.2002, p. 14).

⁽³⁾ Council Decision 2003/847/JHA of 27 November 2003 concerning control measures and criminal sanctions in respect of the new synthetic drugs 2C-I, 2C-T-2, 2C-T-7 and TMA-2 (OJ L 321, 6.12.2003, p. 64).

⁽⁴⁾ Council Decision 2008/206/JHA of 3 March 2008 on defining 1-benzylpiperazine (BZP) as a new psychoactive substance which is to be made subject to control measures and criminal provisions (OJ L 63, 7.3.2008, p. 45).

⁽⁵⁾ Council Decision 2010/759/EU of 2 December 2010 on submitting 4-methylmethcathinone (mephedrone) to control measures (OJ L 322, 8.12.2010, p. 44).

⁽⁶⁾ Council Implementing Decision (EU) 2015/1873 of 8 October 2015 on subjecting 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4'-DMAR) and 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45) to control measures (OJ L 275, 20.10.2015, p. 32).

⁽⁷⁾ Council Implementing Decision (EU) 2015/1874 of 8 October 2015 on subjecting 4-methylamphetamine to control measures (OJ L 275, 20.10.2015, p. 35).

⁽⁸⁾ Council Implementing Decision (EU) 2015/1875 of 8 October 2015 on subjecting 4-iodo-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25I-NBOMe), 3,4-dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]benzamide (AH-7921), 3,4-methylenedioxypyrovalerone (MDPV) and 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone (methoxetamine) to control measures (OJ L 275, 20.10.2015, p. 38).

⁽⁹⁾ Council Implementing Decision (EU) 2015/1876 of 8 October 2015 on subjecting 5-(2-aminopropyl)indole to control measures (OJ L 275, 20.10.2015, p. 43).

⁽¹⁰⁾ Council Implementing Decision (EU) 2016/1070 of 27 June 2016 on subjecting 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (α-pyrrolidinovalerophenone, α-PVP) to control measures (OJ L 178, 2.7.2016, p. 18).

⁽¹¹⁾ Council Implementing Decision (EU) 2017/369 of 27 February 2017 on subjecting methyl 2-[[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) to control measures (OJ L 56, 3.3.2017, p. 210).

⁽¹²⁾ Council Implementing Decision (EU) 2017/1774 of 25 September 2017 on subjecting N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryloylfentanyl) to control measures (OJ L 251, 29.9.2017, p. 21).

