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#### **LEGISLATIVE ACTS AND OTHER INSTRUMENTS**

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Subject: Position of the Council at first reading with a view to the adoption of a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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  
- Adopted by the Council on 25 September 2017

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

of ...

**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<sup>1</sup>,

Acting in accordance with the ordinary legislative procedure<sup>2</sup>,

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<sup>1</sup> OJ C 177, 11.6.2014, p. 52.

<sup>2</sup> Position of the European Parliament of 17 April 2014 [(OJ ...)/(not yet published in the Official Journal)] and position of the Council at first reading of 25 September 2017 [(OJ ...)/(not yet published in the Official Journal)]. Position of the European Parliament of ... [(OJ ...)/(not yet published in the Official Journal)].

Whereas:

- (1) Council Framework Decision 2004/757/JHA<sup>1</sup> 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<sup>2</sup>, which pose public health risks comparable to those posed by the substances scheduled under the UN Conventions.

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<sup>1</sup> 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).

<sup>2</sup> 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).

- (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<sup>1</sup>, 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) .../... of the European Parliament and of the Council<sup>2+</sup> 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.

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<sup>1</sup> 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).

<sup>2</sup> Regulation (EU) .../... of the European Parliament and of the Council of ...amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for new psychoactive substances (OJ L ...).

<sup>+</sup> OJ: please insert the number of the Regulation, contained in document PE 26/2017 (2016/0261(COD)), in the text and complete the footnote.

- (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<sup>1</sup>. 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.

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<sup>1</sup> OJ L 123, 12.5.2016, p. 1.

- (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) .../...<sup>+</sup>, 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.

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<sup>+</sup> OJ: please insert the number of the Regulation, contained in document PE 26/2017 (2016/0261(COD)).

- (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.
- (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.

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\* 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 ... [date of entry into force of this Directive]. 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.

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\* 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 ... [twelve months after entry into force of this Directive]. 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 ... [twelve months after entry into force of this Directive].
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 ... [twelve months after entry into force of this Directive].
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 ... [date of entry into force of this Directive].
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 ...,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

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## 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<sup>1</sup>.
2. Paramethoxymethylamphetamine or N-methyl-1-(4-methoxyphenyl)-2-aminopropane, as referred to in Council Decision 2002/188/JHA<sup>2</sup>.
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<sup>3</sup>.
4. 1-benzylpiperazine or 1-benzyl-1,4-diazacyclohexane or N-benzylpiperazine or benzylpiperazine, as referred to in Council Decision 2008/206/JHA<sup>4</sup>.

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<sup>1</sup> 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).

<sup>2</sup> 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).

<sup>3</sup> 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).

<sup>4</sup> 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. 4-methylmethcathinone, as referred to in Council Decision 2010/759/EU<sup>1</sup>.
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<sup>2</sup>.
7. 4-methylamphetamine, as referred to in Council Implementing Decision (EU) 2015/1874<sup>3</sup>.
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-methylenedioxypropylvalerone (MDPV) and 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone (methoxetamine), as referred to in Council Implementing Decision (EU) 2015/1875<sup>4</sup>.
9. 5-(2-aminopropyl)indole, as referred to in Council Implementing Decision (EU) 2015/1876<sup>5</sup>.

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<sup>1</sup> 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).

<sup>2</sup> 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).

<sup>3</sup> 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).

<sup>4</sup> 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-methylenedioxypropylvalerone (MDPV) and 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone (methoxetamine) to control measures (OJ L 275, 20.10.2015, p. 38).

<sup>5</sup> 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. 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one ( $\alpha$ -pyrrolidinovalerophenone,  $\alpha$ -PVP), as referred to in Council Implementing Decision (EU) 2016/1070<sup>1</sup>.
  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<sup>2</sup>.
  12. N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryloylfentanyl), as referred to in Council Implementing Decision (EU) .../...<sup>3+</sup>.
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<sup>1</sup> Council Implementing Decision (EU) 2016/1070 of 27 June 2016 on subjecting 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one ( $\alpha$ -pyrrolidinovalerophenone,  $\alpha$ -PVP) to control measures (OJ L 178, 2.7. 2016, p. 18).

<sup>2</sup> 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).

<sup>3</sup> Council Implementing Decision (EU) .../... of ... on subjecting N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryloylfentanyl) to control measures (OJ L ...).

<sup>+</sup> OJ: please insert the number of the Decision, contained in document st8858/17, in the text and complete the footnote.