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Subject:	Proposal for a Directive of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug

Delegations will find below the above-mentioned text, representing the compromise reached at the last trilogue on new psychoactive substances legislation held on 29 May 2017.

Proposal for a

DIRECTIVE (EU) .../...

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,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Council Framework Decision 2004/757/JHA¹ provides 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, and to the legal economy, stability and security of the Member States. It sets out minimum common rules on the definition of drug trafficking offences and sanctions, to avoid that problems may arise in 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 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 the 1971 United Nations Convention on Psychotropic Substances ('UN Conventions'), as well as to the synthetic drugs subjected to control across the Union pursuant to Joint Action 97/396/JHA², 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/JHA³, which pose public health risks comparable to those posed by the substances scheduled under the UN Conventions.

¹ 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 Joint Action 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 (97/396/JHA) (OJ L 167, 25.6.1997, p. 1).

³ 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).

- (4) New psychoactive substances, which imitate the effects of substances scheduled under the UN Conventions, are emerging frequently and are spreading fast in the Union. Certain new psychoactive substances pose severe public health, and social risks. Regulation (EU) No .../... of the European Parliament and of the Council ⁴⁺ provides the framework for exchange of information on new psychoactive substances and for risk evaluation procedure based on initial report and risk assessment report drawn up to estimate if 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 and, where applicable, social risks, and to deter trafficking in those substances across the Union, as well as the involvement of criminal organisations, these substances should be included in the definition of drug in line with the provisions of this Directive and underpinned by proportionate criminal law provisions.
- (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 the Framework Decision 2004/757/JHA should, therefore, be amended.

⁴ Regulation (EU) .../... of the European Parliament and of the Council of ...amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances (OJ L ...).

⁺ *OJ: please insert the number of the Regulation of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances 2016/0261 (COD) in the text and complete the footnote.*

- (5a) The essential elements of the definition of drug as well as the procedure and the criteria for inclusion of new psychoactive substances into that definition should be laid down in this Directive. Furthermore an Annex should be added to Framework Decision 2004/757/JHA, containing a list of new psychoactive substances already subjected to control measures by Council decisions adopted in accordance with Article 5(1) of Joint Action 97/396/JHA and Article 8(3) of Decision 2005/387/JHA and thereby including them in the definition of drug. 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 should be delegated to the Commission in order to amend 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-Making⁵. 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.

- (6) In order to swiftly address the emergence and spread of harmful new psychoactive substances in the Union, Member States should apply the provisions of the Framework Decision 2004/757/JHA to new psychoactive substances posing severe public health and, where applicable, social risks as soon as possible but no later than six months from the entry into force of the delegated act including them in the definition of drug. Member States should undertake every effort to shorten that deadline to the extent possible.

⁵ OJ L 123, 12.5.2016, p. 1.

- (7) 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 and, where applicable, social risks, cannot be sufficiently achieved by the Member States acting alone, but can rather 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 Directive does not go beyond what is necessary in order to achieve that objective.
- (8) This Directive respects the fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, and notably 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.
- (8a) As this Directive together with Regulation (EU) No .../...⁺ is designed to replace the mechanism established by Decision 2005/387/JHA, that Decision should be repealed.
- (9) 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 Treaty on European Union and to the Treaty on the Functioning of the European Union, Ireland has notified its wish to take part in the adoption and application of this Directive.

⁺ *OJ: please insert the number of the Regulation of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances 2016/0261 (COD).*

- (10) 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 Treaty on European Union and to the Treaty on the Functioning of the European Union, 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 or subject to its application.
- (11) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark is not taking part in the adoption of this Directive and is not bound by it or subject to its application.
- (12) 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) paragraph 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 the 1971 United Nations Convention on Psychotropic Substances;
- (b) any of the substances listed in the Annex.";

(b) the following paragraphs 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, nor by the 1971 United Nations Convention on Psychotropic Substances but may pose similar health or social risks;
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, the Commission shall, without undue delay, adopt a delegated act in accordance with Article 8a amending the Annex to this Framework Decision by adding the new psychoactive substance to it and providing that the new psychoactive substance(s) pose(s) severe public health and, where applicable, social risks at the Union level and that it should be included in the definition of drug referred to in Article 1 (1) of this Framework Decision.
2. When considering whether to adopt a delegated act referred to in paragraph 1, the Commission shall take into account whether the extent of use or patterns of use of the new psychoactive substance, its availability and potential for distribution 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, a significant spread of diseases, including 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, 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 other persons or to property; or whether the criminal activities, including organised crime, associated with the new psychoactive substance are systematic, illicit profits, or economic costs are significant.

3. If, within six weeks from the date of receipt of the risk assessment or combined risk assessment report carried out pursuant to Article 5c of Regulation (EC) No 1920/2006, the Commission deems it not necessary to adopt a delegated act to include the new psychoactive substance(s) in the definition of drug, it shall present a report to the Council and the Parliament explaining the reasons for not doing so.

4. [...]

5. In respect of 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 entry into force of the delegated act amending the Annex.

They shall immediately communicate to the Commission the text of those provisions. When Member States adopt those provisions, they shall contain a reference to this Framework Decision or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 1b

National control measures

Without prejudice to the obligations of the Member States referred to in this Framework Decision, Member States may maintain or introduce on their territories, with regard to new psychoactive substances, any national control measures that they deem 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)."

"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."

(3) 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 communicate the text of those measures to the Commission.

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. Member States shall determine how such reference is to be made.

* OJ L 123, 12.5.2016, p. 1.

Article 2a

Repeal of Decision 2005/387/JHA

Decision 2005/387/JHA is repealed with effect from ... [*the same day as the day for transposition of Directive (EU) .../ ... [amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provision on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking]*], 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 references to this Directive.

Article 3

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 4

Addressees

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

Done at ..., ...

For the European Parliament

For the Council

The President

The President

List of substances referred to in point (3) of Article 8a

- (a) P-Methylthioamphetamine or 4-Methylthioamphetamine, as referred to in 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 penalties⁶.
- (b) Paramethoxymethylamphetamine or N-methyl-1-(4-methoxyphenyl)-2-aminopropane, as referred to in Council Decision 2002/188/JHA of 28 February 2002 concerning control measures and criminal sanctions in respect of the new synthetic drug PMMA⁷.
- (c) 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 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-2⁸.
- (d) 1-benzylpiperazine or 1-benzyl-1,4-diazacyclohexane or N-benzylpiperazine or benzylpiperazine as referred to in 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 provisions⁹.
- (e) 4-methylmethcathinone, as referred to in Council Decision 2010/759/EU of 2 December 2010 on submitting 4-methylmethcathinone (mephedrone) to control measures¹⁰.
- (f) 4-methylamphetamine, as referred to in Council Implementing Decision (EU) 2015/1874 on subjecting 4-methylamphetamine to control measures¹¹.

⁶ OJ L 244, 16.9.1999, p.1.

⁷ OJ L 063, 6.3.2002, p. 14.

⁸ OJ L 321, 6.12.2003, p. 64.

⁹ OJ L 63, 7.3.2008, p. 45.

¹⁰ OJ L 322, 8.12.2010, p. 44.

¹¹ OJ L [...], [...], p. [...]

- (g) 5-(2-aminopropyl)indole, as referred to in Council Implementing Decision Council Implementing Decision (EU) 2015/1876 on subjecting 5-(2-aminopropyl)indole to control measures¹².
- (h) 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 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 (2014/688/EU)¹³.
- (i) 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 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 measures¹⁴.
- (j) 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (α -pyrrolidinovalerophenone, α -PVP), as referred to in 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 measures¹⁵.

¹² OJ L [...], [...], p. [...]

¹³ OJ L [...], [...], p. [...]

¹⁴ OJ L 275, 20.10.2015, p. 32.

¹⁵ OJ L 178, 2.7. 2016, p. 18.

- (k) Methyl 2-[[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA), as referred to in 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 measures¹⁶.
- (l) N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryloylfentanyl), as referred to in Council Implementing Decision (EU) [...] of [...] on subjecting N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryloylfentanyl) to control measures¹⁷.
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¹⁶ OJ L 56, 3.3.2017, p. 210.

¹⁷ OJ L [...], [...], p. [...]