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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Delegations will find attached document C(2018) 8460 final.

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Brussels, 13.12.2018
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COMMISSION DELEGATED DIRECTIVE (EU) .../...

of 13.12.2018

**amending the Annex to Council Framework Decision 2004/757/JHA as regards the
inclusion of new psychoactive substances in the definition of 'drug'**

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

In 2017, the European Union adopted a legislative package to enable the Union to react to the resurgence of new psychoactive substances (NPS) in a more effective and efficient way. The legislative package consists of the two following acts:

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 substances¹, and

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/JHA² ("the Directive").

The new rules entered into force on 22 November 2017 and became applicable on 23 November 2018, i.e. 12 months after the entry into force of the package.

The Directive amends Framework Decision 2004/757/JHA³ ("the Framework Decision"), which lays down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking. It also repeals Council Decision 2005/387/JHA⁴, which was the legal basis for the information exchange, risk assessment and control of new psychoactive substances. This procedure is now largely covered by Regulation (EC) No 1920/2006⁵ as amended by Regulation (EU) 2017/2101.

The Framework Decision as amended by the Directive defines 'drug' as a substance covered by the applicable UN Conventions as well as "any of the substances listed in the Annex" (see Article 1(1) of the amended Framework Decision).

The Directive lists in an Annex all the new psychoactive substances which were subjected to control measures and criminal penalties pursuant to Council Decision 2005/387/JHA before the adoption of the legislative package. This Annex became the Annex to the amended Framework Decision.

Since the day of adoption of the Directive, five new psychoactive substances have been subjected to control measures by Council Implementing Decisions adopted pursuant to Council Decision 2005/387/JHA (see Article 3(2) of the Directive). These substances are furanylfentanyl⁶, ADB-CHMINACA⁷, CUMYL-4CN-BINACA⁸, cyclopropylfentanyl and

¹ OJ L 305, 21.11.2017, p. 1.

² OJ L 305, 21.11.2017, p. 12.

³ OJ L 335, 11.11.2004, p. 8.

⁴ OJ L 127, 20.5.2005, p. 32.

⁵ OJ L 376, 27.12.2006, p. 1.

⁶ Adoption also on 15 November 2017; however, as the adoption was on the same day as the adoption of the Directive, the substance could not have been taken into account in the list in the annex anymore; see Council Implementing Decision (EU) 2017/2170, OJ L 306, 22.11.2017, p. 19.

⁷ Adoption on 14 May 2018; see Council Implementing Decision (EU) 2018/747, OJ L 125, 22.5.2018, p. 8.

methoxyacetylfentanyl⁹. They have to be added to the Annex of the Framework Decision in order to be included in the definition of drugs in line with the amended Framework Decision.

In order to be able to add to the Annex new psychoactive substances which have been subjected to control measures in the transitional period, i.e. between the entry into force of the new legislation and its full application, Article 3 of the Directive provides for transitional provisions. Its paragraph 3 reads: "*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*".

Therefore, the Commission needs to adopt a Delegated Directive amending the Annex of Framework Decision 2004/757/JHA in order to include the new psychoactive substances referred to above in the definition of 'drug'.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In line with paragraph 4 of the Common Understanding on Delegated Acts between the European Parliament, the Council and the European Commission, annexed to the Interinstitutional Agreement on better law-making of 19 April 2016¹⁰, appropriate and transparent consultations, including at expert level, have been carried out in the preparation of this delegated act. The relevant documents have been transmitted in a timely and appropriate manner to the European Parliament and to the Council.

The Group of Experts on New Psychoactive Substances was consulted in the meeting held on 16 October 2018.

As the substantive decision about the subjecting of the five new psychoactive substances to control measures at EU level has already been taken through the applicable Council Implementing Decisions, as the insertion of the substances in the Annex of the Directive is a mere administrative necessity, and as Article 3(3) of Directive (EU) 2017/2103 does not provide for any discretion, the proposal was not published for feedback from the public.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 3 of Directive (EU) 2017/2103 provides for provisions in order to cover the transitional period between the adoption of the Directive (15 November 2017) and it becoming fully effective (23 November 2018). A delegated act is needed to add the substances subjected to control measures at EU level during this transitional period to the list in the Annex to Framework Decision 2004/757/JHA.

⁸ Adoption on 14 May 2018; see Council Implementing Decision (EU) 2018/748, OJ L 125, 22.5.2018, p. 10.

⁹ Adoption on 28 September 2018; see Council Implementing Decision (EU) 2018/1463, OJ L 245, 01.10.2018, p. 9.

¹⁰ OJ L 123, 12.5.2016, p. 1.

COMMISSION DELEGATED DIRECTIVE (EU) .../...

of 13.12.2018

amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of new psychoactive substances in the definition of 'drug'

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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/JHA¹¹, and in particular Article 3(3) thereof,

Whereas:

- (1) The Annex to Council Framework Decision 2004/757/JHA¹² contains a list of substances which fall under the definition of drug under point 1(b) of Article 1 of that Framework Decision.
- (2) The Annex to Framework Decision 2004/757/JHA was added by Directive (EU) 2017/2103. It lists all the new psychoactive substances, which were subjected to control measures and criminal penalties pursuant to Council Decision 2005/387/JHA¹³ before the adoption of Directive (EU) 2017/2103.
- (3) Directive (EU) 2017/2103 repealed Decision 2005/387/JHA with effect from 23 November 2018. From the adoption of Directive (EU) 2017/2103 until 23 November 2018, five new psychoactive substances were subjected to control measures and criminal penalties under Decision 2005/387/JHA. However, those new psychoactive substances are not yet included into the Annex to Framework Decision 2004/757/JHA.
- (4) Therefore, due to the repeal of Decision 2005/387/JHA, the following new psychoactive substances should be included in the Annex to Framework Decision 2004/757/JHA:

¹¹ OJ L 305, 21.11.2017, p. 12.

¹² 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).

¹³ 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).

- (a) *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl) subjected to control measures by Council Implementing Decision (EU) 2017/2170¹⁴;
 - (b) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (ADB-CHMINACA) subjected to control measures by Council Implementing Decision (EU) 2018/747¹⁵;
 - (c) 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (CUMYL-4CN-BINACA) subjected to control measures by Council Implementing Decision (EU) 2018/748¹⁶;
 - (d) *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl) and 2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl) subjected to control measures by Council Implementing Decision (EU) 2018/1463¹⁷.
- (5) Ireland is bound by Directive (EU) 2017/2103 and is therefore taking part in the adoption and application of this delegated directive.
- (6) The United Kingdom is not bound by Directive (EU) 2017/2103 and is therefore not taking part in the adoption and application of this delegated directive and is not bound by it or subject to its application.
- (7) Denmark is not bound by Directive (EU) 2017/2103 and is therefore not taking part in the adoption and application of this delegated directive and is not bound by it or subject to its application.
- (8) Framework Decision 2004/757/JHA should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Amendment to Framework Decision 2004/757/JHA

The following is added to the list in the Annex to Framework Decision 2004/757/JHA:

¹⁴ Council Implementing Decision (EU) 2017/2170 of 15 November 2017 on subjecting *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl) to control measures (OJ L 306, 22.11.2017, p. 19).

¹⁵ Council Implementing Decision (EU) 2018/747 of 14 May 2018 on subjecting the new psychoactive substance *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (ADB-CHMINACA) to control measures (OJ L 125, 22.5.2018, p. 8).

¹⁶ Council Implementing Decision (EU) 2018/748 of 14 May 2018 on subjecting the new psychoactive substance 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (CUMYL-4CN-BINACA) to control measures (OJ L 125, 22.5.2018, p. 10).

¹⁷ Council Implementing Decision (EU) 2018/1463 of 28 September 2018 on subjecting the new psychoactive substances *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl) and 2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl) to control measures (OJ L 245, 1.10.2018, p. 9).

„13. *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl), as referred to in Council Implementing Decision (EU) 2017/2170*.

14. *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (ADB-CHMINACA), as referred to in Council Implementing Decision (EU) 2018/747**.

15. 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (CUMYL-4CN-BINACA), as referred to in Council Implementing Decision (EU) 2018/748***

16. *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl) and 2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl), as referred to in Council Implementing Decision (EU) 2018/1463****.

* Council Implementing Decision (EU) 2017/2170 of 15 November 2017 on subjecting *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl) to control measures (OJ L 306, 22.11.2017, p. 19).

** Council Implementing Decision (EU) 2018/747 of 14 May 2018 on subjecting the new psychoactive substance *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (ADB-CHMINACA) to control measures (OJ L 125, 22.5.2018, p. 8).

*** Council Implementing Decision (EU) 2018/748 of 14 May 2018 on subjecting the new psychoactive substance 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (CUMYL-4CN-BINACA) to control measures (OJ L 125, 22.5.2018, p. 10).

**** Council Implementing Decision (EU) 2018/1463 of 28 September 2018 on subjecting the new psychoactive substances *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl) and 2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl) to control measures (OJ L 245, 1.10.2018, p. 9).“.

Article 2

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by at the latest. However, they shall bring into force the laws, regulations and administrative provisions necessary to comply with point 16 of the Annex to Framework Decision 2004/757/JHA referred to in Article 1 of this Directive by 29 September 2019. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, 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.

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

Article 3

Entry into force

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 in accordance with the Treaties.

Done at Brussels, 13.12.2018

For the Commission
The President
Jean-Claude JUNCKER