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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION DELEGATED DIRECTIVE (EU) .../… of 18.3.2022 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of new psychoactive substances in the definition of 'drug'

Delegations will find attached document C(2022) 1552 final.

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EUROPEAN
COMMISSION

Brussels, 18.3.2022
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COMMISSION DELEGATED DIRECTIVE (EU) .../…

of 18.3.2022

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

Council Framework Decision 2004/757/JHA laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking[1] and Regulation (EC) 1920/2006 on the European Monitoring Centre for Drugs and Drug Addiction[2] provide for a three-step procedure that may lead to the inclusion of a new psychoactive substance in the definition of 'drug' and thereby covering it by the Union criminal law provisions on illicit drug trafficking.

On 18 October 2021, two initial reports of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) drawn up in accordance with Article 5b of Regulation (EC) 1920/2006 were issued. On 27 October 2021, the European Commission requested in accordance with Article 5c (1) of Regulation (EC) 1920/2006 assessments of the risks posed by the new psychoactive substances 2-(methylamino)-1-(3-methylphenyl)propan-1-one (3-methylmethcathinone, 3-MMC) and 1-(3-chlorophenyl)-2-(methylamino)propan-1-one (3-chloromethcathinone, 3-CMC).

The risks of 3-MMC and 3-CMC were assessed by the Extended Scientific Committee of the EMCDDA, acting in compliance with the provisions of Article 5c of Regulation (EC) 1920/2006. The risk assessment reports were submitted to the Commission and to the Member States on 25 November 2021 in line with the deadline set out in Article 5c(6) of Regulation (EC) 1920/2006.

The main results of the risk assessments are the following:

- 3-MMC is a synthetic cathinone with psychostimulant effects. It is a derivative of cathinone, and closely related to and shares similar psychostimulant effects with methcathinone (ephedrone) and mephedrone (4-methylmethcathinone; 4-MMC). Cathinone, methcathinone, and mephedrone are controlled under the 1971 United Nations Convention on Psychotropic Substances.

- 3-MMC has been available in the European Union since at least 2012 and has been detected in 23 Member States. A total of 27 deaths with confirmed exposure to 3-MMC have been reported by five Member States. Fourteen acute non-fatal poisonings with confirmed exposeure to 3-MMC have also been reported by four Member States.

- 3-CMC is a synthetic cathinone with psychostimulant effects. It is a derivative of cathinone, and closely related to and shares similar psychostimulant effects with methcathinone and 4-chloromethcathinone (4-CMC; clephedrone). Cathinone, methcathinone, and 4-CMC are controlled under the 1971 United Nations Convention on Psychotropic Substances.

- 3-CMC has been available in the European Union since at least 2014 and has been detected in 23 Member States. A total of 10 deaths with confirmed exposure to 3-

[1] OJ L 335, 11.11.2004, p. 8.
[2] OJ L 376, 27.12.2006, p. 1.

CMC have been reported by two Member States. One acute non-fatal poisoning with confirmed exposeure to 3-CMC has also been reported by one Member State.

- Information from law enforcement seizures that took place in 2020 and 2021 indicates that its availability and potential for diffusion within the Union of both 3-MMC and of 3-CMC has recently increased and may be significant.

Pursuant to Article 1a of Council Framework Decision 2004/757/JHA, the Commission shall, without undue delay and in accordance with the criteria set out in paragraph 2 of this Article, adopt a delegated act in accordance with Article 8a amending the Annex to the Framework Decision in order to add the new psychoactive substances to it and thereby including them in the definiton of 'drug'. If within six weeks from the submission of a risk assessment report, the Commission considers that it is not necessary to adopt a delegated act to include the new psychoactive substance in the definition of 'drug', it shall report to the European Parliament and the Council explaining the reasons for not doing so.

Based on the findings of the risk assessment reports, the Commission considers that there are grounds for including 3-MMC and 3-CMC in the definition of 'drug'. According to the risk assessment reports, it can be concluded that 3-MMC and 3-CMC pose severe public health risks at Union level.

The objective of this draft delegated act is therefore to adopt a Delegated Directive in order to add 3-MMC and 3-CMC to the Annex of Council Framework Decision 2004/757/JHA, thereby covering them by provisions on the criminal offences and sanctions as defined in the Framework Decision.

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 2016[3], appropriate and transparent consultations, including at expert level, have been carried out in the preparation of this delegated act.

The Group of Experts on New Psychoactive Substances was consulted in written form between 04 and 19 January 2022.

As the decision about including 3-MMC and 3-CMC in the definition of 'drug' is based on the risk assessment reports of the Scientific Committee of the EMCDDA, the insertion of the substances in the Annex to the Framework Decision is a technical act and the Commission therefore has limited discretion, the draft delegated act was not published for feedback from the public.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 1a of Council Framework Decision 2004/757/JHA provides for a delegated act to add substances to the Annex to Framework Decision 2004/757/JHA. The exercise of the delegation is governed by Article 8a of Council Framework Decision 2004/757/JHA.

[3] OJ L 123, 12.5.2016, p. 1.

COMMISSION DELEGATED DIRECTIVE (EU) .../…

of 18.3.2022

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 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[1], and in particular Articles 1a and 8a thereof,

Whereas:

(1) Risk assessment reports on the new psychoactive substances 2-(methylamino)-1-(3-methylphenyl)propan-1-one (3-methylmethcathinone, 3-MMC) and 1-(3-chlorophenyl)-2-(methylamino)propan-1-one (3-chloromethcathinone, 3-CMC) were drawn up in compliance with Article 5c of Regulation (EC) 1920/2006 of the European Parliament and of the Council[2] by the Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA; the Centre), extended following the procedure laid down in Article 5c(4) of the same Regulation, on 18 and 19 November 2021. The Centre submitted the risk assessment reports to the Commission and to the Member States on 25 November 2021.

(2) 3-MMC and 3-CMC are synthetic cathinones with psychostimulant effects. They are derivatives of cathinone, and closely related to and sharing similar psychostimulant effects with methcathinone (ephedrone) and mephedrone (4-methylmethcathinone; 4-MMC) and, respectively, with methcathinone and 4-chloromethcathinone (4-CMC; clephedrone). Cathinone, methcathinone, mephedrone, and 4-CMC are controlled under the 1971 United Nations Convention on Psychotropic Substances.

(3) 3-MMC has been available in the European Union since at least 2012 and has been detected in 23 Member States. After a decline in seizures in Europe between 2016 and 2018, 3-MMC appears to have re-emerged with approximately 740 kilograms of it in powder form seized in 2020 and with continued importation, distribution, and use in 2021, including a single large-scale seizure of just over 120 kilograms of powder at an external Union border.

(4) Information provided from seizures and collected samples show that 3-MMC is typically available on the drug market as a powder. Other physical forms, such as tablets and capsules, have also been reported, but to a much smaller extent.

[1] OJ L 335, 11.11.2004, p. 8.

[2] Regulation (EC) 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).

Occasionally liquids, herbal material, and blotters containing 3-MMC have also been reported.

(5) A total of 27 deaths with confirmed exposure to 3-MMC have been reported by five Member States. Fourteen acute non-fatal poisonings with confirmed exposeure to 3-MMC have also been reported by four Member States.

(6) 3-CMC has been available in the European Union since at least 2014 and has been detected in 23 Member States. During 2020 and 2021, approximately 2500 kilograms of 3-CMC in powder form was seized, representing over 90% of the total quantity of 3-CMC powders seized since monitoring of the substance began in Europe.

(7) Information provided from seizures and collected samples show that 3-CMC is typically available on the drug market as a powder. Other physical forms, such as tablets and capsules, have also been reported, but to a much smaller extent. Occasionally liquids, herbal material, and blotters containing 3-CMC have also been reported.

(8) A total of 10 deaths with confirmed exposure to 3-CMC have been reported by two Member States. One acute non-fatal poisoning with confirmed exposeure to 3-CMC has also been reported by one Member State.

(9) The available information suggests that while 3-MMC and 3-CMC are typically sold and sought after as stimulant drugs in their own right, at least in part it appears that these substances are being manufactured, imported, distributed, sold, and used as a 'legal' replacement to controlled stimulants, including amphetamine, cocaine, and MDMA. In addition, it may also be missold as other drugs.

(10) There is limited information on the involvement of organised crime in the manufacture, trafficking, and distribution of 3-MMC and of 3-CMC within the Union. However, there is information to suggest criminal acts, such as trafficking, illicit production, and supply offences, involving both substances.

(11) The available information suggests that 3-MMC and 3-CMC are manufactured by chemical companies outside the Union and imported into it on an industrial-scale. In addition, limited information indicates that some production has taken place in illicit laboratories in Europe.

(12) 3-MMC and 3-CMC have no recognised human or veterinary medical use in the Union nor, it appears, elsewhere. There are no indications that the substances may be used for any other purpose aside from as an analytical reference standard and in scientific research.

(13) The health and social risks associated with 3-MMC and 3-CMC are likely to share some similarities with other closely related synthetic cathinones and psychostimulants under international control. The available evidence and information on the health and social risks that the substances pose provide sufficient ground for including 3-MMC and 3-CMC in the definition of 'drug'. Nevertheless, the risk assessment reports reveal also that many of the questions related to 3-MMC and 3-CMC that are posed by the lack of data on the risks to individual health, risks to public health and social risks could be answered through further research.

(14) 3-MMC and 3-CMC are not listed for control under the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or under the 1971 United Nations Convention on Psychotropic Substances. 3-CMC has not yet been assessed under the United Nations system whereas 3-MMC has been subject to a non-conclusive critical review by the WHO Expert Committee on Drug Dependence in November 2016. The Committee was unable to reach consensus, and instead it deferred an opinion, and requested the Secretariat to arrange another critical review of 3- MMC at a subsequent meeting of the Expert Committee. A further ECDD review of 3-MMC has not taken place yet. Since this critical review in 2016, significant new information has been reported by the Member States that suggests that 3-MMC might pose health and social threats at Union level and thus needs to be added in the definition of 'drug' in Union law.

(15) Information from law enforcement seizures that took place in 2020 and 2021 indicates that its availability and potential for diffusion within the Union of both 3-MMC and of 3-CMC has recently increased and may be significant. The available information would suggest that the consumption of 3-MMC and of 3-CMC causes harm to health associated with their acute toxicity and, in the case of 3-MMC, its abuse liability or dependence producing potential. Due to lack of studies, there is uncertainty on the dependence potential and abuse liability of 3-CMC. This harm to health is considered life-threatening because it may cause death or lethal injury, severe disease, severe physical or mental impairment or a spread of diseases, including the transmission of blood-borne viruses, such as hepatitis C and HIV. These effects are comparable with other closely related synthetic cathinones and psychostimulants under international control, although this requires further study.

(16) The available information would also suggest that the consumption of 3-MMC and of 3-CMC could cause social risks and may result in marginalisation and increased vulnerability. Moreover, it also has a potential for a wider risk to public safety, notably in case of driving under the influence of these substances.

(17) Fifteen Member States control 3-MMC under national drug control legislation, six Member States control it under new psychoactive substances legislation and one Member State controls it under other legislation. Thirteen Member States control 3-CMC under national drug control legislation, seven Member States control it under new psychoactive substances legislation and one Member State controls it under other legislation. Given that these national control measures are already in place, including 3-MMC and 3-CMC in the definition of 'drug' and thereby covering them by provisions on the criminal offences and sanctions as defined in Framework Decision 2004/757/JHA would help avoiding the emergence of obstacles in cross-border law enforcement and judicial cooperation, and would help protecting from the risks that their availability and use can pose.

(18) Article 1a of Framework Decision 2004/757/JHA confers the power to adopt delegated acts upon the Commission with a view to giving a quick and expertise-based response at Union level to the emergence of new psychoactive substances detected and reported by the Member States, by amending the Annex to that Framework Decision to include those substances in the definition of 'drug'.

(19) As the conditions and procedure for triggering the exercise of the powers to adopt a delegated act have been met, a delegated directive should be adopted in order to include 3-MMC and 3-CMC in the Annex to Framework Decision 2004/757/JHA.

(20) Ireland is bound by Framework Decision 2004/757/JHA, as amended by Directive (EU) 2017/2103[3], and is therefore taking part in the adoption and application of this Directive.

(21) Denmark is bound by Framework Decision 2004/757/JHA as applicable until 21 November 2018, but is not bound by Directive (EU) 2017/2103. It is therefore not taking part in the adoption and application of this Directive and is not bound by it or subject to its application.

(22) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents[4], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1
Amendment to Framework Decision 2004/757/JHA

In the Annex to Framework Decision 2004/757/JHA, the following points 20 and 21 are added:

‘20. 2-(methylamino)-1-(3-methylphenyl)propan-1-one (3-MMC)*.

21. 1-(3-chlorophenyl)-2-(methylamino)propan-1-one (3-CMC) *.

* Commission Delegated Directive (EU) .../… of XXX amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of new psychoactive substances in the definition of 'drug' (OJ L xxx, xx.xx.2022, p. xx).’

Article 2
Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [6 months after the entry into force] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

[3] 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 (OJ L 305, 21.11.2017, p. 12).

[4] OJ C 369, 17.12.2011, p. 14.

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, 18.3.2022

For the Commission
The President
Ursula VON DER LEYEN