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# LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: COUNCIL DECISION on the position to be taken on behalf of the

European Union in the 67th session of the Commission on Narcotic Drugs on the scheduling of substances under the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the Convention on

Psychotropic Substances of 1971

## **COUNCIL DECISION (EU) 2024/...**

of ...

on the position to be taken on behalf of the European Union in the 67th session of the Commission on Narcotic Drugs on the scheduling of substances under the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 83(1), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

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#### Whereas:

- (1) The United Nations (UN) Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol (the 'Convention on Narcotic Drugs') entered into force on 8 August 1975.
- (2) Pursuant to Article 3 of the Convention on Narcotic Drugs, the Commission on Narcotic Drugs (CND) can decide to add substances to the Schedules of that Convention. It can make changes to the Schedules only in accordance with recommendations of the World Health Organisation (WHO), but it can also decide not to make changes recommended by the WHO.
- (3) The UN Convention on Psychotropic Substances of 1971 (the 'Convention on Psychotropic Substances') entered into force on 16 August 1976.
- (4) Pursuant to Article 2 of the Convention on Psychotropic Substances, the CND can decide to add substances to the Schedules of that Convention or to remove them, on the basis of recommendations of the WHO. The CND has broad discretionary powers to take into account economic, social, legal, administrative and other factors, but cannot act arbitrarily.

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- (5) Changes to the Schedules of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances have direct repercussions on the scope of application of Union law in the area of drug control. Council Framework Decision 2004/757/JHA¹ applies to substances listed in the Schedules of those Conventions. Thus, any change to the Schedules of those Conventions is directly incorporated into common Union rules.
- (6) The CND is to decide, during its 67th session scheduled to take place on 14 to 22 March 2024 in Vienna, on the addition of five new substances to the Schedules of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances.
- (7) The Union is not a party to the Convention on Narcotic Drugs or to the Convention on Psychotropic Substances. It has observer status with no voting rights in the CND, of which 13 Member States are members with the right to vote at its 67th session<sup>2</sup>. It is necessary for the Council to authorise those Member States to express the position of the Union on the scheduling of substances under those Conventions since such decisions on the addition of new substances to those Schedules fall under the competence of the Union.
- (8) The WHO has recommended the addition of one new substance to Schedule I of the Convention on Narcotic Drugs, three new substances to Schedule II of the Convention on Psychotropic Substances, and one new substance to Schedule IV of the Convention on Psychotropic Substances.

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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>&</sup>lt;sup>2</sup> Austria, Belgium, France, Finland, Hungary, Italy, Lithuania, Malta, Netherlands, Poland, Portugal, Slovenia, and Spain.

- (9) All substances reviewed by the WHO Expert Committee on Drug Dependence (ECDD) and recommended for scheduling by the WHO are monitored by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) as new psychoactive substances under the terms of Regulation (EC) No 1920/2006 of the European Parliament and of the Council<sup>3</sup>.
- (10) According to the assessment by the ECDD, bromazolam (IUPAC name: 8-bromo-1-methyl-6-phenyl-4*H*-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine) is a benzodiazepine with a relatively high potency. Bromazolam was previously reviewed by the ECDD at its 45th meeting and placed under surveillance. Bromazolam has no known therapeutic uses or marketing authorisations. There is sufficient evidence that bromazolam is being or is likely to be abused and may constitute a public health and social problem that warrants placing it under international control. Thus, the WHO recommends that bromazolam be placed in Schedule IV of the Convention on Psychotropic Substances.
- (11) Bromazolam has been detected in 19 Member States and is controlled in at least four Member States. Bromazolam is subject to monitoring by the EMCDDA. One case of acute poisoning with confirmed exposure to bromazolam has been reported by one Member State. An additional case of acute poisoning with suspected exposure to bromazolam has been reported by one Member State. A total of 15 deaths with confirmed exposure to bromazolam have been reported by five Member States.

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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).

- (12) Therefore, the position of the Union should be to add bromazolam to Schedule IV of the Convention on Psychotropic Substances.
- (13) According to the assessment by the ECDD, butonitazene (IUPAC name: 2-[(4-butoxyphenyl)methyl]-*N*,*N*-diethyl-5-nitro-1*H*-benzimidazole-1-ethanamine) is a benzimidazole-derived synthetic opioid ('nitazene') with a chemical structure and pharmacological action similar to those of drugs under Schedule I of the Convention on Narcotic Drugs. Butonitazene has not previously been reviewed by the ECDD. Butonitazene has no known therapeutic uses or marketing authorisations. There is sufficient evidence that butonitazene is being or is likely to be abused and may constitute a public health and social problem that warrants placing it under international control. Thus, the WHO recommends that butonitazene be placed in Schedule I of the Convention on Narcotic Drugs.
- (14) Butonitazene has been detected in seven Member States and is controlled in at least three Member States. Butonitazene is under intensive monitoring by the EMCDDA. One death with confirmed exposure to butonitazene has been reported by one Member State.
- (15) Therefore, the position of the Union should be to add butonitazene to Schedule I of the Convention on Narcotic Drugs.

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- According to the assessment by the ECDD, 3-chloromethcathinone (3-CMC; IUPAC (16)name: 1-(3-chlorophenyl)-2-(methylamino)propan-1-one) is a synthetic stimulant of the cathinone family. 3-CMC is an analogue to the drug methcathinone which is controlled under Schedule I of the Convention on Psychotropic Substances. 3-CMC is not currently under international control, but its isomer 4-CMC was placed under international control in 2020. 3-CMC has not previously been reviewed by the ECDD. 3-CMC has no known therapeutic uses or marketing authorisations. There is sufficient evidence that 3-CMC is being or is likely to be abused and may constitute a public health and social problem that warrants placing it under international control. Thus, the WHO recommends that 3-CMC be placed in Schedule II of the Convention on Psychotropic Substances.
- (17)The risks of 3-CMC have been assessed by the scientific committee of the EMCDDA and it has already been included in the definition of 'drug' under Framework Decision 2004/757/JHA by Commission Delegated Directive (EU) 2022/1326<sup>4</sup>. It is subject to monitoring by the EMCDDA. At the time of the risk assessment, in November 2021, 3-CMC had been detected in 23 Member States. A total of 10 deaths with confirmed exposure to 3-CMC had been reported by two Member States and one case of acute poisoning with confirmed exposure to 3-CMC had been reported by one Member State.
- (18)Therefore, the position of the Union should be to add 3-CMC to Schedule II of the Convention on Psychotropic Substances.

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<sup>4</sup> Commission Delegated Directive (EU) 2022/1326 of 18 March 2022 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 200, 29.7.2022, p. 148).

- (19) According to the assessment by the ECDD, dipentylone (IUPAC name:

  1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)pentan-1-one) is a synthetic stimulant of the cathinone family. It has a chemical structure and pharmacology similar to those of other synthetic cathinones of Schedule II of the Convention on Psychotropic Substances.

  Dipentylone has not previously been reviewed by the ECDD. Dipentylone has no known therapeutic uses or marketing authorisations. There is sufficient evidence that dipentylone is being or is likely to be abused and may constitute a public health and social problem that warrants placing it under international control. No approved medical use has been reported. Thus, the WHO recommends that dipentylone be placed in Schedule II of the Convention on Psychotropic Substances.
- (20) Dipentylone has been detected in 16 Member States and is controlled in at least four Member States. Dipentylone is subject to monitoring by the EMCDDA.
- (21) Therefore, the position of the Union should be to add dipentylone to Schedule II of the Convention on Psychotropic Substances.

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- According to the assessment by the ECDD, 2-fluorodeschloroketamine (2-FDCK; IUPAC name: 2-(2-fluorophenyl)-2-methylamino-cyclohexanone) is an arylcyclohexylamine that is chemically related to the dissociative anaesthetic ketamine. 2-FDCK has not previously been reviewed by the ECDD. 2-FDCK has no known therapeutic uses or marketing authorisations. There is sufficient evidence that 2-FDCK is being or is likely to be abused and may constitute a public health and social problem that warrants placing it under international control. Thus, the WHO recommends that 2-FDCK be placed in Schedule II of the Convention on Psychotropic Substances.
- 2-FDCK has been detected in 22 Member States and is controlled in at least five Member States. 2-FDCK is under intensive monitoring by the EMCDDA. Two deaths with confirmed exposure to 2-FDCK have been reported by two Member States. A total of 11 cases of acute poisoning with confirmed exposure to 2-FDCK have been reported by three Member States. One additional case of acute poisoning with suspected exposure to 2-FDCK has been reported by one Member State.
- (24) Therefore, the position of the Union should be to add 2-FDCK to Schedule II of the Convention on Psychotropic Substances.
- (25) It is appropriate to establish the position to be taken on behalf of the Union in the CND, as the decisions on scheduling as regards the five substances will directly influence the content of Union law, namely Framework Decision 2004/757/JHA.

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- The position of the Union is to be expressed by the Member States that are members of the (26)CND, acting jointly in the interest of the Union.
- (27) Denmark is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision.
- (28)Ireland is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision,

HAS ADOPTED THIS DECISION:

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### Article 1

The position to be taken on behalf of the Union by the Member States in the 67th session of the Commission on Narcotic Drugs taking place from 14 to 22 March 2024, as regards the adoption of decisions on the addition of substances to the Schedules of the United Nations Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the United Nations Convention on Psychotropic Substances of 1971, shall be in accordance with that set out in the Annex to this Decision.

### Article 2

The position referred to in Article 1 shall be expressed by the Member States that are members of the Commission on Narcotic Drugs, acting jointly in the interest of the Union.

#### Article 3

This Decision shall enter into force on the date of its adoption.

Done at ...,

For the Council
The President

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# **ANNEX**

Position to be taken by the Member States that are members of the Commission on Narcotic Drugs, acting jointly, in the interest of the Union, during the 67th session of the Commission on Narcotic Drugs from 14 to 22 March 2024 on the scheduling of substances:

- (1) Bromazolam is to be included in Schedule IV of the Convention on Psychotropic Substances.
- (2) Butonitazene is to be included in the Schedule I of the Convention on Narcotic Drugs.
- (3) 3-Chloromethcathinone (3-CMC) is to be included in Schedule II of the Convention on Psychotropic Substances.
- (4) Dipentylone is to be included in Schedule II of the Convention on Psychotropic Substances.
- (5) 2-Fluorodeschloroketamine (2-FDCK) is to be included in Schedule II of the Convention on Psychotropic Substances.

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