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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 66th 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) 2023/…

of …

on the position to be taken, on behalf of the European Union,
in the 66th 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,

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 may decide to add substances to the Schedules of that Convention. It can make changes in the Schedules only in accordance with the recommendations of the World Health Organisation ('WHO'), but it can also decide not to make the 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 Commission on Narcotic Drugs may decide to add substances to the Schedules of that Convention or to remove them, on the basis of the recommendations of the WHO. It has broad discretionary powers to take into account economic, social, legal, administrative and other factors, but may not act arbitrarily.

(5) Changes to the Schedules of the Convention on Narcotic Drugs and to the Convention on Psychotropic Substances have direct repercussions for the scope of application of Union law in the area of drug control. Council Framework Decision 2004/757/JHA[1] applies to substances listed in the Schedules of those Conventions. Thus, any change to the Schedules annexed to those Conventions is directly incorporated into common Union rules.

(6) During its 66th session, which is scheduled for 13 to 17 March 2023 in Vienna, the Commission on Narcotic Drugs is to decide on the addition of seven new substances to the Schedules of the Convention on Narcotic Drugs and of 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 an observer status with no voting rights in the Commission on Narcotic Drugs, of which 12 Member States are members with the right to vote in March 2023[2]. 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 as such decisions fall under the competence of the Union.

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[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] Austria, Belgium, France, Germany, Hungary, Italy, Lithuania, Netherlands, Poland, Slovenia, Spain, and Sweden.

(8) The WHO has recommended the addition of four new substances to Schedule I of the Convention on Narcotic Drugs, and the addition of three new substances to Schedule II of the Convention on Psychotropic Substances.

(9) All substances reviewed by the WHO Expert Committee on Drug Dependence ('the Expert Committee') 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[1].

(10) According to the assessment by the Expert Committee, ADB-BUTINACA (IUPAC name: *N*-[1-(aminocarbonyl)-2,2-dimethylpropyl]-1-butyl-1*H*-indazole-3-carboxamide) is an indazole-derived synthetic cannabinoid, the *S*-enantiomer being the active compound (CAS No.: 2682867-55-4). ADB-BUTINACA has no therapeutic uses and it has not received a medicinal product marketing authorisation. There is sufficient evidence that ADB-BUTINACA is being or is likely to be abused and that it may constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that ADB-BUTINACA is placed in Schedule II of the Convention on Psychotropic Substances.

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[1] 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).

(11) ADB-BUTINACA has been detected in 26 Member States and is controlled in at least five Member States. ADB-BUTINACA is subject to intensive monitoring by the EMCDDA. It has been the subject of a public-health alert issued by the Early Warning and Response System of the European Union ('EWRS'). ADB-BUTINACA is also mentioned in two additional public health-related alerts. It has been associated with serious adverse events, including 14 deaths reported by two Member States.

(12) Therefore, the position of the Union should be to add ADB-BUTINACA to Schedule II of the Convention on Psychotropic Substances.

(13) According to the assessment of the Expert Committee, protonitazene (IUPAC name: *N,N*-diethyl-5-nitro-2-[(4-propoxyphenyl)methyl]-1-*H*-benzimidazole-1-ethanamine) is a benzimidazole opioid. Protonitazene was first synthetized as an alternative to morphine but there is no approved therapeutic use of protonitazene. There is sufficient evidence that protonitazene is being or is likely to be abused and that it may constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that protonitazene be placed in Schedule I of the Convention on Narcotic Drugs.

(14) Protonitazene has been detected in two Member States and is controlled in at least three Member States. Protonitazene is subject to intensive monitoring by the EMCDDA. No information on serious adverse events involving protonitazene has been reported to the EMCDDA.

(15) Therefore, the position of the Union should be to add protonitazene to the Schedule I of the Convention on Narcotic Drugs.

(16) According to the assessment of the Expert Committee, etazene (IUPAC name: 2-[(4-ethoxyphenyl)methyl]-*N,N*-diethyl-1*H*-benzimidazole-1-ethanamine) is a benzimidazole-derived synthetic opioid with a chemical structure and pharmacological similar to drugs scheduled under Schedule I (under the Convention on Narcotic Drugs) such as clonitazene, etonitazene and isotonitazene. Etazene was studied for its analgesic properties but there is no known medical use of etazene. There is sufficient evidence that etazene is being or is likely to be abused and that it may constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that etazene be placed in Schedule I of the Convention on Narcotic Drugs.

(17) Etazene has been detected in eight Member States and is controlled in at least five Member States. Etazene is subject to intensive monitoring by the EMCDDA. It has been associated with serious adverse events, including four deaths, reported by two Member States.

(18) Therefore, the position of the Union should be to add etazene to the Schedule I of the Convention on Narcotic Drugs.

(19) According to the assessment of the Expert Committee, etonitazepyne (IUPAC name: 2-[(4-ethoxyphenyl)methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)-1*H*-benzoimidazole) is a benzimidazole-derived synthetic opioid with a chemical structure and pharmacological similar to drugs scheduled under Schedule I (under the Convention on Narcotic Drugs) such as etonitazene. Etonitazepyne was studied for its analgesic properties but there is no known medical use of etonitazepyne. There is sufficient evidence that etonitazepyne is being or is likely to be abused and that it may constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that etonitazepyne be placed in Schedule I of the Convention on Narcotic Drugs.

(20) Etonitazepyne has been detected in six Member States and is controlled in at least two Member States. Similar to other new opioids, etonitazepyne may be sold as a replacement to controlled opioids, and has been the subject of a public health-related alert issued by the EWRS. Etonitazepyne is subject to intensive monitoring by the EMCDDA. A death with confirmed exposure to etonitazepyne has been reported by one country.

(21) Therefore, the position of the Union should be to add etonitazepyne to the Schedule I of the Convention on Narcotic Drugs.

(22) According to the assessment of the Expert Committee, 2-methyl-AP-237 (IUPAC name: 1-{2-methyl-4-[(2E)-3-phenylprop-2-en-1-yl]piperazin-1-yl}butan-1-one) is a synthetic opioid typically classed as a 1-cinnamylpiperazine. There is no known therapeutic use for 2-methyl-AP-237, nor has it received a medicinal product marketing authorisation. There is sufficient evidence that 2-methyl-AP-237 is being or is likely to be abused and that it may constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that 2-methyl-AP-237 be placed in Schedule I of the Convention on Narcotic Drugs.

(23) 2-Methyl-AP-237 has been detected in six Member States and is controlled in at least four Member States. It has been associated with serious adverse events, including a death.

(24) Therefore, the position of the Union should be to add 2-methyl-AP-237 to the Schedule I of the Convention on Narcotic Drugs.

(25) According to the assessment of the Expert Committee, alpha-PiHP (α-PiHP, IUPAC name: 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one) is a synthetic cathinone. There is no known therapeutic use for alpha-PiHP, nor has it received a medicinal product marketing authorisation. There is sufficient evidence that alpha-PiHP is being or is likely to be abused and that it may constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that alpha-PiHP be placed in Schedule II of the Convention on Psychotropic Substances.

(26) Alpha-PiHP has been detected in 18 Member States and is controlled in at least seven Member States. Alpha-PiHP is mentioned in a public health-related alert issued by the EWRS. It has been associated with serious adverse events, including four deaths, reported by one Member State and detected in biological samples linked to serious adverse events, reported by four Member States.

(27) Therefore, the position of the Union should be to add alpha-PiHP to the Schedule II of the Convention on Psychotropic Substances.

(28) According to the assessment of the Expert Committee, 3-methylmethcathinone (3-MMC, IUPAC name: 2-(methylamino)-1-(3-methylphenyl)propan-1-one) is a synthetic cathinone and a positional isomer of the internationally controlled 4-methylmethcathinone (4-MMC, mephedrone, Schedule II of the Convention on Psychotropic Substances). 3-MMC was critically reviewed in 2016, but it was decided to request another critical review, to be considered at a subsequent meeting, pending the availability of more information. Some patent applications including the use of 3-MMC were found but no current clinical trials were identified on therapeutic use of 3-MMC. 3-MMC also has no recognised human or veterinary medical use in the Union.

(29) The risks of 3-MMC have been assessed by the scientific committee of the EMCDDA and 3-MMC has already been included in the definition of 'drug' under Framework Decision 2004/757/JHA by Commission Delegated Directive (EU) 2022/1326[1]. 3-MMC is subject to intensive monitoring by the EMCDDA. At the time of risk assessment, in November 2021, 3-MMC had been detected in 23 Member States. A total of 27 deaths with confirmed exposure to 3-MMC had been reported by five Member States and 14 acute non-fatal poisonings with confirmed exposure to 3-MMC had been reported by four Member States.

(30) Therefore, the position of the Union should be to add 3-MMC to the Schedule II of the Convention on Psychotropic Substances.

(31) It is appropriate to establish the position to be taken on behalf of the Union in the Commission on Narcotic Drugs, as the decisions on scheduling as regards the seven substances will directly influence the content of Union law, namely Framework Decision 2004/757/JHA.

(32) The position of the Union is to be expressed by the Member States that are members of the Commission on Narcotic Drugs, acting jointly.

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[1] 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).

(33) Denmark is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision.

(34) 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:

Article 1

The position to be taken on behalf of the Union by the Member States in the 66th session of the Commission on Narcotic Drugs, which takes place from 13 to 17 March 2023, when that body is called upon to adopt 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 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 of Narcotic Drugs, acting jointly in the interest of the Union.

Article 3

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

Done at …,

For the Council
The President

ANNEX

Position to be taken by the Member States which are members of the Commission on Narcotic Drugs, acting jointly in the interest of the Union during the 66th session of the Commission on Narcotic Drugs, which takes place from 13 to 17 March 2023, on the scheduling of substances:

(1) ADB-BUTINACA is to be included in Schedule II of the Convention on Psychotropic Substances.

(2) Protonitazene is to be included in Schedule I of the Convention on Narcotic Drugs.

(3) Etazene is to be included in Schedule I of the Convention on Narcotic Drugs.

(4) Etonitazepyne is to be included in Schedule I of the Convention on Narcotic Drugs.

(5) 2-methyl-AP-237 is to be included in Schedule I of the Convention on Narcotic Drugs.

(6) Alpha-PiHP is to be included in the Schedule II of the Convention on Psychotropic Substances.

(7) 3-MMC is to be included in the Schedule II of the Convention on Psychotropic Substances.