Council of the European Union

Brussels, 6 January 2023
(OR. en)

5039/23

Interinstitutional File:
2023/0001 (NLE)

CORDROGUE 1
SAN 5
RELEX 4

PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	3 January 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 2 final
Subject:	Proposal for a COUNCIL DECISION on the position to be taken, on behalf of the European Union, in the sixty-sixth 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

Delegations will find attached document COM(2023) 2 final.

Encl.: COM(2023) 2 final

EUROPEAN
COMMISSION

Brussels, 3.1.2023
COM(2023) 2 final

2023/0001 (NLE)

Proposal for a

COUNCIL DECISION

on the position to be taken, on behalf of the European Union, in the sixty-sixth 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

EXPLANATORY MEMORANDUM

1. SUBJECT MATTER OF THE PROPOSAL

This proposal concerns the decision establishing the position to be taken on the Union's behalf in the 66th session of the Commission on Narcotic Drugs on the scheduling of substances under the UN Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the UN Convention on Psychotropic Substances of 1971. The 66th session of the Commission on Narcotic Drugs is scheduled to take place from 13 to 17 March 2023.

2. CONTEXT OF THE PROPOSAL

2.1. The UN Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the UN Convention on Psychotropic Substances of 1971

The United Nations (UN) Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, (the 'Convention on Narcotic Drugs')[1] aims to combat drug abuse by coordinated international action. There are two forms of intervention and control that work together. First, it seeks to limit the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes. Second, it combats drug trafficking through international cooperation to deter and discourage drug traffickers.

The United Nations (UN) Convention on Psychotropic Substances of 1971 (the 'Convention on Psychotropic Substances')[2] establishes an international control system for psychotropic substances. It responded to the diversification and expansion of the spectrum of drugs of abuse and introduced controls over a number of synthetic drugs according to their abuse potential on the one hand and their therapeutic value on the other.

All EU Member States are parties to the above Conventions, whereas the Union is not.

2.2. The Commission on Narcotic Drugs

The Commission on Narcotic Drugs (CND) is a commission of the UN Economic and Social Council (ECOSOC) and its functions and powers are *inter alia* set out in the two Conventions. It is made up of 53 UN Member States elected by ECOSOC. 12 Member States will be members of the CND with the right to vote in March 2023[3]. The Union has an observer status in the CND.

2.3. The envisaged act of the Commission on Narcotic Drugs

The CND regularly amends the list of substances that are annexed to the Conventions on the basis of recommendations of the World Health Organisation (WHO) which is advised by its Expert Committee on Drug Dependence.

---

1 United Nations Treaty Series, vol. 978, No. 14152.

2 United Nations Treaty Series, vol. 1019, No. 14956.

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

The WHO recommended on 2 December 2022 to the Secretary General of the UN[4] to add seven of the substances which were critically reviewed by the WHO Expert Committee on Drug Dependence to the schedules of the Conventions.

The CND, in its 66th session, taking place in Vienna from 13 to 17 March 2023, is called upon to adopt decisions on the scheduling of these substances under the Conventions.

3. POSITION TO BE TAKEN ON THE UNION'S BEHALF

Changes to the schedules of the Conventions have direct repercussions for the scope of application of Union law in the area of drug control for all Member States. Article 1(1) of 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[5] (the 'Framework Decision') states that, for the purposes of the Framework Decision, "drug" means a substance covered by either the Convention on Narcotic Drugs or the Convention on Psychotropic Substances and any of the substances listed in the Annex to the Framework Decision. The Framework Decision therefore applies to substances listed in the Schedules to the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. Thus any change to the schedules annexed to these Conventions directly affects common EU rules and alters their scope, in accordance with Article 3(2) of the Treaty on the Functioning of the European Union (TFEU). This is irrespective of whether the substance in question is controlled in the Union.[6]

The WHO Expert Committee on Drug Dependence considered nine substances in its 45th meeting and decided to recommend seven of these for scheduling, while keeping two additional substances under surveillance. One substance proposed for scheduling is already subject to control measures across the Union: 3-MMC has been added to the list of drugs of the Framework Decision in 2022. Four substances (ADB-BUTINACA, protonitazene, etazene, etonitazepyne) are under intensive monitoring[7] by the European Monitoring Centre for Drugs and Drug Addiction. The two remaining substances (2-methyl-AP-237 and α-PiHP) are being monitored by the European Monitoring Centre for Drugs and Drug Addiction. The two substances for surveillance are adinazolam and bromazolam, which are also being monitored by the European Monitoring Centre for Drugs and Drug Addiction.

The Commission proposal for a Union position suggests supporting the WHO recommendations, this is the control of the above mentioned seven substances, as these are in line with the current state of play of scientific knowledge. As regards these new psychoactive substances, their addition to the Schedules of the Conventions is supported also by information available from the European Database on New Drugs of the European Monitoring Centre for Drugs and Drug Addiction.

---

4 https://cdn.who.int/media/docs/default-source/controlled-substances/45th-ecdd/45th-ecdd-unsg-letter.pdf?sfvrsn=27124af4_3

5 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, s. 12.

6 See the Annex to the Framework Decision.

7 For more information on the implications of intensive monitoring, see https://www.emcdda.europa.eu/system/files/publications/12213/downloads/Guidance%20Note%206-%20Intensive%20monitoring.pdf.

It is necessary that the Council establishes the Union's position for the meeting of the CND when it is called to decide on the scheduling of substances. Such position, due to the limitations intrinsic to the observer status of the Union, should be expressed by the Member States that will be members of the CND in March 2023, acting jointly in the interest of the Union within the CND. The Union is not a party to these Conventions but has exclusive competence in this area.

To this end, the Commission is proposing a Union position to be expressed by the Member States that will be members of the CND in March 2023, on behalf of the European Union, in the 66th session of the CND on the scheduling of substances under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. In the past, the Council adopted such Union positions, thereby allowing the EU to speak with one voice at the previous CND meetings regarding the international scheduling, since the Member States participating in the CND voted in favour of the scheduling in line with the adopted Union position[8].

4. LEGAL BASIS

4.1. Procedural legal basis

Article 218(9) of the Treaty on the Functioning of the European Union (TFEU) provides for decisions establishing '*the positions to be adopted on the Union's behalf in a body set up by an agreement, when that body is called upon to adopt acts having legal effects, with the exception of acts supplementing or amending the institutional framework of the agreement*.'

Article 218(9) TFEU applies regardless of whether the Union is a member of the body or a party to the agreement[9]. The concept of '*acts having legal effects*' includes acts that have legal effects by virtue of the rules of international law governing the body in question. It also includes instruments that do not have a binding effect under international law, but that are '*capable of decisively influencing the content of the legislation adopted by the EU legislature*'[10].

The CND is "a body set up by an agreement" within the meaning of this Article, given that it is a body established by ECOSOC – an organ of the United Nations – and that it has been given specific tasks under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances.

The CND's scheduling-decisions are "acts having legal effects" within the meaning of Article 218(9) TFEU. According to the Convention on Narcotic Drugs and the Convention on Psychotropic Substances, decisions of the CND automatically become binding, unless a party has submitted the decision for review to ECOSOC within the applicable time-limit[11]. The decisions of ECOSOC on the matter are final. The CND's scheduling decisions also have legal effects in the EU legal order by virtue of Union law, given the fact that they are capable

[8] With one single exception which is the object of an ongoing infringement procedure.

[9] Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraph 64.

[10] Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraphs 61 to 64.

[11] Article 3(7) of the Convention on Narcotic Drugs; Article 2(7) of the Convention on Psychotropic Substances.

of decisively influencing the content of EU legislation, namely Council Framework Decision 2004/757/JHA. Changes to the schedules of the Conventions have direct repercussions for the scope of application of this EU legal instrument.

The envisaged act does not supplement or amend the institutional framework of the Agreement.

Therefore, the procedural legal basis for the proposed decision is Article 218(9) TFEU.

4.2. Substantive legal basis

The substantive legal basis for a decision under Article 218(9) TFEU depends primarily on the objective and content of the envisaged act in respect of which a position is taken on the Union's behalf.

The main objective and content of the envisaged act relate to illicit drug trafficking.

Therefore, the substantive legal basis of the proposed decision is Article 83(1) TFEU, which identifies illicit drug trafficking as one of the crimes with a particular cross-border dimension and empowers the European Parliament and the Council to establish minimum rules concerning the definition of offences and sanctions in the area of illicit drug trafficking.

4.3. Variable geometry

Denmark is bound by Council Framework Decision 2004/757/JHA as applicable until 21 November 2018 which states in its Article 1 that “drugs” shall mean any of the substances covered by either the Convention on Narcotic Drugs or the Convention on Psychotropic Substances.

Since the CND’s scheduling decisions affect common rules in the area of illicit drug trafficking by which Denmark is bound, Denmark takes part in the adoption of a Council Decision establishing the position to be adopted on the Union’s behalf when such scheduling decisions are adopted.

Ireland is bound by the Framework Decision and is therefore taking part in the adoption of a Council Decision establishing the position to be adopted on the Union’s behalf when such scheduling decisions are adopted.

4.4. Conclusion

The legal basis for this proposal is Article 83(1) TFEU in conjunction with Article 218(9) TFEU.

5. BUDGETARY IMPLICATIONS

No budgetary implications.

2023/0001 (NLE)

Proposal for a

COUNCIL DECISION

on the position to be taken, on behalf of the European Union, in the sixty-sixth 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[1] ('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 United Nations (UN) Convention on Psychotropic Substances of 1971 ('the Convention on Psychotropic Substances')[2] 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 both Conventions have direct repercussions on the scope of application of Union law in the area of drug control. Council Framework Decision 2004/757/JHA[3] applies to substances listed in the Schedules to these Conventions. Thus any change to the Schedules annexed to the Conventions directly affects

[1] United Nations Treaty Series, vol. 978, No. 14152.

[2] United Nations Treaty Series, vol. 1019, No. 14956.

[3] 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).

common Union rules and alters their scope, in accordance with Article 3(2) of the Treaty on the Functioning of the European Union.

(6) The Commission on Narcotic Drugs, during its sixty-six session scheduled for 13 to 17 March 2023 in Vienna, is to adopt decisions on the adding of seven new substances to the Schedules of the above Conventions.

(7) The Union is not a party to the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. It has an observer status with no voting rights in the Commission on Narcotic Drugs where twelve Member States are to be members with the right to vote in March 2023[4]. It is therefore necessary for the Council to authorise the Member States to express the position of the Union on the scheduling of substances under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances since the decisions on the addition of new substances to the Schedules of the Conventions fall under the exclusive competence of the Union.

(8) The WHO recommended to add four new substances to Schedule I of the Convention on Narcotic Drugs, and three new substances to Schedule II of the Convention on Psychotropic Substances[5].

(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 as a new psychoactive substance under the terms of Regulation (EC) No 1920/2006 of the European Parliament and of the Council[6].

(10) According to the assessment of the Expert Committee on Drug Dependence, 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 nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that ADB-BUTINACA is being or is likely to be abused and may constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that ADB-BUTINACA be placed in Schedule II of the Convention on Psychotropic Substances.

(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 European Monitoring Centre for Drugs and Drug Addiction. It has been the subject of a public health-related alert issued by the European Union Early Warning System. 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.

---

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

5 https://cdn.who.int/media/docs/default-source/controlled-substances/45th-ecdd/45th-ecdd-unsg-letter.pdf?sfvrsn=27124af4_3

6 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 Member States should take the position 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 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 European Monitoring Centre for Drugs and Drug Addiction. No information on serious adverse events involving protonitazene has been reported to the EMCDDA.

(15) Therefore, the Member States should take the position 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 1961 United Nations Conventions) 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 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 European Monitoring Centre for Drugs and Drug Addiction. It has been associated with serious adverse events, including four deaths, reported by two Member States.

(18) Therefore, the Member States should take the position 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 1961 United Nations Conventions) 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 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 European Union Early Warning System. Etonitazepyne is subject to intensive monitoring by the European Monitoring Centre for Drugs and Drug Addiction. A death with confirmed exposure to etonitazepyne has been reported by one country.

(21) Therefore, the Member States should take the position 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 marketing authorisation as medicinal product. There is sufficient evidence that 2-methyl-AP-237 is being or is likely to be abused and 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 the Member States should take the position 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 marketing authorisation as medicinal product. There is sufficient evidence that alpha-PiHP is being or is likely to be abused and 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 European Union Early Warning System. 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 the Member States should take the position 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 European Monitoring Centre for Drugs and Drug Addiction 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[7]. 3-MMC is subject to intensive monitoring by the European Monitoring Centre for Drugs and Drug Addiction. 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 Member States should take the position 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 the Union's behalf in the Commission on Narcotic Drugs, as the decisions on the different scheduling decisions as regards the nine substances will be capable of decisively influencing the content of Union law, namely Framework Decision 2004/757/JHA.

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

(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 adopted on the Union's behalf in the sixty-six session of the Commission on Narcotic Drugs 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, is 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.

Article 3

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

[7] 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).

Done at Brussels,

For the Council
The President