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2025/0002 (NLE)

Proposal for a

COUNCIL DECISION

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

SUBJECT MATTER OF THE PROPOSAL

This proposal concerns the decision establishing the position to be taken on behalf of the European Union (EU) in the 68th session of the United Nations (UN) Commission on Narcotic Drugs (CND) 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 68th session of the CND is scheduled to take place from 10 to 14 March 2025.

CONTEXT OF THE PROPOSAL

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

The Commission on Narcotic Drugs

The 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 the ECOSOC. 13 EU Member States will be members of the CND with the right to vote in March 2025.[3] The Union has an observer status in the CND.

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 (ECDD).

The WHO recommended on 21 November to the UN Secretary General[4] to add six substances which were critically reviewed by the ECDD to the schedules of the Conventions.

The CND, in its 68th session taking place in Vienna 10 to 14 March 2025, is called upon to adopt decisions on the scheduling of these substances under the Conventions.

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1 United Nations Treaty Series, vol. 978, No. 14152.
2 United Nations Treaty Series, vol. 1019, No. 14956.
3 Austria, Belgium, France, Finland, Hungary, Italy, Lithuania, Malta, Netherlands, Poland, Portugal, Slovenia, and Spain.
4 https://www.who.int/groups/ecdd/forty-seventh-ecdd-documents

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 (the 'Framework Decision')[5] 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 ECDD critically reviewed eight substances at its 47th meeting, namely one synthetic cannabinoid – hexahydrocannabinol –, four novel synthetic opioids – *N*-pyrrolidino protonitazene (protonitazepyne), *N*-pyrrolidino metonitazene (metonitazepyne), etonitazepipne (*N*-Piperidinyl etonitazene), *N*-desethyl-isotonitazene –, one dissociative-type substance – 3-OH-PCP (3-Hydroxy-phencyclidine) –, one cathinone/stimulant – *N*-ethylheptedrone – and one medicine – carisoprodol.

All of the eight substances are monitored by the European Union Drugs Agency (EUDA)[7]. Furthermore, four of these substances – hexahydrocannabinol, protonitazepyne, metonitazepyne, *N*-desethyl-isotonitazene – are under intensive monitoring by the EUDA. The ECDD decided to recommend six of these for scheduling: protonitazepyne, metonitazepyne, etonitazepipne, *N*-desethyl-isotonitazene, hexahydrocannabinol and carisoprodol.

The Commission proposal for a Union position suggests supporting the WHO recommendations, the control of the above-mentioned six 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 EUDA.

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 2025, 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 2025, on behalf of the European Union, in the 68th session of the CND on the scheduling of substances under the Convention on

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 Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006, OJ L 166, 30.6.2023, p. 6–47.

Narcotic Drugs and the Convention on Psychotropic Substances. In the past, the Council adopted such Union positions and thus allowed the EU to speak with one voice at the previous CND meetings regarding the international scheduling, as the Member States participating in the CND voted in favour of the scheduling in line with the adopted Union position[8].

LEGAL BASIS

Procedural legal basis

1.1.1. Principles

Article 218(9) of the 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].

1.1.2. Application to the present case

The CND is "a body set up by an agreement" within the meaning of this Article, given that it is a body established by the United Nations Economic and Social Council (ECOSOC) 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 are binding. If a party submits a CND decision for review to the ECOSOC within the applicable time-limit,[11] the decisions of the 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 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.

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8 With one single exception which has been referred to the Court of Justice.

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(8) of the Convention on Narcotic Drugs; Article 2(7) of the Convention on Psychotropic Substances.

1.2. Substantive legal basis

1.2.1. Principles

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.

1.2.2. Application to the present case

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.

1.3. 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 taken 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 taken on the Union’s behalf when such scheduling decisions are adopted.

1.4. Conclusion

The legal basis of the proposed decision is Article 83(1) TFEU in conjunction with Article 218(9) TFEU.

2. BUDGETARY IMPLICATIONS

There are no budgetary implications.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union (TFEU), 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')[12] entered into force on 8 August 1975.

(2) Pursuant to Article 3 of the Convention on Narcotic Drugs, the Commission on Narcotic Drugs (CND) 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')[13] entered into force on 16 August 1976.

(4) Pursuant to Article 2 of the Convention on Psychotropic Substances, the CND may decide to add substances to the Schedules of that Convention or to remove them, on the basis of 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 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/JHA[14] applies to substances listed in the Schedules of those Conventions. Thus, any change to the Schedules annexed to those Conventions directly affects common Union rules and alters their scope, in accordance with Article 3(2) of the TFEU.

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

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

14 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).

(6) The CND is to decide, during its 68th session scheduled for 10 to 14 March 2025 in Vienna, on the addition of six new substances to the Schedules of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances.

(7) The Union is neither a party to the Convention on Narcotic Drugs nor to the Convention on Psychotropic Substances. It has an observer status with no voting rights in the Commission on Narcotic Drugs, of which 13 Member States are members with the right to vote in March 2025.[15] 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 decisions on the addition of new substances to their Schedules fall under the exclusive competence of the Union.

(8) The WHO has recommended the addition of four new substances 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[16].

(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 Union Drugs Agency (EUDA) as new psychoactive substances under the terms of Regulation (EU) 2023/1322 of the European Parliament and of the Council[17].

(10) According to the assessment by the ECDD, protonitazepyne (IUPAC name: 5-nitro-2-[(4-propoxyphenyl)methyl]-1-(2-pyrrolidin-1-ylethyl)benzimidazole) is a synthetic opioid in the nitazene analogue family. Protonitazepyne has not previously been formally reviewed by WHO. Protonitazepyne has no known therapeutic uses or marketing authorizations. There is sufficient evidence that protonitazepyne 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 protonitazepyne be placed in Schedule I of the Convention on Narcotic Drugs.

(11) Protonitazepyne has been detected in six Member States and is controlled in at least two Member States. Protonitazepyne is under intensive monitoring by the EUDA. Seventy four acute poisonings with suspected exposure to protonitazepyne were reported by one Member State.

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

(13) According to the assessment by the ECDD, metonitazepyne (IUPAC name: 2-[(4-methoxyphenyl)methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)-1*H*-benzoimidazole) is a synthetic opioid of the nitazene analogue family. Metonitazepyne has not previously been formally reviewed by WHO. Metonitazepyne has no known therapeutic uses or marketing authorizations. There is sufficient evidence that metonitazepyne 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 metonitazepyne be placed in Schedule I of the Convention on Narcotic Drugs.

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15 Austria, Belgium, France, Finland, Hungary, Italy, Lithuania, Malta, Netherlands, Poland, Portugal, Slovenia, and Spain.

16 https://www.who.int/groups/ecdd/forty-seventh-ecdd-documents

17 Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006, OJ L 166, 30.6.2023, p. 6–47.

(14) Metonitazepyne has been detected in four Member States and is controlled in at least two Member States. Metonitazepyne is under intensive monitoring by the EUDA.

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

(16) According to the assessment by the ECDD, etonitazepipne (IUPAC name: 2-[(4-Ethoxyphenyl)methyl]-5-nitro-1-(2-piperidin-1-ylethyl)-1*H*-benzoimidazole) is one of several synthetic 2-benzylbenzimidazoles opioids, collectively known as "nitazenes". Etonitazepipne has not previously been formally reviewed by WHO. Etonitazepipne has no known therapeutic uses or marketing authorizations. There is sufficient evidence that etonitazepipne 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 etonitazepipne be placed in Schedule I of the Convention on Narcotic Drugs.

(17) Etonitazepipne has been detected in five Member States and is controlled in at least six Member States. Etonitazepipne is under monitoring by the EUDA. Two deaths and one acute poisoning with confirmed exposure to etonitazepipne have been reported by three Member States.

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

(19) According to the assessment by the ECDD, *N*-desethyl isotonitazene (IUPAC name: *N*-ethyl-2-[2-[(4-isopropoxyphenyl)methyl]-5-nitro-benzimidazol-1-yl]ethanamine) is a benzimidazole-derived synthetic opioid with a chemical structure and pharmacological similarities to drugs under Schedule I of the 1961 United Nations Conventions), such as isotonitazene, and is a metabolite of isotonitazene. *N*-desethyl isotonitazene has not previously been formally reviewed by WHO. *N*-desethyl isotonitazene has no known therapeutic uses or marketing authorizations. There is sufficient evidence that *N*-desethyl isotonitazene 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 *N*-desethyl isotonitazene be placed in Schedule I of the Convention on Narcotic Drugs.

(20) *N*-desethyl isotonitazene has been detected in two Member States and is controlled in at least two Member States. *N*-desethyl isotonitazene is under intensive monitoring by the EUDA. Two deaths with confirmed exposure to *N*-desethyl isotonitazene have been reported by one Member State.

(21) Therefore, the position of the Union should be to add *N*-desethyl isotonitazene to Schedule I of the Convention on Narcotic Drugs.

(22) According to the assessment by the ECDD, hexahydrocannabinol (HHC) (IUPAC name: 6a,7,8,9,10,10a-hexahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo[*b,d*]pyran-1-ol) is a semi-synthetic cannabinoid that is most commonly synthesized from cannabidiol as a precursor. Hexahydrocannabinol has not previously been formally reviewed by WHO. Hexahydrocannabinol has no known therapeutic uses or marketing authorizations. There is sufficient evidence that hexahydrocannabinol 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 hexahydrocannabinol be placed in Schedule II of the Convention on Psychotropic Substances.

(23) Hexahydrocannabinol has been detected in twenty-five Member States and is controlled in at least twenty Member States. Hexahydrocannabinol is under intensive monitoring by the EUDA. Four cases of acute poisoings with confirmed exposure to hexahydrocannabinol have been reported by two Member States. Seven cases of acute poisoning with probable exposure to hexahydrocannabinol have been reported by two Member States. Six cases of acute poisoning with suspected exposure to hexahydrocannabinol have been reported by three Member States.

(24) Therefore, the position of the Union should be to add hexahydrocannabinol to Schedule II of the Convention on Psychotropic Substances.According to the assessment by the ECDD, carisoprodol (IUPAC name: (2RS)-2-[(carbamoyloxy)methyl]-2-methylpentyl(1-methylethyl)carbamate) is a centrally acting muscle relaxant used in the short term as an adjunct to symptomatic treatment of acute musculoskeletal disorders associated with painful muscle spasm. The potential for misuse of carisoprodol may be related to both its sedative effects and its capacity to enhance the effects of other substances. Thus, the sedative effects of carisoprodol can be potentiated when it is combined with benzodiazepines, opioids or alcohol. Prolonged or excessive use of carisoprodol can lead to dependence. Carisoprodol may be diverted from legitimate medical channels and enter the illicit market to be sold without proper medical supervision, increasing potential abuse and adverse consequences. Carisoprodol was pre-reviewed in 2001 at the 32nd ECDD meeting. The Committee did not recommend critical review of carisoprodol at that time. Carisoprodol was further presented, discussed and pre-reviewed in 2023 at the 46th ECDD meeting, where proceeding to critical review was recommended. Carisoprodol is a prescription medication and appears to be a licensed drug in several countries and territories. However, it is no longer used medically in Europe since the European Medicines Agency Committee for Medicinal Products for Human Use suspended all marketing authorizations for carisoprodol throughout Europe. Carisoprodol has no known industrial use. There is sufficient evidence that carisoprodol 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 carisoprodol be placed in Schedule IV of the Convention on Psychotropic Substances.

(25) Carisoprodol has been detected in two Member States. Carisoprodol is under monitoring by the EUDA. Two deaths with confirmed exposure to carisoprodol have been reported by one Member State.

(26) Therefore, the position of the Union should be to add carisoprodol to Schedule IV of the Convention on Psychotropic Substances.

(27) It is appropriate to establish the position to be taken on the Union’s behalf in the CND, as the decisions on scheduling as regards the six substances will be capable of decisively influencing the content of Union law, namely Framework Decision 2004/757/JHA.

(28) The Union's position is to be expressed by the Member States that are members of the CND, acting jointly.

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

(30) 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 the Union's behalf in the sixty-eighth session of the Commission on Narcotic Drugs, from 10 to 14 March 2025, 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 on Narcotic Drugs, acting jointly in the interest of the Union.

Article 3

This Decision is addressed to the Member States.

Done at Brussels,

For the Council
The President