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**PROPOSAL**

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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 18 December 2025

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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No. Cion doc.: COM(2025) 777 final

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Subject: Proposal for a COUNCIL DECISION on the position to be taken on behalf of the European Union in the sixty-ninth 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

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Delegations will find attached document COM(2025) 777 final.

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Encl.: COM(2025) 777 final



Brussels, 18.12.2025  
COM(2025) 777 final

2025/0415 (NLE)

Proposal for a

## **COUNCIL DECISION**

**on the position to be taken on behalf of the European Union in the sixty-ninth 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. CONTEXT OF THE PROPOSAL**

- **Reasons for and objectives of the proposal**

#### **1.1. 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 69<sup>th</sup> 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 69<sup>th</sup> session of the CND is scheduled to take place from 9 to 13 March 2026.

#### **1.2. 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')<sup>(1)</sup> establishes an international control system for drugs in order to combat drug abuse by coordinated international action, by limiting the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes.

The UN Convention on Psychotropic Substances of 1971 (the 'Convention on Psychotropic Substances')<sup>(2)</sup> 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.

#### **1.3. The Commission on Narcotic Drugs (CND)**

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 the ECOSOC. 14 EU Member States will be members of the CND with the right to vote in March 2026.<sup>(3)</sup> The Union has an observer status in the CND.

#### **1.4. 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 Expert Committee on Drug Dependence (ECDD) recommended on 27 November 2025 to the UN Secretary General<sup>(4)</sup> to add three substances which were critically reviewed by the ECDD to the schedules of the Conventions.

The CND, in its 69<sup>th</sup> session taking place in Vienna from 9 to 13 March 2026, is called upon to adopt decisions on the scheduling of these substances under the Conventions.

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<sup>(1)</sup> United Nations Treaty Series, vol. 978, No. 14152.

<sup>(2)</sup> United Nations Treaty Series, vol. 1019, No. 14956.

<sup>(3)</sup> Austria, Belgium, France, Finland, Germany, Hungary, Italy, Lithuania, Malta, Netherlands, Poland, Portugal, Slovenia, and Spain.

<sup>(4)</sup> <https://www.who.int/groups/ecdd/48th-expert-committee-on-drug-dependence-documents>

## 1.5. Position to be taken on behalf of 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')<sup>(5)</sup> 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.<sup>(6)</sup>

The ECDD critically reviewed four substances at its 48<sup>th</sup> meeting, namely the coca leaf and three new psychoactive substances, i.e. one synthetic cannabinoid – MDMB-FUBINACA – and two novel synthetic opioids – *N*-pyrrolidino isotonitazene (Isotonitazepyne) and *N*-desethyl etonitazene.

The coca leaf is controlled under Schedule I of the 1961 Single Convention on Narcotic Drugs and has been the subject of a notification from a Party to the 1961 or the 1971 Convention concerning the scheduling of a substance. The ECDD recommended that coca leaf be retained in Schedule I of the 1961 Single Convention on Narcotic Drugs.

All of the three new psychoactive substances are under intensive monitoring by the European Union Drugs Agency (EUDA).<sup>(7)</sup> The ECDD decided to recommend all these substances for scheduling.

The Commission proposal for a Union position suggests supporting the WHO recommendations, the control of the above-mentioned three 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 2026, 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 2026, on behalf of the European Union, in the 69<sup>th</sup> 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 and thus allowed the EU to speak with one voice at the previous

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<sup>(5)</sup> 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.

<sup>(6)</sup> See the Annex to the Framework Decision.

<sup>(7)</sup> 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.

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.<sup>(8)</sup>

- **Consistency with existing policy provisions in the policy area**

Not Applicable

- **Consistency with other Union policies**

Not Applicable

## **2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY**

- **Legal basis**

### **2.1. Procedural legal basis**

#### *2.1.1. 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.<sup>(9)</sup>

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’.<sup>(10)</sup>

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, 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.

### **2.2. Substantive legal basis**

#### *2.2.1. 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.

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<sup>(8)</sup> With one single exception which has been referred to the Court of Justice.

<sup>(9)</sup> Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraph 64.

<sup>(10)</sup> 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.

### 2.2.2. 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.

### 2.3. 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.

### 2.4. Conclusion

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

- **Subsidiarity (for non-exclusive competence)**

Not Applicable

- **Proportionality**

Not Applicable

- **Choice of the instrument**

Not Applicable

## 3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

Not Applicable

- **Stakeholder consultations**

Not Applicable

- **Collection and use of expertise**

Not Applicable

- **Impact assessment**

Not Applicable

- **Regulatory fitness and simplification**

Not Applicable

- **Fundamental rights**

Not Applicable

#### **4. BUDGETARY IMPLICATIONS**

There are no budgetary implications.

#### **5. OTHER ELEMENTS**

- **Implementation plans and monitoring, evaluation and reporting arrangements**

Not Applicable

- **Detailed explanation of the specific provisions of the proposal**

Not Applicable

Proposal for a

## COUNCIL DECISION

**on the position to be taken on behalf of the European Union in the sixty-ninth 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')<sup>(1)</sup> 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')<sup>(2)</sup> 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<sup>(3)</sup> 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. It is necessary for the Council to authorise the Member States to express the position of the Union on the scheduling of substances under those Conventions since

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<sup>(1)</sup> United Nations Treaty Series, vol. 978, No. 14152.

<sup>(2)</sup> United Nations Treaty Series, vol. 1019, No. 14956.

<sup>(3)</sup> 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).

decisions on the addition of new substances to their Schedules fall under the exclusive competence of the Union.

- (6) The CND is to decide, during its 69th session scheduled for 9 to 13 March 2026 in Vienna, on the addition of [three] new substances to the Schedules of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances.
- (7) The WHO has recommended the addition of two new substances to Schedule I of the Convention on Narcotic Drugs and one new substance to Schedule II of the Convention on Psychotropic Substances.<sup>(5)</sup>
- (8) 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.<sup>(6)</sup> All three of them are under intensive monitoring.
- (9) According to the assessment by the ECDD, *N*-pyrrolidino isotonitazene (Isotonitazepyne) (IUPAC name: 5-nitro-2-({4-[(propan-2-yl)oxy]phenyl}methyl)-1-[2-(pyrrolidin-1-yl)ethyl]-1*H*-1,3-benzimidazole) is a synthetic opioid belonging to the class of benzimidazoles or nitazenes. *N*-pyrrolidino isotonitazene has not previously been formally reviewed by the WHO. *N*-pyrrolidino isotonitazene has no known therapeutic uses or marketing authorisations. There is sufficient evidence that *N*-pyrrolidino isotonitazene is being, or is likely to be, abused and can constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that *N*-pyrrolidino isotonitazene be listed in Schedule I to the Convention on Narcotic Drugs.
- (10) *N*-pyrrolidino isotonitazene has been detected in nine Member States and is controlled in at least two Member States. *N*-pyrrolidino isotonitazene is under intensive monitoring by the EUDA. At least three deaths with confirmed exposure to *N*-pyrrolidino isotonitazene have been reported by two Member States. At least one acute poisoning with suspected exposure to *N*-pyrrolidino isotonitazene has been reported by one Member State.
- (11) Therefore, the position of the Union should be to support adding *N*-pyrrolidino isotonitazene to Schedule I of the Convention on Narcotic Drugs.
- (12) According to the assessment by the ECDD, *N*-desethyl etonitazene (IUPAC name: 2-[2-[(4-ethoxyphenyl)methyl]-5-nitro-benzimidazol-1-yl]-*N*-ethyl-ethanamine) is a novel synthetic opioid belonging to the class of benzimidazoles or nitazenes. It is a metabolite of etonitazene, another benzimidazole opioid that is controlled under Schedule I of the Convention on Narcotic Drugs. *N*-desethyl etonitazene has not been formally reviewed by WHO. *N*-desethyl etonitazene has no known therapeutic uses or marketing authorisations. There is sufficient evidence that *N*-desethyl etonitazene is being, or is likely to be, abused and can constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that *N*-desethyl etonitazene be listed in Schedule I to the Convention on Narcotic Drugs.

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<sup>(5)</sup> <https://www.who.int/groups/ecdd/48th-expert-committee-on-drug-dependence-documents>

<sup>(6)</sup> 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.

- (13) *N*-desethyl etonitazene has been detected in four Member States and is controlled in at least six Member States. *N*-desethyl etonitazene is under intensive monitoring by the EUDA.
- (14) Therefore, the position of the Union should be to support adding *N*-desethyl etonitazene to Schedule I of the Convention on Narcotic Drugs.
- (15) According to the assessment by the ECDD, MDMB-FUBINACA (IUPAC name: methyl 2-[[1-[(4-fluorophenyl)methyl]indazole-3-carbonyl]amino]-3,3-dimethyl-butanoate) is a potent synthetic cannabinoid. MDMB-FUBINACA has not been previously reviewed by WHO. MDMB-FUBINACA has no known therapeutic uses or marketing authorisations. There is sufficient evidence that MDMB-FUBINACA is being, or is likely to be, abused and can constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that MDMB-FUBINACA be listed in Schedule II of the Convention on Psychotropic Substances.
- (16) MDMB-FUBINACA has been detected in 14 Member States and is controlled in at least eight Member States. MDMB-FUBINACA is under intensive monitoring by the EUDA. At least one acute poisoning with probable exposure to MDMB-FUBINACA has been reported by one Member State.
- (17) Therefore, the position of the Union should be to support adding MDMB-FUBINACA to Schedule II of the Convention on Psychotropic Substances.
- (18) 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 three substances will be capable of decisively influencing the content of Union law, namely Framework Decision 2004/757/JHA.
- (19) 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 14 Member States are members with the right to vote in March 2026.<sup>1</sup> The Union's position is to be expressed by the Member States that are members of the Commission on Narcotic Drugs in March 2026, acting jointly in the interest of the Union.
- (20) Denmark is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision.
- (21) 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-ninth session of the Commission on Narcotic Drugs, from 9 to 13 March 2026, 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.

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<sup>(4)</sup> Austria, Belgium, France, Finland, Germany, Hungary, Italy, Lithuania, Malta, Netherlands, Poland, Portugal, Slovenia, and Spain.

*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 in accordance with the Treaties.

Done at Brussels,

*For the Council*

*The President*

*[...]*