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PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	9 January 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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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-seventh 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(2024) 2 final.

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EUROPEAN
COMMISSION

Brussels, 9.1.2024
COM(2024) 2 final

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Proposal for a

COUNCIL DECISION

on the position to be taken on behalf of the European Union in the sixty-seventh 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 behalf of the European Union (EU) in the 67th 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 67th session of the CND is scheduled to take place from 14 to 22 March 2024.

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 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.

2.2. 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 2024.³ 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 (ECDD).

The WHO recommended on 15 November to the UN Secretary General⁴ to add five substances which were critically reviewed by the ECDD to the schedules of the Conventions.

The CND, in its 67th session taking place in Vienna 14 to 22 March 2024, is called upon to adopt decisions on the scheduling of these substances under the Conventions.

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/who-expert-committee-on-drug-dependence/46th-ecdd-documents>

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 (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 six substances at its 46th meeting, namely two benzodiazepines – bromazolam and flubromazepam –, one novel synthetic opioid – butonitazene –, two cathinones/stimulants – 3-Chloromethcathinone (3-CMC) and dipentylone – and one dissociative-type substance – 2-fluorodeschloroketamine (2-FDCK).

All of the six substances are monitored by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). In addition, one substance is already subject to control measures across the Union: 3-CMC has been added to the list of drugs of the Framework Decision in 2022. Furthermore, two of these substances – butonitazene and 2-FDCK – are under intensive monitoring by the EMCDDA. The ECDD decided to recommend five of these for scheduling: bromazolam, butonitazene, 3-CMC, dipentylone and 2-FDCK.

The Commission proposal for a Union position suggests supporting the WHO recommendations, the control of the above mentioned five 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 EMCDDA.

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 2024, 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 2024, on behalf of the European Union, in the 67th 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

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.

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 position⁷.

4. LEGAL BASIS

4.1. Procedural legal basis

4.1.1. 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 agreement⁸.

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*’⁹.

4.1.2. 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,¹⁰ 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.

4.2. Substantive legal basis

4.2.1. 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.

⁷ With one single exception which has been referred to the Court of Justice.

⁸ Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraph 64.

⁹ 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.

¹⁰ Article 3(7) of the Convention on Narcotic Drugs; Article 2(7) of the Convention on Psychotropic Substances.

4.2.2. 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.

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 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.

4.4. Conclusion

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

5. BUDGETARY IMPLICATIONS

There are no budgetary implications.

Proposal for a

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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')¹¹ 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')¹² 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/JHA¹³ 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.

¹¹ United Nations Treaty Series, vol. 978, No. 14152.

¹² United Nations Treaty Series, vol. 1019, No. 14956.

¹³ 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 67th session scheduled for 14 to 22 March 2024 in Vienna, on the addition of five new substances to the Schedules of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances.
- (7) The Union is 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 2024.¹⁴ 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 one new substance to Schedule I of the Convention on Narcotic Drugs, three new substances to Schedule II of the Convention on Psychotropic Substances, and one new substance to Schedule IV of the Convention on Psychotropic Substances¹⁵.
- (9) All substances reviewed by the WHO Expert Committee on Drug Dependence (ECDD) and recommended for scheduling by the WHO are monitored by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) as new psychoactive substances under the terms of Regulation (EC) No 1920/2006 of the European Parliament and of the Council.¹⁶
- (10) According to the assessment by the ECDD, bromazolam (IUPAC name: 8-bromo-1-methyl-6-phenyl-4*H*-[1,2,4]triazolo[4,3-*a*][1,4]benzodiazepine) is a benzodiazepine with a relatively high potency. Bromazolam was previously reviewed by the ECDD at its 45th meeting and placed under surveillance. Bromazolam has no known therapeutic uses or marketing authorizations. There is sufficient evidence that bromazolam 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 bromazolam be placed in Schedule IV of the Convention on Psychotropic Substances.
- (11) Bromazolam has been detected in 19 Member States and is controlled in at least four Member States. Bromazolam is under monitoring by the EMCDDA. One acute poisoning with confirmed exposure to bromazolam has been reported by one Member State. An additional acute poisoning with suspected exposure to bromazolam has been reported by one Member State. A total of 15 deaths with confirmed exposure to bromazolam have been reported by five Member States.
- (12) Therefore, the position of the Union should be to add bromazolam to Schedule IV of the Convention on Psychotropic Substances.
- (13) According to the assessment by the ECDD, butonitazene (IUPAC name: 2-[(4-butoxyphenyl)methyl]-*N,N*-diethyl-5-nitro-1*H*-benzimidazole-1-ethanamine) is a benzimidazole-derived synthetic opioid ('nitazene') with a chemical structure and pharmacological action similar to those of drugs under Schedule I of the Convention on Narcotic Drugs. Butonitazene has not previously been reviewed by the ECDD. Butonitazene has no known therapeutic uses or marketing authorizations. There is

¹⁴ Austria, Belgium, France, Finland, Hungary, Italy, Lithuania, Malta, Netherlands, Poland, Portugal, Slovenia, and Spain.

¹⁵ <https://www.who.int/groups/who-expert-committee-on-drug-dependence/46th-ecdd-documents>

¹⁶ 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).

sufficient evidence that butonitazene 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 butonitazene be placed in Schedule I of the Convention on Narcotic Drugs.

- (14) Butonitazene has been detected in seven Member States and is controlled in at least three Member States. Butonitazene is under intensive monitoring by the EMCDDA. One death case with confirmed exposure to butonitazene has been reported by one Member State.
- (15) Therefore, the position of the Union should be to add butonitazene to Schedule I of the Convention on Narcotic Drugs.
- (16) According to the assessment by the ECDD, 3-chloromethcathinone (3-CMC; IUPAC name: 1-(3-chlorophenyl)-2-(methylamino)propan-1-one) is a synthetic stimulant of the cathinone family. 3-CMC is an analogue to the drug methcathinone which is controlled under Schedule I of the Convention on Psychotropic Substances. 3-CMC is not currently under international control, but its isomer 4-CMC was placed under international control in 2020. 3-CMC has not previously been reviewed by the WHO Expert Committee on Drug Dependence. 3-CMC has no known therapeutic uses or marketing authorizations. There is sufficient evidence that 3-CMC 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 3-CMC be placed in Schedule II of the Convention on Psychotropic Substances.
- (17) The risks of 3-CMC have been assessed by the scientific committee of the EMCDDA and 3-CMC has already been included in the definition of ‘drug’ under Framework Decision 2004/757/JHA by Commission Delegated Directive (EU) 2022/1326¹⁷. It is under monitoring by the EMCDDA. At the time of risk assessment, in November 2021, 3-CMC had been detected in 23 Member States. A total of 10 deaths with confirmed exposure to 3-CMC had been reported by two Member States and one acute poisoning with confirmed exposure to 3-CMC had been reported by one Member State.
- (18) Therefore, the position of the Union should be to add 3-CMC to Schedule II of the Convention on Psychotropic Substances.
- (19) According to the assessment by the ECDD, dipentylone (IUPAC name: 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)pentan-1-one) is a synthetic stimulant of the cathinone family. It has a chemical structure and pharmacology similar to those of other synthetic cathinones of Schedule II of the Convention on Psychotropic Substances. Dipentylone has not previously been reviewed by the WHO Expert Committee on Drug Dependence. Dipentylone has no known therapeutic uses or marketing authorizations. There is sufficient evidence that dipentylone 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. No approved medical use has been reported. Thus, the WHO recommends that dipentylone be placed in Schedule II of the Convention on Psychotropic Substances.
- (20) Dipentylone has been detected in 16 Member States and is controlled in at least four Member States. Dipentylone is under monitoring by the EMCDDA.

¹⁷ 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).

- (21) Therefore, the position of the Union should be to add dipentylone to Schedule II of the Convention on Psychotropic Substances.
- (22) According to the assessment by the ECDD, 2-fluorodeschloroketamine (2-FDCK; IUPAC name: 2-(2-fluorophenyl)-2-methylamino-cyclohexanone) is an arylcyclohexylamine that is chemically related to the dissociative anaesthetic ketamine. 2-FDCK has not previously been reviewed by the WHO Expert Committee on Drug Dependence. 2-FDCK has no known therapeutic uses or marketing authorizations. There is sufficient evidence that 2-FDCK 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-FDCK be placed in Schedule II of the Convention on Psychotropic Substances.
- (23) 2-FDCK has been detected in 22 Member States and is controlled in at least five Member States. 2-FDCK is under intensive monitoring by the EMCDDA. Two deaths with confirmed exposure to 2-FDCK have been reported by two Member States. A total of 11 acute poisonings with confirmed exposure to 2-FDCK have been reported by three Member States. One additional case of acute poisoning with suspected exposure to 2-FDCK has been reported by one Member State.
- (24) Therefore, the position of the Union should be to add 2-FDCK to Schedule II of the Convention on Psychotropic Substances.
- (25) It is appropriate to establish the position to be taken on the Union's behalf in the CND, as the decisions on scheduling as regards the five substances will be capable of decisively influencing the content of Union law, namely Framework Decision 2004/757/JHA.
- (26) The Union's position is to be expressed by the Member States that are members of the CND, acting jointly.
- (27) Denmark is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision.
- (28) Ireland is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf in the sixty-seventh session of the Commission on Narcotic Drugs, from 14 to 22 March 2024, 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*