Council of the European Union

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NOTE

From:	Presidency
To:	Horizontal Working Party on Drugs
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Subject:	International scheduling of NPS - Council Decision on the position to be taken, on behalf of the European Union, in the sixty-fourth 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 in the annex the revised version of the draft Council Decision on international scheduling of NPS. Changes compared to the previous version are marked in bold underlined/strikethrough.

The following caveat is to be taken into account: the substances referred to in this draft Council Decision are to be understood as the respective substances contained in the letter addressed to the Secretary-General of the United Nations from the Director-General of the World Health Organization, dated 30 November 2020, containing the recommendations following the Forty-third Meeting of the WHO's Expert Committee on Drug Dependence.

In the case that Delegations have further and final comments to this draft Council Decision, they may send them until 16 February 2021 (cob) to the Presidency (HDG2021PT@sicad.min-saude.pt) and to the Council Secretariat (hdg@consilium.europa.eu).

ANNEX

Proposal for a

COUNCIL DECISION

on the position to be taken, on behalf of the European Union, in the sixty-fourth 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 UN Convention on Psychotropic Substances of 1971 ('the Convention on Psychotropic Substances')[2] entered into force on 16 August 1976.

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1 United Nations Treaty Series, vol. 978, No. 14152.
2 United Nations Treaty Series, vol. 1019, No. 14956.

(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 those Conventions is directly incorporated into common Union rules.

(6) The Commission on Narcotic Drugs, during its sixty-fourth session tentatively scheduled for 12 to 16 April 2021 in Vienna, is to adopt decisions on the adding of 8 new substances to the Schedules of the UN 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 members with the right to vote in April 2021[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 these decisions on the addition of new substances to the Schedules of the Conventions fall under the competence of the Union.

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[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).

[4] Austria, Belgium, Croatia, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Spain and Sweden.

(8) The WHO recommended to add one new substance to Schedule I of the Convention on Narcotic Drugs, four new substances to Schedule II and three new substances to Schedule IV 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, isotonitazene (chemical name: *N*,*N*-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzo[d]imidazol-1-yl)ethan-1-amine) is a synthetic opioid analgesic and is closely related to etonitazene and clonitazene, both of which are under international control under the Convention on Narcotic Drugs. Isotonitazene has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that 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 isotonitazene be placed in Schedule I of the Convention on Narcotic Drugs.

(11) Isotonitazene was included in the definition of 'drug' under Framework Decision 2004/757/JHA through a Commission Delegated Directive.[7]

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5 **The substances referred to in this draft Council Decision are to be understood as the respective substances contained in the letter addressed to the Secretary-General of the United Nations from the Director-General of the World Health Organization, dated 30 November 2020, containing the recommendations following the Forty-third Meeting of the WHO's Expert Committee on Drug Dependence**.

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).

7 Commission Delegated Directive (EU) 2020/1687 of 2 September 2020 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substance *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene) in the definition of 'drug', C(2020) 5897 final, OJ L 379, 13.11.2020, p. 55.

(12) Therefore, the Member States should take the position to add isotonitazene to Schedule I of the Convention on Narcotic Drugs.

(13) According to the assessment of the Expert Committee, MDMB-4en-PINACA (chemical name: methyl~~(S)-~~3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate) is a synthetic cannabinoid. MDMB-4en-PINACA has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that MDMB-4en-PINACA 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 MDMB-4en-PINACA be placed in Schedule II of the Convention on Psychotropic Substances.

(14) MDMB-4en-PINACA has been detected in 20 Member States and is controlled in at 14 Member States. It has been associated with nine deaths~~; it has also been associated with 11 non-fatal intoxications~~. MDMB-4en-PINACA was the subject of a detailed investigation, which le~~a~~d to a risk assessment report by the European Monitoring Centre for Drugs and Drug Addiction.

(15) Therefore, the Member States should take the position to add MDMB-4en-PINACA to Schedule II of the Convention on Psychotropic Substances.

(16) According to the assessment of the Expert Committee, CUMYL-PEGACLONE (chemical name: 5-pentyl-2-(2-phenylpropan-2-yl)-2,5-dihydro-1*H*-pyrido[4,3-b]indol-1-one is a synthetic cannabinoid. CUMYL-PEGACLONE does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that CUMYL-PEGACLONE 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 CUMYL-PEGACLONE be placed in Schedule II of the Convention on Psychotropic Substances.

(17) CUMYL-PEGACLONE has been detected in eleven Member States and is controlled in at least five Member States. It has been associated with at least three deaths and has been detected in six biological samples associated with serious adverse events.

(18) Therefore, the Member States should take the position to add CUMYL-PEGACLONE to Schedule II of the Convention on Psychotropic Substances.

(19) According to the assessment of the Expert Committee, flubromazolam (chemical name: 8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[f][1,2,4]triazolo[4,3-a][1,4]-diazepine) is a benzodiazepine-type substance. Flubromazolam has been researched for its anxiolytic properties and decreased sedative, hypnotic, and ataxic side effects, but it does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that flubromazolam 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 flubromazolam be placed in Schedule IV of the Convention on Psychotropic Substances.

(20) Flubromazolam has been detected in 15 Member States and is controlled in at least seven Member States. It has been associated with two deaths and seven non-fatal intoxications; it has also been detected in 44 biological samples associated with deaths.

(21) Therefore, the Member States should take the position to add flubromazolam to Schedule IV of the Convention on Psychotropic Substances.

(22) According to the assessment of the Expert Committee, clonazolam (also known as clonitrazolam; chemical name: 6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine) is a benzodiazepine-type substance. Clonazolam does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that clonazolam 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 clonazolam be placed in Schedule IV of the Convention on Psychotropic Substances.

(23) Clonazolam has been detected in 15 Member States and is controlled in at least four Member States. It has been associated with two deaths and five non-fatal intoxications.

(24) Therefore, the Member States should take the position to add clonazolam to Schedule IV of the Convention on Psychotropic Substances.

(25) According to the assessment of the Expert Committee, diclazepam (also known as or Ro 5-3448; chemical name: 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2*H*-benzo[e][1,4]diazepin2-one) is a benzodiazepine-type substance. Diclazepam does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that diclazepam 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 diclazepam be placed in Schedule IV of the Convention on Psychotropic Substances.

(26) Diclazepam has been detected in 16 Member States and is controlled in at least eight Member States. It has been associated with two deaths; it has also been detected in 8 biological samples associated with deaths.

(27) Therefore, the Member States should take the position to add diclazepam to Schedule IV of the Convention on Psychotropic Substances.

(28) According to the assessment of the Expert Committee, 3-methoxyphencyclidine (other name: **3-MeO-PCP;** ~~**2-MeO-Diphenidine;**~~ chemical name:**1-(1-(3-methoxyphenyl)cyclohexyl)piperidine** ~~1-[1-(23-methoxyphenyl)-2-phenylethylcyclohexyl]piperidine~~) is a dissociative-type substance.

3-M-ethoxyphencyclidine does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that 3-methoxyphencyclidine 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-methoxyphencyclidine be placed in Schedule II of the Convention on Psychotropic Substances.

(29) 3-Methoxyphencyclidine has been detected in 18 Member States and is controlled in at least eight Member States. It has been associated with at least seven deaths and five non-fatal intoxications; it has also been detected in 18 biological samples associated with serious adverse events.

(30) Therefore, the Member States should take the position to add 3-methoxyphencyclidine to Schedule II of the Convention on Psychotropic Substances.

(31) According to the assessment of the Expert Committee, diphenidine (chemical name: 1-(1,2-diphenylethyl)piperidine) is a dissociative-type substance. Diphenidine does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that diphenidine 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 diphenidine be placed in Schedule II of the Convention on Psychotropic Substances.

(32) Diphenidine has been detected in 17 Member States and is controlled in at least eight Member States. It has been associated with at least two non-fatal intoxications and detected in five biological samples associated with serious adverse events.

(33) Therefore, the Member States should take the position to add diphenidine to Schedule II of the Convention on Psychotropic Substances.

(34) 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 scheduling as regards the eight substances will directly influence the content of Union law, namely Framework Decision 2004/757/JHA.

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

(36) Denmark is bound by Framework Decision 2004/757/JHA as applicable until 21 November 2018 and is therefore taking part in the adoption and application of this Decision.

(37) 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 by the Member States in the sixty-fourth session of the Commission on Narcotic Drugs from 12 to 16 April 2021, when that body is called upon to adopt decisions on the addition of substances to the Schedules of the United Nations Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the United Nations Convention on Psychotropic Substances of 1971 shall be in accordance with the Annex to this Decision.

Article 2

The position referred to in Article 1 shall be taken by the Member States that are members of the Commission of Narcotic Drugs, acting jointly in the interest of the Union.

Article 3

This Decision is addressed to the Member States in accordance with the Treaties.
Done at Brussels,

For the Council
The President

ANNEX

Position to be taken by the Member States which are members of the Commission on Narcotic Drugs, acting jointly, in the interest of the Union during the sixty-fourth session of the Commission on Narcotic Drugs tentatively scheduled from 12 to 16 April 2021:

(1) Isotonitazene is to be included in Schedule I of the Convention on Narcotic Drugs;

(2) MDMB-4en-PINACA is to be included in Schedule II of the Convention on Psychotropic Substances;

(3) CUMYL-PEGACLONE is to be included in Schedule II of the Convention on Psychotropic Substances;

(4) Flubromazolam is to be included in Schedule IV of the Convention on Psychotropic Substances;

(5) Clonazolam is to be included in Schedule IV of the Convention on Psychotropic Substances;

(6) Diclazepam is to be included in Schedule IV of the Convention on Psychotropic Substances;

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

(8) Diphenidine is to be included in Schedule II of the Convention on Psychotropic Substances.