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Subject: COUNCIL DECISION on the position to be taken on behalf of the European Union in the 65th 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

COUNCIL DECISION (EU) 2022/...

of ...

**on the position to be taken on behalf of the European Union
in the 65th 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') 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 to the Schedules only in accordance with recommendations of the World Health Organisation (WHO), but it can also decide not to make changes recommended by the WHO.
- (3) The UN Convention on Psychotropic Substances of 1971 (the 'Convention on Psychotropic Substances') 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 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/JHA¹ applies to substances listed in the Schedules of those Conventions. Thus, any change to the Schedules annexed to those Conventions is directly incorporated into common Union rules.
- (6) The Commission on Narcotic Drugs is to decide, during its 65th session scheduled for 14 to 18 March 2022 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 Union is not a party to the Convention on Narcotic Drugs or the Convention on Psychotropic Substances. It has an observer status with no voting rights in the Commission on Narcotic Drugs, of which 12 Member States are members with the right to vote at its 65th session². 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 such decisions on the addition of new substances to their Schedules fall under the competence of the Union.

¹ 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).

² Austria, Belgium, France, Germany, Hungary, Italy, Lithuania, Netherlands, Poland, Slovenia, Spain and Sweden.

- (8) 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.
- (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 new psychoactive substances under the terms of Regulation (EC) No 1920/2006 of the European Parliament and of the Council¹.
- (10) According to the assessment by the Expert Committee, brorphine (chemical name: 1-{1-[1-(4-bromophenyl)ethyl]piperidin-4-yl}-1,3-dihydro-2*H*-benzimidazol-2-one) is a synthetic opioid similar to other synthetic opioids such as morphine and fentanyl. Brorphine may be convertible to bezitramide, which is an opioid listed in Schedule I of the Convention on Narcotic Drugs. Brorphine has no therapeutic uses nor has it received a marketing authorisation as a medicinal product. There is sufficient evidence that brorphine is being or is likely to be abused and may constitute a public health and social problem that warrants placing it under international control. Thus, the WHO recommends that brorphine be placed in Schedule I of the Convention on Narcotic Drugs.

¹ 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).

- (11) Brorphine has been detected in four Member States and is controlled in at least three Member States. It has been associated with one non-fatal intoxication and is currently under intensive monitoring by the European Monitoring Centre for Drugs and Drug Addiction.
- (12) Therefore, the position of the Union should be to add brorphine to Schedule I of the Convention on Narcotic Drugs.
- (13) According to the assessment of the Expert Committee, metonitazene (chemical name: *N,N*-diethyl-2-(2-(4-methoxybenzyl)-5-nitro-1*H*-benzo[d]imidazol-1-yl)ethan-1-amine) is a synthetic opioid structurally similar to isotonitazene and etonitazene, both of which are listed in Schedule I of the Convention on Narcotic Drugs. Metonitazene has been studied in preclinical models for its analgesic effects but it is not known to have any therapeutic use. There is sufficient evidence that metonitazene is being or is likely to be abused and may constitute a public health and social problem that warrants placing it under international control. Thus, the WHO recommends that metonitazene be placed in Schedule I of the Convention on Narcotic Drugs.
- (14) Metonitazene has been detected in three Member States and is controlled in at least three Member States. It has been associated with one death and is currently under intensive monitoring by the European Monitoring Centre for Drugs and Drug Addiction.

- (15) Therefore, the position of the Union should be to add metonitazene to Schedule I of the Convention on Narcotic Drugs.
- (16) According to the assessment of the Expert Committee, eutylone (chemical name: 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)butan-1-one) is a synthetic cathinone, presenting a chemical structure similar to, and pharmacological similarities to, amphetamines and cathinones already under international control. Related cathinones, such as methylone and *N*-ethylnorpentylone, are listed under Schedule II of the Convention on Psychotropic Substances. There is no known therapeutic use for eutylone, nor has it received a marketing authorisation as a medicinal product. There is sufficient evidence that eutylone is being or is likely to be abused and may constitute a public health and social problem that warrants placing it under international control. Thus, the WHO recommends that eutylone be placed in Schedule II of the Convention on Psychotropic Substances.
- (17) Eutylone has been detected in 20 Member States and is controlled in at least two Member States. It has been associated with one non-fatal intoxication and has been detected in three biological samples associated with serious adverse events. Eutylone is currently under intensive monitoring by the European Monitoring Centre for Drugs and Drug Addiction.
- (18) Therefore, the position of the Union should be to add eutylone to Schedule II of the Convention on Psychotropic Substances.

- (19) It is appropriate to establish the position to be taken on behalf of the Union in the Commission on Narcotic Drugs, as the decisions on scheduling as regards the three substances will directly influence the content of Union law, namely Framework Decision 2004/757/JHA.
- (20) The position of the Union is to be expressed by the Member States that are members of the Commission on Narcotic Drugs, acting jointly in the interest of the Union.
- (21) Denmark is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision.
- (22) 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 behalf of the Union by the Member States in the 65th session of the Commission on Narcotic Drugs from 14 to 18 March 2022, 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 that 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 in accordance with the Treaties.

Done at ...,

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 65th session of the Commission on Narcotic Drugs from 14 to 18 March 2022 on the scheduling of substances:

- (1) Brorphine is to be included in Schedule I of the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol.
- (2) Metonitazene is to be included in Schedule I of the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol.
- (3) Eutylone is to be included in Schedule II of the Convention on Psychotropic Substances of 1971.