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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	COUNCIL DECISION on the position to be adopted, on behalf of the European Union, in the sixty-second 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) 2019/…

of …

on the position to be adopted, on behalf of the European Union,
in the sixty-second 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 (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') 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 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 the application of Union law in the area of drug control. Council Framework Decision 2004/757/JHA[1] applies to substances listed in the Schedules of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. Therefore, any change to the Schedules of those Conventions is directly incorporated into common Union rules.

(6) The CND, during its sixty-second session of 18 to 22 March 2019 in Vienna, is to adopt decisions on the scheduling of substances under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances.

(7) The Union is not a party to the relevant UN Conventions. It has an observer status in the CND where currently eleven Member States are members with the right to vote. 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 those decisions on the inclusion of substances in the Schedules of the Conventions fall under the competence of the Union.

(8) By letter dated 24 January 2019, the WHO recommended to the Secretary-General of the United Nations that four new substances be added to Schedule I of the Convention on Narcotic Drugs and five new substances be added to Schedule II of the Convention on Psychotropic Substances.

[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).

(9) According to the assessment of the WHO Expert Committee on Drug Dependence (the 'Expert Committee'), ADB-FUBINACA (chemical name: *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-*1*H-indazole-3-carboxamide) is a synthetic cannabinoid receptor agonist that shows similar effects to Tetrahydrocannabinol (THC), which is responsible for the major psychoactive effects of cannabis. ADB-FUBINACA has no therapeutic uses nor has it received a marketing authorisation as a medicinal product. There is sufficient evidence that ADB-FUBINACA 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 ADB-FUBINACA be placed in Schedule II of the Convention on Psychotropic Substances.

(10) ADB-FUBINACA is monitored by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) as a new psychoactive substance under the terms of Regulation (EC) No 1920/2006 of the European Parliament and of the Council.[1] ADB-FUBINACA has been detected in 19 Member States and is controlled in at least 10 Member States. It has been associated with at least two deaths and four acute intoxications, and has been the subject of a public health-related alert issued to the European Union Early Warning System on New Psychoactive Substances.

(11) Therefore, the Member States should take the position to add ADB-FUBINACA to Schedule II of the Convention on Psychotropic Substances.

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[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).

(12) According to the assessment of the Expert Committee, FUB-AMB (also referred to as MMB-FUBINACA or AMB-FUBINACA; chemical name: methyl (2S)-2-[[1-[(4-fluorophenyl)methyl]indazole-3-carbonyl]amino]-3-methylbutanoate; methyl-2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide)-3-methylbutanoate) is a synthetic cannabinoid receptor agonist that shows similar effects to THC, which is responsible for the major psychoactive effects of cannabis. FUB-AMB has no therapeutic uses nor has it received a marketing authorisation as a medicinal product. There is sufficient evidence that FUB-AMB 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 FUB-AMB be placed in Schedule II of the Convention on Psychotropic Substances.

(13) FUB-AMB is monitored by the EMCDDA as a new psychoactive substance under the terms of Regulation (EC) No 1920/2006. FUB-AMB has been detected in 23 Member States and is controlled in at least four Member States. It has been associated with at least two deaths and two acute intoxications.

(14) Therefore, the Member States should take the position to add FUB-AMB to Schedule II of the Convention on Psychotropic Substances.

(15) According to the assessment of the Expert Committee, ADB-CHMINACA (chemical name: *N*-[(2S)-1-amino-3,3-dimethyl-1-oxobutan-2-yl]-1-(cyclohexylmethyl)indazole-3-carboxamide; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide) is a synthetic cannabinoid receptor agonist that shows similar effects to THC, which is responsible for the major psychoactive effects of cannabis. ADB-CHMINACA has no therapeutic uses nor has it received a marketing authorisation as a medicinal product. There is sufficient evidence that ADB-CHMINACA 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 ADB-CHMINACA be placed in Schedule II of the Convention on Psychotropic Substances.

(16) ADB-CHMINACA has already been subjected to control measures at Union level by Council Implementing Decision (EU) 2018/747.[1]

(17) Therefore, the Member States should take the position to add ADB-CHMINACA to Schedule II of the Convention on Psychotropic Substances.

[1] Council Implementing Decision (EU) 2018/747 of 14 May 2018 on subjecting the new psychoactive substance *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (ADB-CHMINACA) to control measures (OJ L 125, 22.5.2018, p. 8).

(18) According to the assessment of the Expert Committee, CUMYL-4CN-BINACA (chemical name: 1-(4-cyanobutyl)-*N*-(1-methyl-1-phenylethyl)-1*H*-indazole-3-carboxamide) is a synthetic cannabinoid receptor agonist that shows similar effects to THC, which is responsible for the major psychoactive effects of cannabis. CUMYL-4CN-BINACA has no therapeutic uses nor has it received a marketing authorisation as a medicinal product. There is sufficient evidence that CUMYL-4CN-BINACA 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-4CN-BINACA be placed in Schedule II of the Convention on Psychotropic Substances.

(19) CUMYL-4CN-BINACA has already been subjected to control measures at Union level by Council Implementing Decision (EU) 2018/748.[1]

(20) Therefore, the Member States should take the position to add CUMYL-4CN-BINACA to Schedule II of the Convention on Psychotropic Substances.

[1] Council Implementing Decision (EU) 2018/748 of 14 May 2018 on subjecting the new psychoactive substance 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (CUMYL-4CN-BINACA) to control measures (OJ L 125, 22.5.2018, p. 10).

(21) According to the assessment of the the Expert Committee, cyclopropylfentanyl (chemical name: *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide) is a synthetic opioid and is structurally similar to fentanyl, a controlled substance widely used in medicine for general anaesthesia during surgery and for pain management. Cyclopropylfentanyl has no recorded therapeutic use and its use has resulted in fatalities. There is sufficient evidence that cyclopropylfentanyl 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 cyclopropylfentanyl be placed in Schedule I of the Convention on Narcotic Drugs.

(22) Cyclopropylfentanyl has already been subjected to control measures at Union level by Council Implementing Decision (EU) 2018/1463.[1]

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

[1] Council Implementing Decision (EU) 2018/1463 of 28 September 2018 on subjecting the new psychoactive substances *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl) and 2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl) to control measures (OJ L 245, 1.10.2018, p. 9).

(24) According to the assessment of the Expert Committee, methoxyacetylfentanyl (chemical name: 2-methoxy-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide) is a synthetic opioid and is structurally similar to fentanyl, a controlled substance widely used in medicine for general anaesthesia during surgery and for pain management. Methoxyacetylfentanyl has no recorded therapeutic use and its use has resulted in fatalities. There is sufficient evidence that methoxyacetylfentanyl 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 methoxyacetylfentanyl be placed in Schedule I of the Convention on Narcotic Drugs.

(25) Methoxyacetylfentanyl has already been subjected to control measures at Union level by Council Implementing Decision (EU) 2018/1463.

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

(27) According to the assessment of the Expert Committee, *ortho*-fluorofentanyl (chemical name: *N*-(2-fluorophenyl)-*N*-[1-(2-phenylethyl)-4-piperidinyl]-propanamide) is a synthetic opioid and is structurally similar to fentanyl, a controlled substance widely used in medicine for general anaesthesia during surgery and for pain management. *Ortho*-fluorofentanyl has no recorded therapeutic use and its use has resulted in fatalities. There is sufficient evidence that *ortho*-fluorofentanyl 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 *ortho*-fluorofentanyl be placed in Schedule I of the Convention on Narcotic Drugs.

(28) *Ortho*-fluorofentanyl is monitored by the EMCDDA as a new psychoactive substance under the terms of Regulation (EC) No 1920/2006. *Ortho*-fluorofentanyl has been detected in five Member States and is controlled in at least four Member States. It has been associated with at least four deaths and two acute intoxications.

(29) Therefore, the Member States should take the position to add *ortho*-fluorofentanyl to Schedule I of the Convention on Narcotic Drugs.

(30) According to the assessment of the Expert Committee, *p*-fluoro-butyrylfentanyl (also known as 4-fluoro-butyrfentanyl or 4F-BF; chemical name: *N*-(4-fluorophenyl)-*N*-[1-(2-phenylethyl)piperidin-4-yl]butanamide) is a synthetic opioid and is structurally similar to fentanyl, a controlled substance widely used in medicine for general anaesthesia during surgery and for pain management. *p*-Fluoro-butyrylfentanyl could be converted to its isomer *p*-fluoro-isobutyrylfentanyl, which is listed in Schedule I of the Convention on Narcotic Drugs. *p*-Fluoro-butyrylfentanyl has no recorded therapeutic use and its use has resulted in fatalities. There is sufficient evidence that *p*-fluoro-butyrylfentanyl 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 *p*-fluoro-butyrylfentanyl be placed in Schedule I of the Convention on Narcotic Drugs.

(31) *p*-Fluoro-butyrylfentanyl is monitored by the EMCDDA as a new psychoactive substance under the terms of Regulation (EC) No 1920/2006 (under the name 4-fluoro-butyrfentanyl / 4F-B). *p*-Fluoro-butyrylfentanyl has been detected in seven Member States and is controlled in at least seven Member States. It is being sold openly on the market. It has been associated with at least three deaths.

(32) Therefore, the Member States should take the position to add *p*-fluoro-butyrylfentanyl to Schedule I of the Convention on Narcotic Drugs.

(33) According to the assessment of the Expert Committee, *N*-ethylnorpentylone (chemical name: 1-(2*H*-1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one) is a synthetic cathinone. *N*-Ethylnorpentylone has no therapeutic uses nor has it received a marketing authorisation as a medicinal product. Seizures indicate that *N*-ethylnorpentylone is available in powder, crystal, capsule, and tablet forms. Examples exist where this drug has been surreptitiously sold as MDMA (3,4-Methylenedioxymethamphetamine, also known as 'ecstasy') . There is sufficient evidence that *N*-ethylnorpentylone 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*-ethylnorpentylone be placed in Schedule II of the Convention on Psychotropic Substances.

(34) *N*-Ethylnorpentylone is monitored by the EMCDDA as a new psychoactive substance under the terms of Regulation (EC) No 1920/2006 (under the name Ephylone). *N*-Ethylnorpentylone has been detected in 24 Member States and is controlled in at lest six Member States. It is being sold openly on the market as well as in mixtures with MDMA, cocaine and ketamine. It has been associated with at least seven deaths and seven acute intoxications.

(35) Therefore, the Member States should take the position to add *N*-ethylnorpentylone to Schedule II of the Convention on Psychotropic Substances.

(36) By a separate letter of 24 January 2019, the WHO recommended to the Secretary-General of the United Nations to take scheduling decisions regarding the following substances, hereinafter referred to as 'cannabis and cannabis-related substances' as follows: cannabis and cannabis resin to be deleted from Schedule IV of the Convention on Narcotic Drugs; dronabinol (*delta*-9-tetrahydrocannabinol; Δ^9-THC) to be added to Schedule I of the Convention on Narcotic Drugs and to be deleted from Schedule II of the Convention on Psychotropic Substances; tetrahydrocannabinol (isomers of *delta*-9-tetrahydrocannabinol) to be added to Schedule I of the Convention on Narcotic Drugs and to be deleted from Schedule I of the Convention on Psychotropic Substances; 'extracts and tinctures of cannabis' to be deleted from Schedule I of the Convention on Narcotic Drugs; preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health to be added to Schedule III of the Convention on Narcotic Drugs; an additional footnote reading 'preparations containing predominantly cannabidiol and not more than 0,2 percent of *delta*-9-tetrahydrocannabinol are not under international control' to be included after the term 'cannabis and cannabis resin' in Schedule I of the Convention on Narcotic Drugs.

(37) Due to the late submission by the WHO of the recommendations related to cannabis and cannabis-related substances, which were not announced at the reconvened sixty-first session of the CND in December 2018, there is not sufficient time to evaluate the impact of these recommendations in order to sufficiently inform the Union's position.

(38) Therefore, the Member States should take the position that the vote on the recommendations in relation to the scheduling of cannabis and cannabis-related substances should be postponed to a later CND session and, in case the said recommendations are put to a decision by the CND during its sixty-second session from 18 to 22 March 2019, Member States should take the position to abstain from the vote on these recommendations.

(39) It is appropriate to establish the position to be adopted on the Union's behalf in the CND, as the decisions on scheduling as regards the above-mentioned substances will directly influence the content of Union law, namely Framework Decision 2004/757/JHA.

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

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

(42) Ireland is bound by Framework Decision 2004/757/JHA, as amended, and is therefore taking part in the adoption and application of this Decision.

(43) The United Kingdom is not bound by Framework Decision 2004/757/JHA, as amended, and is therefore not taking part in the adoption of this Decision, and is not bound by it or subject to its application,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the Union's behalf by the Member States in the sixty-second session of the Commission on Narcotic Drugs from 18 to 22 March 2019, 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 expressed 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 (CND), acting jointly in the interest of the Union during the sixty-second session of the Commission on Narcotic Drugs of 18 to 22 March 2019:

(1) ADB-FUBINACA is to be included in Schedule II of the Convention on Psychotropic Substances.

(2) FUB-AMB is to be included in Schedule II of the Convention on Psychotropic Substances.

(3) ADB-CHMINACA is to be included in Schedule II of the Convention on Psychotropic Substances.

(4) CUMYL-4CN-BINACA is to be included in Schedule II of the Convention on Psychotropic Substances.

(5) Cyclopropylfentanyl is to be included in Schedule I of the Convention on Narcotic Drugs.

(6) Methoxyacetylfentanyl is to be included in Schedule I of the Convention on Narcotic Drugs.

(7) *Ortho*-fluorofentanyl is to be included in Schedule I of the Convention on Narcotic Drugs.

(8) *p*-Fluoro-butyrylfentanyl is to be included in Schedule I of the Convention on Narcotic Drugs.

(9) *N*-ethylnorpentylone is to be included in Schedule II of the Convention on Psychotropic Substances.

(10) For the following substances, referred to as 'cannabis and cannabis-related substances', the CND decisions in relation to the scheduling are to be postponed to a later CND session and, in case the said recommendations are put to a decision by the CND during its sixty-second session from 18 to 22 March 2019, Member States should take the position to abstain from the vote on these recommendations: cannabis and cannabis resin, dronabinol (*delta*-9-tetrahydrocannabinol; Δ^9-THC), tetrahydrocannabinol (isomers of *delta*-9- tetrahydrocannabinol), 'extracts and tinctures of cannabis', preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health; additional footnote reading 'preparations containing predominantly cannabidiol and not more than 0,2 percent of *delta*-9-tetrahydrocannabinol are not under international control' after the term 'cannabis and cannabis resin'.