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Delegations will find attached document COM(2018) 862 final.

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Brussels, 7.1.2019
COM(2018) 862 final

2018/0437 (NLE)

Proposal for a

COUNCIL DECISION

on the position to be taken, 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 1954, 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 the Union's behalf in the 62nd session of the Commission on Narcotic Drugs 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.

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 United Nations (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 EU Member States are parties to the Convention on Narcotic Drugs and to the Convention on Psychotropic Substances. The Union is not a party to the Conventions.

2.2. The Commission on Narcotic Drugs

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 Convention on Narcotic Drugs and in the Convention on Psychotropic Substances. It is made up of 53 UN Member States elected by ECOSOC. 11 Member States are currently members of the CND with the right to vote³. 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 Convention on Narcotic Drugs and to the Convention on Psychotropic Substances on the basis of

¹ United Nations Treaty Series, vol. 978, No. 14152.

² United Nations Treaty Series, vol. 1019, No. 14956.

³ Austria, Belgium, Croatia, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Slovakia, Spain.

recommendations of the World Health Organisation (WHO) which is advised by its Expert Committee on Drug Dependence.

The WHO recommended on 7 December 2018 to the Secretary General of the UN⁴ to add 10 of the substances which were critically reviewed by the WHO Expert Committee on Drug Dependence to the schedules of the Conventions. As regards the other substances reviewed by the WHO Expert Committee on Drug Dependence, no scheduling recommendations will be made.

The CND, in its sixty-second session taking place in Vienna from 18 to 22 March 2019, will adopt decisions on the scheduling of these 10 substances under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances, respectively.

3. POSITION TO BE TAKEN ON THE UNION'S BEHALF

Changes to the schedules of the Convention on Narcotic Drugs and of the Convention on Psychotropic Substances have direct repercussions for the scope of application of Union law in the area of drug control for all Member States. Article 1(1)(a) 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 trafficking⁵ 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. Council Framework Decision 2004/757/JHA 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) TFEU. This is irrespective of whether the substance in question was already placed under control across the Union on the basis of Council Decision 2005/387/JHA.⁶

From the 10 substances which were critically reviewed by the WHO Expert Committee on Drug Dependence and are recommended for scheduling, only four substances, ADB-CHMINACA⁷, CUMYL-4CN-BINACA⁸, methoxyacetylfentanyl and cyclopropylfentanyl⁹,

⁴ Oral statement at the reconvened 61st session of the Commission on Narcotic Drugs on 7 December 2018.

⁵ OJ L 335, 11.11.2004, p. 8, as amended by 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, p. 12.

⁶ Council Decision 2005/387/JHA was repealed as of 23 November 2018 by Directive (EU) 2017/2103. All substances subjected to control measures and criminal penalties pursuant to Council Decision 2005/387/JHA by the date of adoption of Directive (EU) 2017/2103 were included in an Annex to the Directive, which became the Annex to the amended Council Framework Decision 2004/757/JHA. The substances which have been subjected to control measures and criminal penalties pursuant to Council Decision 2005/387/JHA between November 2017, when the new legislation was adopted, and 23 November 2018 will be added to the Annex of the Framework Decision through a delegated act which is currently subject to scrutiny by the European Parliament and the Council (C(2018) 8460).

⁷ 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.

are already subject to control measures across the Union. The other substances are not subject to control measures across the Union yet.

The Commission proposal for the draft EU common position suggests supporting the WHO recommendations as these are in line with the current state of play of scientific knowledge. As regards the new psychoactive substances, the addition of these substances to the Schedules of the two Conventions is supported also by information available from the European Database on New Drugs of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

It is necessary that Member States prepare the meeting of the CND when it is called to decide on the scheduling of substances by reaching a common position in the Council. Such position, due to the limitations intrinsic to the observer status of the Union, should be expressed by the Member States that are currently members of the CND, acting jointly in the interest of the Union within the CND. The Union, who is not a party to the Convention on Narcotic Drugs and to the Convention on Psychotropic Substances, does not have the right to vote in the CND.

To this end, the Commission is proposing a common position to be taken, on behalf of the European Union, in the sixty-second session of the CND on the scheduling of substances under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. This is the third time that the Commission presents such a draft proposal for a common EU position, after those adopted for the CND meeting in March 2017 and 2018.¹⁰ The Council adopted the common positions¹¹ and this allowed the EU to speak with one voice at the previous CND meetings regarding the international scheduling, since the Member States participating in the CND voted in favour of the scheduling in line with the adopted common position.

4. LEGAL BASIS

4.1. Procedural legal basis

Article 218(9) of the Treaty on the Functioning of the European Union (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 at issue. The CND is "a body set up by an agreement" within the

⁸ 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.

⁹ 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 (methoxyacetyl fentanyl) to control measures, OJ L 245, 1.10.2018, p. 9.

¹⁰ COM(2017) 72 final and COM(2018) 31 final.

¹¹ Adopted by the General Affairs Council on 7 March 2017 and on 27 February 2018, respectively.

meaning of this Article, given that it is a body that has been given specific tasks under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances.

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*'¹².

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 automatically become binding, unless a party has submitted the decision for review to ECOSOC within the applicable time-limit¹³. The decisions of 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, namely Council Framework Decision 2004/757/JHA. Changes to the schedules of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances have direct repercussions for the scope of application of this EU legal instrument.

4.2. Substantive legal basis

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) of the Treaty on the Functioning of the European Union (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

In accordance with Article 10(4) of Protocol (No 36) on transitional provisions annexed to the Treaties, the United Kingdom notified that it does not accept the full powers of the Commission and the Court of Justice with regard to acts in the field of police and judicial cooperation in criminal matters adopted before the entry into force of the Lisbon Treaty. As a consequence, Council Framework Decision 2004/757 JHA has ceased to apply to the United Kingdom as from 1 December 2014¹⁴.

Since the CND's scheduling decisions do not affect common rules in the area of illicit drug trafficking by which the United Kingdom is bound, the United Kingdom does not take part in the adoption of a Council Decision establishing the position to be adopted on the Union's behalf when such scheduling decisions are adopted.

¹² Judgment of the Court of Justice of 7 October 2014, Germany v Council, Case C-399/12, ECLI:EU:C:2014:2258, paragraphs 61 to 64.

¹³ Article 3(7) of the Convention on Narcotic Drugs; Article 2(7) of the Convention on Psychotropic Substances.

¹⁴ See point 29 of the List of Union acts adopted before the entry into force of the Lisbon Treaty in the field of police cooperation and judicial cooperation in criminal matters which cease to apply to the United Kingdom as from 1 December 2014 pursuant to Article 10(4), second sentence, of Protocol (No 36) on transitional provisions (OJ C 430 of 1.12.2014, p. 17).

Denmark is bound by Council Framework Decision 2004/757/JHA as applicable until 22 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 adopted on the Union’s behalf when such scheduling decisions are adopted.

4.4. Conclusion

The legal basis for this proposal is Article 83(1) in conjunction with Article 218(9) of the Treaty on the Functioning of the European Union (TFEU).

5. BUDGETARY IMPLICATIONS

No budgetary implications.

Proposal for a

COUNCIL DECISION

on the position to be taken, 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 Protocol¹⁵, (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')¹⁶ 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 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/JHA¹⁷ applies to substances listed in the Schedules to the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. Thus any change to

¹⁵ United Nations Treaty Series, vol. 978, No. 14152.

¹⁶ United Nations Treaty Series, vol. 1019, No. 14956.

¹⁷ 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).

the Schedules annexed to those Conventions directly affects common Union rules and alters their scope, in accordance with Article 3(2) of the Treaty on the Functioning of the European Union (TFEU).

- (6) The Commission on Narcotic Drugs, during its sixty-second session of 18 to 22 March 2019 in Vienna, is to adopt decisions on the adding of 10 new substances to the Schedules of the UN Conventions.
- (7) The Union is not a party to the relevant UN Conventions. It has an observer status in the Commission on Narcotic Drugs 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 the decisions on the addition of new substances to the Schedules of the Conventions fall under the exclusive competence of the Union.
- (8) The WHO recommended to add five new substances to Schedule I of the Convention on Narcotic Drugs and five new substances to Schedule II of the Convention on Psychotropic Substances.¹⁸
- (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 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.¹⁹ ADB-FUBINACA has been detected in 19 Member States and is controlled in at least ten 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.
- (11) Therefore, the Member States should take the position to add ADB-FUBINACA to Schedule II of the Convention on Psychotropic Substances.
- (12) According to the assessment of the Expert Committee, FUB-AMB (also referred to as MMB-FUBINACA or AMB-FUBINACA; chemical name: methyl (2*S*)-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

¹⁸ Oral statement at the reconvened 61st session of the Commission on Narcotic Drugs on 7 December 2018.

¹⁹ 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).

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 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*-[(2*S*)-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 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) 2018/747.²⁰
- (17) Therefore, the Member States should take the position to add ADB-CHMINACA to Schedule II of the Convention on Psychotropic Substances.
- (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 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) 2018/748.²¹

²⁰ 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).

- (20) Therefore, the Member States should take the position to add CUMYL-4CN-BINACA to Schedule II of the Convention on Psychotropic Substances.
- (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) 2018/1463.²²
- (23) Therefore, the Member States should take the position to add cyclopropylfentanyl to Schedule I of the Convention on Narcotic Drugs.
- (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.

²¹ Council Implementing Decision (EU) 2018/748 of 14 May 2018 on subjecting the new psychoactive substance 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (CUMYL-4CN-BINACA) to control measures (OJ L 125, 22.5.2018, p. 10).

²² 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.

- (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-butyrylfentanyl 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-butyrylfentanyl / 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, *p*-methoxy-butyrylfentanyl (chemical name: *N*-(4-methoxyphenyl)-*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*-Methoxy-butyrylfentanyl has no recorded therapeutic use and its use has resulted in fatalities. There is sufficient evidence that *p*-methoxy-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*-methoxy-butyrylfentanyl be placed in Schedule I of the Convention on Narcotic Drugs.
- (34) *p*-Methoxy-butyrylfentanyl is monitored by the EMCDDA as a new psychoactive substance under the terms of Regulation (EC) No 1920/2006 (under the name 4-methoxybutyrylfentanyl / 4-MeO-BF). *p*-Methoxy-butyrylfentanyl has been detected in two Member States and is controlled in at least four Member States. It is being sold openly on the market. It has been associated with at least two deaths.
- (35) Therefore, the Member States should take the position to add *p*-methoxy-butyrylfentanyl to Schedule I of the Convention on Narcotic Drugs.
- (36) 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 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 ‘ecstasy’/MDMA²³. 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.

- (37) *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 least 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.
- (38) Therefore, the Member States should take the position to add *N*-ethylnorpentylone to Schedule II of the Convention on Psychotropic Substances.
- (39) 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 the different scheduling decisions as regards the 10 substances will be capable of decisively influencing the content of Union law, namely Framework Decision 2004/757/JHA.
- (40) The Union's position is to be expressed by the Member States that are members of the Commission on Narcotic Drugs, 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 in the sixty-second session of the Commission on Narcotic Drugs from 18 to 22 March 2018, 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.

²³ MDMA stands for 3,4-Methylenedioxymethamphetamine, commonly known as ecstasy.

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.

Article 3

This Decision is addressed to the Member States in accordance with the Treaties.

Done at Brussels,

*For the Council
The President*