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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	6 February 2017
То:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	Proposal for a COUNCIL DECISION on the position to be adopted, on behalf of the European Union, in the sixtieth 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(2017) 72 final.

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Brussels, 6.2.2017 COM(2017) 72 final

2017/0026 (NLE)

Proposal for a

COUNCIL DECISION

on the position to be adopted, on behalf of the European Union, in the sixtieth 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. CONTEXT OF THE PROPOSAL

Reasons for and objectives of the proposal

The Commission on Narcotic Drugs (CND) regularly amends the list of substances that are annexed to the United Nations (UN) Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol (the 1961 UN Convention)¹ and to the UN Convention on Psychotropic Substances of 1971 (the 1971 UN Convention)² on the basis of recommendations of the World Health Organisation (WHO) which is advised by its Expert Committee on Drug Dependence.

All EU Member States are signatories of the 1961 UN Convention and to the 1971 UN Convention. The Union is not a signatory of the conventions.

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 1961 UN Convention and in the 1971 UN Convention. It is made up of 53 UN Member States elected by ECOSOC. 12 Member States are currently members of the CND with the right to vote.³ The Union has an observer status in the CND.

The WHO recommended on 2 December 2016 to the Secretary General of the UN⁴ to add ten new substances to the schedules of the conventions. Only one of these substances, MDMB-CHMICA is already in the process to be submitted to control measures at EU level. Based on a risk assessment report of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) conducted in compliance with the provisions of Article 6(2), (3) and (4) of Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances,⁵ the Commission tabled on 31 August 2016 a proposal to subjecting MDMB-CHMICA to EU-wide control measures.⁶

Changes to the schedules of the 1961 UN Convention and the 1971 UN Convention have direct repercussions for the scope of application of Union law in the area of drug control for all Member States. Article 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 states that, for the purposes of the Framework Decision, "drugs" shall mean any of the substances covered by either the 1961 UN

OJ L 335, 11.11.2004, p. 8.

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

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

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

Oral statement at the reconvened 59th session of the Commission on Narcotic Drugs on 2 December 2016; see also extract from the report the 38th Expert Committee on Drug Dependence https://unodc.org/documents/commissions/CND/CND_Sessions/CND_59Reconvened/ECN72016_CRP 13 V1610192.pdf.

OJ L 127, 20.5.2005, p. 32.

Proposal for a Council Decision subjecting the new psychoactive substance MDMB-CHMICA to control measures of 31 August 2016 (COM(2016)548 final).

Convention or by the 1971 UN Convention. Framework Decision 2004/757/JHA therefore applies to substances listed in the Schedules to the 1961 UN Convention and the 1971 UN Convention. Thus any change to the schedules annexed to these conventions directly affects common EU rules and alters their scope, within the meaning of Article 3(2) TFEU. This is irrespective of whether the substance in question is already placed under control at EU level on the basis of Council Decision 2005/387/JHA on information exchange, risk assessment and control of new psychoactive substances.

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 in the Union within the CND. The Union, who is not a party to the 1961 UN Convention and to the 1971 UN Convention would not vote in the CND.

To this end, the Commission is proposing a position to be adopted, on behalf of the European Union, in the sixtieth session of the CND taking place in Vienna from 13 to 17 March 2017 on the scheduling of substances under the 1961 UN Convention and the 1971 UN Convention.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

Legal basis

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).

Article 83(1) TFUE 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.

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 meaning of this Article, given that it is body that has been given specific tasks under the 1961 UN Convention and the 1971 UN Convention.

The CND's scheduling-decisions are "acts having legal effects" within the meaning of Article 218(9) TFEU. According to the 1961 UN Convention and the 1971 UN Convention, decisions of the CND automatically become binding, unless a party has submitted the decision for review to ECOSOC within the applicable time-limit. 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 Framework Decision 2004/757/JHA. Changes to the schedules of the 1961 UN Convention and the 1971 UN Convention have direct repercussions for the scope of application of this EU legal instrument.

Variable geometry

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Article 3(7) of the 1961 UN Convention; Article 2(7) of the 1971 UN Convention.

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, Framework Decision 2004/757 JHA and Council Decision 2005/387/JHA have ceased to apply to the United Kingdom as from 1 December 2014.

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, that Member State 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.

Subsidiarity

Not applicable.

Proportionality

The proposal is proportionate and does not go beyond what is necessary to achieve the objectives as it addresses new psychoactive substances that are of concern for the Union.

• Choice of the instrument

The use of a Council Decision is required by Article 218(9) TFEU in order to establish the position to be adopted on the Union's behalf in a body set up by an international agreement.

See Commission Decision 2014/858/EU of 1 December 2014 on the notification by the United Kingdom of Great Britain and Northern Ireland of its wish to participate in acts of the Union in the field of police cooperation and judicial cooperation in criminal matters adopted before the entry into force of the Treaty of Lisbon and which are not part of the Schengen acquis (OJ L 345 of 1.12.2014, p. 6). Points 29 and 33 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).

Proposal for a

COUNCIL DECISION

on the position to be adopted, on behalf of the European Union, in the sixtieth 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, 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 1961¹⁰ as amended by the 1972 Protocol, 11 entered into force on 8 August 1975.
- (2) Pursuant to Article 3 of the UN Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, 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 entered into force on 16 August 1976.
- (4) Pursuant to Article 2 of the UN Convention on Psychotropic Substances of 1971, 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 for all Member States. Council Framework Decision 2004/757/JHA ¹² applies to substances listed in the Schedules to the UN Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971. Thus any change to the Schedules annexed to those

11.11.2004, p. 8).

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

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

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,

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

- (6) The Commission on Narcotic Drugs should, during its sixtieth session of 13 to 17 March 2017 in Vienna, take decisions on the addition of ten new substances to the Schedules of the 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 12 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 Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the Convention on Psychotropic Substances of 1971 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 on 2 December 2016 to Secretary-General of the UN to add two new substances to Schedule I of the UN Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and eight new substances to Schedule II of the UN Convention on Psychotropic Substances of 1971.
- (9) U-47700 (3,4-dichloro-N-(2-dimethylamino-cyclohexyl)-N-methyl-benzamide) is, according to the assessment of the WHO Expert Committee on Drug Dependence, a compound liable to similar abuse and with similar ill-effects to controlled opioids such as morphine and AH-7921, that are included in Schedule I of the UN Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use, and its use has resulted in fatalities. There is sufficient evidence that it is being or is likely to be abused, and may become a public health and social problem warranting the placing of the substance under international control. Consequently, the WHO recommends that U-47700 be placed in Schedule I of the UN Single Convention on Narcotic Drugs of 1961.
- (10) U-47700 is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA¹³. U-47700 has been detected in fourteen Union Member States. It is being sold openly on the market. It has been associated with serious adverse events, including deaths and has been a subject of a public health-related alert issued to the Union Early Warning System.
- (11) Therefore, the Member States of the Union should take the position to add U-47700 to Schedule I of the UN Single Convention on Narcotic Drugs of 1961.
- (12) Butyrfentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-iperidinyl]butanamide) is, according to the assessment of the WHO Expert Committee on Drug Dependence, a compound liable to similar abuse and with similar ill-effects to controlled opioids such as morphine and fentanyl that are included in Schedule I of the UN Single Convention on Narcotic Drugs of 1961. It can also be converted into fentanyl. It has no recorded therapeutic use and its use has resulted in fatalities. There is sufficient evidence that it

Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances (OJ L 127, 20.5.2005, p. 32).

- 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 butyrfentanyl be placed in Schedule I of the UN Single Convention on Narcotic Drugs of 1961.
- (13) Butyrfentanyl is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. Butyrfentanyl has been detected in six Union Member States. It has been sold openly on the market. It has been associated with serious adverse events, including detection in at least one death and has been the subject of a public health-related alert issued to the Union Early Warning System.
- (14) Therefore, the Member States of the Union should take the position to add butyrfentanyl to Schedule I of the UN Single Convention on Narcotic Drugs of 1961.
- (15) The degree of risk to public health and society associated with the abuse of 4-Methylethcathinone or 4-MEC (2-(ethylamino)-1-(4-methylphenyl) propan-1-one) is, according to the assessment of the WHO Expert Committee on Drug Dependence, substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse potential and similar ill-effects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that 4-MEC is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that 4-MEC be placed in Schedule II under the UN Convention on Psychotropic Substances of 1971.
- (16) 4-MEC is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. 4-MEC has been detected in nineteen Union Member States. It has been sold openly on the market. It has been associated with small number of serious adverse events, including deaths.
- (17) Therefore, the Member States of the Union should take the position to add 4-MEC to Schedule I of the UN Convention on Psychotropic Substances of 1971.
- (18)The degree of risk to public health and society associated with the abuse of ethylone (1-(2H-1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one) is, according to the assessment of the WHO Expert Committee on Drug Dependence, substantial. Therapeutic usefulness has not been recorded. The WHO Expert Committee on Drug Dependence recognized that ethylone (1-(2H-1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one) has similar abuse potential and similar ill-effects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that ethylone is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that ethylone be placed in Schedule II under the UN Convention on Psychotropic Substances 1971.
- (19) Ethylone is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new

- psychoactive substances. Ethylone has been detected in 19 EU Member States. It has been sold openly on the market. It has been associated with small number of serious adverse events, including deaths.
- (20) Therefore, the Member States of the Union should take the position to add ethylone to Schedule I of the UN Convention on Psychotropic Substances of 1971.
- (21) The degree of risk to public health and society associated with the abuse of pentedrone or α-Methylaminovalerophenone (2-(methylamino)-1-phenylpentan-1-one), according to the WHO Expert Committee on Drug Dependence, is substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse and similar illeffects as substances in Schedule II of the United Nations 1971 Convention on Psychotropic Substances. The Committee considered that there is sufficient evidence that pentedrone is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that pentedrone be placed in Schedule II under the United Nations 1971 Convention on Psychotropic Substances.
- (22) Pentedrone is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. Pentedrone has been detected in eighteen Union Member States. It has been sold openly on the market. It has been associated with a small number of serious adverse events, including deaths.
- (23) Therefore, the Member States of the Union should take the position to add pentedrone to Schedule I of the UN Convention on Psychotropic Substances of 1971.
- (24) The degree of risk to public health and society associated with the abuse of ethylphenidate or EPH (ethyl phenyl(piperidin-2-yl)acetate) is, according to the WHO Expert Committee on Drug Dependence, substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse potential and similar ill-effects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that ethylphenidate is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that ethylphenidate be placed in Schedule II under the United Nations Convention on Psychotropic Substances of 1971.
- (25) Ethylphenidate is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. Ethylphenidate has been detected in thirteen UnionMember States. It has been sold openly on the market. It has been associated with serious adverse events, including soft tissue infections and deaths. Soft tissue infections related to injection have been the subject of a public health-related alert issued to the Union Early Warning System.
- (26) Therefore, the Member States of the Union should take the position to add ethylphenidate to Schedule I of the UN Convention on Psychotropic Substances of 1971.
- (27) The degree of risk to public health and society associated with the abuse of MPA or methiopropamine (N-methyl-1-(thiophen-2-yl)propan-2-amine) is, according to the

WHO Expert Committee on Drug Dependence (ECDD), substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse potential and similar ill-effects as substances in Schedule II of the United Nations 1971 Convention on Psychotropic Substances. The Committee considered that there is sufficient evidence that methiopropamine is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus the WHO recommends that methiopropamine be placed in Schedule II under the UN Convention on Psychotropic Substances of 1971.

- (28) MPA is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. MPA has been detected in seventeen Union Member States. It has been sold openly on the market. It has been associated with serious adverse events, including deaths.
- (29) Therefore, the Member States of the Union should take the position to add methiopropamine to Schedule I of the UN Convention on Psychotropic Substances of 1971.
- (30) The degree of risk to public health and society associated with the abuse of MDMB-CHMICA (N-{[1-(cyclohexylmethyl)-1H-indol-3-yl]carbonyl}-3-methyl-L-valinate) is, according to the WHO Expert Committee on Drug Dependence, substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse and similar ill-effects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that MDMB-CHMICA is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that MDMB-CHMICA be placed in Schedule II under the UN Convention on Psychotropic Substances of 1971.
- (31) According the risk assessment report of the European Monitoring Centre for Drugs and Drug Addiction conducted compliance with the provisions of Article 6(2), (3) and (4) of Council Decision Council Decision 2005/387/JHA ¹⁴ and submitted on 28 July 2016 to Commission and the Council, the high potency of MDMB-CHMICA and the highly variable amounts of the compound in "legal high" products constitute a high risk of acute toxicity. Eight Member States have reported a total of 28 deaths and 25 acute intoxications associated with MDMB-CHMICA. The Commission therefore adopted on 31 August 2016 a proposal in order to subject MDMB-CHMICA to Union-wide control measures. ¹⁵
- (32) Therefore, the Member States of the Union should take the position to add MDMB-CHMICA to Schedule I of the UN Convention on Psychotropic Substances of 1971.
- (33) The degree of risk to public health and society associated with the abuse of 5F-APINACA or 5F-AKB-48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide) is according to the WHO Expert Committee on Drug Dependence considered substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse potential and similar ill-effects as substances in Schedule II of

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OJ L 127, 20.5.2005, p. 32.

Proposal for a Council Decision on subjecting the new psychoactive substance methyl 2-[[1-(cyclohexylmethyl)-1*H*-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) to control measures (COM(2016)548 final).

the UN Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that 5F-APINACA is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that 5F-APINACA be placed in Schedule II under the UN Convention on Psychotropic Substances of 1971.

- (34) 5F-APINACA is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. 5F-APINACA has been detected in twenty three Union Member States. It has been sold openly on the market. It has been associated with serious adverse events, including deaths.
- (35) Therefore, the Member States of the Union should take the position to add 5F-APINACA to Schedule I of the UN Convention on Psychotropic Substances of 1971.
- (36) The degree of risk to public health and society associated with the abuse of XLR-11 [1-(5-fluoropentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl) is according to the WHO Expert Committee on Drug Dependence substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse potential and similar illeffects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971 such as JWH-018 and AM-2201. The Committee considered that there is sufficient evidence that XLR-11 is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that XLR-11 be placed in Schedule II under the UN Convention on Psychotropic Substances of 1971.
- (37) XLR-11 is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. XLR-11 has been detected in seventeen Union Member States. It has been sold openly on the market. It has been associated with small number of serious adverse events, including detections in at least one death and has been the subject of a public health-related alert issued to the Union Early Warning System.
- (38) Therefore, the Member States of the Union should take the position to add XLR-11 to Schedule I of the UN Convention on Psychotropic Substances of 1971.
- (39) In accordance with Article 10(4) of the Protocol No 36 on transitional measures, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Framework Decision 2004/757 JHA and Council Decision 2005/387/JHA have ceased to apply to the United Kingdom as from 1 December 2014. The United Kingdom is therefore not taking part in the adoption of this Decision.

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the Union's behalf by the Member States in the Commission on Narcotic Drugs in March 2017 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 at its sixtieth session shall be in accordance with the Annex to this Decision.

The position shall be expressed by the Member States which are members of the Commission of Narcotic Drugs, acting jointly in the interest of the Union.

Article 2

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

Done at Brussels,

For the Council The President