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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-first 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) 2018/…

of …

on the position to be adopted,
on behalf of the European Union,
in the sixty-first 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 in the Schedules only in accordance with the recommendations of the World Health Organization (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 Commission on Narcotic Drugs may decide to add substances to the Schedules of that Convention, or to remove them, on the basis of the recommendations of the WHO. It has broad discretionary powers to take into account economic, social, legal, administrative and other factors, but may not act arbitrarily.

(5) Changes to the Schedules of both Conventions have direct repercussions on the scope of application of Union law in the area of drug control. Council Framework Decision 2004/757/JHA[1] applies to substances listed in the Schedules to the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. Council Decision 2005/387/JHA[2] does not apply to substances listed in the Schedules to the Convention on Narcotic Drugs or to the Convention on Psychotropic Substances. Thus any change to the Schedules annexed to those Conventions is directly incorporated into common Union rules.

(6) The Commission on Narcotic Drugs, during its sixty-first session of 12 to 16 March 2018 in Vienna, is to adopt decisions on the addition of 12 new substances to the Schedules of the Conventions.

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[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] Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances (OJ L 127, 20.5.2005, p. 32).

(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 11 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 competence of the Union.

(8) Action 42 of the EU Action Plan on Drugs 2017-2020 calls on the Union to contribute to shaping the agenda on international drugs policy, including through, *inter alia*, preparation, coordination and adoption of Union common positions and joint resolutions in the UN General Assembly and the Commission on Narcotic Drugs, including, ahead of the Commission on Narcotic Drugs, on scheduling of substances, and ensuring that the Union speaks with one strong voice in these fora.

(9) On 8 December 2017, the WHO recommended thatthe Secretary-General of the UN add one new substance to Schedules I and IV of the Convention on Narcotic Drugs, five new substances to Schedule I of the Convention on Narcotic Drugs and six new substances to Schedule II of the Convention on Psychotropic Substances.

(10) According to the assessment of the WHO Expert Committee on Drug Dependence (the Expert Committee), carfentanil (Methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate) is a synthetic opioid and is considered to be one of the most potent opioids known. Carfentanil is a controlled compound in 16 Member States and is used primarily as a tranquiliser in large animals. Carfentanil is not intended for therapeutic use in humans. Carfentantil 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 constitute a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that carfentanil be placed in Schedules I and IV of the Convention on Narcotic Drugs.

(11) Carfentanil is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. Seizures of carfentanil have been reported by seven Member States. It is being sold openly on the market as well as in mixtures with heroin and other opioids. It has been associated with serious adverse events, including detection in at least 60 deaths in the Union. Carfentanil has been the subject of a Risk Assessment by the European Monitoring Centre for Drugs and Drug Addiction. The Commission proposed on 15 December 2017 to subject carfentanil to control measures under Decision 2005/387/JHA.

(12) Therefore, the Member States should take the position to add carfentanil to Schedules I and IV of the Convention on Narcotic Drugs.

(13) According to the assessment of the Expert Committee, ocfentanil (*N*-(2-Fluorophenyl)-2-methoxy-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide) is a compound structurally similar to the opioid analgesic fentanyl. Ocfentanil is not approved in any country for medical use. There is sufficient evidence that it is being or is likely to be abused, and may become a public health and social problem that warrants placing the substance under international control. Consequently, the WHO recommends that ocfentanil be placed in Schedule I of the Convention on Narcotic Drugs.

(14) Ocfentanil is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. Ocfentanil has been detected in 12 Member States. It is being sold openly on the market as well as in samples sold as heroin. It has been associated with serious adverse events, including deaths, and has been the subject of two public health-related alerts issued by the Union Early Warning System.

(15) Therefore, the Member States should take the position toadd ocfentanil to Schedule I of the Convention on Narcotic Drugs.

(16) According to the assessment of the Expert Committee, furanylfentanyl (*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide) 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. It is a derivative of fentanyl with two distinctive characteristics: (a) higher liposolubility that allows its rapid absorption into general circulation; and (b) it binds to μ-opioid receptors with significant higher affinity than morphine. These characteristics give furanylfentanyl a highly risky pharmacological profile. In the last several years there has been an increase in deaths due to the use of this substance. Furanylfentanyl has itself no recorded therapeutic use. There is sufficient evidence that it is being or is likely to be abused and may constitute a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that furanylfentanyl be placed in Schedule I of the Convention on Narcotic Drugs.

(17) Furanylfentanyl is already subject to control measures at Union level under Decision 2005/387/JHA and Council Implementing Decision (EU) 2017/2170[1].

(18) Therefore, Member States should take the position toadd furanylfentanyl to Schedule I of the Convention on Narcotic Drugs.

[1] Council Implementing Decision (EU) 2017/2170 of 15 November 2017 on subjecting *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4- yl]furan-2-carboxamide (furanylfentanyl) to control measures (OJ L 306, 22.11.2017, p. 19).

(19) According to the assessment of the Expert Committee, acryloylfentanyl (acrylfentanyl; *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide) 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. Acryloylfentanyl is being used and abused for non-medical purposes in the same setting and for the same desired effects as other opioids. Acryloylfentanyl has itself 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 constitute a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that acryloylfentanyl be placed in Schedule I of the Convention on Narcotic Drugs.

(20) Acryloylfentanyl is already subject to control measures at Union level under Decision 2005/387/JHA and Council Implementing Decision (EU) 2017/1774[1].

(21) Therefore, the Member States should take the position toadd acryloylfentanyl to Schedule I of the Convention on Narcotic Drugs.

[1] Council Implementing Decision (EU) 2017/1774 of 25 September 2017 on subjecting *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl) to control measures (OJ L 251, 29.9.2017, p. 21).

(22) According to the assessment of the Expert Committee, 4-Fluoroisobutyrfentanyl (4-FIBF, pFIBF; *N*-(4-Fluorophenyl)-2-methyl-*N*-[1-(2-phenethyl)piperidin-4-yl]propanamide) is a synthetic opioid. 4-Fluoroisobutyrfentanyl is one of the latest fentanyl derivatives to be sold and used in a similar manner as other licit and illicit opioids. At the current time, there is evidence that 4-Fluoroisobutyrfentanyl poses similar public health risks as the fentanyl derivatives that preceded it. 4-Fluoroisobutyrfentanyl 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 constitute a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that 4-Fluoroisobutyrfentanyl be placed in Schedule I of the Convention on Narcotic Drugs.

(23) 4-Fluoroisobutyrfentanyl is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. 4-Fluoroisobutyrfentanyl has been seized in four Member States. It is being sold openly on the market. It has been associated with serious adverse events, including detection in at least 16 deaths. 4-Fluoroisobutyrfentanyl has been the subject of risk assessment by the European Monitoring Centre for Drugs and Drug Addiction. The Commission proposed on 15 December 2017 to subject 4-Fluoroisobutyrfentanyl to control measures under Decision 2005/387/JHA.

(24) Therefore, the Member States should take the position toadd 4-Fluoroisobutyrfentanyl to Schedule I of the Convention on Narcotic Drugs.

(25) According to the assessment of the Expert Committee, tetrahydrofuranylfentanyl (THF-F; *N*-phenyl-*N*-[1-(2-Phenylethyl)piperidin-4-yl] oxolane-2-carboxamide) is a synthetic opioid. The data collected so far from in vitro studies and the toxicological findings, and patterns of use indicate that tetrahydrofuranylfentanyl is likely an opioid narcotic analgesic in humans with abuse liability and dependence potential similar to fentanyl and other illicit opioids. Tetrahydrofuranylfentanyl 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 constitute a public health and social problem that warrantsplacing the substance under international control. Thus, the WHO recommends that tetrahydrofuranylfentanyl be placed in Schedule I of the Convention on Narcotic Drugs.

(26) Tetrahydrofuranylfentanyl is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. Tetrahydrofuranylfentanyl has been seized in one Member State. It is being sold openly on the market. It has been associated with serious adverse events, including detection in at least 14 deaths. Tetrahydrofuranylfentanyl has been the subject of risk assessment by the European Monitoring Centre for Drugs and Drug Addiction. The Commission proposed on 15 December 2017 to subject tetrahydrofuranylfentanyl to control measures under Decision 2005/387/JHA.

(27) Therefore, the Member States should take the position toadd tetrahydrofuranylfentanyl (THF-F) to Schedule I of the Convention on Narcotic Drugs.

(28) According to the assessment of the Expert Committee, 4-Fluoroamphetamine (4-FA; 1-(4-Fluorophenyl)propan-2-amine) is a phenethylamine. It underwent a critical review in November 2015 at the 37th meeting of the WHO Expert Committee on Drug Dependence. The Committee recommended at the time that 4-Fluoroamphetamine not be placed under international control due to insufficiency of data regarding dependence, abuse and risks to public health but be kept under surveillance. Most of the new data collected stems from Europe and indicates increased use and popularity alongside increased numbers of notifications associated with severe adverse drug effects including serious cardiovascular toxicity. There is sufficient evidence that it is being or is likely to be abused and may constitute a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that 4-Fluoroamphetamine be placed in Schedule II of the Convention on Psychotropic Substances.

(29) 4-Fluoroamphetamine is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. 4-Fluoroamphetamine has been detected in 21 Member States. It is being sold openly on the market and is often mixed with or sold as amphetamine. It has been associated with serious adverse events, including deaths.

(30) Therefore, the Member States should take the position toadd 4-Fluoroamphetamine (4-FA) to Schedule II of the Convention on Psychotropic Substances.

(31) According to the assessment of the Expert Committee, the degree of risk to public health and society associated with the abuse of AB-PINACA (*N*-[(2*S*)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-pentyl-1*H*-indazole-3-carboxamide) is substantial. AB-PINACA is a synthetic cannabinoid receptor agonist. There is sufficient evidence that it is being or is likely to be abused and may constitute a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that AB-PINACA be placed in Schedule II of the Convention on Psychotropic Substances.

(32) AB-PINACA is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. AB-PINACA has been detected in 12 Member States. It is being sold openly on the market.

(33) Therefore, the Member States should take the position toadd AB-PINACA to Schedule II of the Convention on Psychotropic Substances.

(34) According to the assessment of the Expert Committee, the degree of risk to public health and society associated with the abuse of AB-CHMINACA (*N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide) is substantial. AB-CHMINACA is a synthetic cannabinoid receptor agonist with an aminoalkylindazole structure used as an active ingredient of products sold as cannabis substitutes. AB-CHMINACA has no known therapeutic or medical use. There is sufficient evidence that it is being or is likely to be abused and may constitute a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that AB-CHMINACA be placed in Schedule II of the Convention on Psychotropic Substances.

(35) AB-CHMINACA is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. AB-CHMINACA has been detected in 24 Member States. It is being sold openly on the market. It has been associated with serious adverse events, including detection in at least 31 deaths. AB-CHMINACA has been the subject of risk assessment by the European Monitoring Centre for Drugs and Drug Addiction. On 18 December 2017, the Commission proposed that AB-CHMINACA be subject to control measures under Decision 2005/387/JHA.

(36) Therefore, the Member States should take the position toadd AB-CHMINACA to Schedule II of the Convention on Psychotropic Substances.

(37) According to the assessment of the Expert Committee, the degree of risk to public health and society associated with the abuse of 5F-PB-22 (Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate) is substantial. 5F-PB-22 is a synthetic cannabinoid receptor agonist. There is sufficient evidence that it is being or is likely to be abused and may constitute a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that 5F-PB-22 be placed in Schedule II of the Convention on Psychotropic Substances.

(38) 5F-PB-22 is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. 5F-PB-22 has been detected in four Member States. It is being sold openly on the market.

(39) Therefore, the Member States should take the position toadd 5F-PB-22 to Schedule II of the Convention on Psychotropic Substances.

(40) According to the assessment of the Expert Committee, the degree of risk to public health and society associated with the abuse of UR-144 ((1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone) is substantial. UR-144 is a synthetic cannabinoid receptor agonist which has been previously critically reviewed by the 36th meeting of the WHO Expert Committee on Drug Dependence in 2014. The Committee recommended at that time that UR-144 be kept under surveillance due to lack of scientific data on non-fatal and fatal intoxications involving solely UR-144. There is now sufficient evidence that it is being or is likely to be abused and may constitute a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that UR-144 be placed in Schedule II of the Convention on Psychotropic Substances.

(41) UR-144 is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. UR-144 has been detected in 16 Member States. It is being sold openly on the market. It has been associated with serious adverse events and has been the subject of a public health-related alert issued to the Union Early Warning System.

(42) Therefore, the Member States should take the position toadd UR-144 to Schedule II of the Convention on Psychotropic Substances.

(43) According to the assessment of the Expert Committee, the degree of risk to public health and society associated with the abuse of 5F-MDMB-PINACA (5F-ADB; Methyl 2-{[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino}-3,3-dimethylbutanoate) is substantial. 5F-MDMB-PINACA is a synthetic cannabinoid receptor agonist with an aminoalkylindazole structure used as an active ingredient of products sold as cannabis substitutes. 5F-MDMB-PINACA has no known therapeutic or medical use. There is sufficient evidence that it is being or is likely to be abused and may constitute a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that 5F-MDMB-PINACA be placed in Schedule II of the Convention on Psychotropic Substances.

(44) 5F-MDMB-PINACA is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. 5F-MDMB-PINACA has been detected in 25 Member States. It is being sold openly on the market. It has been associated with serious adverse events, including detection in at least 28 deaths. 5F-MDMB-PINACA has been the subject of a risk assessment by the European Monitoring Centre for Drugs and Drug Addiction. The Commission proposed on 15 December 2017 to subject 5F-MDMB-PINACA to control measures under Decision 2005/387/JHA.

(45) Therefore, the Member States should take the position toadd 5F-MDMB-PINACA to Schedule II of the Convention on Psychotropic Substances.

(46) It is appropriate to establish the position to be adopted on the Union's behalf in the Commission on Narcotic Drugs, as the decisions on the addition of 12 new substances to the Schedules of the relevant UN Conventions will directly influencethe content of Union law, namely Framework Decision 2004/757/JHA and Decision 2005/387/JHA.

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

(48) Denmark is bound by Framework Decision 2004/757/JHA and Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.

(49) Ireland is bound by Framework Decision 2004/757/JHA and Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.

(50) The United Kingdom is not bound by Framework Decision 2004/757/JHA and Decision 2005/387/JHA 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-first session of the Commission on Narcotic Drugs from 12 to 16 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, shall be in accordance with the Annex to this Decision.

The position 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 2

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 that are members of the Commission on Narcotic Drugs acting jointly in the interest of the Union during the sixty-first session of the Commission on Narcotic Drugs of 12 to 16 March 2018 regarding changes in the scope of control of substances:

(1) Carfentanil is to be included in Schedules I and IV of the Convention on Narcotic Drugs.

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

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

(4) Acryloylfentanyl (acrylfentanyl) is to be included in Schedule I of the Convention on Narcotic Drugs.

(5) 4-Fluoroisobutyrfentanyl (4-FIBF, pFIBF) is to be included in Schedule I of the Convention on Narcotic Drugs.

(6) Tetrahydrofuranylfentanyl (THF-F) is to be included in Schedule I of the Convention on Narcotic Drugs.

(7) 4-Fluoroamphetamine (4-FA) is to be included in Schedule II of the Convention on Psychotropic Substances.

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

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

(10) 5F-PB-22 is to be included in Schedule II of the Convention on Psychotropic Substances.

(11) UR-144 is to be included in Schedule II of the Convention on Psychotropic Substances.

(12) 5F-MDMB-PINACA (5F-ADB) is to be included in Schedule II of the Convention on Psychotropic Substances.