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PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	17 December 2020
To:	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 expressed, on behalf of the European Union, in the sixty-fourth 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(2020) 814 final.

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EUROPEAN
COMMISSION

Brussels, 17.12.2020
COM(2020) 814 final

2020/0357 (NLE)

Proposal for a

COUNCIL DECISION

on the position to be expressed, on behalf of the European Union, in the sixty-fourth 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. SUBJECT MATTER OF THE PROPOSAL

THIS PROPOSAL CONCERNS THE DECISION ESTABLISHING THE POSITION TO BE EXPRESSED ON THE UNION'S BEHALF IN THE 64TH 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. THE 64TH SESSION OF THE COMMISSION ON NARCOTIC DRUGS IS SCHEDULED TO TAKE PLACE FROM 12 TO 16 APRIL 2021.2. 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 Conventions, whereas the Union is not.

2.2. The Commission on Narcotic Drugs

The Commission on Narcotic Drugs is a commission of the UN Economic and Social Council and its functions and powers are *inter alia* set out in the two Conventions. It is made up of 53 UN Member States elected by UN Economic and Social Council. 12 Member States are members of the Commission on Narcotic Drugs with the right to vote in March 2021[3]. The Union has an observer status in the Commission on Narcotic Drugs.

2.3. The envisaged act of the Commission on Narcotic Drugs

The Commission on Narcotic Drugs regularly amends the list of substances that are annexed to the Conventions on the basis of recommendations of the World Health Organisation (WHO) which is advised by its Expert Committee on Drug Dependence.

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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, Poland, Spain and Sweden.

The WHO recommended to the Secretary General of the UN to add eight out of the eleven substances, which were critically reviewed by the WHO Expert Committee on Drug Dependence, to the schedules of the Conventions.

The Commission on Narcotic Drugs, in its 64th session, taking place in Vienna from 12 to 16 April 2021, is called upon to adopt decisions on the scheduling of these substances under the Conventions.

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

Changes to the schedules of the Conventions have direct repercussions for the scope of application of Union law in the area of drug control for all Member States. Article 1(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[4] (the 'Framework Decision') 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. The Framework Decision 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) of the Treaty on the Functioning of the European Union (TFEU). This is irrespective of whether the substance in question is controlled in the Union.[5]

One of the eleven substances, which have been reviewed by the Expert Committee on Drug Dependence, is subject to control measures across the Union. Isotonitazene was included in the definition of 'drug' in the Council Framework Decision 2004/757/JHA.[6] One substance, MDMB-4en-PINACA, is under intensive monitoring by the European Monitoring Centre for Drugs and Drug Addiction; it is also the subject of a risk assessment report. The other 9 substances are being monitored by the European Monitoring Centre for Drugs and Drug Addiction.

The Commission proposal for a Union 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 Conventions is supported also by information available from the European Database on New Drugs of the European Monitoring Centre for Drugs and Drug Addiction.

It is necessary that the Council establishes the Union's position for the meeting of the Commission on Narcotic Drugs when it is called to decide on the scheduling of substances.

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4 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.

5 See the Annex to the Framework Decision.

6 Commission Delegated Directive (EU) 2020/1687 of 2 September 2020 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substance *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene) in the definition of 'drug', OJ L 379, 13.11.2020, p. 55.

Such position, due to the limitations intrinsic to the observer status of the Union, should be expressed by the Member States that will be members of the Commission on Narcotic Drugs in March 2021, acting jointly in the interest of the Union within the Commission on Narcotic Drugs. The Union is not a party to these Conventions but has exclusive competence in this area.

To this end, the Commission is proposing a Union position to be expressed by the Member States that will be members of the Commission on Narcotic Drugs in March 2021, on behalf of the European Union, in the 64th session of the Commission on Narcotic Drugs on the scheduling of substances under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. This is the fifth time that the Commission presents such a proposal for a Union position.[7] The Council adopted the Union positions[8] and this allowed the EU to speak with one voice at the previous Commission on Narcotic Drugs meetings regarding the international scheduling, since the Member States participating in the Commission on Narcotic Drugs voted in favour of the scheduling in line with the adopted Union 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[9]. 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*'[10].

The Commission on Narcotic Drugs is "a body set up by an agreement" within the meaning of this Article, given that it is a body established by UN Economic and Social Council – an organ of the United Nations – and that it has been given specific tasks under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances.

The Commission on Narcotic Drugs'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 Commission on Narcotic Drugs automatically become binding, unless a party has submitted the decision for review to

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7 COM(2017) 72 final; COM(2018) 31 final; COM(2018) 862 final; COM(2019) 631 final.

8 Adopted by the Council on 7 March 2017, on 27 February 2018, on 5 March 2019, and on 11 February 2020, respectively.

9 Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraph 64.

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

UN Economic and Social Council within the applicable time-limit[11]. The decisions of UN Economic and Social Council on the matter are final. The Commission on Narcotic Drugs's scheduling decisions also have legal effects in the EU legal order by virtue of Union law, given the fact that they are capable of decisively influencing the content of EU legislation, namely Council Framework Decision 2004/757/JHA. Changes to the schedules of the Conventions have direct repercussions for the scope of application of this EU legal instrument.

The envisaged act does not supplement or amend the institutional framework of the Agreement.

Therefore, the procedural legal basis for the proposed decision is Article 218(9) TFEU.

4.2. Substantive legal basis

The substantive legal basis for a decision under Article 218(9) TFEU depends primarily on the objective and content of the envisaged act in respect of which a position is taken on the Union's behalf.

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) 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

Denmark is bound by Council Framework Decision 2004/757/JHA as applicable until 21 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 Commission on Narcotic Drugs'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) TFEU in conjunction with Article 218(9) TFEU.

5. BUDGETARY IMPLICATIONS

No budgetary implications.

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

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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[1], ('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')[2] 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[3] applies to substances listed in the Schedules to these Conventions.

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

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

3 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).

Thus any change to the Schedules annexed to the 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.

(6) The Commission on Narcotic Drugs, during its sixty-fourth session tentatively scheduled for 12 to 16 April 2021 in Vienna, is to adopt decisions on the adding of 8 new substances to the Schedules of the UN Conventions.

(7) The Union is not a party to the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. It has an observer status with no voting rights in the Commission on Narcotic Drugs where twelve Member States are members with the right to vote in March 2021[4]. 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 one new substance to Schedule I of the Convention on Narcotic Drugs, four new substances to Schedule II and three new substances to Schedule IV of the Convention on Psychotropic Substances.

(9) All substances reviewed by the WHO Expert Committee on Drug Dependence ('the Expert Committee') and recommended for scheduling by the WHO are monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Regulation (EC) No 1920/2006 of the European Parliament and of the Council[5].

(10) According to the assessment of the Expert Committee, isotonitazene (chemical name: *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine) is a synthetic opioid analgesic and is closely related to etonitazene and clonitazene, both of which are under international control under the 1961 Convention on Narcotic Drugs. Isotonitazene has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that isotonitazene 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 isotonitazene be placed in Schedule I of the Convention on Narcotic Drugs.

(11) Isotonitazene was included in the definition of 'drug' under Framework Decision 2004/757/JHA through a Commission Delegated Directive.[6]

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

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4 Austria, Belgium, Croatia, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Spain and Sweden.

5 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).

6 Commission Delegated Directive (EU) 2020/1687 of 2 September 2020 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substance *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene) in the definition of 'drug', C(2020) 5897 final, OJ L 379, 13.11.2020, p. 55.

(13) According to the assessment of the Expert Committee, MDMB-4en-PINACA (chemical name: methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate) is a synthetic cannabinoid. MDMB-4en-PINACA has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that MDMB-4en-PINACA 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 MDMB-4en-PINACA be placed in Schedule II of the Convention on Psychotropic Substances.

(14) MDMB-4en-PINACA has been detected in 20 Member States and is controlled in at 14 Member States. It has been associated with nine deaths; it has also been associated with 11 non-fatal intoxications. MDMB-4en-PINACA is currently the subject of a detailed investigation, which will lead to a risk assessment report by the European Monitoring Centre for Drugs and Drug Addiction.

(15) Therefore, the Member States should take the position to add MDMB-4en-PINACA to Schedule II of the Convention on Psychotropic Substances.

(16) According to the assessment of the Expert Committee, CUMYL-PeGACLONE (chemical name: 2-(1-methyl-1-phenyl-ethyl)-5-pentyl-pyrido[4,3-b]indol-1-one) is a synthetic cannabinoid. CUMYL-PeGACLONE does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that CUMYL-PeGACLONE 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-PeGACLONE be placed in Schedule II of the Convention on Psychotropic Substances.

(17) CUMYL-PeGACLONE has been detected in eleven Member States and is controlled in at least five Member States. It has been associated with at least three deaths and has been detected in six biological samples associated with serious adverse events.

(18) Therefore, the Member States should take the position to add CUMYL-PeGACLONE to Schedule II of the Convention on Psychotropic Substances.

(19) According to the assessment of the Expert Committee, flubromazolam (chemical name: 8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-[1,2,4]triazolo[4,3-a][1,4] benzodiazepine) is a benzodiazepine-type substance. Flubromazolam has been researched for its anxiolytic properties and decreased sedative, hypnotic, and ataxic side effects, but it does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that flubromazolam 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 flubromazolam be placed in Schedule IV of the Convention on Psychotropic Substances.

(20) Flubromazolam has been detected in 15 Member States and is controlled in at least seven Member States. It has been associated with two deaths and seven non-fatal intoxications; it has also been detected in 44 biological samples associated with deaths.

(21) Therefore, the Member States should take the position to add flubromazolam to Schedule IV of the Convention on Psychotropic Substances.

(22) According to the assessment of the Expert Committee, clonazolam (also known as clonitrazolam; chemical name: 6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine) is a benzodiazepine-type substance. Clonazolam does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that clonazolam 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 clonazolam be placed in Schedule IV of the Convention on Psychotropic Substances.

(23) Clonazolam has been detected in 15 Member States and is controlled in at least four Member States. It has been associated with two deaths and five non-fatal intoxications.

(24) Therefore, the Member States should take the position to add clonazolam to Schedule IV of the Convention on Psychotropic Substances.

(25) According to the assessment of the Expert Committee, diclazepam (also known as or Ro 5-3448; chemical name: 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one) is a benzodiazepine-type substance. Diclazepam does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that diclazepam 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 diclazepam be placed in Schedule IV of the Convention on Psychotropic Substances.

(26) Diclazepam has been detected in 16 Member States and is controlled in at least eight Member States. It has been associated with two deaths; it has also been detected in 8 biological samples associated with deaths.

(27) Therefore, the Member States should take the position to add diclazepam to Schedule IV of the Convention on Psychotropic Substances.

(28) According to the assessment of the Expert Committee, 3-MeO-PCP (chemical name: 1-[1-(3-methoxyphenyl)cyclohexyl]piperidine) is a dissociative-type substance. 3-MeO-PCP does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that 3-MeO-PCP 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 3-MeO-PCP be placed in Schedule II of the Convention on Psychotropic Substances.

(29) 3-MeO-PCP has been detected in 18 Member States and is controlled in at least eight Member States. It has been associated with at least seven deaths and five non-fatal intoxications; it has also been detected in 18 biological samples associated with serious adverse events.

(30) Therefore, the Member States should take the position to add 3-MeO-PCP to Schedule II of the Convention on Psychotropic Substances.

(31) According to the assessment of the Expert Committee, diphenidine (chemical name: 1-(1,2-diphenylethyl)piperidine) is a dissociative-type substance. Diphenidine does not appear to be licensed for therapeutic uses nor have received a marketing authorisation as medicinal product. There is sufficient evidence that diphenidine 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 diphenidine be placed in Schedule II of the Convention on Psychotropic Substances.

(32) Diphenidine has been detected in 17 Member States and is controlled in at least eight Member States. It has been associated with at least two non-fatal intoxications and detected in five biological samples associated with serious adverse events.

(33) Therefore, the Member States should take the position to add diphenidine to Schedule II of the Convention on Psychotropic Substances.

(34) 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 eight substances will be capable of decisively influencing the content of Union law, namely Framework Decision 2004/757/JHA.

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

(36) Denmark is bound by Framework Decision 2004/757/JHA as applicable until 21 November 2018 and is therefore taking part in the adoption and application of this Decision.

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

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the Union's behalf in the sixty-fourth session of the Commission on Narcotic Drugs from 12 to 16 April 2021, 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.

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