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Proposal for a

## **COUNCIL DECISION**

**on the position to be taken, on behalf of the European Union, in the sixty-third 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 taken on the Union's behalf in the 63<sup>rd</sup> 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 63<sup>rd</sup> session of the Commission on Narcotic Drugs is scheduled to take place from 2 to 6 March 2020.

### **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')<sup>1</sup> 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')<sup>2</sup> 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 (CND) is a commission of the UN Economic and Social Council (ECOSOC) 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 ECOSOC. 13 Member States will be members of the CND with the right to vote in March 2020<sup>3</sup>. 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 Conventions on the basis of recommendations of the World Health Organisation (WHO) which is advised by its Expert Committee on Drug Dependence (ECDD).

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<sup>1</sup> United Nations Treaty Series, vol. 978, No. 14152.

<sup>2</sup> United Nations Treaty Series, vol. 1019, No. 14956.

<sup>3</sup> As of 1 January 2020, the following 13 Member States will be members of the CND with the right to vote: Austria, Belgium, Croatia, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Spain, Sweden, and the United Kingdom.

The WHO submitted on 24 January 2019 to the Secretary General of the UN<sup>4</sup> six recommendations issued from the critical review carried out at the 41<sup>st</sup> meeting of the ECDD concerning cannabis and cannabis-related substances.

The agenda of the 63<sup>rd</sup> session of the CND, taking place in Vienna from 2 to 6 March 2020, might include a point on the adoption of 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<sup>5</sup> (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 was already placed under control across the Union.

Cannabis and cannabis-related substances which were the object of the critical review of the 41<sup>st</sup> ECDD meeting and of the six WHO recommendation from 24 January 2019 are currently controlled at international level under either the Convention on Narcotic Drugs or the Convention on Psychotropic Substances:

- **“Cannabis and cannabis resin”** are included in Schedule I of the Convention on Narcotic Drugs. Moreover, *“Cannabis and cannabis resin”* are also included in Schedule IV of the Convention on Narcotic Drugs containing substances that are considered especially dangerous;
- **Dronabinol (delta-9-tetrahydrocannabinol)** is included into Schedule II of the Convention of Psychotropic Substances;
- **Tetrahydrocannabinol** (isomers of delta-9-tetrahydrocannabinol) is included in Schedule I of the Convention of Psychotropic Substances;
- **“Extracts and tinctures of cannabis”** are included in Schedule I of the Convention on Narcotic Drugs;
- **“Cannabidiol preparations”** are controlled under the entry “Extracts and tinctures of cannabis” in Schedule I of the Convention on Narcotic Drugs;
- **“Pharmaceutical preparations of cannabis and dronabinol”** are controlled as cannabis based preparations under Schedule I of the Single Convention on Narcotic

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<sup>4</sup> [https://www.who.int/medicines/access/controlled-substances/UNSG\\_letter\\_ECDD41\\_recommendations\\_cannabis\\_24Jan19.pdf?ua=1](https://www.who.int/medicines/access/controlled-substances/UNSG_letter_ECDD41_recommendations_cannabis_24Jan19.pdf?ua=1)

<sup>5</sup> 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.

Drugs or, as preparations using synthetic delta-9-tetrahydrocannabinol, under Schedule II of the Convention on Psychotropic Substances.

The Commission proposal for a Union position is based on the available documents for the meetings of the WHO Expert Committee on Drug Dependence and on the answers provided at the 4<sup>th</sup> and 5<sup>th</sup> Intersessional Meeting of the CND on 24 June 2019 and 23 September 2019 by the WHO, the International Narcotics Control Board (INCB) and the United Nations Office on Drugs and Crime (UNODC), within their respective mandate<sup>6</sup>. It also takes into account exchanges with the Member States in the Horizontal Drugs Group and the work of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in this field.

The Commission proposal for a Union position suggests supporting only some of the WHO recommendations, which reflect developments of the scientific knowledge in their regard and would not result in a significant change in the control of these substances.

Conversely, a number of the recommendations are characterised by a lack of clarity surrounding their legal and practical implications and consequences in terms of new control measures or lack thereof. The Commission proposal for a Union position suggests therefore opposing these recommendations. Alternatively, as a fall back option, the Commission proposal suggests not to vote on these recommendations and request further assessment by WHO.

It is necessary that the Council establishes the Union's position for the meeting of the CND when it is called to decide on the scheduling of substances. 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 CND in March 2020, acting jointly in the interest of the Union within the CND. 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 CND in March 2020 on behalf of the European Union, in the 63<sup>rd</sup> session of the CND on the scheduling of substances under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. This is the fourth time that the Commission presents such a proposal for a Union position.<sup>7</sup> The Council adopted the Union positions<sup>8</sup> 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 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.'*

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<sup>6</sup> See the compilation of all questions and answers as of 26 November at [https://www.unodc.org/documents/commissions/CND/Scheduling\\_Resource\\_Material/Cannabis/Consultations\\_with\\_WHO\\_Questions\\_and\\_Answers\\_26\\_November\\_2019.pdf](https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Consultations_with_WHO_Questions_and_Answers_26_November_2019.pdf)

<sup>7</sup> COM(2017) 72 final; COM(2018) 31 final; COM(2018) 862 final. To be noted that a separate proposal is put forward in parallel by the Commission concerning the scheduling of new psychoactive substances.

<sup>8</sup> Adopted by the Council on 7 March 2017, on 27 February 2018, and on 5 March 2019, respectively.

Article 218(9) TFEU applies regardless of whether the Union is a member of the body or a party to the agreement<sup>9</sup>. 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’<sup>10</sup>.

The CND is "a body set up by an agreement" within the meaning of this Article, given that it is a body established by the ECOSOC – 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 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-limit<sup>11</sup>. 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, 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**

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

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

<sup>10</sup> 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.

<sup>11</sup> Article 3(7) of the Convention on Narcotic Drugs; Article 2(7) of the Convention on Psychotropic Substances.

consequence, Council Framework Decision 2004/757/JHA has ceased to apply to the United Kingdom as from 1 December 2014<sup>12</sup>.

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<sup>13</sup>.

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 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) TFEU.

### **5. BUDGETARY IMPLICATIONS**

No budgetary implications.

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<sup>12</sup> 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).

<sup>13</sup> This proposal concerns establishing the position to be adopted on the Union's behalf at a meeting that will take place after the United Kingdom withdrawal from the Union, unless the United Kingdom requests a fourth extension of the period under Article 50 of the Treaty, to which the European Council (Article 50) agrees by unanimity. However, at the moment when the Commission adopts its proposal, the United Kingdom is a Member State. Therefore, e.g. references to a number of "Member States" that are members of the Commission on Narcotic Drugs, etc. cover also United Kingdom.

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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<sup>1</sup>, ('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')<sup>2</sup> 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<sup>3</sup> applies to substances listed in the Schedules to these Conventions. 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 (TFEU).
- (6) The Commission on Narcotic Drugs, during its sixty-third session of 2 to 6 March 2020 in Vienna, is to adopt decisions concerning cannabis and cannabis-related

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<sup>1</sup> United Nations Treaty Series, vol. 978, No. 14152.

<sup>2</sup> United Nations Treaty Series, vol. 1019, No. 14956.

<sup>3</sup> 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).

substances which are already under control on the basis of the Convention on Narcotic Drugs or the Convention on Psychotropic Substances.

- (7) The Union is not a party to the relevant UN Conventions. It has an observer status in the Commission on Narcotic Drugs where thirteen Member States are to be members with the right to vote in March 2020<sup>4</sup>. 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 international scheduling of substances under the Conventions fall under the exclusive competence of the Union.
- (8) The WHO submitted on 24 January 2019<sup>5</sup> six recommendations issued following the critical review carried out at the 41<sup>st</sup> meeting of its Expert Committee on Drug Dependence (the 'WHO Expert Committee') concerning cannabis and cannabis-related substances. These recommendations do not aim at authorising the recreational use of cannabis or cannabis-related substances.
- (9) According to the assessment of the WHO Expert Committee, **cannabis and cannabis resin** are not particularly liable to produce ill-effects similar to the effects of the other substances in Schedule IV of the Convention on Narcotic Drugs. In addition, preparations of cannabis have shown therapeutic potential for treatment of pain and other medical conditions such as epilepsy and spasticity associated with multiple sclerosis.
- (10) The WHO considered that cannabis and cannabis resin should be scheduled at a level of control that will prevent harm caused by cannabis use and at the same time will not act as a barrier to access and to research and development of cannabis-related preparations for medical use. Thus, the WHO concluded that the inclusion of cannabis and cannabis resin in Schedule IV is not consistent with the criteria for a drug to be placed in Schedule IV.
- (11) That recommendation implies no change in the international control level of cannabis and cannabis resin as they will continue to be included in Schedule I of the Convention on Narcotic Drugs. It duly takes into account scientific developments in the field since the first introduction of cannabis and cannabis resin into the Convention on Narcotic Drugs. The deletion of cannabis and cannabis resin from Schedule IV of the Convention on Narcotic Drugs would be beneficial to the advancement of collective knowledge of both the therapeutic utility as well as any associated harms of cannabis.
- (12) Therefore, the Member States should take the position to delete cannabis and cannabis resin from Schedule IV of the Convention on Narcotic Drugs.
- (13) According to the assessment of the WHO Expert Committee, **delta-9-tetrahydrocannabinol and its active stereoisomer dronabinol**, especially in high purity illicitly derived forms, can produce ill-effects, dependence, and abuse potential that is at least as great as for cannabis, which is placed in Schedule I of the Convention on Narcotic Drugs. A substance liable to similar abuse and productive of similar ill-effects as that of a substance already scheduled within the Convention on Narcotic

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<sup>4</sup> As of 1 January 2020, the following 13 Member States will be members of the CND with the right to vote: Austria, Belgium, Croatia, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Spain, Sweden, and the United Kingdom.

<sup>5</sup> [https://www.who.int/medicines/access/controlled-substances/UNSG\\_letter\\_ECDD41\\_recommendations\\_cannabis\\_24Jan19.pdf?ua=1](https://www.who.int/medicines/access/controlled-substances/UNSG_letter_ECDD41_recommendations_cannabis_24Jan19.pdf?ua=1)



Drugs would normally be scheduled in the same way as that substance. As delta-9-tetrahydrocannabinol is liable to similar abuse as cannabis and has similar ill effects, it meets the criteria for inclusion in Schedule I of the Convention on Narcotic Drugs.

- (14) Moreover, the WHO understood that placing delta-9- tetrahydrocannabinol under the same Convention and in the same schedule as cannabis, i.e. Schedule I of the Convention on Narcotic Drugs, would greatly facilitate the implementation of the control measures of the Conventions in Member States. Thus, the WHO recommended that delta-9- tetrahydrocannabinol and its active stereoisomer dronabinol be placed in Schedule I of the Convention on Narcotic Drugs and, if this recommendation is adopted, to be deleted from Schedule II of the Convention on Psychotropic Substances.
- (15) That recommendation implies no change in the international control level of delta-9-tetrahydrocannabinol and its active stereoisomer dronabinol. It could also facilitate the implementation of the control measures in Member States.
- (16) Therefore, the Member States should take the position to add delta-9-tetrahydrocannabinol and its active stereoisomer dronabinol to Schedule I of the Convention on Narcotic Drugs and, if that recommendation is adopted, to delete them from Schedule II of the Convention on Psychotropic Substances. Alternatively, the recommendation should not be put to vote and further assessment by the WHO should be requested.
- (17) According to the assessment of the WHO Expert Committee, **tetrahydrocannabinol (isomers of delta-9-tetrahydrocannabinol)**, which is placed in Schedule I of the Convention on Psychotropic Substances, does not have abuse and ill effects similar to those associated with delta-9-tetrahydrocannabinol but, due to the chemical similarity of each of the six isomers to delta-9-tetrahydrocannabinol, it is very difficult to differentiate any of these six isomers from delta-9-tetrahydrocannabinol using standard methods of chemical analysis. Moreover, placing these six isomers under the same Convention and in the same Schedule as delta-9-tetrahydrocannabinol, i.e. Schedule I of the Convention on Narcotic Drugs, would facilitate the implementation of international control of delta-9-tetrahydrocannabinol, as well as assist Member States in the implementation of control measures at country level. Thus, the WHO recommended that tetrahydrocannabinol (isomers of delta-9-tetrahydrocannabinol) is added to Schedule I of the Convention on Narcotic Drugs subject to adoption of the recommendation by the Commission on Narcotic Drugs (CND) to add dronabinol and its stereoisomers (delta-9-tetrahydrocannabinol) to Schedule I of the Convention on Narcotic Drugs, and, if that recommendation is adopted, to be deleted from Schedule I of the Convention on Psychotropic Substances.
- (18) That recommendation implies no change in the international control level of tetrahydrocannabinol (isomers of delta-9-tetrahydrocannabinol). It could also facilitate the implementation of the control measures in Member States.
- (19) Therefore, the Member States should take the position to add tetrahydrocannabinol (isomers of delta-9-tetrahydrocannabinol) to Schedule I of the Convention on Narcotic Drugs subject to the CND's adoption of the recommendation to add dronabinol and its stereoisomers (delta-9-tetrahydrocannabinol) to Schedule I of the Convention on Narcotic Drugs, and, if that recommendation is adopted, to delete it from Schedule I of the Convention on Psychotropic Substances. Alternatively, the recommendation should not be put to vote and further assessment by WHO should be requested.

- (20) According to the assessment of the WHO Expert Committee, the variability in psychoactive properties of **extracts and tinctures of cannabis**, as cited in the Convention on Narcotic Drugs, is due principally to varying concentrations of delta-9-tetrahydrocannabinol contained in these extracts and tinctures. Some extracts and tinctures of cannabis without psychoactive properties and including predominantly cannabidiol have promising therapeutic applications. The fact that diverse preparations with a variable concentration of delta-9-tetrahydrocannabinol are controlled within the same entry “Extract and Tinctures” and the same schedule, is a challenge for responsible authorities that implement control measures in the individual countries. Moreover, the definition of preparations under the Convention on Narcotic Drugs may cover all products that are ‘extracts and tinctures’ of cannabis as “preparations” of cannabis and also, if the Committee’s recommendation to move dronabinol to Schedule I of the Convention on Narcotic Drugs was followed, as “preparations” of dronabinol and its stereoisomers. Thus, the WHO recommended that extracts and tinctures should be deleted from Schedule I of the Convention on Narcotic Drugs.
- (21) However, notwithstanding the clarifications provided by the WHO after the issuance of that recommendation, there is no apparent public health justification for it and it is difficult to assess fully its implications, including in terms of comprehensiveness of the international control system.
- (22) Therefore, the Member States should take the position that the recommendation should not be put to vote and further assessment by WHO should be requested.
- (23) According to the assessment of the WHO Expert Committee, **cannabidiol** is found in cannabis and cannabis resin but does not have psychoactive properties and has no potential for abuse and no potential to produce dependence. It does not have significant ill-effects. Moreover, cannabidiol has been shown to be effective in the management of certain treatment-resistant, childhood-onset epilepsy disorders.
- (24) The WHO noted that medicines without psychoactive effects that are produced as preparations of the cannabis plant will contain trace amounts of delta-9-tetrahydrocannabinol and acknowledged that chemical analysis of delta-9-tetrahydrocannabinol to an accuracy of 0.15 % may be difficult for some Member States. Thus, the WHO recommended that a footnote be added to Schedule I of the Convention on Narcotic Drugs to read: “Preparations containing predominantly cannabidiol and not more than 0,2 % of delta-9-tetrahydrocannabinol are not under international control.”
- (25) However, that recommendation would lower current control level for these preparations, the establishment of any THC limit for preparations containing predominantly cannabidiol is not supported by scientific evidence, and the wording of the recommendation does not exclude possible divergent interpretations concerning the way of calculating such limit. The differentiated treatment of cannabidiol compared to other cannabinoids is not justified and is not in line with the existing structure of the Schedules of the Conventions.
- (26) Therefore, the Member States should take the position that the recommendation should not be put to vote and further assessment by WHO should be requested.
- (27) According to the assessment of the WHO Expert Committee, medicines containing delta-9-tetrahydrocannabinol are not associated with problems of abuse and dependence and they are not diverted for the purpose of non-medical use. Moreover, the WHO recognised that such preparations are formulated in a way that they are not

likely to be abused and there is no evidence of actual abuse or ill effects to an extent that would justify the current level of control associated with Schedule I of the Convention on Narcotic Drugs or the level of control associated with Schedule II of the Convention on Psychotropic Substances. Thus, the WHO recommended that “**preparations produced either by chemical synthesis or as preparation of cannabis**, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-tetrahydrocannabinol cannot be recovered by readily available means or in a yield which would constitute a risk to public health” to be added to Schedule III of the Convention on Narcotic Drugs.

- (28) However, that recommendation could imply additional regulatory burden on Member States. Moreover, the wording of the recommendation concerning “pharmaceutical” preparations is not based on any defined term under the Convention on Narcotic Drugs and may not be compatible with the EU terminology as provided by Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>6</sup>.
- (29) Therefore, the Member States should take the position to vote against the recommendation to add “preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health” to Schedule III of the Convention on Narcotic Drugs. Alternatively, that recommendation should not be put to vote and further assessment by WHO should be requested.
- (30) 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 cannabis and cannabis-related substances will be capable of decisively influencing the content of Union law, namely Framework Decision 2004/757/JHA.
- (31) The Union's position is to be expressed by the Member States that are members of the Commission on Narcotic Drugs, acting jointly.
- (32) 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.
- (33) Ireland is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision.
- (34) The United Kingdom is not bound by Framework Decision 2004/757/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 in the sixty-third session of the Commission on Narcotic Drugs from 2 to 6 March 2020, when that body is called upon to adopt decisions on the addition of substances to the Schedules of the United Nations Single Convention on

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<sup>6</sup> OJ L 311, 28.11.2001, p. 67–128

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*