CBD as a ‘narcotic’? Food for thought.

Analysis of the European Commission’s preliminary conclusions qualifying cannabidiol in food and foodstuff as a narcotic drug.

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European Commission headquarters in Brussels. Photo: Guillaume Meurice / Pexels.

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Early July 2020, the European Commission's Directorate-General for Health and Food Safety (DG SANTE) announced that it might adopt a position in which food products containing cannabidiol (CBD) derived from *Cannabis sativa* L. (hemp plant) would not be authorized for sale in the European Union, being assimilated to medicines under control ("narcotic drugs").

The information was circulated to applicants for the registration of a CBD-containing product within the EU Novel Food regulations, but not all of them: only the applicants whose CBD was plant-derived received the advice. Applicants for CBD obtained by full chemical *in vitro* synthesis were not notified.

> *"The Commission [...] preliminarily concludes that [plant-derived CBD] must be qualified as an extract from Cannabis [...], cannot be qualified as 'food' [...] and, consequently, falls outside the scope of [the Novel Foods] Regulation"*

The analysis over which DG SANTE bases its preliminary conclusions is well-intentioned, and acknowledges key elements such as the non-inclusion of CBD among the Schedules listing "narcotic drugs" within the international drug control Conventions (IDCC).

DG SANTE's analysis is, however, incomplete, leading to misinterpretations of the letter and spirit of the IDCC.

This note analyses the interpretation of the IDCC by DG SANTE from a technical perspective, finding, contrary to the preliminary conclusions, that:

- ➔ **CBD, when used in food, should neither be qualified as a "drug,"** nor as a "narcotic drug." Substances are commonly used in the confection of both medical and food products, subject to different regulations. The analogy with chili pepper-derived capsaicin is useful (pp. 7–8);
- ➔ Substances placed under control **should not be distinguished** according to their **"synthetic" or "natural"** properties;
- ➔ **The *part* differs from the *whole***: controls that apply to the *whole* (cannabis & cannabis resin) do not apply to the sum of its *parts* (CBD and other herbal compounds) – unless, like for THC, the *part* is specifically listed in the Schedules. Opium-derived papaverine provides for an insightful analogy (see p. 10);
- ➔ There is no reason to consider that **the recommendation of the WHO Expert Committee on Drug Dependence (ECDD) regarding CBD** applies to food (or to any other non-medical products). The scope of the Convention, and the mandate of the ECDD, **relate only to medical and scientific purposes. Not to foods.**

Dispositions of the Single Convention exempting CBD from control

"Parties cannot legally authorize the possession of drugs for other than medical and scientific purposes, except in the **cases in which non-medical consumption or industrial use is** exceptionally **permitted by the Single Convention**."[1]

Article 4, discussing the general obligations of countries party to the Single Convention on Narcotic drugs of 1961 (C61), explains that the measures to be taken "**to limit exclusively to medical and scientific purposes** the production, manufacture, export, import, distribution of, trade in, use and possession of drugs" are "**subject to the provisions of this Convention**."

The Commentary on C61, prepared by United Nations Secretary-General, explains that "the provisions to which [this paragraph] is 'subject,' i.e. which are excepted from its application, are article 49, article 2, paragraph 9"[2] (among others).

Article 2, discussing substances under control, specifies in its paragraph 9 that "**Parties are not required to apply the provisions of this Convention to drugs which are commonly used in industry for other than medical or scientific purposes.**"

The UN Secretariat[3] is of the opinion that "it cannot [...] be excluded that a drug falling under the international narcotics regime [...] might be needed for wide use in industrial processes other than those of pharmaceutical factories."

The 1971 Convention on Psychotropic substances (C71) which only controls THC, includes similar dispositions exempting drugs used for "industrial purposes" (C71, Art. 4(b)), corroborated in the 1988 UN Convention against illicit trafficking.

Additionally, C61's Article 28, discussing the cultivation of the cannabis plant, adds that "this **Convention shall not apply** to the cultivation of the cannabis plant **exclusively for industrial purposes** (fibre and seed) and horticultural purposes."

The Commentary explains that "a Party permitting the cultivation of the plant for the drugs, but also permitting cultivation elsewhere **exclusively for other purposes**, must apply [controls] to the former, but not to the latter."[4]

Some have argued that the exemption only covers "fibre and seed" – an assumption dismissed by the UN Secretariat when clarifying that the "**cultivation of the plant for any other purpose [than obtaining drugs], and not only for** the purposes mentioned in paragraph 2 [i.e., '**industrial purposes (fibre and seed) and horticultural purposes**'] **is consequently exempted from the control régime**."[5]

It results that the cultivation, production, manufacture, export, import, distribution of, trade in, use and possession of cannabis and all its components, for other than medical and scientific purposes, is exempt from the régime of control of C61.

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[1] United Nations Secretary-General (1973). *Commentary on the Single Convention on Narcotic Drugs, 1961 (Prepared by the Secretary-General in accordance with paragraph 1 of Economic and Social Council resolution 914D(XXXIV) of 3 August 1962)*. New-York: United Nations; pp. 113–114. www.unodc.org/documents/commissions/CND/Int_Drug_Control_Conventions/Commentaries-OfficialRecords/1961Convention/1961_COMMENTARY_en.pdf
[2] *Ibid.*, pp. 110–111.
[3] *Ibid.*, p. 72.
[4] *Ibid.*, p. 314.
[5] *Ibid.*, p. 312.

Cannabis plant. Photo: Gio Bartlett / Unsplash

“Narcotics” vs. “narcotic drugs”

Denominations vary between EU documents, alternatively using the noun “narcotics” or the expression “narcotic substances.” It should be noted however that the Convention is, above all, a treaty regulating drugs, *i.e.* medicines. “Narcotic” is merely an adjective attached to “drugs”.

Using “Narcotics Convention” instead of “Convention on Narcotic Drugs” can lead to misunderstandings with regards to the scope of control of the Convention.

The UN Secretariat provides some clarifications, explaining that the terms “stupéfiants” (in French) and “estupefaciente” (in Spanish) are cluster-words that correspond to the **dual meaning “narcotic” + “drugs”**, not to “narcotics”[6]. The presence of the noun “drug” (i.e. medical product) alongside the adjective “narcotic” is quintessential to the spirit of the Convention, which focuses on drugs and medical uses.

It seems that the noun “narcotic” in EU regulatory language corresponds to the expression “narcotic drugs” in international law, *i.e.*, a certain type of medicine. This appears for instance in Council Directive 65/65/EEC on medicinal products in which “narcotics” are only considered as a subset of medicinal products (see Article 16).

[6] *Ibid.*, pp. 9–10.

Defining and delimiting "food"

DG SANTE's preliminary conclusions

"The definition of 'food' set out in Article 2 of Regulation (EC) No 178/2002 , to which Articles 2 and 3 of Regulation (EU) 2015/2283 make reference, when defining the scope of application of the novel food regime, excludes (under lit. g) substances that are 'narcotic or psychotropic' within the meaning of the applicable United Nations Single Convention on Narcotic Drugs of 1961 (hereafter 'Narcotics Convention')."

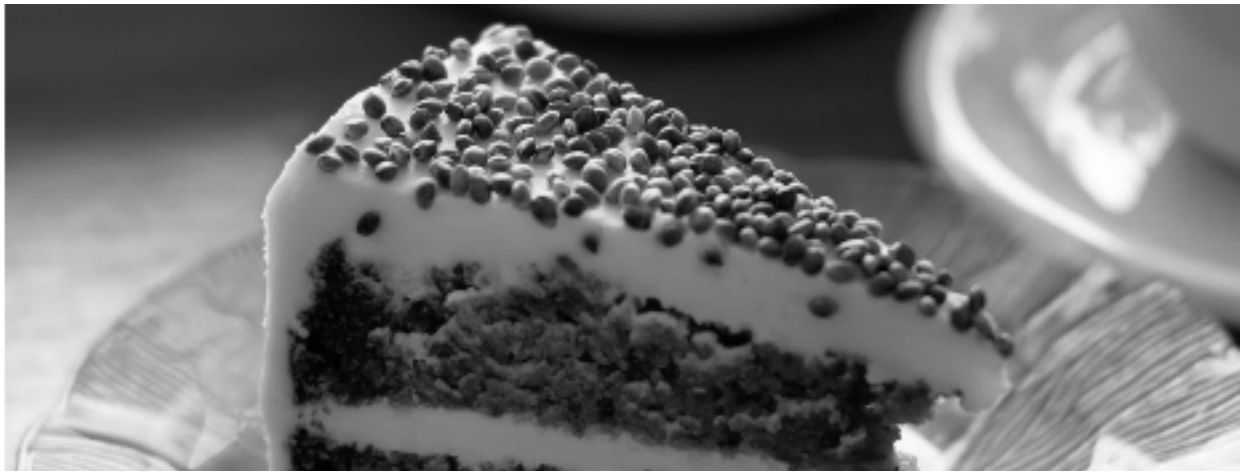
"**Drug**" in the "meaning of the applicable [C61]" is clear enough: **any of the substances in Schedule I and II, whether natural or synthetic, used for medical or scientific purposes**. It is explicit in the Convention, particularly:

- in Article 1(1)(j), defines "drugs" as "any of the substances in Schedule I and II, whether natural or synthetic,"
- and in Article 2(9), specifies that countries are "not required to apply the provisions of this Convention to drugs which are commonly used in industry for other than medical or scientific purposes."

A "drug," for the Convention, is a substance used for medical and scientific purposes that is placed under control. The qualifier "drug" hence does not refer to the chemical composition of a substance or preparation, but to its status of placement in the Schedule I or II and to its purposes of use. An addition, deletion, or change in Scheduling will have as a consequence that "a particular substance may thus become or cease to be a 'drug.'"[7] In a similar fashion, a substance ceases to be a drug insofar it stops meeting one or two of the criteria: listing in the Schedules + use for medical and scientific purpose. **The Convention comprehensively controls substances used in medicine and research, but does not extend the scope of its control beyond these purposes.**

The only consideration of chemical composition is the equivalent made between "natural" and "synthetic," but, again, it applies only (1) if the substance is listed in the Schedules and (2) if it is used for medical or scientific purposes.

[7] *Ibid.*, p. 10.



Hemp cake. Photo: K8 / Unsplash

Nutrition and alimentation are not "medical or scientific purposes" and, therefore, **when used in other fields than medicine or research, Scheduled substances are not "drugs" "within the meaning of the applicable [C61]."**

Directive 2001/83/EC on medicinal products for human use systematically considers "narcotic substances" as medicinal products for human use, particularly in its articles 71, 87, and 96. Article 71(2) acknowledges the existence of exemptions over narcotic drugs by submitting to special medical prescriptions only those narcotic substances present "in a non-exempt quantity" in medicinal products. It does not extend regulations to "exempt quantities" of scheduled substances.

Regulation (EC) No 178/2002

"'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. [...] 'Food' shall not include: [...] (d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC; [...] (e) cosmetics within the meaning of Council Directive 76/768/EEC; [...] (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971.

The definition of food in Regulation (EC) No 178/2002 states that "narcotic substances" (in its § g), but also (non-narcotic) "medicinal products" (§ d) as well as "cosmetics" (§ e), cannot be considered as "food."

Article 2 of Regulation (EC) 178/2002 does not disqualify compounds used for other purposes to be used in foodstuff, it disqualifies products which are prepared under a different regulation to be sold as such as food or foodstuff. Therefore, "narcotic substances" commonly used in

industry for other than medical and scientific purposes (including food industries) are not "drugs" within the meaning of C61.

An interesting parallel is offered by Council Directive 76/768/EEC on cosmetics which lists in its Annex II (substances which cosmetic products must not contain) "narcotics, natural and synthetic : All substances listed in Tables I and II of the single Convention on narcotic drugs." It is important to note that this latter directive also provides for a general exclusion of all medicinal products from use in cosmetics. However, for both narcotic and non-narcotic medicinal products, the exclusion is based on the purpose and context of use, and not only on the mere chemical composition of substances under consideration.

In its preamble, Council Directive 76/768/EEC states that its regulations relate "only to cosmetic products and not to pharmaceutical specialities and medicinal products", that "for this purpose it is necessary to define the scope of the Directive by delimiting the field of cosmetics from that of pharmaceuticals" and explains that such "delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use."

Again, **area of application and purpose of use** are the main ways of **defining and delimiting** cosmetics. The **chemical composition is not mentioned** among the defining characteristics.

This approach echoes that of C61 described above. It also makes sense because, **in cosmetics like in food and any other areas, the same substances, products, plants, can be used to obtain different kinds of products, to which different regulations will apply**.

Chilli peppers. Photo: Rio Lecatompessy / Unsplash

A good and clear example is provided on the cover page of the French Pharmacopeia's section on "vegetable substances" which states that "Plants whose French name is grayed out in this document have been identified as possibly also being used as food and/or condiments."[8] There are several examples of plants used for different purposes, with different applicable regulations depending on the "areas of application" and purposes.

The chili pepper plant (*Capsicum annuum* L.) and its non-narcotic capsaicin compound (responsible for the pungent and "hot" of some chilli pepper fruits) is one of these. *Capsicum* and capsaicin are used as food and foodstuff, condiment and spice. But they are also used as ingredient in cosmetics,[9] as a compounding herbal product and API for medicinal formulations,

[8] Pharmacopée française (janvier 2020). *Liste A des Plantes Médicinales.* Paris: ANSM. ansm.sante.fr/var/ansm_site/storage/original/application/dc6398f1f676936f296909ec52fc2213.pdf

[9] See for instance the entry for "Capsaicin" in the CosIng Database: ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=74864

[10] as well as in the confection of other industrial products like police-grade and personal defense sprays.[11]

In each of these areas, although the same product / substance is dealt with, different laws, rules and standards apply for different purposes, regardless of which apply in other areas.

There are potential harms and adverse effects associated with capsaicin and chilli pepper. According to Appendino,[12] capsaicin can cause "transient bronchoconstriction and induces coughing, especially in individuals with severe asthma, potentially triggering fatal crises" which is "a major problem with the use of pepper sprays as anti-riot agents." However, discussions on the regulations concerning the use of capsaicin in sprays should not –and will not– affect food regulations, or the use of capsaicin in medicine.

The exact **same logic should apply for CBD**.

Synthetic vs. natural

DG SANTE's preliminary conclusions

Article 1(1)(b) of the Narcotics Convention defines the term 'Cannabis' as meaning 'the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated'. Article 1(1)(j) qualifies as 'drugs' in the framework of the Narcotics Convention any of the substances falling within the scope of Schedules I and II of the Narcotics Convention. Schedule I of the Narcotics Convention includes 'Cannabis and cannabis resin, and extracts and tinctures of cannabis'.

The letter forgets to note that article 1(1)(j) of C61 also specifies "natural" and "synthetic" versions of the substance are considered alike. According to this definition, DG SANTE should have sent its communication, not only to applicants for plant-derived CBD, but also for applicants of *in vitro* CBD foodstuff – or to none.

It appears that there is little ground to justify a distinction between substances placed under control according to their "synthetic" or "natural" characteristics.

[10] See for example European Pharmacopeia, monographs of "Capsicum," "Capsicum oleoresin, refined and standardised," "Capsicum soft extract, standardised," and "Capsicum tincture, standardised."
[11] It should be noted that, in addition, the chili pepper plant for personal, home-bound cultivation, possession and consumption, is usually not submitted to any sort of regulation, regardless of its purpose of use or cultivation.
[12] Appendino G (2008). Capsaicin and Capsaicinoids. In: Fattorusso E and Taglialatela-Scafati O (Eds). *Modern Alkaloids: Structure, Isolation, Synthesis and Biology.* 73–109. Weinheim: Wiley.

The whole is different than the sum of its parts

DG SANTE's preliminary conclusions

Although cannabidiol that can be obtained from the Cannabis sativa L plant are not explicitly mentioned in the schedules of the International Drug Control Conventions, they are, in the Commission's preliminary view, covered by the description of the production method laid out in Schedule I of the Narcotics Convention (i.e. 'extracts and tinctures of cannabis'). It follows that cannabidiol, when extracted from 'cannabis', has to be considered as a substance falling within the scope and under the control mechanisms of that Convention and that is qualified as 'drug' thereunder.

This analysis is misled in two points when it considers that:

- CBD would be an "extract and tincture of cannabis"
- CBD would be under control merely for being part of a controlled substance.

In its landmark *Herbal medical products*, Gaedcke and Steinhof[13] inform that "it is a decisive aspect that the plants or parts of a plant which are used for pharmaceutical purposes are regarded as an active substance in its entirety" specifying that "herbal medicinal products, in this regard, are always mixtures of a number of substances." Such an approach is widely accepted among scientists and key institutions such as the German Commission E and the Council of Europe's European Pharmacopoeia Commission.

According to this approach, flowering or fruiting cannabis tops would be a single substance. A raw extract (or resin) obtained from such whole-plant cannabis would be considered a different substance. And a refined concentrate extract of that raw resin would be yet another substance. Such an approach is reflected in the IDCC and the way in which *Cannabis* derivatives are scheduled.

Beyond medicines, this analysis is also widely accepted among chemists, as Weisberg explains in *Water is* not H_2O.[14,15] Similarly, it can be stated that *CBD is* not *Cannabis resin*, and *CBD is* not *Extracts and tinctures*.[16]

"Extract and tincture of cannabis," or yet indeed "cannabis resin" are part of "cannabis flowering and fruiting tops." Yet, they are different entities, different legal objects, subject to different régimes of control when they are part of the whole, and when they are isolated. On this particular issue, the United Nations Secretariat explains that "'cannabis resin' is a 'drug' within

[13] Gaedcke F and Steinhoff B (2003) *Herbal Medicinal Products, Scientific and Regulatory Basis for Development, Quality Assurance and Marketing Authorisation.* Stuttgart: Medpharm GmbH Scientific Publishers.
[14] Weisberg M (2006). Water is *not* H_2O. In: Baidr D, Scerri E and McIntyre L (Eds). *Philosophy of chemistry: synthesis of a new discipline.* New-York: Springer. 337–345. web.archive.org/web/20191123131111/http://bespalovseminar.narod.ru/literature/Ph_of_Ch.pdf
[15] See also http://branemrys.blogspot.com/2011/10/water-is-not-h2o.html
[16] See also p. 10 in: Riboulet-Zemouli K (2020). 'Cannabis' ontologies I: Conceptual issues with *Cannabis* and cannabinoids terminology. *Drug Science, Policy and Law* 2020; in press.

the meaning of the Single Convention. It is defined separately from 'cannabis.'"[17] Later on it is specified that "the resin, however, becomes 'cannabis resin' only when 'separated' from the plant; without such separation it remains as part of the cannabis plant, and if in the top part, of 'cannabis.'"[18]

The exact same logic applies for "extracts and tinctures," which, although never defined in the C61, "are considered to be drugs different from cannabis or cannabis resin, which indeed they legally are"[19] according to the Secretary-General's office.

THC, listed in the Schedules of the C71, is obviously also "legally" a different drug.

It is difficult to understand why all *parts* of cannabis are distinguished from the *whole*, considered their own substance, and accordingly subject to their own regulations... but not CBD!

Importantly, a parallel with papaverine, an active compound derived from Opium and not listed in the Scheduled, to which international control does not apply. Papaverine, although derived from opium in the same fashion as CBD is derived from cannabis or cannabis resin, is not a controlled substance when separated from "opium."

It should also be noted that "extracts and tinctures of cannabis" does not denote "the description of [a] production method." Methods of obtention (production, separation, extraction, manufacture) are defined in C61's Article 1, as resumed as in the table below. However these methods are outlined in the Convention in order to apply specific controls along the production chain within the pharmaceutical sector. They do not affect the status of control of a drug, which depends on (1) its placement or not in a Schedule and (2) its purpose of production and use.

Starting material	**Method of obtention** (Article of C61)	**Resulting drug**
cannabis plant	Production (Art. 1(t))	**cannabis**
cannabis plant	Production (Art. 1(t)) Separation (Art. 1(c))	**cannabis resin**
cannabis	Manufacture (Art. 1(t)) Extraction (Art. 1(b))	
	Manufacture (Art. 1(t))	**extracts and tinctures**
cannabis plant	Manufacture (Art. 1(t))	
cannabis resin	Manufacture (Art. 1(t))	
crude cannabis resin	Manufacture (Art. 1(t), 1(j))	**refined cannabis resin**
not a scheduled drug (*e.g.*, *in vitro* synthesis)	Manufacture (Art. 1(t), 1(j))	**cannabis resin**
	Manufacture (Art. 1(t), 1(j))	**extracts and tinctures**

The products in bold are those defined as 'drugs' in the Convention (Art. 1[j]), as of August 2020.
Table adapted from *Riboulet-Zemouli, 2020*.[16]

[17] United Nations Secretary-General (1973). *Commentary on the Single Convention on Narcotic Drugs, 1961 (Prepared by the Secretary-General in accordance with paragraph 1 of Economic and Social Council resolution 914D(XXXIV) of 3 August 1962)*. New-York: United Nations; p. 5.
[18] *Ibid.*, p. 5.
[19] *Ibid.*, p. 314.

The applicable Convention

The reference to the "applicable" Convention implies DG SANTE's expectation that the text of C61, or the annexes (the "Schedules"), may change. According to the January 2019 **recommendations of the World Health Organization's ECDD**,[20] which will be discussed in December 2020, a possible change is indeed in sight. However, **these recommendations only concern drugs** – again, **substances used for medical and scientific purposes** – and not food, foodstuff, feed or other "industrial" products within the meaning of the C61.

Therefore, the recommendation of WHO that concerns CBD[21] only concerns medicines. "Preparation" is to be understood in the meaning of the Convention, as a medical product containing a drug (in this case, THC).

The text preceding the recommendation is clearly and **unequivocally referring to medicines and pharmaceutical preparations**, since it justifies the recommendation by mentioning "medicines without psychoactive effects that are produced as preparations of the cannabis plant" and "contain trace amounts of delta-9-tetrahydrocannabinol,"[22] giving as example the "cannabidiol preparation approved for the treatment of childhood-onset epilepsy, Epidiolex." Foods containing CBD or other non-medical products (e.g. cosmetics) are never discussed by the ECDD's assessment leading to the recommendation.

Such medical preparations (containing predominantly CBD and not more than 0.2 % THC) would not be under control if the recommendation were adopted. **No connection with food and foodstuff whatsoever.**

Plants on display. Photo: v2osk / Unsplash

[20] Letter from WHO Director-General to UN Secretary-General following the 41st ECDD meeting https://www.who.int/medicines/access/controlled-substances/UNSG_letter_ECDD41_recommendations_cannabis_24Jan19.pdf

[21] The recommendation proposes that "a footnote be added to Schedule I of the 1961 Single Convention on Narcotic Drugs to read: 'Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control.'"

[22] WHO Expert Committee on Drug Dependence (2019) *Forty-first report. WHO Technical Report Series 1018.* Geneva: World Health Organisation. https://apps.who.int/iris/bitstream/handle/10665/325073/9789241210270-eng.pdf

Conclusion

The status of CBD products varies according to the purposes of production and use of these products. Controls only apply with regards to "medical and scientific" purposes.

The changes implied by WHO ECDD recommendations are peripheral, and only concern the case CBD products are used in medicine, as a medical product (drug), or in research.

On the exemption for industrial purposes present in the C61, "it was mentioned [...] during the discussion of the draft of the paragraph under consideration, that the provision [exempting industrial purposes] was of no immediate practical importance, but had been inserted to anticipate possible future developments."[23] **In 1973** the UN Secretariat thought that these "developments appear still to be **in the future at the time** of this writing." **We are not in 1973 anymore**; these developments, called **"cannabidiol for non-medical purposes", appear to have been anticipated, and clearly exempted, by the writers of C61**.

Name used by EU institutions	Name used in C61	Purpose of use	C61 status of control	Where food products fit
Preparations of **hemp flowers** (flowering /fruiting tops)	Preparations of "cannabis"	Medical & scientific	Controlled[b]	Not a food product
		Industrial	Exempt from control	Food product
Preparations of **hemp extracts**	Crude "cannabis resin" *or* "Extract and tinctures of cannabis"[a]	Medical & scientific	Controlled[b]	Not a food product
		Industrial	Exempt from control	Food product
Preparations of **refined CBD extracts** with % of THC ≥ 0.2	Refined "cannabis resin" *or* "Extract and tinctures of cannabis"[a]	Medical & scientific	Controlled[b]	Not a food product
		Industrial	Exempt from control	Food product
Preparations of **refined CBD extracts** with % of THC < 0.2	Extract and tincture of cannabis[a]	Medical & scientific	Controlled[c] / Exempt from control[d]	Not a food product
		Industrial	Exempt from control	Food product

[a] If WHO ECDD's recommendation #5.4 is adopted, "extract and tincture of cannabis" would be called "preparations of cannabis."
[b] Under Schedule I régime as of August 2020, might be controlled under a Schedule III régime (depending on jurisdictions) if WHO ECDD's recommendation #5.6 is adopted.
[c] Under Schedule I régime as of August 2020.
[d] Status of control if WHO ECDD's recommendation #5.5 is adopted.

[23] United Nations Secretary-General (1973). *Commentary on the Single Convention on Narcotic Drugs, 1961 (Prepared by the Secretary-General in accordance with paragraph 1 of Economic and Social Council resolution 914D(XXXIV) of 3 August 1962)*. New-York: United Nations; p. 72