EIHA European Industrial Hemp Association

Common position of the hemp industries on the international drug control system.

In light of the global developments of industrial hemp markets and its raw material Cannabis sativa L., the European Industrial Hemp Association (EIHA), joined by the Canadian Hemp Trade Association, as well as other body representatives, would like to reiterate its position and stress the need for clarification, and a transparent debate on international law and the regulations of industrial hemp. The current market barriers and challenges for a growing hemp industry originate in one particular interpretation of international law to which EU regulations on food and cosmetics make reference.

Two main international legal instruments are referred to, they include schedules in their annexes where are listed those drugs that are subject to international control: the Single Convention on narcotic drugs of 1961, as amended by the 1972 Protocol ("Single Convention" or "C61") and the Contention on psychotropic substances of 1971 ("C71"). It is appropriate to recall that (i) the cultivation of industrial hemp has been clearly exempt from the scope of these two Conventions since their inception, that (ii) downstream products and derivatives of industrial hemp are not, and have never been listed in the Schedules of these Conventions, and that (iii) the Conventions actually disregard hemp in their rationale and in their general obligations.

Scientifically, industrial hemp plants cannot be distinguished a priori from "drug-type" Cannabis. During cultivation, methods and standards of cultivation used by farmers allow for crops with low levels of THC[1], while a posteriori, thresholds and analysis applied by regulators determine the suitability for market. Hemp derivatives are obtained virtually from any part of the plant (e.g.: leaves, flowers, fruits, roots, seeds) and have one common characteristic: their low levels of THC and absence of THC-related effects. Hence, the definition of "industrial hemp" (or "hemp") by EIHA as "a Cannabis plant with low levels of THC that is grown specifically for the industrial, non-intoxicating uses of its derived products."

[1] THC refers, in this document, to Δ9-tetrahydrocannabinol. THC was not mentioned yet in the Single Convention 1961 because its chemical structure had not yet been elucidated. THC is listed in Schedule II of C71 as "dronabinol" (IDS code PD 010).

1. Hemp disregarded in the spirit and rationale of the Conventions.

The preamble of C61 clearly states that the set of regulations enacted in the Convention aims at protecting the health and welfare of mankind, ensuring access to drugs for the relief of pain and suffering, while combating health hazards, abuse, and dependence to drugs, as well as their illicit trafficking. In international law, a preamble is the preliminary part of a legal instrument which states the reasons for, and intention of the text; it expresses the general purposes of a piece of legislation. Preambles can be referred to for statutory interpretation by setting out what it is all about or why it has been prepared.

As clearly framed in its preamble, the purpose, spirit of, and rationale behind C61 fundamentally concerns "drugs" (i.e., medicines and pharmaceutical products) and the prevention of their misuse (in terms of consumption and commercialization). Industrial hemp products are not medicines; they have neither potential to relieve pain and suffering, nor can they lead to misuse, abuse or dependence; trafficking in hemp products is non-existent. In light of the spirit set out in the Convention's preamble, this should be sufficient to consider hemp outside the scope of the Conventions.

The "general obligations" of C61[2] refer to the exclusive limitation to medical and scientific purposes of all activities related to "drugs" (i.e., present in Schedule I or II). Being absent from these Schedules, industrial hemp products do not fall under the provisions of strict limitation to medical or scientific use.

2. Hemp products not controlled under the régime of the Schedules.

Exemption for stems and roots

The drugs, substances and preparations falling under the scope of these Conventions are defined strictly as "any of the substances in Schedules I and II, whether natural or synthetic" by C61[3] and as "any substance, natural or synthetic, or any natural material in Schedule I, II, III or IV" in C71[4].

Exemption for seeds and leaves

"Cannabis" is defined in C61[5] as the "flowering of fruiting tops" excluding seeds and leaves. Seeds and leaves accompanying tops fall under the definition of "cannabis", but seeds and leaves separated from the tops falls out of the scope of the definition. Therefore, seeds and leaves, and any product derived thereof, common ingredients of "hemp" product, are not present in the Schedules; not concerned by their régime of control. As long as the leaves are used to obtain "hemp products" and not intoxicating substances, they do not trigger Art. 28(3) which seeks to prevent illicit trafficking in Cannabis leaves.

Exemption for flowers and fruits

Hemp products derived from "flowering and fruiting tops" of C. sativa plants should also be considered exempt on the basis of Article 2(9) which excludes from the scope of international control the use of drugs in industrial settings, for non-medical and non-scientific purposes. As long as the flowering and fruiting tops are used to obtain "hemp products" and not intoxicating substances, they do not fall under the Convention's régime. If THC is recovered during the obtention of hemp products from flowering or fruiting tops, only this THC recovered is subject to control under the relevant national laws.

[2] C61, Art. 4.
[3] C61, Art. 1-1(j).
[4] C71, Art. 1(e).
[5] C61, Art. 1-1(b).

Trace amounts of resin or THC do not justify control

THC is currently controlled in Schedule II of C71. It is therefore exempt from international control, as per Article 4(b), when used for industrial purposes. If the WHO's recommendation to transfer THC from C71 to Schedule I of C61 is adopted[6], THC would still be exempted in industrial settings under Art. 2(9) of C61. The presence of trace amounts of THC, in a yield that does not allow it in practice to be recovered, is not a valid justification for control. The Commentary discusses the exemption, explaining that products which "contain only a very insignificant quantity of the psychoactive principle" are also exempted[7].

3. Hemp cultivation exempt from the régime of control over the production.

To precise their intention to exclude industrial hemp from the Convention's law régime, the writers of this international instrument mention a clear distinction between Cannabis plants grown for the production of drugs (falling under the scope of the treaties) and those grown for any other purpose, exempted. In Article 1, the definition of "Cannabis plant"[8] is only referring to Cannabis plants used for the "production" and "manufacture" of drugs (i.e., of products listed in the Schedules).

As a matter of clarification, the writers of the Single Convention explained that: "this Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes"[9], being underscored in the official Commentary published by UN Secretary-General's office, that "[this] control régime applies only to the cultivation of the cannabis plant for the production of cannabis and cannabis resin [i.e., drugs present in the Schedules]" and hence the "cultivation for any other purpose, and not only for the purposes mentioned in paragraph 2 [i.e. "industrial purposes", "horticultural purposes", "fibre and seed"], is consequently exempted from the control regime provided for in article 23 [i.e. falls out of the scope of C61]".[10]

4. Conclusions.

The exclusion of "hemp" in the text and spirit of the Single Convention is unequivocal and comprehensive. In light of the above reflections and assumptions, EIHA suggests elements to consider when moving forward:

1. Cannabis sativa L. is per se an "agricultural product", and considered as such in the EU. Similarly, C. sativa is considered as an "industrial plant" as long as it is not used to obtain drugs.
2. All parts of the plant and their derived products are excluded from the scope of control measures conveyed by the Conventions when used for other than drug-related medical and scientific purposes.
3. In practice, the exemption for the cultivation and processing of C. sativa for industrial purposes is enforced via the compliance with specific levels of THC; no other substance (i.e. cannabidiol (CBD) or any other cannabinoid) shall be considered for the determination of the lawfulness of industrial Cannabis crops and products.
4. The eventual misuse of Cannabis leaves should continue to be prevented through the setting of low THC limits, to comply with the provisions of C61's Article 28(3).
5. EIHA proposes a threshold established at ≤ 0.3 % post-decarboxylation as a limit of THC in industrial hemp (see other examples in Annex 2).

[6] See: WHO Expert Committee on Drug Dependence, Fortieth report (2018). https://apps.who.int/iris/bitstream/handle/10665/279948/9789241210225-eng.pdf ; and WHO Expert Committee on Drug Dependence, Forty-first report (2019). https://apps.who.int/iris/bitstream/handle/10665/325073/9789241210270-eng.pdf

[7] Commentary, p. 4.

[8] Art. 1-1(c)

[9] C61, Art. 28

[10] Commentary, p. 312.

6. The reason for international control of “cannabis”, drug preparations of “cannabis” and THC, is their placement in the Schedules due to their intoxicating effects and potential for medicine; the reason for the exemption of hemp and hemp products from international control is the absence of these effects and the lack of liability to misuse.
7. “Industrial hemp” (or “hemp”) should be defined as “a Cannabis plant with low levels of THC that is grown specifically for the industrial, non-intoxicating uses of its derived products”; “hemp extracts” or “hemp products” should be defined as “non-intoxicating products or preparations from Cannabis plants with low levels of THC that have been grown specifically for industrial purposes.”

The lawfulness, legislation, criteria of suitability for the market, and scope of products considered hemp products, are totally disregarded by the international drug control system that, as it names says, is a set of international law regulating the pharmaceutical sector. Thresholds, analysis, lists of varieties, or any other type of legislation applied in different jurisdictions are not subject to the provisions of neither C61 nor C71, and regulators have the full sovereignty to determine the laws and regulations affecting hemp.

Diverging interpretations would mean the creation of a new layer of sui generis regulations[11] likely to enshrine stricter and overly restrictive measures of controls than those applied to hemp by most signatories of the Conventions. Stricter interpretations will with no doubt undermining an agricultural sector already subject to an important set of rulings, and oppose the global trend (in countries such as Australia, Canada, China, Uruguay and the United States of America) of simplifying hemp-related laws in support to a non-problematic and constantly growing industrial hemp market.

Authors: Boris Baňas, Dr. Bernhard Beitzke, Daniel Kruse, Kenzi Riboulet-Zemouli, Lorenza Romanese, Catherine Wilson

[11] Because they would be unrelated to the Single Convention, would disregard the interpretation of the Secretary-General’s Commentary, and undermining the more recent update contained in the scientific assessment of CBD made by the World Health Organization, and its recommendation that CBD it should not fall under the scope of international drug control.

Annex 1: regulatory elements.

Current regulations of industrial hemp in the European Union

At EU level, the TFEU (Treaty on the Functioning of the European Union), in annex I, lists the agricultural products for which the provisions of the Treaty itself are applied, among them under chapter 57.01 is "True hemp (Cannabis sativa), raw or processed but not spun; tow and waste of true hemp (including pulled or garnetted rags or ropes)". Regulation (EU) 1308/2013 considers C. sativa an agricultural product and an industrial plant, both for cultivation and seed production.

Articles 32(6), 35(3), and 52 of Regulation (EU) 1307/2013 underline that "areas used for the production of hemp shall only be eligible hectares if the varieties used have a tetrahydrocannabinol content not exceeding 0.2 %", and that "in order to preserve public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 70 laying down rules making the granting of payments conditional upon the use of certified seeds of certain hemp varieties and the procedure for the determination of hemp varieties and the verification of their tetrahydrocannabinol content referred to in Article 32(6)."

Basically, the lawfulness of the cannabis production and trading as "agricultural product" and "industrial plant" depends on the THC (tetrahydrocannabinol) percentage that cannot be higher than (currently) 0.2 %, in accordance to the methods indicated by the above-mentioned law and specified in Commission Delegated Regulation (EU) 639/2014 and Commission Implementing Regulation 809/2014. According to the same regulation, European farmers cultivating industrial hemp and respecting the imposed limits of THC are entitled to receive CAP payments.

Industrial hemp at a national level in the EU

Countries have adopted their own drug control laws making in their turn a clear distinction between drug-type cannabis plant and low-THC industrial hemp.

Examples of THC levels for this distinction: EU in general (currently) ≤ 0.2 %, Austria ≤ 0.3 %, Czechia ≤ 0.3 %, Canada ≤ 0.3 %, USA ≤ 0.3 %, Australia ≤ 0.3 %, Switzerland < 1.0 %. With these national drug laws all Parties acknowledge the competence of the UN and stay within the framework of its Conventions. They clearly exempt industrial hemp from the jurisdiction of the 1961 treaty.

Several EU member states have completely exempted varieties of Cannabis sativa L. complying with provisions of EU Common Agricultural Policy[12] from the scope of their drug-related schedules. These exemptions do not only mention the cannabis plant itself, but also its flowering and fruiting tops, extracts, tinctures and even the resin. Examples of such member states are Luxembourg and Slovakia. Other states, such as Austria, applied an arbitrary value of 0.3% of THC as a concentration to delimitate between drug and non-drug derivatives of the plants of genus Cannabis.

In 2015, Slovak Republic included hemp leaves into a list of plants and their parts suitable for production of teas.[13]

[12] Article 9 of Commission Delegated Regulation (EU) No 639/2014 of 11 March 2014 supplementing Regulation (EU) No 1307/2013 of the European Parliament and of the Council establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and amending Annex X to that Regulation.

[13] See Annex III, Table 1 of DECREE 09/2015 Z.z. of Ministry of Agriculture and Rural Development of Slovak Republic, of December 4, 2015, on spices, table salt, dehydrated food, soup preparations and on aromas

Recently, in July 2019, Belgium created a room for marketing industrial hemp herbal products for smoking not containing tobacco as long as business operators are registered as excise-tax payers.[14]

Thanks to such and similar legislative clarifications adopted at a national level, a flourishing hemp industry has started to grow significantly in the last ten years.

In the USA, the Congress has passed an Agriculture Improvement Act of 2018[15] (so-called "2018 Farm Bill") which defines hemp as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing of not" and exempts it form the federal definition of "Marijuana" provided the delta-9 THC concentration is not higher than 0.3% post-decarboxylation on a dry weight basis.

The case of Croatia

On April 25, 2019 the Drug Abuse Act have been amended making it easier for farmers to grow industrial hemp. It is now possible to use the whole industrial hemp plant for industrial purposes in the construction, textile, food and cosmetics, paper, automotive and biofuels industries.

The Croatian Ministry of Agriculture decided to create a definition for industrial hemp that clearly exempt it from the list of controlled substances. In article 2, paragraph 1 item 5 of the current Drug abuse Act it states that "Industrial hemp is cannabis (Cannabis sativa L.) with a total THC content of 0,2%[16] and less, of which the varieties are on the European Union Common Variety List and not listed in the list of drugs, psychotropic substances and herbal drugs."[17] As per article 13 of the same Act, "the production of industrial hemp referred to in article 2, paragraph 1 item 5 of this Act is authorized."

EIHA welcomes Croatia's interpretation and suggests its adoption at the European level.

[14] Belgian Federal Public Service: Health, Food chain and Environment (2019). Positive list of Herbal product for smoking (19/12/2019). https://www.health.belgium.be/fr/liste-positive-des-produits-fumer-base-de-plantes

[15] US Public Law 115-334: https://www.govinfo.gov/link/plaw/115/public/334?link-type=pdf

[16] EIHA advocates to restore the former 0,3% level of THC in the plant entitled for CAP payments (Art 32, point 6 of EU Regulation 1307/2013). The EU hemp sector has a significant competitive disadvantage to producers in Switzerland, North America, Asia and Canada (where limits from 0.3% up to 1% are successfully and legally established).

[17] Official Gazette 39/19

Annex 2: technical elements.

Case study on hemp extracts and hemp resin

Taking into consideration all the above reflections and assumptions, EIHA would like to point out that "hemp plant extracts" may be defined as extracts of the cannabis plant that contain various constituents of the cannabis plant, but that have a very low, if any, content of THC. They are obtained virtually from any part of the plant, e.g.: leaves, fruits, flowers, roots, seeds.

The European hemp industry does not separate the resin from the plant. Besides the harvest of seed and fibre, the extraction of remaining biomass is undertaken, with naturally present levels of cannabinoids. This extraction of industrial hemp biomass, and the dilution of resulting extracts, needs to comply with national drug control laws.

In "hemp plant extracts", the starting material is already low in THC. The extraction of industrial hemp biomass and the dilution of hemp extracts need to comply with national narcotic laws. Thus, due to their low THC content, these products cannot be, in practice, abused or the THC recovered from them. "Hemp plant extracts" so become "products not covered by the 1961 Convention" - they are neither a narcotic drug nor a psychotropic substance. Additionally, these products and the plants used to obtain them are not associated with the purposes of pharmaceutical applications or of scientific research. "Hemp plant extracts" therefore correspond to all criteria defining the products not covered by the 1961 Convention.

Remaining trace-amounts of THC in "hemp plant extracts" obviously do not disqualify this reasoning, and are permitted as these quantities are "not liable to be abused or have ill effects" and are present "in such ways that THC cannot be recovered by readily available means or in a yield which would constitute a risk to public health."[18] It was neither the intention of the Single Convention nor the objective of the Regulation (EC) No 178/2002 on food to disqualify products such as "hemp plant extracts" that contain quantities of THC not liable to abuse. The international drug control conventions do not consider this product as dangerous. It would be absurd, if these Regulations would disqualify "hemp plant extracts" by referring to the drug control conventions.

In this connection, it should be noted that there are also other cases when controlled substances are present in food. This is the case of morphine and other controlled opium alkaloids in poppy seeds (due to unavoidable contamination of the seeds with poppy straw dust during the process of their industrial separation). Poppy seeds continue to be allowed for use as food while limits on opium alkaloids content are set, where necessary.

European hemp farmers and industries use hemp seeds, hemp roots, flowers, leaves (after the flowering and mostly even after the seed ripening) for producing different types of hemp extracts. These products were already excluded from the scope of the control regime of the Single Convention as enforceable and enforced regulations complying with the Convention have been in place for two decades. New regulations should be aimed at simplifying and correcting errors, not adding layers of complexity.

[18] Questions to WHO on 41st ECDD recommendations, 5th CND Intersessional meeting, 23 September, 2019, page 19.

Case study on Cannabidiol

Pure Cannabidiol (whether produced synthetically or by isolation from Cannabis plants) has been given a clear "carte blanche" by the 40th WHO ECDD Critical review.

In this context, the outcomes of the 39th and 40th WHO ECDD meetings, merits attention. In July 2018, WHO recommend "that preparations considered to be pure CBD should not be scheduled within the International Drug Control Conventions."

EIHA has welcomed this recommendation not to include products considered to be pure Cannabidiol (CBD) in the Schedules of the International Drug Control Conventions, published in a Note Verbale to the United Nations Secretary-General dated July 23rd, 2018. However, EIHA has formally objected[19] to the reasoning of the Experts according to which "… if prepared as an extract or tincture of cannabis [Cannabidiol] is controlled in Schedule I of the 1961 Single Convention on Narcotic Drugs."

An important element of the WHO ECDD outcome is a refusal of the differentiation between Cannabis compounds produced obtained by isolation from the C. sativa plants, or obtained by synthesis. This applies to THC as well as CBD, and the Experts, while considering the issue on the basis of evidence, dismissed the option of differentiating Cannabis compounds according to their method of isolation. For example, German DAC/NRF monograph C-052 on Cannabidiol[20] mentions a chromatographic purity between 98.0–102.0 % and defines Δ9-THC, Δ8-THC and Cannabinol (CBN) as "specified impurities". Moreover, it states that the CBD may be of natural as well as of synthetic origin. Without prejudice to other legal requirements concerning the manufacture of the extracts of cannabis and subsequent isolation of pure CBD there from, considering "Cannabidiol" of plant origin as an "extract of cannabis" does not hold up to principles of any of the relevant international standards; neither the nomenclature of organic chemistry (IUPAC) system, Chemical Abstracts Service (CAS), nor WTO Harmonized System Codes:

Extracts and tinctures of cannabis	Cannabis sativa, ext. (Hemp Extract)	Cannabidiol	Hempseed / Hemp oil	Hemp Essential oil
CAS: 6465-30-1	CAS: 89958-21-4	CAS: 13956-29-1	CAS: 8016-24-8	CAS: none particular
HS Code: 1302.19	HS Code: 1302.19	HS Code: 2907.29	HS Code: 1515.90	HS Code: 3301.90
IDS Code: NC008	IDS Code: N/A	IDS Code: N/A	IDS Code: N/A	IDS Code: N/A

The toxicological and pharmacological properties of a substance or extract as well as its potential for abuse mainly depend on its constituents and composition. What matters is the content of a drug component and the substance's effect, not the origin of the substance or its manufacturing procedure.

Moreover, the impurity profile of an isolated chemical compound (in this case with Δ9-THC as an impurity) may not be unique or characteristic in order to distinguish it from a synthetic version. The impurity profile (by-products) of a synthetic product may even be very similar to the "impurity profile" of the natural isolated product, in particular if the synthetic pathway is a biomimetic one.

On these same grounds, purified Cannabidiol (CBD) obtained from C. sativa is not an "Extract of cannabis" and therefore is not scheduled under the Single Convention (1961), with trace amounts of THC not justifying control.

[19] Banas B, Beitzke B, Kruse D, Pachta P, Riboulet-Zemouli K (2018). EIHA statement on recommendations of the 40th ECDD on Cannabidiol and contribution to the 41st ECDD Critical reviews of Cannabis-related substances. EIHA, 2018. http://eiha.org/media/2014/08/18-12-04_EIHA_contribution_41th_ECDD.pdf

[20] DAC/NRF 2016/2, C-052, Cannabidiol, 12 pages.