Common Position of the Industrial Hemp Sector on the Single Convention and the International Drug Control System

ACU 亚太工业大麻产业协会 Asia-Pacific CBD Union

Australian Hemp Council

BHA British Hemp Alliance

CHTA ACCC Canadian Hemp Trade Alliance Alliance Commerciale Canadienne du Chanvre

EIHA European Industrial Hemp Association

Hokkaido.JP Industrial Hemp Association

HEMP INDUSTRIES ASSOCIATION thehia.org

LAIHA LATIN AMERICAN

MONGOLIAN HEMP ASSOCIATION

МОНГОЛЫН ХЭМП ХОЛБОО

NATIONAL HEMP ASSOCIATION

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Abstract

In light of the global development of industrial hemp (hereinafter "hemp") markets and its raw material *Cannabis sativa* L., the international industrial hemp sector (hereinafter "hemp sector"), as represented by the undersigned organizations, would like to reiterate its position on this topic and stress the need for clarification and a transparent debate on international law and regulations related to hemp. The current market barriers and challenges for a flourishing hemp sector originate in one particular interpretation of the international law to which regulations on food and cosmetics make reference.

In particular, there are two international legal instruments that we would like to make reference to in this position paper: The Single Convention on narcotic drugs of 1961, as amended by the 1972 Protocol ("Single Convention" or "**C61**") and the Convention on psychotropic substances of 1971 ("**C71**"). These two texts contain in their annex the schedules where the drugs are listed.

It is appropriate to recall that (i) **the cultivation of hemp has been clearly exempted from the scope of these two Conventions since their inception**. As a consequence, all (ii) **downstream products and derivatives of 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.

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 tetrahydrocannabinol (THC[1]), while *a posteriori*, thresholds and analyses applied by regulators determine market suitability. Hemp derivatives are obtained from all parts of the plant (e.g. leaves, flowers, roots, seeds, stems, branches) and have one common characteristic: their low levels of THC and absence of THC-related effects. Hence, the international hemp sector defines "industrial hemp" ("hemp") as **"a *Cannabis sativa* L. plant – or any part of the plant – in which the concentration of tetrahydrocannabinol (THC) in the flowering tops and leaves is less than the regulated maximum level, as established by authorities having jurisdiction."**

[1] THC refers, in this document, to delta-9-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 on 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; thus, it expresses the general purposes of a piece of legislation. Preambles can be referred to for statutory interpretation by clarifying the subject matter or the objective behind its preparation.

As clearly framed in its preamble of the C61, the purpose, notion, spirit and rationale behind C61 fundamentally concerns "narcotic drugs" (i.e., opiate medicines and pharmaceutical products) and the prevention of their misuse (in terms of consumption and commercialization) as well as their illicit trafficking. **Hemp products do not** lead to abuse, addiction or dependence, as the level of THC in these products is extremely low. 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 Art. 4 C61 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, hemp products do not fall under the provisions of strict limitation to medical or scientific use.

2. Hemp products not controlled under C61 and C71 Schedules

Exemption for stems and roots

The drugs, substances and preparations falling under the scope of C61 and C71 are defined strictly as: "any of the substances in Schedules I and II, whether natural or synthetic"(Art. 1-1(j) C61); and, "any substance, natural or synthetic, or any natural material in Schedule I, II, III or IV" (Art. 1(e)C71).

Exemption for seeds and leaves

"Cannabis" is defined in Art. 1-1(b) C61 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, hemp seeds and leaves, and any product derived thereof, are not present in the Schedules; not covered by their régime of control. Therefore, leaves 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 *Cannabis sativa* L. plants should also be considered exempted 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. Flowering and fruiting tops used to obtain "hemp products" do not fall under the Convention's régime. Low-THC hemp products are non-intoxicating, non-addicting and non-habituating. If THC is recovered during the obtainment of hemp products from flowering or fruiting tops only this recovered THC is subject to control under the relevant national laws.

Trace amounts of resin or THC do not justify control

THC is currently controlled in Schedule II of C71. It is therefore exempted 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[2], THC would still be exempted in industrial settings under Art. 2(9) of C61. The Commentary discusses the exemption, explaining that products which "contain only a very insignificant quantity of the psychoactive principle" are also exempted[3].

3. Hemp cultivation exempted from the régime of control

The authors of this international instrument made a clear distinction between including cannabis plants grown for the production of drugs (falling under the scope of the treaties) and exempting those grown for any other purposes. In Article 1-1(c), the definition of "Cannabis plant" refers only 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 in Art. 28-2 that: "this Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes", being underscored in the official Commentary published by the 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]*".[4]

[2] 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
[3] Commentary, p. 4.
[4] Commentary, p. 312.

4. Conclusions

The exclusion of "hemp" in the text and spirit of the Single Convention is unequivocal and comprehensive. In light of the reflections and assumptions above-mentioned, the international hemp industry suggests various elements to be considered when moving forward:

1. *Cannabis sativa* L. is *per se* an "**agricultural product,**" and considered as such e. g. in the European Union (EU), the United States of America (USA), Canada, New Zealand, and many other national jurisdictions. 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 *Cannabis 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 potential for misuse of *Cannabis* leaves should continue to be prevented through the setting of appropriate THC limits (as established by authorities having jurisdiction), to comply with the provisions of C61's Article 28(3).
5. The international hemp sector proposes a THC threshold in hemp flowers and leaves to be established at 1.0% post-decarboxylation (see examples in Annex 2).
6. The reason for international control of "cannabis", drug preparations and THC is their placement in the Schedules due to their potential for intoxication, addiction and habituation. The reason for exempting hemp (*Cannabis sativa* L.) and hemp products from international control is the absence of these effects and the lack of ability to misuse.
7. "Hemp" (or "hemp") should be defined as "**a *Cannabis sativa L.* plant - or any part of the plant - in which the concentration of tetrahydrocannabinol (THC) in the flowering or fruiting tops is less than the regulated maximum level, as established by authorities having jurisdiction."** "Hemp extracts" or "hemp products" should be defined as "**products or preparations derived from *industrial hemp.*"**

The international drug control system totally disregards the lawfulness, legislation, criteria for market suitability, and scope of hemp products. The international drug control system, as its name suggests, is a set of international laws regulating the pharmaceutical sector. **Authorities having jurisdiction maintain the full sovereignty to determine their laws and regulations affecting hemp** (e.g. THC thresholds, testing methodology, lists of approved varieties). In fact, all legislation and regulations applied by national and regional authorities having jurisdiction are not subject to the provisions of neither C61 nor C71.

Diverging interpretations would mean the creation of a new layer of *sui generis* regulations[5] likely to enshrine stricter and overly restrictive measures of controls than those applied to hemp by most signatories of the Conventions. Stricter interpretations will,

[5] Such regulations are unrelated to the Single Convention, would disregard the interpretation of the Secretary-General's Commentary.

without any doubt, undermine an agricultural sector already subject to an important set of rulings and oppose the global trend of simplifying hemp-related laws in support to a non-problematic and constantly expanding hemp industry.

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Annex 1: Regulatory Overview

Hemp Regulations 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 garneted rags or ropes)". Regulation (EU) 1308/2013 considers *Cannabis sativa* L. as 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 hemp and respecting the imposed limits of THC are entitled to receive CAP payments.

Hemp Regulations in Croatia (EU)

On April 25, 2019 the Drug Abuse Act has been amended making it easier for farmers to grow hemp. It is now possible to use the whole 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 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 "Hemp is cannabis (*Cannabis sativa* L.) with a total THC content of 0.2 %[6] 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."[7] As per article 13 of the same Act, "the production of hemp referred to in article 2, paragraph 1 item 5 of this Act is authorized."

[6] 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).

[7] Official Gazette 39/19

The international hemp sector welcomes Croatia's and other examples interpretation and suggests its adoption at the European level.

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.

Hemp Regulations in Canada

Canada re-legalized the production and processing of hemp in 1998. Health Canada is the responsible authority for hemp (and cannabis) regulation. All hemp regulations were consolidated under the Cannabis Act and associated under the Industrial Hemp Regulation (IHR) in 2018. The IHR simplified agricultural operations within the Canadian industry.

The Canadian definition of Hemp is: a cannabis plant – or any part of that plant – in which the concentration of THC is 0.3 % w/w or less in the flowering tops and leaves. The determination of the THC concentration must take into account the potential to convert delta-9-tetrahydrocannabinolic acid into THC.

A Health Canada licence is required to conduct any of the following activities: sell hemp; import or export hemp seed; cultivate hemp; propagate hemp (breeding); possess hemp seed for the purposes of cleaning/conditioning it; possess hemp seed for the purpose of processing (food); harvest and possess hemp flowers, leaves and branches (chaff) for the purpose of selling to a Canadian Licenced Cannabis Processor. Hemp fibre (stripped stalks) and hemp roots can be sold and processed without a Health Canada License. A Health Canada Cannabis Licence is required to process and sell hemp-derived (and cannabis-derived) cannabinoids.

Hemp can only be cultivated from approved cultivars using Pedigreed hemp seed of at least Certified status. Approved cultivars are varieties of industrial hemp set out in the List of Approved Cultivars, published by the Government of Canada on its website, as amended from time to time.

Processed hemp seed products (e.g. dehulled hemp seed, hemp seed oil, hemp seed protein concentrate, and toasted hemp seed) can be imported, exported, and sold without a Health Canada licence if the THC concentration is ≤10 mg/kg (10 ppm).

Processed cannabinoids, and products containing processed cannabinoids can be sold by Licenced Cannabis Processors within the national medical cannabis (prescription) program and provincially-regulated cannabis retail markets (age restricted). These products can be exported to jurisdictions for medical and research purposes. They can be imported for research purposes.

Livestock feed ingredients are regulated in Canada under the Feeds Act and Regulations administered by the Canadian Food Inspection Agency. All feed must be safe for livestock, for humans (by the potential transfer of residues into human food, that is, meat, milk and eggs, and via worker/bystander exposure) and for the environment. Hemp seed is not currently registered as a feed ingredient in Canada. The Canadian hemp industry is seeking livestock feed ingredient registration of hemp seed and its derivatives (≤ 10 ppm THC) for all major livestock species.

Hemp Regulations in the USA

The USA re-legalized hemp with the passage of the Agriculture Improvement Act of 2018 ("2018 Farm Bill"). Hemp is defined 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 or not" and exempts it from the federal definition of "marijuana" provided the delta-9-tetrahydrocannabinol concentration is not higher than 0.3% post-decarboxylation on a dry weight basis.

To produce hemp under the USDA plan, producers must apply for and be issued a [three year] license from USDA. Producers are required to register all land where hemp is grown with State or Tribal authorities.

Within 15 days prior to the anticipated harvest of cannabis plants, a producer shall have an approved Federal, State, local law enforcement agency or other USDA designated person collect samples from the flower material of such cannabis material for delta-9 tetrahydrocannabinol concentration level testing to ensure that THC levels do not exceed 0.5 %. Plants must be destroyed by a person authorized under the CSA to handle marijuana if they are found to contain more than 0.5 % THC (dry weight).

Approved testing protocols (including gas or liquid chromatography) require that certified labs be used (standards to be further developed) and that THCA must be converted to delta-9-THC (post-decarboxylation) in order to calculate a total delta-9-THC level. USDA requires that all samples tested for THC concentration levels be conducted in DEA registered laboratories.

Criminal background checks are required for all individual hemp growers and all key persons for corporate hemp growers at the time of application. Authorities must prohibit any person convicted of a felony related to a controlled substance under State or Federal law before, on, or after the enactment of the 2018 Farm Bill from participating in the State or Tribal plan and from producing hemp for 10-years following the date of conviction.

Hemp producers will be found to commit a negligent violation if they produce plants that exceed the acceptable hemp THC level and use reasonable efforts to grow hemp and the plant does not have a THC concentration of more than 0.5 % on a dry weight basis. Using certified seed is an example of a reasonable effort to grow hemp. A producer who negligently violates a State or Tribal plan three times in a five-year period will be ineligible to produce hemp for a period of five years from the date of the third violation. Negligent violations are not subject to criminal enforcement action by local, Tribal, State, or Federal Government authorities. If it is determined a violation was committed with a culpable mental state greater than negligence (Reference Black's Law), the State department of agriculture or tribal government, as applicable, shall immediately report the producer to the Attorney General, USDA, and the chief law enforcement officer of the State or Tribe.

All State and Tribal plans submitted for USDA approval must also have a certification stating the State or Tribe has the resources and personnel necessary to carry out the practices and procedures described in their plan. USDA has the authority to audit States and Tribes to determine if they are in compliance with the terms and conditions of their

approved plans. If a State or Tribe is noncompliant with their plan, USDA will work with that State or Tribe to develop a corrective action plan following the first case of noncompliance. However, if additional instances of noncompliance occur, USDA has the authority to revoke the approval of the State or Tribal plan for one year. If USDA disapproves a State or Tribal hemp production plan, individual producers located in the State or Tribal Nation may apply for a USDA hemp production license.

Nothing in this rule prohibits the interstate commerce of hemp. No State or Indian Tribe may prohibit the transportation or shipment of hemp produced in accordance with this part and with section 7606 of the 2014 Farm Bill through the State or the territory of the Indian Tribe, as applicable. The Food and Drug Administration (FDA) will eventually regulate inter-state commerce of processed products containing processed hemp-derived cannabinoids.

Hemp Regulations in Latin America

Latin American countries have followed the global trend of creating regulatory frameworks for the cannabis and hemp industries, specially over the last 4 years, when the financial markets were eager for investments in the sector. The main examples of regulations are Colombia and Uruguay, due to its progressive approach and pioneering position in putting forward comprehensive regulations and laws to allow the production and processing of hemp and cannabis as an economic activity. Brazil is often pointed out as the largest market of the region with its 210 million population, but so far the country only allowed access to patients through pharmacies and under physician prescription, and prohibited any form of cultivation of the species, causing all available products to be imported into the country.

The most advanced legislation in the region is Colombia. Since 2017 it allows licenses in each process of the hemp production and medicinal cannabis. There are several types of licenses: seed source, cultivation of psychoactive cannabis, cultivation of non-psychoactive cannabis, manufacture of derivatives, and export. Ministries, such as the Justice and Health, and the ICA (Instituto Colombiano Agropecuario) participate in this licensing. For this year (2020) Colombia has 137 licenses for psychoactive cannabis and 103 for non-psychoactive cannabis, of which it has produced 56.5 tons of flowers and biomass. The next challenge is to strengthen the different hemp varieties for National production, classifying each in approach, adapting such plants to different end uses, fiber, grains or cannabinoids. In Colombia, it is considered non-psychoactive cannabis the production that contains less than 1% delta-9-tetrahydrocannabinol (THC), in dry weight basis. There is quite a lot of potential and permission to work with hemp in the country.

In Uruguay, cannabis was first regulated in 2013, through the Law 19.972. Almost one year after this law was enacted, the government published an updated version in December 16, 2014, with specifications of "non-psychoactive" cannabis, nominated hemp. The law specifies that any parts of the hemp plants can surpass the limit of 1% of delta-9-tetrahydrocannabinol (THC). This decree also established that all authorizations for production or processing of hemp and its by-products must be issued by the Agriculture, Livestock and Fishing Ministry, with no relationship with the Health Ministry or the IRRCA

(Uruguay's Institute for Regulation and Control of Cannabis), thus stating very clearly that hemp and cannabis are separately regulated and the competencies for this are distinct. All Hemp seeds used within the country must undergo registry within the Agriculture Ministry, similar to what is required for any other crop. Seed producers must also register with the Agriculture Ministry to be able to reproduce and sell seeds for growing.

Brazil currently does not have a regulation for growing of any type of Cannabis, either psychoactive or non-psychoactive. Nevertheless, recently the National Health Agency of Brazil (ANVISA) published a regulatory framework (RDC 327/2019), that established the possibility to sell cannabidiol derived products in pharmacies, not as registered medicines, but in a special class similar to phytotherapeutic medicines. The limitations follow the example of the European Union, meaning that products cannot have more than 0.2% levels of delta-9-tetrahydrocannabinol (THC), must be imported into the country (no local production), and should contain stability and safety data to its composition. As long as the product follows these regulations, they can be sold, with proper prescription and physician monitoring, on any pharmacy in the country.

In June 2020, Ecuador regulated the production of industrial hemp. The country allowed for an upper limit of 1% of THC, facilitating the production of hemp in such an equatorial climate, joining Uruguay, Colombia, Switzerland, Thailand and South Africa. All hemp will be regulated by the Ministry of Agriculture, who has the power to allow, inspect, terminate and sanction crops at the country. Ecuador's Ministry of Agriculture has 120 days of the law's enactment in late June to issue the new regulations.

Paraguay, through the Decree 2729 from 21/10/2019, from the Ministry of Agriculture and Livestock, has regulated the production and industrialization of hemp products, with the limit of 0.5% of THC. Licensed companies are allowed to import hemp varieties into the country. All varieties that are brought must be tested for 2 growth cycles inside the facilities of IPTA - *Instituto Paraguayo de Tecnologia Agraria* (Paraguayan Institute of Agrarian Technology). After that, the variety is considered able to be produced commercially by the licensed company responsible for the registration process. Within the country there is an association, CCIP – Cámara de Cáñamo Industrial del Paraguay, who is interacting with the government to promote a strong and sustainable growth of the country's industry.

Other countries, in an attempt to capture the economic benefits of the inclusion of hemp and cannabis to its agricultural models, are following the footsteps of Colombia and Uruguay. Currently Chile has a regulation that allows for the cultivation of small areas of hemp for industrial and medicinal purposes and there is a movement inside the government to facilitate the process and ease the access to industrial hemp that is not dedicated to pharmaceutical or medicinal ends. Peru also had advances in its legislation to introduce hemp as an agricultural commodity, in fact there was an expectation that Peru would produce a more progressive legislation than its neighbour country, Colombia, which means a more open regulation that would allow for hemp to be cultivated at very large scales and the use of hemp derived products would be legalized for the population of the country. So far, these advances have not yet been fulfilled and the local industry is yet to see significant increase of hemp production and processing.

Mexico is another good example, the country was on the brink of legalizing adult use of cannabis and allowing cultivation in large scales, but due to the COVID pandemic

situation, the vote on this matter was postponed to December 2020. Although cultivation is not yet allowed in the country, the import of hemp derived products is legal as long as the limit of 0.3 % THC is respected, allowing for the uses of fibers for construction, textiles, medicinal uses, grains for food and more. The proposed regulation would also be focused on people that were harmed by the years of war on drug cartels within the country, the president of Mexico stated that he expected 40% of all cultivation licenses to be used as reparations for people affected by drug trafficking and war on drugs.

Jamaica is an excellent example of regulated state in the Caribbean, the government created an office called Cannabis Licensing Authority, whose function is to create regulations to guide the development of an orderly legal cannabis and hemp industry in Jamaica, for the use of the plant and its by-products for medical, therapeutic and scientific purposes. The country allows for several different types of licenses between growing, handling and selling these products.

Hemp Regulations in Australia

In Australia there is a positive process of change building. There have been several ministerial inquiries into aspects of the hemp industry and how regulations can be improved to make it easier to grow and sell industrial hemp in Australia.

The Therapeutic Goods Administration have put forward a proposal to change the scheduling of CBD from schedule 4 to schedule 3, making it accessible through pharmacies. Also, federal legislation has been changed to allow Australian companies to secure export certificates for selling medicinal hemp products overseas.
There is still much more to be done on easing regulations for the production of industrial hemp, in particular the production and sale of CBD products.

Each state has different legislation governing the production of industrial hemp, although obtaining licenses is not a difficult process for the production of food and fiber. In the case of CBD, it is treated the same as THC production which has extensive paperwork and licensing requirements through the federal bodies including the Therapeutic Goods Administration, Office of Drug Control and the Drug Control Section.

Industrial hemp is defined in Australia as hemp with less than 1% THC, which can be used for the production of food and fiber. Only hemp seeds derived from a crop with less than 0.5% THC can be used for planting as industrial hemp.

Hemp Regulations in Japan

In Japan, hemp was a general crop that anybody could freely cultivate from over 10,000 years ago until the end of World War II. At first, *Cannabis indica* (Indian hemp) was regulated as a drug in accordance with the former drug enforcement regulations that were instituted in 1930. After World War II, the GHQ (Supreme Commander of the Allied Powers), led by the United States, indicated that *Cannabis indica* and the domestic hemp plant were the same, and a blanket ban on the cultivation of cannabis plants was temporarily ordered.

However, since hemp was essential for fishing nets, ropes, and other materials for daily life at the time, the Cannabis Control Act (enacted on July 10th, 1948, Act No. 124) was established to protect domestic hemp farmers. Drugs handled by doctors fell under the

Narcotics Control Act (established on July 10th, 1948, Act No. 123), and cannabis handled by farmers fell under the Cannabis Control Act. Local authorities granted licenses to hemp farmers. Medicinal cannabis and medicine derived from cannabis were prohibited both for administration by doctors and reception by patients.

Then, as a result of the spread of synthetic fiber and lifestyle changes, the demand for hemp fiber fell drastically, and the number of cultivators fell from 30,000 in the 1950s to 1,000 in the 1970s. Since the number of marijuana-related criminals surpassed 1,000 in the 1970s as European and American hippie culture entered the country, the nature of the law changed to one that cracks down on these criminals. **Over the 70 years following the end of World War II, the Cannabis Control Act changed from a law that protects farmers to a law that regulates marijuana.**

At the moment the crop acreage of hemp is less than 10 hectares, there are roughly 30 hemp cultivators, and 400 cannabis researchers work to crack down on marijuana. With this scale of cultivation, hemp products are only used for religious ceremonies at Shinto shrines, traditional crafts, and folk customs[8].

Definition of Cannabis[9]

Article 1

The term "Cannabis" as used in this Act means the cannabis plant (Cannabis sativa L.) and its products; provided, however, that the grown stalk of the cannabis plant and its products (excluding resin) and the seed of cannabis plant and its products are excluded.

Based on this Act, the flowers and leaves of the cannabis plant are illegal, while its stalks (fibers) and seeds are legal.

This Act presents the following issues when promoting the cultivation and use of hemp.

(1) Since standards for tetrahydrocannabinol (THC) concentration are not listed, there is no distinction between marijuana and hemp.
(2) Although the cultivation of hemp is allowed, it is substantially prohibited due to the licensing system. Hardly any new licenses are granted.

(3) Flowers, leaves, and their products are all illegal and possession of them will be punished severely as a violation of the Cannabis Control Act.

(4) Cannabidiol (CBD) products that have been manufactured in a country where the use of the leaves and flowers is legal are illegal in Japan and cannot be imported. Even for CBD products that have been successfully imported, there will be incidents of product recalls if even a trace amount of THC is detected.

(5) Although seeds, grown stalks, and their products are legal in Japan, it is illegal to import viable seeds. Therefore, it is not even possible to try test cultivation of excellent industrial hemp varieties from overseas in Japan.

In order to these issues to be resolved, the Cannabis Control Act must be revised to include the definition of industrial hemp as having a THC concentration of 0.3%, which is the standard for hemp varieties. At the moment HIHA is taking the lead in presenting this request for approval to the Government of Japan and the National Diet.

[8] In 1985, the major production areas of hemp in Japan switched to new varieties with a THC concentration of 0.2%. This is the first case in the world to apply the current definition of industrial hemp.
[9] Cannabis Control Act (1948) http://hokkaido-hemp.net/CannabisControlAct.pdf

Hemp Regulations in Mongolia

In Mongolia, many positive changes are occurring. The Mongolian innovation centre (Government agency) is strongly supporting hemp growing and processing. Many cases of CBD for personal usage have been dismissed as criminal act. The Ministry of health and the Ministry of Agriculture are showing a strong interest to set THC limit at 1%.

Mongolia is working and studying international hemp regulations to establish complete synchronistic regulatory system.

Hemp Regulations in New Zealand

In New Zealand, industrial hemp is regulated by the Ministry of Health, under the Misuse of Drugs (Industrial Hemp) Regulations 2006.

The regulations define industrial hemp as having a low THC content, generally below 0.35% (% of dry weight) – for a "General Licence" and not above 0.5% for a "Research and Breeders Licence".

These licences cover various approved activities:

a) the procurement within New Zealand of industrial hemp
b) the cultivation of industrial hemp
c) the supply of industrial hemp within New Zealand
d) the processing of industrial hemp into specified hemp products
e) the possession of industrial hemp for the purposes of the activities specified in the licence

The licence lasts one year (but can be extended for a further two years), processing facilities are licenced for three years.

The Industrial Hemp Regulations were amended in December 2018, to include both THC and THC-a in the calculation of total "THC content".

A General Licence holder can only grow cultivars that have been approved by the Ministry of Health.

Other National Hemp Regulations

Many countries have adopted their own drug control laws making in their turn a clear distinction between **drug-type cannabis** and **hemp**, based on the THC concentration in the "flowering tops and leaves."

Examples of THC levels for this distinction include Austria ≤ 0.3%, Czechia ≤ 0.3%, New Zealand <0.35%, Australia ≤ 1.0 %, Switzerland < 1.0 %. Within these national drug laws, all parties acknowledge the competence of the UN and stay within the framework of its Conventions. They clearly exempt hemp from the jurisdiction of C61.

Several EU member states have completely exempted varieties of *Cannabis sativa* L. complying with provisions of EU Common Agricultural Policy[10] 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.[11]

Belgium (July 2019) allowed the marketing of hemp herbal products for smoking, as long as it does not contain tobacco and business operators are registered as excise-tax payers.[12]

[10] 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.
[11] 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
[12] 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

Annex 2: Technical Elements – European Union

Case study on European Union hemp extracts and hemp resin

Taking into consideration all the above reflections and assumptions, the international hemp industry 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 an extremely low content of THC. They are obtained from virtually any part of the plant (e.g. leaves, 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 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 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."[13] 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 these products 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 where 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

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

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.

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, 40th and 41st 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."

The international hemp industry 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[14] 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 by isolation from the *Cannabis 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[15] mentions a chromatographic purity between 98.0–102.0% and defines delta-9-tetrahydrocannabinol, delta-8-tetrahydrocannabinol, 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 therefrom, 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**

[14] Bañas 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

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

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 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 delta-9-tetrahydrocannabinol 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 *Cannabis sativa* L. is not an "extract of cannabis" and therefore is not scheduled under the Single Convention (1961).