Position Paper of the European Industrial Hemp Association (EIHA) on

Reasonable regulation of cannabidiol (CBD) in food, supplements, medicine and cosmetics

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PREAMBLE

In 2016 EIHA published the much referenced and highly regarded position paper on CBD ("Reasonable regulation of cannabidiol (CBD) in food, cosmetics, as herbal natural medicine and as medicinal product", Hürth, Update January 2017). Since then, we have seen dramatic changes and expansion across the global hemp industry. As a result, we have taken this opportunity to update and revise this key document, including a summary of the new regulatory environment and EIHA's position on how to navigate and drive positive development for the hemp sector.

1. INTRODUCTION TO CANNABIDIOL (CBD)

During 2019, approximately 50.000 ha of industrial hemp were cultivated in the European Union. One of the naturally occurring cannabinoids in industrial hemp is called Cannabidiol or CBD.

EIHA has already shared substantial evidence with the European Commission proving that, apart from hemp seeds and hemp seed products, hemp flowers, leaves and extracts have been consumed as food for centuries. The so-called "low-THC" varieties, defined as industrial hemp, have always contained natural levels of cannabidiol (CBD). Particularly in these industrial hemp varieties, including those that were already listed in the EU catalogue of varieties long before 1997, the respective content of CBD in relation to THC is very high compared to "high-THC" cannabis varieties. CBD and its natural precursor CBDA (Cannabidiolic Acid) are the primary cannabinoids in European industrial hemp and are present in concentrations ranging from 0.5 % to 6.0 % (based on dry matter) primarily in the upper third of the plant. This is particularly the case for certified EU hemp varieties of the common catalogue containing up to 0.2%

of THC on the field. CBD is not psychotropic, intoxicating or addictive and has no significant side effects even if consumed in high doses[1]. However, it does offer numerous health & wellness benefits. As a result, triggered by the boom in the US of the CBD market, the last five years in particular have witnessed a considerable increase in consumer's interest around CBD all over Europe and a rapid growth in the market to supply a diverse range of CBD-based products across multiple categories from food supplements, edibles, topicals, cosmetics and vape oils. Consequently, new investment has been generated for the hemp sector and plenty of jobs have been created across all parts of the value chain, from cultivation to manufacturing. In addition, several medicinal products have been developed with CBD as an active pharmaceutical ingredient.

Hemp extracts containing CBD/CBDA as well as isolated CBD (single substance) represent an important additional (and profitable) income stream for hemp farmers, and business operators – especially small and medium enterprises. Historically, fibres and shives together with leaves, flowers and seeds for food applications have been the main products derived from hemp cultivation.

2. TRADITIONAL HEMP FOOD, CBD AND NOVEL FOOD

Until January 2019, extracts of Cannabis sativa L. were considered novel **only if the levels of cannabidiol were "*higher than the CBD levels in the source Cannabis sativa L.*" (former Novel Food catalogue entry l).**

The EU **Standing Committee** for Foodstuffs already **decided in December 1997** and the **Commission confirmed** to the European hemp industry in writing in the beginning of 1998, **literally** what follows:

> *"it was decided that foods containing parts of the hemp plant do not fall under the scope of the regulations EC 258/97" and also "that hemp flowers … are considered to be food ingredients" (e. g. used for the production of beer-like beverages)".*

Obviously, hemp flowers and leaves being parts of the hemp plant were not considered to be Novel Food.

However, **in January 2019**, Member States' representatives updated the Novel Food Catalogue entry for "*Cannabis sativa* L." and created a new one for "Cannabinoids". These updates are demonstrably incorrect, based on logic and historical facts, as EIHA

[1] Bergamaschi, M. M., Queiroz, R. H. C., Zuardi, A. W. & Crippa, J. A. S. (2011): Safety and side effects of cannabidiol, a Cannabis sativa constituent. Current drug safety, 6(4), 237-249, DOI: 10.2174/157488611798280924.

repeatedly explained to Member States and the European Commission.

- The new entry for **"*Cannabis sativa* L." does not mention hemp leaves and flowers, although they have been traditionally consumed as food for centuries**. Hence, it is obvious that the latest changes, which seem to be hastily written, concerning the entries in the Novel Food Catalogue are not correct. Moreover, the **traditionally produced hemp extracts are also missing**, although preparation of such extracts has been described since the invention of the art of printing, and extraction is considered as a traditional and conventional method of food processing.
- In the new entry for **"Cannabinoids" any "extracts of *Cannabis sativa* L. and derived products containing cannabinoids are considered novel foods" without exempting those with the naturally occurring levels of cannabinoids**, although they were mentioned in the previous entry formulation. Such products were already on the market and consumed before 1997 to a significant degree.

Hemp extracts or CBD extracts can be aqueous extracts (e. g. "for beer-like beverages"), extracts by pressing, extracts produced by fat extraction ("defatted hemp seed") or extracts produced with traditional extraction agents.

Since 2009, the EU directive 2009/32/EC clearly states that traditional extraction solvents, such as ethanol (alcohol) or CO2 (carbon dioxide), are permitted in the EU to be used in compliance with good manufacturing practice in the production of all foodstuffs, food components or food ingredients.

In simple terms, this means that when a food or food ingredient is processed through a traditional method of extraction by means of the extraction agents listed and authorised in the Directive 2009/32/EC, it remains a food or food ingredient and is not to be considered a "novel food" product.

The position conveyed by EIHA has always been consistent and aligned to the following:

Hemp leaves and flowers as well as such hemp extracts from industrial hemp with the natural content of cannabinoids, (i.e., those that do not contain "CBD isolates" or "CBD-enriched hemp extracts") are traditional foods and do not fall under the scope of the Novel Food Regulation.

3. A NEW POSITION ON THRESHOLDS FOR THC IN FOOD

Full spectrum extracts from industrial hemp – the core product for the European hemp sector and its value chain from farm to shelf – apart from CBD naturally contain all other cannabinoids, inter alia Tetrahydrocannabinol (THC), more exactly the naturally occurring delta-9-THC (aka Δ9-THC).

At the EU level, the **Health Based Guidance Value (HBGV) for THC intake from food recommended by EFSA (2015)** is based on an incomplete consideration of studies, and the risk assessment led to an unnecessarily strict result (an **Acute Reference Dose of 0.001 mg/kg of body weight**). The difference is particularly striking if compared to the HBGV's or intake limits of our international competitors, like Canada (max. 10 mg of THC per discrete unit & per package), Switzerland (0.007 mg/kg bw) or Australia and New Zealand (0.006 mg/kg bw). In fact, the guidance value for THC recommended by EFSA, upon which the Council will most probably base its decision on THC limits in food, is based on conclusions on studies which do not bear up against generally accepted rules of risk assessment, even those established by EFSA.

In particular, **we would like to highlight the following biases** of the EFSA Scientific Opinion on THC:

- The Lowest Observed Adverse Effect Level (LOAEL) of 2.5 mg of delta9-THC, defined by EFSA and German BfR for adverse effects on the central nervous system, is derived from only a few clinical studies or trials, respectively, results of which are not conclusive. On the contrary, the whole ensemble of clinical and observational **studies on THC shows that the LOAEL is 5 mg of delta-9-THC per day and adult**.

- The overall **uncertainty factor of around 36** applied to the LOAEL for deriving a **HBGV for THC is set much too high** for such a substance of relatively low acute toxicity, compared to other substances (toxins) of concern in food or consumer products such as alcohol, caffeine, nicotine, glycoalkaloids (e. g. solanine) or morphine (from poppy seeds). There is no scientific evidence that sub-psychoactive levels of THC on foods have any significant effects on human health. During the last 50 years, the threshold amount of THC that is required for psychoactivity has been carefully studied in humans and is quite well known by now.

- The **competent authority for Australia and New Zealand (FSANZ)** has derived a dose of 5 mg THC per day as LOAEL in a re-examination (2011) of its careful risk assessment of THC in food. On this basis a **HBGV of 6 µg/kg bw** was derived for delta-9-THC.

- The **Swiss Federal Office of Public Health (SFOPH)** had derived a **HBGV of 7 µg/kg bw** on the basis of various studies, also using a LOAEL of 5 mg/d of THC per adult person.

- **Croatia** is also an EU country with a HBGV of **7 µg/kg bw**.

Based on scientific studies and on experience, the HBGV for delta-9-THC may reach up to 7 µg/kg bw (or 490 µg per day and adult).

4. BENEFITS AND PHARMACOLOGICAL EFFECTS OF CBD IN DIFFERENT CONCENTRATIONS AND APPLICATIONS

Numerous scientific studies have proven CBD's therapeutic potential both to relieve the symptoms of disease and to tackle the cause of a disorder. Just a few examples would include severe anxiety (e.g., PTSD), psychosis, epilepsy, dystonia, diabetes, cancer and Alzheimer's disease. It has acknowledged antimicrobial properties and is effective against several pathogenic gram-positive bacteria including Staphylococci, Streptococci and Enterococci (E. faecalis is a frequent cause of many serious human infections, including urinary tract infections, and wound infections, as well as of endocarditis and bacteraemia). Indeed, CBD could represent a considerable addition to medicines 'armoury' in the fight against MRSA (Methicillin-resistant Staphylococcus aureus; van Klingeren et al., 1976, Appendino et al., 2008).

Equally important as CBD's pharmacological effects are its health-maintaining properties (physiological effects) in lower doses. These include antioxidative and neuroprotective effects. For example, CBD as a neuroprotective antioxidant has been shown to be more potent than ascorbate ("Vitamin C") or tocopherol ("Vitamin E"; Hampson et al., 1998). CBD can also have a beneficial effect on skin problems and diseases (neurodermatitis), and on skin ageing.

A comprehensive review on the safety and side effects of CBD shows that even remarkably high doses of CBD are safe and well tolerated without significant side effects. In a total of 132 reviewed publications, CBD did not induce catalepsy; it did not affect factors such as heart rate, blood pressure, body temperature, gastrointestinal transit, nor did it alter psychomotor or cognitive functions (Bergamaschi et al., 2011).

Various clinical trials with a broad range of CBD doses have been performed since 2011. These studies confirmed CBD's effectiveness in the treatment of, for instance, epilepsy and psychosis, and demonstrated CBD's better tolerability and milder side effects compared to classical medication for these diseases (Iffland and Grotenhermen, 2016).

5. MEDICINE, SUPPLEMENT & FOOD: A THREE-TIER REGULATION AND DAILY INTAKE PROPOSITION FOR CBD

The concept of medicinal products has been harmonised throughout the EU by the European Directive 2001/83/EC. In this respect, medicinal products by presentation and medicinal products by function must be distinguished in accordance with Art. 1,2. of the Directive. Medicines by function are those which influence physiological functions through their pharmacological, immunological or metabolic action.

Medicinal products by Presentation (according to Art. 1 Nr. 2 of Dir. 2001/83/EC) are those intended as having properties for curing or preventing human diseases. A medicinal product by presentation can already be assumed as soon as a promise of cure is made. Accordingly, a product is a medicinal product if it is either expressly described or recommended as having properties for curing, alleviating or preventing human diseases, or if a reasonably well-informed consumer otherwise has the impression, even conclusively but with certainty, that the product in view of its presentation must have the relevant properties (Erbs/Kohlhaas/Pfohl, German Medicines Act, AMG, § 2 para. 5-8). In this case, it is immediately subject to the provisions of the respective Medicines Acts of the member states and requires a corresponding, time-consuming and cost-intensive approval. Such an approval can cost several million euros, as extensive clinical studies must be conducted to prove the claims made.

For medicinal products by function the pharmacological, immunological, or metabolic action is crucial. According to the European Court of Justice (judgement of 6 September 2012, Case C-308/11), such a substance is to be presumed if it leads to interactions with any cellular component present in the user's body (an interpretation which challenges the critics of the natural scientist because this also holds for food components). A substance may also be regarded as a functional medicinal product if its composition, when used as intended, significantly restores, corrects, or influences physiological functions in humans.

It is assumed that CBD has positive effects on various diseases, such as depression, multiple sclerosis, pain, inflammation, etc. However, only one medicinal product containing pure CBD has yet been approved in the EU, under its European name Epidyolex® (produced by GW Pharmaceuticals). Another one is Sativex® containing a mixture of a CBD-rich extract and a THC-rich extract. Whether a CBD product can develop such a pharmacological effect, can ultimately be answered only by a scientific expert opinion. The mere possibility or even probability of a classification as a functional drug is not sufficient, but rather a pharmacological effect must be established for the concrete product and the concrete dosage (BGH[2], judgment of 15.3.2012, file number I ZR 44/11; ECJ, judgment of 15.1.2009, file number C-140-07 and judgment of 10.7.2014, file number C-358/13).

The competent authority would have to scientifically demonstrate the principle of action and the positive therapeutic effect for the specific product. It is also not sufficient if a possible positive therapeutic effect is scientifically discussed. Rather, there is a need for valid scientific evidence in concrete individual cases. If the authority is unable to provide such proof, the products are therefore freely marketable, depending on their intended use and compliance with the relevant regulations.

[2] German Federal Court of Justice

As a rule – which can be demonstrated scientifically – the various biological and physiological effects of CBD mainly depend on the dose that is taken daily[3].

A pharmacological effect with the consequence of the classification as a functional drug and a correspondingly required approval according to pharmaceutical law is only to be assumed with a recommended daily dose of considerably more than 175 mg CBD.

For different doses and applications of CBD, EIHA proposes a three-tier regulation:

- At high doses, CBD-containing products are considered medicinal products and should be regulated as such.

- At low to medium doses up to 70 mg/d and adult, irrespective of delivery mechanism (capsules, tinctures, etc.), CBD for oral intake should be regarded as a food supplement. This dual approach is already applied for many substances, such as valerian, glucosamine, products to improve the bacterial flora of the intestine, essential oils, chondroitin (sulphate), Ginkgo Biloba, silymarin, some vitamins and iron products.

- Low CBD concentrations should be allowed in food products insofar as the recommended daily dose that is far enough from exerting pharmaceutical effects, is not exceeded.

CBD in high doses as a potential medicinal product with prescription:

Products with a high concentration of CBD, for example a product recommending more than 175 mg orally/day for the average adult may be treated as medicinal product requiring a prescription. This would apply only to products making the stated dosage recommendations, including any product containing high levels of isolated, pure CBD, and extracts containing high levels of CBD, with a corresponding daily intake.

CBD in medium doses should be available without prescription:

Products with a low to medium CBD concentration and a recommended intake of 10 to 70 mg orally /day for the average adult should be available in retail, drugstores and pharmacies as food supplements. This would apply only to products making the stated dose recommendations, including any product containing isolated, pure CBD and extracts containing lower levels of CBD. The FSA also commented on CBD

[3] Melchor, S. R., Timmermanns, L.: "It's the Dosage, stupid": The ECJ clarifies the Border between Medicines and Botanical Food Supplements, European Food and Feed Law Review Vol. 4, No. 3 (2009), pp. 185-191, *JSTOR*, www.jstor.org/stable/24325222

(pointing out to a certain remaining risk for 70 mg/d of CBD[4] and advising against its use by young children and pregnant or breastfeeding women and those taking medication (which could interfere with liver metabolism of substances). EIHA points out that this is a reference dose, basing on assumptions (Uncertainty Factors) and current toxicological as well as pharmacological knowledge, both rapidly evolving.

This approach, as proposed, is already in common practice. Products – hemp extracts rich in naturally occurring cannabinoids, and tinctures in particular – should preferably be standardised to a certain CBD-concentration. EIHA concludes that these extracts and tinctures should not fall under the Novel Food framework if not containing higher levels of cannabinoids than in the plant material. This is due to the fact that CBD and other phytocannabinoids are indigenous constituents in hemp food which have been extensively consumed across Europe for over 2,000 years. The European Commission stated on 18 December 1997 that food containing parts of the hemp crop is not considered "novel food." In the same vein, hop extracts, used for example for beer brewing instead of hop flowers, were never considered to be a novel food.

Numerous clinical studies demonstrate that CBD does not have significant pharmacological activity below 100 mg oral/day for an average adult. These references also highlight, that starting from ca. 20 mg CBD per day to ca. 100 mg CBD exerts physiological effects in the meaning of the European Food Supplement Directive[5] (Devinsky et al., 2014, dos Santos et al., 2014, Food Standards Australia P1042; Friedman et al., 2015; Hill et al., 2012, Iffland et al., 2016; Schubart et al., 2013.). Indeed, Spindle et al. 2020 observed that a 100mg/day/adult oral doses of CBD in the verum-group delivered the same result for ratings on several subjective items as in the Placebo control group.

CBD products can contain traces of THC, the main psychotropic cannabinoid of hemp. The THC level should be regulated, but not as strictly as for food, because of the much lower daily intake amount of food supplements compared to other food categories such as staple food.

EIHA also urges the industry to not make any unwarranted health claims when advertising and marketing CBD-rich extracts or tinctures as food supplements.

Low CBD concentrations to be allowed in food products

Low CBD concentrations (intake 1-10 mg/day for the average adult) should be allowed in food products without any restrictions.

[4] Food Standards Agency sets deadline for the CBD industry and provides safety advice to consumers | Food Standards Agency

[5] DIRECTIVE 2002/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, Art. 2 (a).

Having no restrictions for CBD levels below 10 mg per day can be justified because studies as early as the one by Belgrave and colleagues (1979), showed in a placebo-controlled, randomized, double-blind study that a single dose of approx. 224 mg CBD per 70 kg body weight, did neither elicit cognitive, perceptual or psychomotor effects nor showed any interaction with concomitant alcohol administration. This dose was a No-Effect-Dose, and higher doses had not been administered in the same trial. So, a dose with any effect could even be higher.

Anyway, there has always been CBD and or CBDA in hemp products, even in hemp seed oil, as has been shown in recent scientific and analytical studies.

6. COMMON POSITION ON SINGLE CONVENTION AND INDUSTRIAL HEMP

The preamble of the Single Convention on Narcotic Drugs from 1961 (C 61) 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. **Hemp products do not** lead to abuse, addiction, or dependence, as the level of THC in these products is extremely low. Considering the spirit set out in the Convention's preamble, this should be sufficient to consider hemp outside the scope of the Convention.

"Cannabis" is defined in Art. 1-1(b) C 61 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 fall out of the scope of the definition. **Therefore, hemp seeds and leaves, and any product derived thereof, are not present in the Schedules** and not covered by their régime of control.

Hemp products derived from "flowering and fruiting tops" of *C. sativa L.* 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. Flowering and fruiting tops used to obtain "hemp products" for the food industry do not fall under the Convention's régime.

The authors of this international instrument made a clear distinction between *Cannabis* plants grown for the production of drugs (falling under the scope of the treaties) and exempting those grown for any other purpose.

As a matter of clarification, the writers of the Single Convention explained in Art. 28 II 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 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 and hence the "cultivation for any other purpose, and not only for the purposes mentioned in paragraph 2 *[i.e. "industrial purposes"]*, is consequently exempted from the control regime provided for in article 23 *[i.e. falls out of the scope of C61]*".[6]

At the time of the agreement on the Single Convention, the low THC cannabis varieties as we know them today were not yet known. Their breeding was first started in France and the former Soviet Union in the 1970s, followed by Hungary in the early 1980s. Subsequently, they were standardized, and an EU catalogue of varieties was developed whose hemp varieties have less than 0.2 % THC at the time of harvest.

The low-THC cannabis varieties with 0.2 to 1.0 % THC are nowadays standardized around the world, regulated in the laws of the member states of the Convention and thus, a confusion with psychoactive "cannabis" as well as an abuse are excluded. Precisely for this purpose, to ensure the industrial use of cannabis, Art. 28 (2) regulates a corresponding exception.

The exclusion of "hemp" in the text and spirit of the Single Convention is unequivocal and comprehensive. Considering the above reflections and assumptions, EIHA and the international hemp industry suggest the following elements to consider when moving forward:

1. *Cannabis sativa* L. is *per se* an "**agricultural plant,**" 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, *Cannabis sativa L.* is considered as an "**industrial plant**" if 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 Convention when used for other than drug-related medical and scientific purposes or abuse
3. In practice, the exemption for the cultivation and processing of *Cannabis sativa L.* 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. Any 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 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 and hemp products from international control is the absence of these effects and the lack of liability to misuse.

[6] Commentary on the Single Convention on Narcotic Drugs, 1961, United Nations, New York, 1973, p. 312.

6. "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 and fruiting tops and leaves 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 plants".

Overall, it follows from the historical, systematic and teleological context that neither the leaves, nor the flowers, nor the resin or extracts obtained from the modern, regulated and standardized industrial hemp fall within the scope of the Convention, provided that the cultivation is carried out exclusively for corresponding industrial purposes, like the food and cosmetic industry.

Hemp extracts in food, which have been consumed for centuries in the EU and worldwide, should therefore be considered as food and be subject to respective legal frameworks for food.

The European Court of Justice has taken up many of the above mentioned arguments and decided on the 19th of November 2020 (Case C-663/18) that hemp extracts, including those from the entire plant (with flowering or fruiting tops being a part of it), and not only from the leaves and seeds (whole plant approach), do not fall within the scope of the Single Convention and are subject to the principle of the free movement of goods.

The Court emphasized that the objective of the Single Convention, namely the protection of the health and well-being of mankind, must be taken into account in the interpretation of its provisions and concluded that "since, according to the current state of scientific knowledge, CBD does not contain a psychoactive component, it would be contrary to the purpose and general spirit of the Single Convention to include hemp extracts as cannabis extracts under the definition of 'drugs' within the meaning of that Convention".

This decision, with which the Court of Justice has given a binding interpretation of European law, will also bind the European Union member states. At EU level, the following now applies: hemp extracts in industrial products are marketable in principle, provided they do not contain a psychoactive ingredient and do have psychoactive effects, and all other regulations applying to the respective sector are observed (for example Novel Food regulation, EU cosmetic regulation etc.). If a member state wants to continue to classify hemp extracts as narcotics on the basis of its current national narcotics law (e.g. Slovakia, Latvia, Lithuania, France, courts in Germany), the affected business circles can now directly refer to the decision of the European Court of Justice of 19 November 2020 as a binding precedent as well as to the decision of the EU Commission to accept Novel Food applications for hemp extracts as food and not classifying them as narcotics (with decision from December 2020).

7. CBD IN COSMETICS

According to Art. 14 para. 1 lit. a in conjunction with Annex 2 No. 306 of Regulation (EC) No. 1223/2009, the use of natural and synthetic narcotics in cosmetics is prohibited. This is any substance listed in Tables 1 and 2 of the 1961 UN Standard Convention on Narcotic Drugs, including cannabis and its extracts.

In the Central European Register for Cosmetic Ingredients (CosIng) all extracts from the cannabis plant are therefore marked to be restricted accordingly. However, this restriction is expressly not to apply to synthetically produced CBD, which is not listed in the annex to the Single Convention.

This interpretation by the Directorate-General for the Internal Market (reflected in the CosIng catalogue) is not uncontroversial, as leaves and seeds are excluded from the scope of application of the Single Convention of 1961 (Art. 1 para. 1), as well industrial hemp for industrial purposes in general (see above). EIHA therefore sent a position paper to the European Commission at the beginning of October 2019 and requested that, as a first step, cannabis extracts from the leaves of the plant be exempted from the restrictions in the COSING database. The European Commission followed this view at the beginning of November 2019 and lifted the restriction on Cannabis Sativa Leaf Extract.

EIHA is demanding further changes, in particular the use of flower extract and isolate, derived from flower and leaves, as a consequence of the ruling of the ECJ from 19.11.2010 (Case C-663/18). EIHA already asked the EU-Commission to lift the bans for all Cannabis Sativa Extracts and ingredients as defined with the existing INCI terms in the CosIng database. The database is not legally binding but is regarded by authorities and courts in the Member States as a strong indication of the legality of an addition. An explicit clarification would thus be desirable. But since the European Court of Justice has expressly ruled that hemp extracts, including those from the entire plant, and not only from the leaves and seeds (whole plant approach), are not narcotics, all hemp extracts can therefore already be used in cosmetic products today. Therefore, we deem important to lift the ban on natural CBD extracts in cosmetics and add new INCI codes in line with the ECJ's ruling.

REFERENCES AND FURTHER LITERATURE ON PHARMACOLOGICAL AND PHYSIOLOGICAL EFFECTS OF CBD

Ali, E. M., Almagboul, A. Z., Khogali, S. M., & Gergeir, U. M. (2012): Antimicrobial activity of Cannabis sativa L. Chinese Medicine, 3(1), 61.

Appendino, G., Gibbons, S., Giana, A., Pagani, A., Grassi, G., Stavri, M., Smith, E. & Rahman, M. M. (2008): Antibacterial cannabinoids from Cannabis sativa: a structure-activity study. Journal of natural products, 71(8), 1427-1430.

Belgrave, B. E., Bird, K. D., Chesher, G. B., Jackson, D. M., Lubble, K. E., Starmer, G. A., & Teo, R. K. C. (1979): The effect of cannabidiol, alone and in combination with ethanol, on human performance. Psychopharmacology, 64(2), 243-246.

Bergamaschi, M. M., Queiroz, R. H. C., Zuardi, A. W. & Crippa, J. A. S. (2011): Safety and side effects of cannabidiol, a Cannabis sativa constituent. Current drug safety, 6(4), 237-249.

Best, W. (2016): Personal communication, Wim Best, Inspectie voor de Gezondheidszorg (www.igz.nl).

Booz, G. W. (2011): Cannabidiol as an emergent therapeutic strategy for lessening the impact of inflammation on oxidative stress. Free Radical Biology and Medicine, 51(5), 1054-1061.

Borges, R. S., Batista, J., Viana, R. B., Baetas, A. C., Orestes, E., Andrade, M. A., Honorio, K. M. & da Silva, A. B. (2013): Understanding the molecular aspects of tetrahydrocannabinol and cannabidiol as antioxidants. Molecules, 18(10), 12663- 12674.

Devinsky, O., Cilio, M. R., Cross, H., Fernandez Ruiz, J., French, J., Hill, C., ... & Martinez Orgado, J. (2014): Cannabidiol – pharmacology and potential therapeutic role in epilepsy and other neuropsychiatric disorders. Epilepsia, 55(6), 791-802.

Drysdale, A. J., Ryan, D., Pertwee, R. G., & Platt, B. (2006): Cannabidiol- induced intracellular Ca 2+ elevations in hippocampal cells. Neuropharmacology, 50(5), 621-631.

Food Standards Australia New Zealand: Supporting Document 2, Cannabidiol hazard profile – Proposal P1042, and cit. lit. (www.foodstandards.gov.au/code/proposals/Pages/ P1042LowTHChemp.aspx; accessed on January 10th, 2017).

Friedman, D., & Devinsky, O. (2015): Cannabinoids in the treatment of epilepsy. New England Journal of Medicine, 373(11), 1048-1058.

Hampson, A. J., Grimaldi, M., Axelrod, J., & Wink, D. (1998): Cannabidiol and (-) Δ9-tetrahydrocannabinol are neuroprotective antioxidants. Proceedings of the National Academy of Sciences, 95(14), 8268-8273.

Hill, A. J., Williams, C. M., Whalley, B. J., & Stephens, G. J. (2012): Phytocannabinoids as novel therapeutic agents in CNS disorders. Pharmacology & therapeutics, 133(1), 79-97.

Iffland, K. & Grotenhermen, F. (2016): Safety and Side Effects of Cannabidiol – A review of clinical data and relevant animal studies on chronic CBD administration. Nova- Institute, Hürth.

Oláh, A., Tóth, B. I., Borbíró, I., Sugawara, K., Szöllõsi, A. G., Czifra, G., Pál, B., Ambrus, L., Kloepper, J., Camera, Em., Ludovici, M., Picardo, M., Voets, T., Zouboulis, C. C., Paus, R. & Bíró, T. (2014): Cannabidiol exerts sebostatic and antiinflammatory effects on human sebocytes. The Journal of clinical investigation, 124(9), 3713-3724.

Santos, R. G., Hallak, J. E. C., Leite, J. P., Zuardi, A. W., & Crippa, J. A. S. (2015): Phytocannabinoids and epilepsy. Journal of clinical pharmacy and therapeutics, 40(2), 135-143.

Schubart, C. D., Sommer, I. E. C., Fusar-Poli, P., de Witte, L., Kahn, R. S., & Boks, M. P. M. (2014): Cannabidiol as a potential treatment for psychosis. European Neuropsychopharmacology, 24(1), 51-64.

Van Klingeren, B., & Ten Ham, M. (1976): Antibacterial activity of Δ9-tetrahydrocannabinol and cannabidiol. Antonie van Leeuwenhoek, 42(1-2), 9-12.

Zhornitsky, S., & Potvin, S. (2012): Cannabidiol in humans—the quest for therapeutic targets. Pharmaceuticals, 5(5), 529-552.