Position paper of the European Industrial Hemp Association (EIHA) on:

Reasonable regulation of cannabidiol (CBD) in food, cosmetics, as herbal natural medicine and as medicinal product

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Introduction to cannabidiol (CBD)

Cannabidiol (CBD) is one of the non-psychotropic cannabinoids in industrial hemp. In 2016, 30,000 ha were cultivated in the European Union. The last couple of years have seen growing interest in CBD. Cannabidiol not only has a plethora of beneficial health effects, but it also has no relevant side effects, even when it is administered at high doses[1].

CBD is the primary cannabinoid of industrial hemp, present in concentrations ranging from 0.5 to 4% in the upper third of the plant. Hemp extracts containing CBD as well as isolated CBD can be utilized along with hemp fibres and shives, providing extra income to farmers. Selling hemp extracts containing CBD generates additional income on top of income generated from hemp fibres and shives.

CBD is increasingly used as a food supplement and in food supplement compositions, and as an ingredient in cosmetics, thereby generating new investments and creating employment in the cultivation and processing of hemp and hemp-derived products. Pharmaceutical products with CBD as an active ingredient have also been developed. Another viable application of isolated CBD is its use in electronic cigarette refills.

Many citizens in Europe are already profiting from CBD in its manifold applications.

Benefits and side-effects of CBD in different concentrations and applications

Numerous scientific studies proved CBD's therapeutic potential in a large number of diseases and symptoms. Just to name few: anxiety disorders (such as post-traumatic stress disorder), obesity, epilepsy, dystonia, diabetes, cancer, neurodermatitis and Alzheimer's. Its antibacterial properties may be used to prevent infection and control inflammation: CBD is effective against staphylococci, streptococci and even against clinically relevant 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, neuroprotective and anti-inflammatory effects. For example, CBD is a neuroprotective antioxidant more potent than ascorbate ("Vitamin C") or tocopherol ("Vitamin E"; Hampson et al., 1998). As a cosmetic ingredient, CBD can be used to decrease sebum / sebocytes (Oláh et al., 2014).

A comprehensive review on the safety and side effects of CBD shows that even very 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 and cognitive functions (Bergamaschi et al., 2011). Various clinical trials with a broad range of CBD doses have been performed since 2011. The studies confirmed CBD's effectiveness in the treatment of, for instance, epilepsy and psychosis, and showed CBD's better tolerability and milder side effects compared to classical medication for these diseases (Iffland and Grotenhermen, 2016).

Legal situation – urgent need for proper legislation

At the moment we see no or only a patchwork of CBD-regulation. In contrast to tetrahydrocannabinol (THC), natural CBD is not psychotropic. Therefore, it is just and reasonable that CBD is not covered by the national narcotic acts or drug regulations of the 27 EU Member States (from 28 with the exception of Slovakia) and that CBD is not restricted by any EU legislation. However, regarding CBD-

1 Information on toxicological effects: IVN-MUS LD50: 50 mg/kg; IVN-DOG LD50: >254 mg/kg; IVN-MKY LD50: 212 mg/kg; ORL-MKY TDL: 27 mg/kg; ORL-MUS TDL: 750 mg/kg.

containing hemp extracts, the situation is not as clear as for CBD as a pure substance, because they could also contain THC, which is covered by national narcotics acts in EU Member States.

The European Industrial Hemp Association (EIHA) supports the development of a harmonized legislation in this field, to make sure that consumers are protected, to sustain the industry's current double-digit growth rate, to attract new investors and to boost product development. The legislation should avoid any restrictions for CBD and clarify that extracts and preparations from industrial hemp[2] are not narcotics in the EU.

The European Industrial Hemp Association (EIHA) is strictly opposed to the attempts by a few pharmaceutical companies to make CBD a prescription-only drug. This only serves the interest of a few companies while damaging the young CBD industry. Such legislation would also restrict the access to CBD for many citizens, who are already profiting from CBD in food and cosmetics. It is EIHA's expectation that European and national authorities should not limit the use of CBD in pharmaceuticals (medicinal products) only. There is also no reason to regulate the access to CBD too rigorously, because of the wide spectrum of beneficial physiological effects of CBD and its favourable safety profile.

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

- At high doses, CBD can be a medicinal product and should be regulated as such.
- At physiological doses CBD should be regarded as an OTC-product (= over the counter) or a food supplement. This approach is already applied for many substances, such as valerian, glucosamine, chondroitin(sulfate), Ginkgo Biloba, some vitamins and iron products.
- Low CBD concentrations and doses should be allowed in food products without any restrictions.
- Additional aspects such as route of administration, indication area, maximum single / daily dose and pack size can be used to further fine-tune the regulation. The German BfArM[3] already uses these aspects to differentiate and demarcate between prescription-only and e.g. pharmacy-only substances.

CBD in high doses as a potential medicinal product with or without prescription

Isolated, pure CBD and products with a high CBD concentration (intake more than 200 mg oral/day) for the average adult may be treated as medicinal products with or without prescription.

CBD in medium doses should be available without prescription

Products with a medium CBD concentration (intake 20 - 200 mg oral / day for the average adult) should be available in chemists and pharmacies either as (herbal) medicinal products without prescription or as food supplements (such as valerian or hop pills, silymarin, glucosamine or Gingko Biloba). Examples for medicinal products generally exempt from prescription[4] in lower doses are: aciclovir, almotriptan, beclometasone dipropionate, ibuprofen, colecalciferol, as well as omeprazole and pantoprazole.

So the approach we propose here is already common practice. Products – hemp extracts and tinctures in particular – should preferably be standardised to a certain CBD-concentration. The use of pure CBD in food supplements should also be investigated. Isolated CBD is in process of being enlisted in Novel Food Catalogue. Hemp extracts and tinctures with their natural CBD content shall not fall under Novel Food framework, because CBD is a natural constituent in hemp food which has been used in Europe for 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 recognized as novel food.

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 of food supplements.

Low CBD concentrations allowed in food products

Low CBD concentrations (intake less than 20 mg/day for the average adult) should be allowed in food products without any restrictions.

CBD in other applications such as cosmetics

Cannabidiol has been listed in CosIng with 4 functional claims: "antioxidant, skin conditioning, skin protecting, and antisebhorrhoeic" without any restrictions as per Annex II/III of Regulation 1223/2009.

2 Any cultivar listed in "Common Catalogue of Varieties of Agricultural Plant Species" as per Art. 10 of COMMISSION REGULATION (EC) No 1120/2009.
3 http://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Gremien/Verschreibungspflicht/antragVerkaufsabgrenzung.html, accessed on October 12th 2016.
4 Prescription requirement for medicinal products is up to the responsibility of national authorities in the EU and may differ from country to country.

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