

Augur associates

Summary - White Paper

"Responding to the challenges of a safe and responsible industry - Wellness Hemp in France"

Hemp and "Cannabis" are the same plant which has several uses: industrial, wellness, therapeutic and adult also called "social" or "recreational" uses. If the biological **understanding of this plant is still in its infancy due to restricted legal access**, we nevertheless know that **hemp, contains many active ingredients**, including, depending on the cultivar, more than 120 terpenes and 110 listed cannabinoids.

Among the latter, **cannabidiol (CBD)** was formally isolated in 1940, and is **one of the most frequently found active ingredients in the plant**. It must be distinguished from delta-9-tetrahydrocannabinol (THC), another of the best known cannabinoids. Unlike THC, CBD has **no euphoric effect** and has been recognized by the World Health Organization (WHO) as **non-addictive, non-toxic, safe and well tolerated when consumed, even at high doses**. **The use of CBD within various consumer products is the main subject of this white paper: the wellness hemp chain from regulated varieties in France.**

Pressure, extraction, distillation: many processes can be used to extract active ingredients from hemp. Products, in turn, can be found as a "full spectrum" or "broad spectrum" (integrating many of the active components of hemp), or as a "distillate" or "isolate" (consisting almost exclusively of CBD). **This CBD is extracted from the top of the plant, also commonly called "flowers"** of the "industrial" varieties of hemp. Scientific research around CBD is still in development, its complete understanding still suffering from a **lack of clinical data**. Additionally, research is advancing on the Endocannabinoid System (ECS) with which CBD and other active ingredients from the plant interact. When combined, these molecules can allow an **"entourage effect"**, which **implies that the whole plant can exert greater effects than the sum of its separate parts**.

The products derived from wellness hemp cannot be considered as medicines for four main reasons: they are derived from genetically legal varieties in France; they are produced under conditions that do not allow a seemingly standardisation of the product nor a level of pharmaceutical quality; they have not followed the classical market authorization circuit of a pharmaceutical drug; and its CBD concentrations do not have a therapeutic or curative effect. **However, these products do contain active ingredients of interest for the comfort and wellbeing of their users**. Additionally, CBD could represent a potential for **harm reduction** as a substitute for and to help alleviate withdrawal symptoms from addictive substances.

Cannabinoids have in the past been consumed in large quantities on a regular basis and have been an integral part of the human diet of the European populations. Therefore, it should be noted that in its natural concentration, **CBD should not be considered as a Novel food** as recently declared by the European administration. Marketing authorisations for such a product represent significant constraints both time- (minimum 18 to 24 months) and financial-wise (minimum 300 000€ per



product). The application of the European catalogue of **Novel foods remains non-binding** and would also **represent a major brake on the development of the industrial and wellness hemp sectors in France.**

Consumed in inhaled, topical, oral or sublingual form, **products made from wellness hemp are numerous** and available over the counter: raw "flower", e-liquid, food product (supplement, oil, etc.), cosmetics, product for animals, etc. Their popularity in Europe is constantly increasing and they present today **significant economic opportunities both for French entrepreneurs**, ready to invest in these different markets, **and French farmers** looking for diversification.

Wellness hemp applications represent indeed a **saving opportunity for French farmers seeking diversification and additional income**, while at the same time boosting innovation in terms of eco-responsible agricultural production. In addition, the **cultivation of hemp has always been part of the French agricultural tradition and terroir**, and today has more than **25,000 potential industrial applications**, offering **environmentally responsible alternatives** for plastic, concrete, graphene, steel and fuel to name a few.

Tens of thousands of French citizens use CBD-based products on a daily basis, amounting to in 2019, a **300-million-euro market under current regulatory conditions** which could be expanded to more than **1 billion euros in the event of regulatory clarification**, with a steady growth from that point on. Nearly 1 000 stores, dozens of product creators, farmers and extraction laboratories are investing despite a **complex legal situation** in the development of this segment in France.

In the United States, CBD can be legally transformed under the 2018 Farm Bill, but there are still no clear regulations concerning its consumption. However, between 2017 and 2018, CBD products have multiplied there, and if the market was close to **\$600 million in 2018, it could be multiplied by 40 within 4 years**. In **Switzerland**, the wellness market has been steadily developing for several years, mostly around **CBD "flowers" legally containing a maximum of 1% THC**.

In France, the status of CBD is ambiguous, as it is not classified as a narcotic drug and there is no law prohibiting its use. It however suffers from a **restrictive interpretation of the European regulations**, notably by restricting officially the production and industrial use of hemp to its fibres and seeds, and **de facto prohibiting the use of the tops which contains most of the plant's cannabinoids (and therefore CBD)**. As a result, **local businesses must rely on imported raw products**.

Tops and the products derived from them are however authorised by European law both for trade and industrial uses on condition that their THC level does not exceed 0.2%. It could be argued that this rate is nonetheless quite restrictive in view of the current developments on the global market. Indeed, the **maximum THC level legal limit in the rest of the world for wellness and industrial hemp products is currently between 0.3% and 1.5%**. This limitation therefore has a considerable impact on the competitiveness of French players when faced with other **economic actors subjected to more appropriate national legislation**.

Searches, seizures and closures have impacted the early development of the wellness hemp sector in France as a hundred or so shops initially opened in the summer of 2018. A vast **majority of the**



French courts' rulings, citing the opposition between European law and French law, has so far been largely favourable to French entrepreneurs and hemp growers. As increasingly showed, the French restrictions imposed on hemp-derived products seem on one hand likely to be **contrary to the rules of the organisation of the European common market in the hemp sector, and on the other to the free movement of goods within the EU.**

Moreover, the **authorities' interpretation of the requirement of zero trace of THC in the finished product as-well-as the ban on the use of hemp "flower" are hardly justified by international conventions, European law or even French law.** Today, these interpretations prevent the development of a growing sector. **France, the European leader in industrial hemp, has considerable assets and will have a fundamental role to play in the future of this industry.** In a **very competitive context**, it remains **urgent to change the current regulatory framework** in order to allow the sustainable development of this high-potential sector. In the mid-long term, France risks having to justify the restrictions laid down by French law, where the cultivation, import, export and industrial and commercial use of industrial hemp are in fact limited to the fibre and the seed.

Today, the lack of information and an unsuitable regulatory framework allows the availability of non-verified CBD products to consumers and places all French actors of the value chain in a particularly uncertain and harmful legal situation. It is for this reason that Augur Associates and the Syndicat Professionnel du Chanvre are working with the authorities to establish a framework that will prove to be safe for consumers, reliable for the administration, and unobstructed for French entrepreneurs and farmers.

