

Augur associates

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

The tops / "flowers"

- **Removal of the mention "fibres and seeds" from the Decree of the 22nd August 1990** implementing Article R. 5132-86 of the Public Health Code for cannabis.
- Recognize **the right to use hemp "flowers" for industrial and wellness purposes**, in accordance with the 1961 Convention and European regulations.
- Encourage the emergence of a processing sector for hemp "flowers" through a **voluntarist and supervised policy**, in order to **reduce the potential harm of unregulated products** and to provide a **serene working environment** for concerned professionals.
- If decision is made not to **create an *ex nihilo* status for hemp "flowers"**, it would be possible to consider the latter as a "herbal smoking product", a European legal designation that can offer a precise, coherent and legitimate nomenclature.
- **Limit taxes** to prevent final prices from having too strong of an impact on the consumer and on the smaller actors of the value chain.
- **Establish traceability of the product from producer to consumer** via the "Blockchain" or other methods to ensure traceability.

0% THC in finished products

- **Stop the legal interpretation of 0% THC in finished products** in order to allow the use of the "full spectrum" of extractions and the integration of the "entourage effect".
- **Align the THC limit of the finished product with that of the plant.**
- As a minimum, the THC detection limit in finished products must above all represent a value for finished products in trade, but must not be limited between professionals who have declared a simple constant of stock levels to allow holding and transport; companies having declared themselves beforehand to the regulatory authority.

Cultivars

- **Give farmers access to new cultivars:** if varieties offer a better CBD rate while guaranteeing compliance with THC concentration standards, include them in the national catalogue of varieties authorised for cultivation, as Greece does for example.
- **Allow the development of genetic research by an unrestricted number of licensed actors** for the gradual integration of such new varieties.
- As a minimum, **integrate the relevant varieties from the European catalogue into the French catalogue.**

Non-euphorisant limit of THC

- **Amend the decree of the 22nd August 1990 which specifies the legal limits of THC in hemp (from 0.3 to 1%).**



- **Allow an experimental derogation for trial territories** such as La Réunion Island for researching new varieties with low THC levels up to 1%, and extend this derogation to the French Overseas Departments and Regions (DROM) and the Overseas Collectivities (COM).
- **Support requests for private and public exemptions and subsidies to set up scientific studies for such research**, in particular a study of the indigenous chemotypes locally existing in French metropolitan and overseas territories.

Novel Food

- Consider as soon as possible a **clear position by the French authorities** in order to integrate the current and future stakes on the subject of the Novel Food indicative catalogue **to secure the development of the hemp wellness food chain**.
- **Define a suspension of controls** towards those subject to reviews relating to the Novel Food catalogue until the outcome of the work lead by the parliamentary information mission is known.
- Clarify at the national level that **CBD extracts whose content is not higher than that naturally present in the plant are not considered as novel foods**.

CosIng

- As long as cosmetic products incorporating CBD do not fall within the competence of the medical and pharmaceutical regulations of the Member States, there is **no obligation to prohibit their production, manufacture and use**. States are merely required to submit basic statistical information to INCB for monitoring purposes (in accordance with Article 2(9)(b)).
- At Community level, the hemp plant (*Cannabis sativa* L.) is considered an agricultural product and an "industrial plant" for both cultivation and seed production according to Regulation (EU) 1308/2013, and can be legally cultivated as long as its THC content currently does not exceed 0.2%.

Substitution potential

- No therapeutic claims can currently be attributed to wellness hemp and the CBD extracted from it. It is therefore urgent **to support scientific research in order to develop solutions to addiction-related problems**, such as the use of CBD as a non-medicinal alternative.
- **Implement a public awareness campaign aimed at users**. Just as e-cigarette can be a means of reducing risks, without being a medical device, the CBD in e-liquid, oil or "flower" form could perform a similar function.

Synthetic CBD

- Clarify the 1990 decree in order to truly allow the establishment of a hemp wellness sector in France with high environmental, social and economic value, **exclusively defending the use of phytocannabinoids** (components from the plant).
- Reflect on labelling and **the need to transparently inform the consumer about the biological or synthetic origin of the cannabinoids** present in the product.

Interaction with certain pharmaceutical drugs

- **Raise awareness among users and prescribing staff about the interactions of high-dose CBD with certain prescription drugs**.



- **Integrate this issue into the training of prescribing physicians** who will be part of the French experimentation of medical cannabis.
- Add a warning to the prevention elements around CBD on product labelling.

Unfair competition

- Further reflection on labelling, in particular the **need to indicate the national geographical origin of the hemp from which the CBD in the product is extracted**.
- Open up the possibility of **setting up a certifying body that guarantees the origin of the product** with a "made in France" label for example.
- Invite public authorities to **build a "French model"** that can serve as an example at the EU level.

Driving and THC threshold limit

- Solve the problem of THC detection in drug screening tests for users of CBD products that may contain traces of THC, by **setting up simple procedures to distinguish products at the legal rate from products above it** (example type of a device used in Switzerland).
- In case of traffic violations, allow, at least as of today, **a more adapted screening by raising the detection rate of the presence of cannabinoids to 5ng THC/mL of blood** in order not to accidentally target consumers of wellness hemp.

Production

- All three wellness hemp growing methods (**outdoor, greenhouse, indoor**) are suitable for the production of CBD hemp for extraction or raw use. However, **each method must be regulated according to its possibilities and possible externalities**, with sustainability and public safety and health in mind.
- Set up **specific diploma courses** for the possible applications of hemp.
- **Precise labelling at wholesale and retail level of the resulting crop:** indoor, greenhouse, outdoor, thus allowing a **conscious purchasing choice** for all actors of the value chain, including the consumer.
- **In the medium term, the standards should aim at Good Agricultural Practices (GAP).**
- Hemp grown today **in open fields** is not subject to any particular security measures, without this being problematic. It is therefore **not necessary to impose costly or unnecessary additional safety measures on producers**.
- **Let producers decide on security measures adapted to the type of crop** and their environment, especially if they wish to protect themselves from theft.
- Extraction operations should be secured at the level of extraction laboratories.
- **Differentiate between the CBD used for wellness and medical sectors** (uses, varieties, production / processing conditions), by offering the possibility of having healthy, secure and quality products for both markets.
- **Adapt the Customs code to allow the export of hemp "flowers" and biomass** between European countries as-well-as directed towards the global market.

Laboratory (extraction and analysis)

- **Implement strict safety standards for the extraction of CBD**, both in the extraction process and in the analysis of the finished product.



- **Authorize French laboratories to test the level of concentration of active ingredients** in products.
- Laboratories should be able to **determine**:
 - **cannabinoid concentration test** (THC / CBD, and ideally CBN / CBG);
 - terpene profiling;
 - **presence of pesticides and heavy metals**;
 - **residual solvents** (for derived products);
 - **moisture content** and precision weighing;
 - mycotoxin analysis.
- **Allow the subsidization of analyses for low-income hemp producers.**
- **In the medium term, standards should move towards Good Laboratory Practice (GLP).**

Processing

- Put in place **appropriate labelling in line with the European standards** in force (for example, for food, Regulation No 1169/2011, known as INCO).
- Concerning the packaging of the material: if the transfer of ownership between the seller and the individual customer implies the sealing of the product, this obligation should not be necessary between professionals of the sector.
- **Test the products before they are placed on the market** to ensure that the transformation process has not altered the finished product.

Distribution

- **Incorporate the "wholesalers" level in the CBD value chain.**
- Prohibit bulk sales to individuals: **mandatory sale under seal** with lot number and corresponding analysis number.
- **Introduce harm reduction communication and education elements for use.**
- **Frame the properties of CBD on which merchants can communicate** without falling into either the apology of a narcotic or therapeutic claim.
- **Allow sales in specialised shops and common distribution points** (natural health and well-being networks, parapharmacy, organic food stores, tobacco shops, veterinary clinics, etc.).

Regulation according to CBD concentration

- **Authorise thresholds for THC contaminants in relation to the typology of products** (supplements, oils, etc.).
 - **Food and food supplements**
 - Depending on the dosage and uses of the CBD, three safe levels are possible:
 - At high doses (> 160 mg per day), CBD can be considered as a therapeutic drug and should be regulated as such.
 - At physiological doses (between 20 and 160 mg per day), CBD must be sold without a prescription or as a dietary supplement.
 - At low concentrations and doses (< 20 mg per day), CBD should be allowed in food products without any restrictions.
 - **Cosmetics**



- Authorize the use in finished cosmetic products of all parts and molecules of the plant (roots, stem, seeds, tops) whether in whole, infused or extracted form.
- Establish an authorised THC threshold allowing in particular the marketing of "comfort products", ex intimate comfort (lubricants type), massage products for sportsmen and women...
- Proposal of 1% THC in the finished cosmetic product in order to be able to work in full spectrum.
- Labelling must be strict and reflect the exact composition of the product.
- **Vape products**
 - Allow the presence of THC in products to be stripped at a rate similar to that of hemp "flowers".
 - Manufacturers should be required to have analyses available to regulatory authorities.

Financial services and administrative procedures

- **Create a regulatory body for wellness hemp** within the Ministry of Agriculture.
- **Finance the regulatory authority through the taxation of the sector.**
- **For entrepreneurs:** build up a solid legal file. It can be used to reassure the banking establishments but also all the actors / partners that will need securing incentive be necessarily to reassure (investors, DGCCRF, etc...). In order to be effective on the legal aspects (for example with a lawyer's file), the best position for entrepreneurs is to be transparent in order to create trust and thus obtain the services desired.
- As much as possible, it is currently recommended to **favour the self-financing of an activity** related to the wellness hemp industry. The level of analysis of a file (including ethical issues) is often proportional to the amount of needs and therefore the financial risk for the bank. If the needs are limited, it may then be necessary to resort to private indebtedness.
- If the company's activity is destined to rapidly become international, pending regulatory changes in France, it may be possible to set up a head office in a neighbouring country where a banking institution from there could be more accommodating in view of its own legislation vis-à-vis the CBD.
- Ensure **clear communication with banking actors** as soon as a regulatory change is in place in order to allow entrepreneurs in the sector to access all conventional banking tools without refusing the compliance services of banking institutions.
- **Ensure the possibility** in the medium term for all companies in the sector **to open a head office in France.**
- **For insurance companies:** invest internally today to explore the subject and its current and future opportunities. Put in place dedicated teams to clear up the subject, particularly with regard to changes in legislation.
- **For entrepreneurs:** move up in the sophistication of projects and services to give confidence to financial players by putting yourselves in a position to meet their expectations: transparency; account management; implementation of internal standards common to industry players; and organize the sector with appointed representatives in order to continue the work begun.



- While waiting for a change in behaviour, for entrepreneurs wishing to find an insurance policy, it is recommended in the short term to look on the European market, including in the United Kingdom, to find insurance companies that are starting to offer such services for the wellness hemp industry.

Supporting centres of excellence to create an entrepreneurial ecosystem

- **Support research** to demonstrate that products made from wellness hemp are not only non-addictive but also have **great potential in the fight against multiple addictions** (opioids, nicotine, THC ...).
- Possibility **to apply for private and public grants** to set up the necessary research.
- **Set up a diversified network of donors to support public and private research** in dedicated laboratories, allowing **to explore the health effects of CBD** through fundamental research (accelerator, technology transfer, ...).
- **Support research on the multiple innovative industrial applications allowing to ecologically valorise hemp.**
- Encourage the **development of financial partnerships between wellness hemp startups and private investors** in France and abroad.
- **Granting public subsidies**, notably the French Tech grants, the Prêts Innovations Amorceage (PIA) and the whole range of assistance from the Banque Publique d'Investissement (in direct investment or in "funds of funds").
- **Access to bank debt**, in order to avoid the problems encountered in the United States and Canada, where players are engaged in a frantic race to raise capital that irrationally drives up valuations.
- Encouraging financial players to take equity and quasi-equity risks, in order to **foster the emergence of the French Hemp Tech.**
- **Setting up channels for professional investment funds:**
 - generalist funds (grouped under France Invest);
 - specialized on the cannabinoid / hemp issue;
 - at each stage of the companies' life cycle (seed capital, development capital and capital transmission funds);
- **Channels for individuals wishing to invest and support companies directly:**
 - include companies in the hemp welfare sector in the definition of eligible companies (IR PME - Madelin);
 - allow their eligibility for FIP and FCPI funds;
- **Set up a "Results guaranteed via the Blockchain" label.**

Market framework

- Implementation by the SPC of a **charter of good practices.**
- Development by the SPC of a **professional certification project (PCP).**

