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The green light

Navigating the global CBD landscape, and understanding key limitations, challenges and business opportunities

By Paul Gander and Charlotte Bastiaanse



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The global cannabidiol (CBD) market has drawn tremendous attention from consumers, manufacturers and formulators alike over the past few years. Known therapeutic benefits targeting a range of health concerns has boosted consumer demand for CBD products – clearly reflected in the evolution of CBD capsules, oils, lotions, gummies and more now available at retail.

While demand is there, the vastly different approaches to CBD regulation between nations – and even amongst individual countries – has presented challenges in accelerating products to market. The widely varied ways in which countries reform their CBD laws and establish markets make navigating the global CBD industry a highly complex exercise for companies looking to capitalise on opportunities. Discrepancies have further created semi-secluded markets with differing levels of opportunity and investment – ultimately impacting the size of the regional and global commercial market.

Wider acceptance and legalisation of CBD in prominent nations will likely gain traction in countries where the CBD-consuming population is still relatively small, or where conservative norms and stigmatisms suppress advocacy for legal use.

Regulation aside and while goal posts may shift from country to country, there is a worldwide necessity for further clinical research surrounding CBD to deepen developer and consumer education. Key areas of concern pertaining to consumer use relate to the safety profile, absorption, dosage, long-term use effects, and efficacy for managing symptoms associated with serious health conditions such as epilepsy, forms of cancer, Parkinson's disease and chronic pain.

As research advances, regulatory, government and healthcare bodies carefully lay the foundation for the newly authorised CBD trade. An understanding of legal framework, regional and global limitations, market size, consumer demand and agriculture operations is essential for successfully navigating the CBD landscape and identifying future commercial opportunities.

Market size, growth and trends

Five forces disrupting the global CBD consumer market

Expanding legal access	Therapeutic efficacy	New product innovation	Convenience & discretion	Social acceptance
Global markets are legalising CBD for adult use	Known and proven health benefits are prevalent amongst health practitioners and consumers	Rising investment is fueling development of new products and delivery formats	Ease of production and portability is boosting growth of the market	Mindset shifts are occurring amongst formerly anti-CBD bodies and individuals
Retail channels enable access to commercial products	Consumers are interested in integrating CBD into greater wellness plans	Significant funding is directed at CBD for healthcare	Improved understanding of CBD's potential is addressing conservative areas of concern	Growing consumer awareness is driving acceptance of CBD for health-related use

Source: New Frontier Data

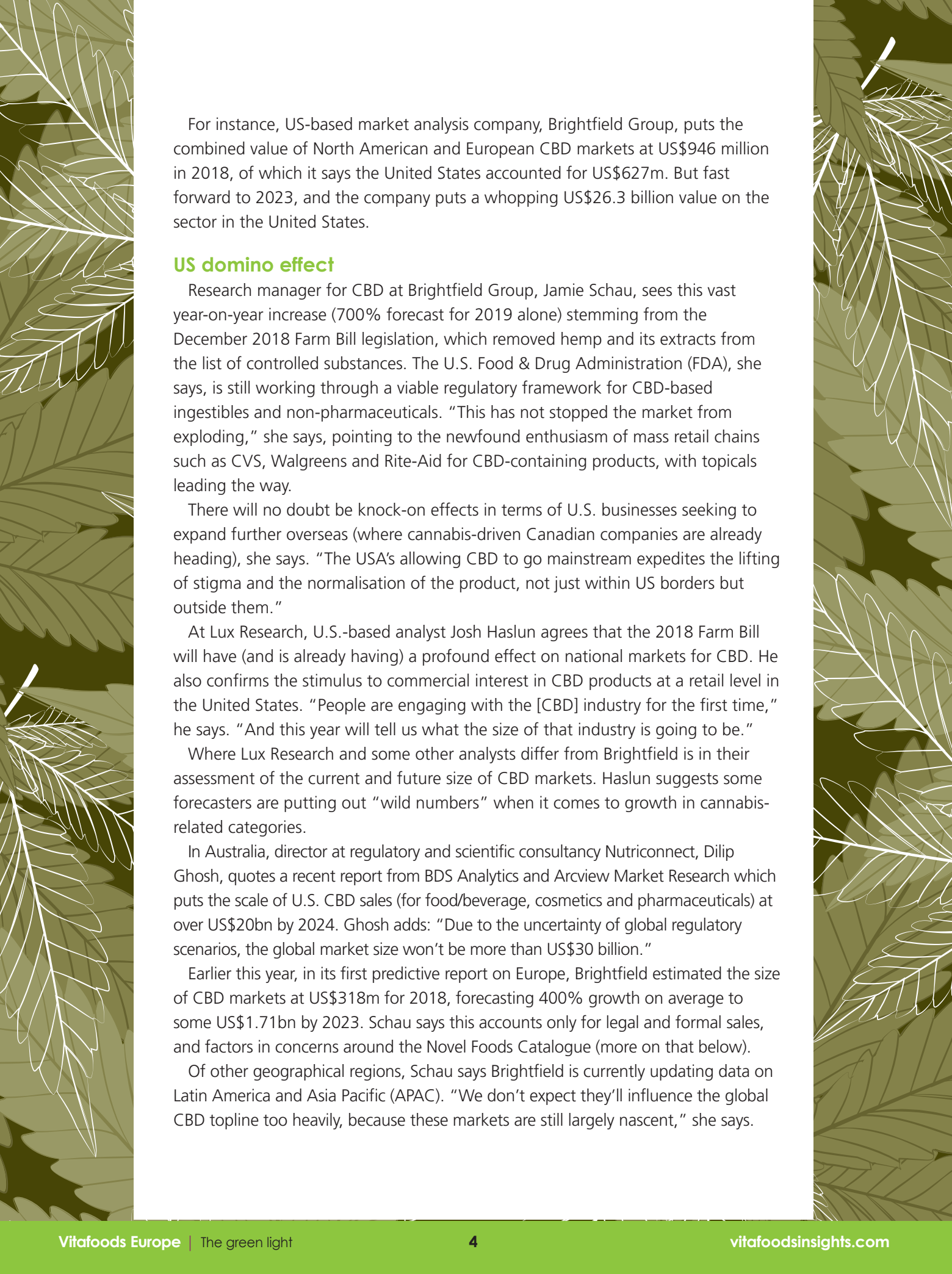
Estimating the value and growth potential—even in the short term—of markets for CBD is notoriously challenging. There are at least two reasons for this. First, in many jurisdictions this sector operates on the fringes of legality, thanks to the close association with cannabis and its psychoactive component tetrahydrocannabinol (THC); accurate counts of acreage of the different cultivars are lacking.

One aspect of this rather marginalised status and ongoing process of navigating toward the mainstream has been a relative lack of industry organisation and, consequently, of accurate market intelligence.

At the European Industrial Hemp Association (EIHA), managing director, Lorenza Romanese, says there are some 40,000 hectares of hemp around Europe, a large portion of which is in France. “The area is doubling in size every year,” she says. But when it comes to CBD itself, information is still lacking. “We are about to launch an initiative to gather more data from our members on sales and CBD market sectors, with outcomes hopefully ready by the autumn of this year.”

A second complicating factor when it comes to accurate estimates is that, because of current or very recent changes to the regulatory standing of CBD, markets have the potential to shift decisively in a short space of time. Most legal markets are new and are expected to experience a degree of regulatory volatility during the initial years of deployment. Many of the countries that have legalised CBD have only done so in the past 12 months, meaning that regulatory systems to secure use and scale are still very young. This is highly relevant to the current situations in both the United States and Europe, and market intelligence can be out of date very quickly.





For instance, US-based market analysis company, Brightfield Group, puts the combined value of North American and European CBD markets at US\$946 million in 2018, of which it says the United States accounted for US\$627m. But fast forward to 2023, and the company puts a whopping US\$26.3 billion value on the sector in the United States.

US domino effect

Research manager for CBD at Brightfield Group, Jamie Schau, sees this vast year-on-year increase (700% forecast for 2019 alone) stemming from the December 2018 Farm Bill legislation, which removed hemp and its extracts from the list of controlled substances. The U.S. Food & Drug Administration (FDA), she says, is still working through a viable regulatory framework for CBD-based ingestibles and non-pharmaceuticals. “This has not stopped the market from exploding,” she says, pointing to the newfound enthusiasm of mass retail chains such as CVS, Walgreens and Rite-Aid for CBD-containing products, with topicals leading the way.

There will no doubt be knock-on effects in terms of U.S. businesses seeking to expand further overseas (where cannabis-driven Canadian companies are already heading), she says. “The USA’s allowing CBD to go mainstream expedites the lifting of stigma and the normalisation of the product, not just within US borders but outside them.”

At Lux Research, U.S.-based analyst Josh Haslun agrees that the 2018 Farm Bill will have (and is already having) a profound effect on national markets for CBD. He also confirms the stimulus to commercial interest in CBD products at a retail level in the United States. “People are engaging with the [CBD] industry for the first time,” he says. “And this year will tell us what the size of that industry is going to be.”

Where Lux Research and some other analysts differ from Brightfield is in their assessment of the current and future size of CBD markets. Haslun suggests some forecasters are putting out “wild numbers” when it comes to growth in cannabis-related categories.

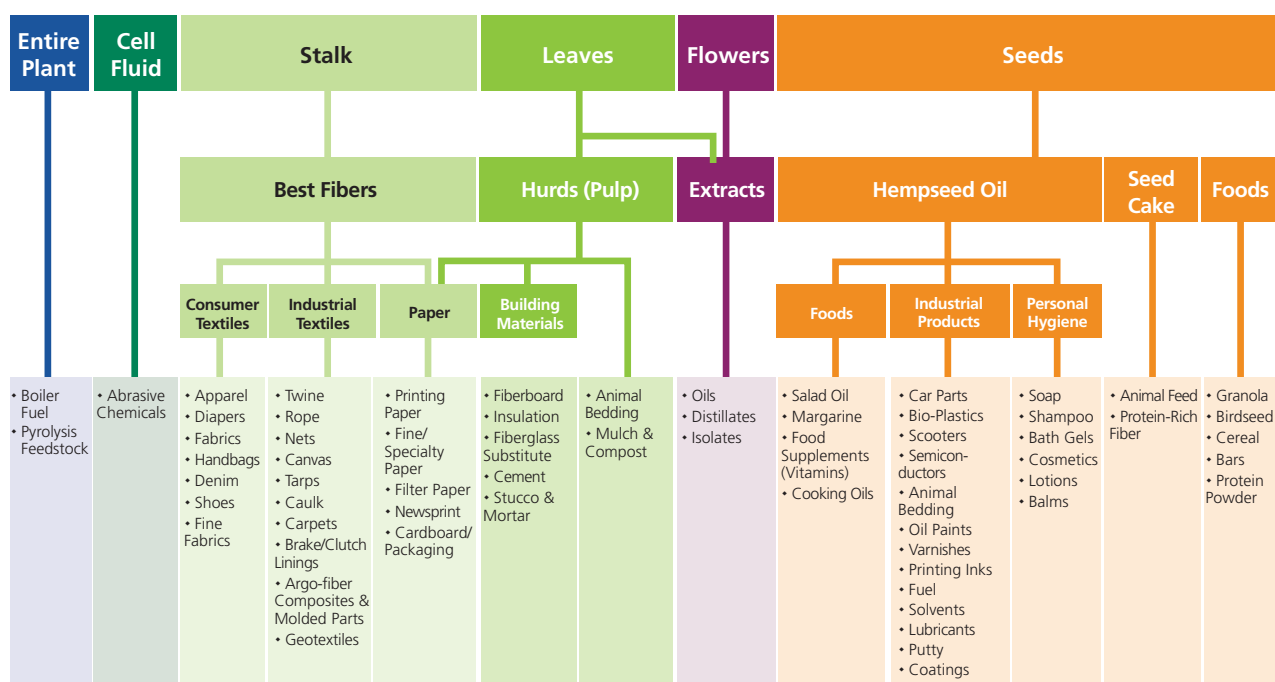
In Australia, director at regulatory and scientific consultancy Nutriconnect, Dilip Ghosh, quotes a recent report from BDS Analytics and Arcview Market Research which puts the scale of U.S. CBD sales (for food/beverage, cosmetics and pharmaceuticals) at over US\$20bn by 2024. Ghosh adds: “Due to the uncertainty of global regulatory scenarios, the global market size won’t be more than US\$30 billion.”

Earlier this year, in its first predictive report on Europe, Brightfield estimated the size of CBD markets at US\$318m for 2018, forecasting 400% growth on average to some US\$1.71bn by 2023. Schau says this accounts only for legal and formal sales, and factors in concerns around the Novel Foods Catalogue (more on that below).

Of other geographical regions, Schau says Brightfield is currently updating data on Latin America and Asia Pacific (APAC). “We don’t expect they’ll influence the global CBD topline too heavily, because these markets are still largely nascent,” she says.

Ghosh at Nutriconnect is more bullish about APAC markets which, he reports, are expected to reach US\$3.1bn in 2026, growing at an average of 29.5% annually. Attitudes towards CBD remain ambivalent in countries such as India and China, but there are positive signs. Nutriconnect points to official approval for the cultivation of cannabis in some regions of India. Haslun at Lux says: "China is starting to grow hemp for CBD in at least two provinces, with the caveat that authorities continue to be extremely strict in monitoring this."

Hemp farming, opportunities, regulation and transparency



Source: New Frontier Data

Across Europe, and more gradually in APAC countries, the hemp cultivation (and consequently, CBD market) landscape is literally shifting from year to year. Hemp is increasingly decoupled from cannabis, and even countries with conservative views on the plant are reconsidering its agricultural and industrial potential.

Additional uses for hemp

Hemp is a quick-growing plant, returning fast and easy wins for farmers in short timelines. Rapid maturation opens the door to experimentation and invites developers to investigate new genetics and cultivation techniques.

Beyond key micronutrients, hemp seed offers high concentrations of protein. The plant is rich in omega-3 fatty acids and vitamin E. With global food insecurity



and malnourishment concerns rising, hemp-based foods have the potential to improve poor dietary staples.

Hemp produces strong plant-based fibres, offering potential for rope and other natural, low-technology building applications.

In 2011, the European Food Safety Authority concluded that hemp seed could be used as feed materials for animal species. The whole hemp plant including stalks and leaves would be, due to high fibre content, suitable feed material for ruminant animals.

Lastly, hemp biochar is being investigated for water and air filtration solutions as the plant is a highly effective 'bioremediator.' Its benefits are already seen through cleaning projects targeting contaminated land, including the Chernobyl nuclear disaster site.

Hemp by region

France has historically been the producer of hemp for fibre, and it remains the largest producer, followed by the Netherlands and Italy," says EIHA's Romanese, adding that countries such as Greece are actively encouraging hemp cultivation. According to EIHA figures, the Baltic States, and in particular Lithuania and Estonia, have also increased output significantly over the last five years or so.

Irish-based Celtic Wind Crops is a prime example of the new generation of hemp-and-CBD businesses growing up around Europe. CEO and co-founder Paul McCourt says the company, which was set up in 2012, spent 10 years testing the potential of different hemp seeds and the most effective harvesting techniques. Of its branded Multi-Complex Hemp CBD Oil, sold in the UK and Ireland, he says: "It differs from that of other brands as we use the whole of the hemp plant and no carrier oils."

According to EIHA, there are challenges for hemp growers in obtaining organic certification, and McCourt makes this important distinction: "We farm to organic standards, but not all of our fields are organic-certified, so we don't claim organic certification." Instead, the company designates its CBD '100% natural'.

Meanwhile, there are additional reasons why newcomers to the sector might favour one type of hemp over another. "A key point here is the permitted level of THC," says EIHA's Romanese. "In the EU, you can only plant crops containing less than 0.2% of THC. In the US and Canada, the permitted level is 0.3%. Having a level playing field with North America would be a huge advantage for our European companies." This would allow access to new strains, and genetic diversity for greater hybrid vigour, including longer and stronger fibres for textiles and other markets.

Other countries such as Switzerland even allow up to 1% THC content, which might help to explain the number of cannabinoid-based businesses located in the country. EIHA, and probably most hemp farmers in the EU, would settle for a 0.3% threshold, and if EU regulatory wheels continue to turn as expected, says Romanese, this could be the permitted level by 2021.

There are other positives for farmers in the EU. Reforms to the Common Agricultural Policy (CAP) mean that 3% of the first ‘pillar’ or tranche of subsidies can go to ‘other crops’, with ‘green crops’—including hemp—especially favoured.

Hemp’s ‘green’ status rests on the fact that it constitutes a notable carbon sink. As Romanese explains, 1 hectare of industrial hemp can sequester 15,000 tonnes of CO₂. “It is the only crop to have a negative carbon footprint all the way from planting to harvesting and processing,” she states.

Related to this is the fact that hemp works best in a regime of crop rotation. “My fear is that, as more and more is planted, we move too far towards a monoculture,” says Romanese. “In fact, it should be used as a rotational crop, because it gives you perfect soil for your next crop, which could be something completely different such as tomatoes.”

Hemp-driven soil improvement can also be a relatively speedy process, she notes, pointing out that farmers in southern Italy, for example, may manage to grow sufficient hemp for two harvests per year, rather than just one.

But for all these positives as regards cultivation, as well as the potentially explosive growth in consumer end-use markets, there is one damaging EU-level challenge which could—unless it is resolved—undercut them all. “The Novel Foods Catalogue is a big issue which could destroy the market,” says Romanese in a dramatic assessment.

Recent changes to the Catalogue argue that no ‘history of consumption’ can be demonstrated for extracts of *Cannabis sativa* containing cannabinoids. According to EIHA, this effectively means that Member States can now interpret hemp-derived extracts, including CBD, as being ‘novel’. Although the Catalogue is not legally binding, this may lead national authorities to judge that a CBD-containing product requires authorisation under the Novel Foods Regulation before it can be sold. Said authorisation can be a long, complex and costly process. As a result, smaller companies may be left out of the market.

“The previous version of the Catalogue stated that if you respect the proportions of cannabinoids in the plant, it’s not a novel but a traditional food,” says Romanese. “But now, there is no harmonised approach, and we’re left in a grey zone where we don’t know whether products are ‘novel’ or not.”



She adds that the EIHA is currently fundraising in order to finance a Novel Food application for products containing more than the naturally-occurring levels of CBD. "This way, smaller businesses especially will have the possibility of counting on our knowledge, while we share the costs," she explains.



Hemp for fibre and other end-uses; CBD formulation and delivery formats

Traditional markets for hemp were to do with fibre, from rope-making and textiles to construction. In other end uses, the fibre can constitute a sustainable form of cavity insulation in house-building. Hemp hurds, or the fibrous inner section of the stem, can also be combined with lime to form a strong building material with good insulation and moisture-regulation properties.

But the EIHA is quick to flag up the differences for farm revenue between fibre-based and CBD-based business models. "The market value of one hectare of hemp is around €1,000, based on fibre, but around €4,000 when you harvest the flowers and leaves for processing," says Romanese, explaining that, while the flowers are important for foods and supplements, the leaves can be used in cosmetics.

Added value for hemp fibre could come from the textiles sector, she says. There has already been an R&D focus on the 'cottonisation' of hemp, or its softening, in order to make it a more attractive raw material, but more work needs to be done, according to EIHA.

Options for extraction

In countries such as France, where hemp was traditionally farmed for fibre, attitudes towards the plant's leaves and flowers are changing. "Instead of being treated as scrap material, as so often happens still today, the flowers can be delivered to a processor for the extraction of CBD using CO₂, for example, or ethanol," says Romanese at EIHA.

“ **The market value** of one hectare of hemp is around €1,000, based on fibre, but around €4,000 when you harvest the flowers and leaves for processing.



As with other natural oils, cold pressing is also possible. However, Romanese seems less than impressed with this as an option, mentioning it in passing as a technique which the UK "loves" and which Ireland is "obsessed with".



Ghosh at Nutriconnect makes no distinction between the different extraction techniques when it comes to end-product quality. But he does say:

“Supercritical systems, which use CO₂ to extract the oil, are considered a cleaner, purer form of extraction because there is no residue after extraction.”

Cibdol, based in Switzerland and the Netherlands, uses CO₂ extraction followed by a purification process and THC separation. “I think the two latter parts of the process are what sets us apart from the competition,” says general manager Liebe Griebenauw. “People are buying CBD, and we want to offer them the largest amount of that and the least possible amount of THC.”

Nutriconnect’s Ghosh sees demand for CBD gravitating towards three main therapeutic areas: pain sensation; mood and anxiety; and memory. He is also clear that these markets will not target CBD in its purest form. “Full-spectrum hemp extract, conversely, provides an equally full spectrum of naturally-occurring phytocannabinoids, including a defined amount of CBD,” he says. “In my opinion, this is the right way to go.”

Celtic Wind is one of those Irish brand-owners which, as EIHA mentions, use a cold-press technique to obtain its oil. The fact that the extract contains no carrier oils means it is better absorbed in the body, argues McCourt. “Its natural blend of not only CBD but over 150 naturally-occurring compounds works synergistically together on your endocannabinoid system,” he says, explaining that this is known as the ‘Entourage Effect’.

Plant to product

Many brand-owners are still finding their way through the multiple options available both in terms of processing and end-use format. At Renviden, based in the Netherlands, partner Waldo van der Hel explains that his company has an exclusive arrangement with supplier Plantine to microencapsulate CBD, using Plantine’s patented technique, and market it for food, beverage and cosmetic applications.

In light of the changes to the Novel Foods Catalogue, Plantine had to think on its feet, moving from a version 1 of its HempCAP product to a version 2. Van der Hel says: “If you look at the current Novel Food entries for CBD oil, extraction is the main reason why it is classified as a novel food. So, we don’t use extraction techniques for our products, but have chosen a one-on-one method, where we micronise the plant parts, such as the flowers and leaves. After micronising, we micro-encapsulate the particles.”

The benefits of micro-encapsulation include the fact that the CBD is tasteless and invisible in a clear beverage. In fact, as one of its products Renviden already has a Full-Spectrum CBD Water, incorporating 5mg of CBD per 500ml of water. The product is already available in the Netherlands and will launch in the UK later this year.



The company also claims that, because the micro-encapsulated CBD is 'protected by proteins', bioavailability and absorption by the body is 'up to 52 times higher' than standard CBD.

Meanwhile, although the EIHA seems to regard the purist approach of the Irish authorities in favour of cold-pressing the plant with rather amused detachment, Renviden approves of this stance. "I think the Irish government is doing things in the right way," says van der Hel. "It's just as outlined in the Novel Foods Catalogue, unlike in some other countries where they simply forbid everything."

When it comes to the ways in which CBD supplements are delivered, Romanese at the EIHA says: "The industry is working to provide wellness in other formats, not necessarily an oil to put under the tongue."

On this theme, Renviden might well be in agreement. As well as its fortified water, the Dutch company currently supplies capsules in 3mg and 6mg doses, but also CBD drops, which combine micro-encapsulated full-spectrum CBD in a vegetable glycerine. But van der Hel says: "We're likely to switch to only using capsules. That way, consumers don't have to measure the dose they're taking."

At Cibdol, Griebenauw says: "We are a multi-faceted company making CBD full-spectrum extracts, natural isolates, synthetic isolates, softgel, pet products and liposomal formulations." Along with other brands, Cibdol talks up the absorption rate of its own particular configuration of CBD, in this case claiming its formulations with liposomes are "up to four times more effective" than the alternatives. And like other brands, it is busy with R&D. "We are looking to the future with soluble CBD for those who want to create their own liquid products," she adds.

For its part, Celtic Wind is sticking with cold-pressed, full-spectrum CBD oil, and recently introduced new 3% and 10% oil variants to complement the existing 5% strength product. "Alongside our range of CBD oil and CBD capsules, we also have a successful CBD powder, which is great mixed into foods such as cereals and smoothies," says McCourt.

Key medical conditions posing opportunities for CBD

- Chronic pain
- Various forms of cancer
- Alzheimer's disease and other dementia
- Opioid use disorders
- HIV/AIDS
- Epilepsy
- Rheumatoid arthritis
- Parkinson's disease
- Glaucoma
- Multiple sclerosis

Source: Global Health Data Exchange



Single market mirage

It is significant that companies such as Celtic Wind and Renviden are highly selective regarding the national markets where they feel they can sell their products. As EIHA's Romanese puts it: "There's no single market for hemp. There are 27 different standards and 27 different types of labelling."

One key area of contention involves THC levels. "In the UK and Ireland there is an obsession with residual levels of THC, which you will find in any hemp-derived product," says Romanese. "There isn't the same fixation in Spain or Portugal, for example."

But then, others point out that, whatever the perceived regulatory position in a given Member State, there may simply be no enforcement, as is widely believed to be the case in the UK.

Van der Hel at Renviden believes many of the larger brand owners it is talking to are hesitant about any involvement with CBD because of regulatory uncertainty across the EU. Others will go ahead with new products using the adapted 'version 2.0' of its CBD, he reports, having been persuaded that it cannot be construed as a 'novel food'.

Meanwhile, there are other ways in which this European regulatory 'grey zone' risks undermining a market on the brink of potentially rapid growth. Recent media reports found that, at least in the UK, the vast majority of a sample of different 'CBD' products tested did not actually contain CBD.

Celtic Wind's McCourt makes the point that, for brands such as his own, there are no government regulations or standard procedures for testing CBD. "As a result, anybody can test CBD using any method to obtain results relating to the effectiveness and content levels of CBD products, which can lead to discrepancies," he says.

Traceability is likely to become even more critical to the CBD sector than it is to other ingredients. "We track our product from seed to shelf, offering full transparency to our customers, which is of growing importance," explains McCourt.



At Cibdol, Griebenauw says: “We follow the Food Safety System Certification (FSSC) 22000 method to ensure transparency and traceability.” She admits there are challenges with this, but says that with CBD these are “the same challenges as with any other food supplement”.

On the topic of legal clarity, she delivers a stern warning: “If Europe doesn’t take a clear stance on its advice regarding Novel Foods, the market will either take a dark turn towards an illegal path or giant Canadian and American companies will buy their way into the market, forcing out strong European CBD brands.”

EIHA flips the same regulatory coin on to its positive side. “We need clear rules, to start with,” says Romanese. “It’s simply not sustainable that the Novel Foods Catalogue is allowed to change all the time. We need to keep the trust of consumers. When it comes to the industry, people are wanting to know whether to invest. With greater legal certainty, this will be a flourishing sector.” ●

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