REGULATORY FOCUS

Global regulatory trends in CBD use in food and food supplements

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This article examines the regulatory trends for using cannabidiol (CBD) as an ingredient in foods and food supplements and provides guidance for companies to interpret current regulation and predict its future direction. The author describes navigating current regulatory complexity to realize commercial opportunities and addresses the challenges and opportunities for bringing food and food supplement products containing CBD to markets around the world.

Introduction

Cannabidiol is one of the naturally occurring cannabinoids found in cannabis plants.[1] The hemp plant *Cannabis sativa L.* (*C. sativa*) contains a number of cannabinoids, with delta-9-tetrahydrocannabinol (THC) and CBD being among the most common.[2]

Hemp-derived CBD ingredients, including plant extracts or isolates, have become extremely popular for use in foods, beverages, and food supplements because of their very low levels of THC (the psychoactive compound of the

plant) and the claimed health benefits related to stress relief, mood enhancement, and so on. CBD ingredients can be found in a range of products such as oils, confectionery, baked products, beverages, food supplements.

The hemp and CBD market is reported to be one of the fastest growing product categories in the world. Among the reasons for this rapid growth are that hemp has been categorized as a legal agricultural commodity; it has been promoted because of the environmental benefits of its cultivation; and recent changes in food policy now consider CBD a suitable ingredient for use in food.

However, the regulatory status of hemp and CBD as a food ingredient is a recent development in several markets around the world. In some cases, there are specific regulations and guidelines with clear conditions of use of CBD in food and food supplements. In other cases, safety assessments still need to be performed before products containing hemp-derived CBD ingredients can be legally marketed. In many other countries, however, CBD ingredients are still not permitted, or are highly restricted, for use in foods and beverages.

Concerns about CBD as an ingredient relate to food safety and public health, mainly due to the presence of THC. There are also concerns around the marketing of CBD products, whose claimed health benefits have to be scientifically substantiated before obtaining an authorized health claim.

In this sense, the result of the safety evaluations could contribute to the further commercialization of foods containing hemp-derived CBD ingredients and encourage other countries to follow suit in also regulating their use.

Given current regulatory status and trends regarding CBD as a food ingredient, companies need to be aware of the critical requirements and conditions to identify challenges and opportunities when planning marketing strategies.

CBD classification in international law

The United Nations Single Convention on Narcotic Drugs, adopted in 1961 and amended in 1972, included cannabis – meaning any plant of the genus cannabis – and certain products derived from cannabis on its lists of controlled substances. These lists include Schedule I for “drugs subject to all measures of control applicable to drugs” and Schedule IV for “drugs subject to all measures of control applicable to drugs included in Schedule I and to additional special control measures.” Although the convention does not apply to the cultivation of the cannabis plant for industrial (e.g., fiber and seed) or horticultural purposes, countries that allow cannabis cultivation are required to adopt control measures deemed necessary to prevent its misuse.[3]

The World Health Organization (WHO) issued a report in June 2018 concluding that there is no evidence of any public health-related problems associated with the use of pure CBD.[1] In addition, in January 2019 the WHO issued specific recommendations to the UN Commission on Narcotic Drugs (CND) regarding the review of cannabis and cannabis-related substances,[4] including the following:

- Cannabis and cannabis resin were to be deleted from Schedule IV of the 1961 Single Convention on Narcotic Drugs.
- Extracts and tinctures of cannabis were to be deleted from Schedule I of the 1961 Single Convention on Narcotic Drugs.
- A footnote should be added to the entry for cannabis and cannabis resin in Schedule I of the 1961 Convention to read as follows: "Preparations containing predominantly cannabidiol and not more than 0.2 percent of THC are not under international control."

The 63rd session of the CND, while voting in favor of deleting cannabis and cannabis resin from Schedule IV, voted against the other two recommendations.[5] Following this decision, extracts and tinctures of cannabis remain in the list of internationally controlled substances, with no exemptions for CBD preparations of not more than 0.2% of THC.

An underlying question in this regard was to what extent the decision would affect the interpretation of the conventions by regulatory authorities across the globe in considering the classification of CBD.

CBD in foodstuffs: Trends by region

There are diverse examples of how foods and food supplements containing hemp-derived CBD ingredients may be marketed in Asia, Europe, Latin America, North America, and Oceania.

Asia

The available rules for marketing CBD in food and food supplements are limited in Asia. In some cases, it is required to observe positive or negative lists of substances for use in foods or for nondrug use as follows:

- **In Japan,** the *C. sativa*'s treated seed is included in the "nondrug list." CBD oil extracted from mature stem and seed is not regarded as cannabis. In this regard, imports of CBD products, such as CBD oil, free of THC, would be permitted according to the 1999 guidelines issued by the Ministry of Health, Labour, and Welfare. Imports of chemically synthesized CBD would also be permitted, provided the importer proves it is not cannabis.[6]
- **In China,** the mature seed of *C. sativa* has a long history of use as traditional medicine (for digestive health) and as food. It was in the first batch of "list of botanical ingredients recognized as food and medicine use" issued by the Chinese authority in 2002.[7] On the other hand, it remains to be seen whether the recent inclusion of four kinds of cannabis-related raw materials including CBD in the lists of banned ingredients and raw materials for cosmetics could have an impact on further bans as regards the use in other product categories.
- **In South Korea,** the hemp seed is also allowed as a food ingredient, provided that the shells (bracts and outer epidermis) have been completely removed.[8]
- **In Hong Kong,** CBD, free of THC, is not in the scope of Dangerous Drug Ordinance, and therefore permitted for use in food.[9]

- In Southeast Asia, **Thailand** adopted a regulation earlier this year aiming to promote and develop hemp as an economic crop. Use of CBD oil, from hemp seeds only, is allowed in foods and food supplements. The regulation establishes clear conditions for the use of hemp or *C. sativa* seeds, hemp seed oil, hemp seed protein in different food categories, including food supplements, and maximum limits of THC and CBD.[10]

Europe

Recent decisions by international organizations and European courts of justice have contributed to changes of assessment in qualifying CBD as a food or even a novel food. In October 2020, the European Commission announced its preliminary view on CBD,[11] which can be summarized as follows:

- CBD extracted from the flowering and fruiting tops of the hemp plant is covered by Schedule I of the UN Convention (i.e., "extracts and tinctures of cannabis") and is therefore considered a narcotic and excluded from the European Union (EU) definition of food.
- Synthetic CBD does not fall in the scope of the UN convention because it is not extracted from the plant and can therefore qualify as "food."
- In cases in which CBD does not fall under the UN convention, the products will fall within the scope of the EU novel foods regulation.

However, the EU Court of Justice ruled in November 2020 in the Case C-663/18,[12] that "a member state may not prohibit the marketing of CBD lawfully produced in another member state when it is extracted from the Cannabis sativa plant in its entirety and not solely from its fiber and seeds." In its ruling, the court noted that:

- CBD cannot be regarded as a "narcotic drug."
- To define the terms "drug" or "narcotic drug," EU law refers to two UN Conventions – the Convention on Psychotropic Substances and the Single Convention on Narcotic Drugs.[13]
- CBD is not mentioned in the former and, while it is true that a literal interpretation of the latter might lead to its being classified as a drug, in so far as it is a cannabis extract, such an interpretation would be contrary to the general spirit of that convention and to its objective of protecting "the health and welfare of mankind."
- According to the current state of scientific knowledge, unlike THC, the CBD at issue does not seem to have any psychotropic effect or any harmful effect on human health.

In light of the court's ruling, the European Commission reviewed its preliminary assessment and concluded in December 2020 that "cannabinoid should not be considered as a drug within the meaning of the United Nation Convention Schedule IV of the 1961 Single Convention on Narcotic Drugs. This means that cannabinoid can be qualified as food."[14]

Foods and ingredients falling within the scope of the EU novel foods regulation[15] require premarket approval. This regulation defines "novel food" as any food

that was not used for human consumption to a significant degree within the EU before 15 May 1997, when the first regulation on novel foods came into force. Only novel foods that are authorized and included in the EU positive list of authorized novel foods may be placed on the EU market as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein. For a decision to take place on whether to authorize a novel food or ingredient, it is required that the European Food Safety Authority (EFSA) carries out a safety assessment.

In view of all this, the question is whether, or to what extent, CBD products fall within the scope of the EU novel food regulation. According to the EU Novel Food Catalogue, a nonbinding instrument that lists various food products as regards their "novel" status:

- "… the cultivation of *C. sativa* varieties is permitted provided they are registered in the EU's Common Catalogue of Varieties of Agricultural Plant Species and the THC content does not exceed 0.2% (w/w). Some products derived from the Cannabis sativa plant or plant parts, such as seeds, seed oil, hemp seed flour, and defatted hemp seed, have a history of consumption in the EU and are therefore not novel. Other specific national legislation may restrict placing this product on the market as a food or food ingredient in some member states. Therefore, it is important to check with the national competent authorities.[16]
- "The hemp plant contains a number of cannabinoids, and the most common ones are as follows: [THC … CBD …] Without prejudice to the information provided in the novel food catalogue for the entry relating to *C. sativa*, extracts of *C. sativa* and derived products containing cannabinoids are considered novel foods as a history of consumption has not been demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are considered as novel."[17]

In this sense, while certain parts of hemp are not regarded as novel, the European Commission further clarified in May this year that:

> In 2019, EU member states considered that no history of human consumption before 15 May 1997 could be demonstrated for CBD, and that it should thus be subject to Novel Food Regulation. This position was entered into the Novel Foods catalogue.[18]
>
> And,
>
> CBD should be regarded as "novel" and must go through a premarket authorization process. To date, no CBD product has been authorized as a novel food in the EU.[19]

It is worth highlighting here that a number of novel food applications for CBD have been submitted, either by companies individually or in consortium through

the European Industrial Hemp Association.[20] These had been on hold due to the European Commission preliminary assessment. However, following its review it also confirmed that the existing novel food applications on CBD could resume as to the verification of their validity. According to the EU novel foods regulation, the European Commission will forward the valid applications to EFSA no later than 1 month after verification of its validity. EFSA shall adopt its opinion within 9 months from the date of receipt of a valid application.

While this process is under way, the application and interpretation by EU member states on the use of hemp and CBD in food seems to be inconsistent, especially if one takes into account that the limits of THC in foodstuff may differ between them.

United Kingdom

On 1 January 2021, the UK became the third country to leave the EU, and, since doing so, EU law no longer applies to it, except for Northern Ireland. Under the agreement between the UK and the EU, any business seeking to market foods and food supplements containing CBD in Northern Ireland is required to observe the EU law requirements and procedures. UK law applies in any instances where CBD-containing foods and food supplements are marketed in England, Wales, or Scotland. The Food Standards Agency (FSA) is the government department with the responsibility for food safety in England and Wales, and Food Standards Scotland (FSS) is responsible for Scotland. The FSA's view is that CBD extracts fall within the scope of the UK novel food regulation. The FSA requires the CBD industry to submit novel food applications for products to the FSA for approval.

Considering the proliferation of CBD-containing food and food supplements in the UK market, the FSA took a different approach and, in contrast to the EU, allows businesses to continue selling CBD products already on sale on 13 February 2020, the date of the agency's announcement of deadline to submit novel foods applications. The products can continue being sold provided they are safe, labelled correctly, free from THC or any other substance falling under drugs legislation, and are linked to a novel foods application submitted before 31 March 2021 that was subsequently validated.[21]

FSS decided otherwise – it does not allow ingredients classed as novel food to be sold on the Scottish market until they have received full authorization. However, applications should go to the FSA without a need to make a separate application to FSS.

In April 2021, the FSA published a list of CBD food products on sale in England and Wales that should be allowed to stay on the market until there has been a decision about their authorization.[22] This list is split into two sections, with products associated with applications that either:

- Have been validated and have gone on to the safety assessment; or
- Are "on hold," with applicants having set out robust plans to complete the risk assessment but yet to supply all the information needed to continue with the process.

Switzerland

Swiss law allows for the use of CBD in food and food supplements. On the one hand, foodstuffs that include cannabinoids such as CBD and extracts of *C. sativa* and derivatives containing cannabinoids (e.g., hemp seed oil with added CBD, food supplements with CBD) are considered as novel foods. Therefore, they must be licensed by the Swiss authorities or authorized by the European Commission before they can be marketed.

On the other hand, products derived from *C. sativa* or from parts of the plant that were documented as safe and in use for human consumption to a significant degree in the EU before 15 May 1997 are not considered novel foodstuffs in Switzerland. This applies in particular to hemp seeds, hemp seed oil, hemp seed flour, and defatted hemp seeds. Furthermore, in Switzerland, herbal tea obtained from the leaves of the cannabis plant *C. sativa* is not considered a novel foodstuff. The latter may be used to flavor foodstuffs without a license. The precondition for this is that the herbal tea is used as an aqueous infusion and in no other form (e.g., concentrated or as a syrup).

Swiss law also includes clear labeling rules on CBD and permitted levels of THC in food products.[23]

Latin America

Although there is regulation in the Latin American region regarding the industrial use of hemp or the therapeutic use of cannabis, Uruguay and Ecuador have adopted specific regulation for the use of hemp seed protein and CBD in foodstuff.

Uruguay. Decree No. 19/2020 modified the National Bromatological Regulation to allow the use in food products of hemp seed protein obtained from the seeds or nuts of industrial hemp, variety *C. sativa*, by processing the remaining product from oil extraction with a maximum THC concentration for the ingredient in powder of up to 10 mg/kg.[24]

Ecuador. Processed foods and food supplement may use as an ingredient all parts of nonpsychoactive cannabis or hemp, or derivatives of nonpsychoactive cannabis or hemp, with a THC concentration of less than 0.3% in the finished product. Nonpsychoactive cannabis or hemp is defined as consisting of oils, resins, tinctures, crude extracts, or other technological development innovations obtained from nonpsychoactive cannabis or hemp, with a THC content of less than 1%, including, cannabinoids, isomers, acids, terpenes, salts, and salts of isomers, used or intended to be used as a raw material for the production of the finished product.[25]

North America

Canada. Following the amendment to Canada's Cannabis Act[26] in 2019, edible cannabis, including processed hemp foods – from dehulled hemp seed, hemp seed oil, protein concentrate and toasted hemp seed – is permitted for sale for human consumption. Hemp foods must contain less than 10 µg/g THC. Most

hemp-related activities are exempt from the Cannabis Act and controlled under the Industrial Hemp Regulations.[27]

Food supplements are, however, classified as natural health products (NHPs) in Canada. According the NHPs regulations,[28] only limited parts of cannabis or hemp plants may be used in an NHP. NHPs may only contain parts of the cannabis and hemp plants that are not considered cannabis under the Cannabis Act or that are excluded from the application of the act. This includes:

- Nonviable seeds,
- Hemp-seed derivatives that are compliant with the Industrial Hemp Regulations, and
- Mature stalks that do not include any leaves, flowers, seeds, or branches and fiber from such stalks.

Deliberately adding phytocannabinoids to such products is not permitted.

United States. The Agriculture Improvement Act, also known as the 2018 Farm Bill,[29] legalized hemp as an agriculture commodity, with a concentration of THC of no more than 0.3%. Since then, there has been a significant proliferation of CBD-containing food and dietary supplements on the US market. Despite of that, the Food and Drug Administration (FDA) has not taken steps for its regulation.

The FDA has consistently declared that CBD cannot be lawfully marketed in food and dietary supplements because the cannabis-derived compound was first studied as a drug. At the same time, while recognizing that CBD is now widely available, the agency has stated there is still limited understanding of the safety profile of CBD and many other cannabis-derived compounds and better data are needed for it to make science-based decisions.

The FDA has taken enforcement action, sending warning letters to companies for using CBD in their products. However, it seems such warning letters have been targeting mainly companies making unsubstantiated health or therapeutic claims in their products.

In the meantime, with the lack of federal regulations, several states, such as New York, Texas, and Virginia more recently, are coming up with their own rules on the use of CBD or hemp extracts in food and dietary supplements, adding regulatory complexity to the market.

At federal level, several bills have been presented at the US Congress to allow the use of hemp and hemp-derived CBD as an ingredient in food and dietary supplements. For example, Bill H.R.841[30] was introduced in the House of Representatives in April this year “to make hemp, cannabidiol derived from hemp, and any other ingredient derived from hemp lawful for use under the Federal Food, Drug, and Cosmetic Act as a dietary ingredient in a dietary supplement, and for other purposes.” In addition, Bill S.1698[31] was introduced in the Senate in May “to allow for hemp-derived cannabidiol and hemp-derived cannabidiol containing substances in dietary supplements and food.”

Despite these initiatives at the federal level, industry continues to petition the FDA to carry out safety assessments on CBD and to regulate it as an ingredient in food and dietary supplements.

Oceania

In 2017, trans-Tasman ministers from Australia and New Zealand approved a change to the Australia New Zealand Food Standards Code to allow the sale of seeds of low-THC hemp – *C. sativa* – as a food or ingredient for human consumption, provided that the only cannabinoids in or on the seeds are naturally present. To make this happen, some amendments had to be made to several food and drug regulations, which entered into force in November 2018. The amended provisions establish clear conditions of use of hemp seeds, including extracts, oils, and beverages, with maximum limits of THC and CBD.[32]

Conclusion

The food status of the hemp plant *C. sativa* and plant parts – such as seeds, seed oil, hemp seed flour, hemp seed protein, and so on – as well as CBD, is well recognized in different parts of the world. However, regulatory complexities persist.

On the one hand, there are divergent regulations and criteria in relation to the parts of the plant that are accepted as the source of the food ingredient, as well as on the maximum limits of THC contamination in the ingredient or in the final product. On the other hand, there are significant differences in the way national authorities interpret and apply current rules in relation to isolate CBD, full spectrum CBD and synthetic CBD.

In the current context, it is apparent that the growth of the market has been mainly due to internet sales of products containing CBD. The larger food and food supplement companies seem to have been waiting for the further clarification of regulatory challenges as well as for the outcome of the ongoing safety assessments. However, there are emerging examples already of international ingredient suppliers getting increasingly involved in hemp-derived ingredients including CBD. In this regard, this trend may eventually turn into a greater engagement of the largest companies with important resources for accessing markets worldwide.

Considering this, companies need to keep current with this evolving regulatory environment to develop successful marketing strategies and identify upcoming business opportunities.

Abbreviations

CND, Commission on Narcotic Drugs; **CBD,** Cannabidiol; **EIHA,** European Industrial Hemp Association; **EU,** European Union; **FDA,** Food and Drug Administration; **FSA,** Food Standards Agency; **FSS,** Food Standards Scotland; **NHPs,** Natural Health Products; **THC,** delta-9-tetrahydrocannabinol; **UN,** United Nations; **UK,** United Kingdom; **WHO,** World Health Organization.

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