The Regulatory and Legal Minefield of Using CBD in Food & Beverages

Note:
This document is intended solely as an educational tool to help the reader gain a general understanding of the many issues that arise in the context of the use of CBD. It is not legal advice nor is it intended as a substitute for consulting legal counsel.

Adding cannabidiol (CBD) to food, beverages and supplements is a hot topic in the food industry today but there’s confusion about its regulation and legality.

Three in four chefs cited CBD- and cannabis-infused food as a top trend for 2019, according to the National Restaurant Association’s annual “What’s Hot” survey. The trend is likely to grow. U.S. retail sales of consumer products with CBD could top $16 billion by 2025, up from an estimated $1 billion in 2019, reports investment banking firm Cowen.

As more consumers ask for CBD, including in foods and beverages, restaurant operators are looking for clarity. They operate in a market already flooded with CBD-infused food and beverage products — but the Food and Drug Administration currently bans CBD use in food and beverages sold in interstate commerce, and many states and cities have adopted their own rules.

Here’s what you need to know about CBD in food.
What is CBD?

Cannabidiol, or CBD, is a cannabinoid, a compound that occurs naturally in cannabis plants. CBD and tetrahydrocannabinol (THC, the active ingredient in marijuana) are two of the best-known examples of cannabinoids in cannabis plants. Cannabis is the umbrella term for the family of plants that includes both hemp and marijuana.

Unlike THC, CBD isn't intoxicating. It doesn't produce the “high” associated with marijuana.

Both hemp and marijuana plants contain CBD but there are key differences:

• **Marijuana plants** — Typically have high amounts of THC and lower amounts of CBD. THC is responsible for the intoxicating effects associated with marijuana use.

• **Hemp plants** — High in CBD and generally contain only trace amounts of THC - i.e., less than 0.3% of THC.

How is CBD used?

CBD is used in products for ingestion like foods, beverages and tincture oils, as well as in topical cosmetic products such as oils and creams. Proponents say it imparts a feeling of calm and relaxation, caused by how the compound interacts with endocannabinoid receptors in the human body.

Although there’s little research available on the health benefits or risks of CBD, many marketers and consumers say CBD can help with everything from anxiety to depression and pain relief. The FDA in 2018 approved CBD as a drug to specifically treat certain severe seizure disorders.
WHAT’S THE LAW ON CBD IN FOOD & BEVERAGES?

Is CBD legal?

In many instances, yes.

In its 2018 farm bill, Congress amended the federal definition of “marijuana” and exempted industrial hemp, as well as hemp-derived CBD, from regulation as “marijuana.” The law provided for hemp — the source of most CBD — to be regulated as an agriculture product. Under the new law, farmers are now allowed to grow and transport industrialized hemp. The law also removed hemp-derived CBD from the federal list of controlled substances, as long as it’s produced and marketed according to the law. Marijuana-derived CBD is still a controlled substance under federal law.

But despite legalizing hemp and its derivatives, the farm bill preserved the FDA’s authority to regulate products containing hemp-derived ingredients, including CBD, in FDA-regulated products (foods, beverages, dietary supplements, cosmetics, drugs).

This means that although hemp-derived CBD is no longer treated as “marijuana” — a controlled substance under federal law— other federal laws, including the Federal Food, Drug, and Cosmetic Act, continue to limit the use of hemp-derived ingredients in finished products, including food and beverages.

The FDA has still not approved CBD as an ingredient in food or drink, including CBD oils and tinctures intended for ingestion.

So can I serve CBD in food and beverages legally?

Federal law currently prohibits CBD in food, beverages and supplements sold in interstate commerce. In addition, FDA’s Federal Food, Drug, and Cosmetic Act provides that in any action to enforce the requirements of the Act, a food is presumed to be in interstate commerce. Therefore, while states can establish their own requirements for CBD-containing foods and beverages, the FDA could nevertheless take enforcement action against CBD-containing foods and beverages in those states.
Here's the latest:

• It is currently illegal under federal law to add CBD to food, beverages or dietary supplements sold in interstate commerce. “[I]t is a prohibited act to introduce or deliver for introduction into interstate commerce any food ... to which THC or CBD has been added,” the FDA says in a Q&A on its CBD resource page.

The FDA’s position is based on a provision of the Federal Food, Drug, and Cosmetic Act (referred to as the “exclusionary clause”), which prohibits the use of a substance that has been the subject of substantial clinical investigations as a drug from being used in a food.

This is the primary basis on which the FDA is objecting to the use of CBD in foods or dietary supplements. However, it’s important to keep in mind that the FDA could raise a number of other issues that would similarly prohibit the use of CBD in food or dietary supplements, such as safety concerns that make CBD inappropriate as a food or dietary ingredient (for example, failure to identify what constitutes a “safe” dosage, potential for interactions with medications, and cumulative exposure and effect on vulnerable populations such as children and the elderly).

Similarly, the types of claims made about a CBD product positioned as a food or supplement could render the product an unapproved drug. For example, a “relieves anxiety” claim would be viewed as a claim appropriate only for drug products.

• Under state law: States have the authority to regulate CBD and hemp within their borders. Most states are following the lead of the FDA and maintain that it’s illegal to add CBD to food and drink under state law until the FDA approves it. Importantly, even if state law authorizes the use of CBD in a food or beverage, the FDA could nevertheless assert jurisdiction over the product.

Some states and cities are stepping in to try to clarify the rules (whether to legalize CBD in food and drink within their borders or prohibit it) or provide enforcement guidance. The regulatory landscape for these products changes rapidly, even by the day, so it’s important to check each state’s regulations to determine permitted use. Each state framework differs and it’s important to understand the nuances.
Here’s a sampling* of some of the activity at the state and local levels as of fall 2019:

• A number of states have passed laws that provide a basis to use hemp-derived CBD in food, subject to the limitations established under state law, including Colorado, Connecticut, Florida, Maine, New Mexico, Ohio, Oregon, Utah, Texas, and West Virginia.

• For example, in COLORADO, all hemp product manufacturers, extractors, processors, and storage facilities that store, wholesale, or process hemp products intended for human consumption are required to register with the state, and must source any hemp or hemp ingredient from

  (1) a grower registered with the state of COLORADO.

  (2) a grower registered with another state with an industrial hemp program.

  (3) a country where hemp is regulated under a food safety program with equivalent criteria to ensure safety for human consumption.

Colorado also requires that any hemp product for human consumption be labeled to clearly identify hemp as an ingredient; identify CBD and the amount of CBD added, if added as an isolate; include the statement “FDA has not evaluated this product for safety and efficacy”; and not bear any health or benefit claims. It is unclear how Colorado would interpret these requirements in the context of a restaurant serving a CBD-infused food.

To illustrate the complexity of the state and local patchwork:

• Agriculture officials in GEORGIA and NORTH CAROLINA have warned restaurants and others that foods and beverages containing CBD are illegal.

• MISSOURI’s alcohol-control division issued an opinion in February 2019 allowing CBD-infused alcohol.

• NEW YORK CITY’s health department said it may begin issuing fines against restaurants and other businesses that sell CBD-infused foods. The department’s guidance notes city’s prohibition on CBD in food and drink, and warns that the department is embargoing products and issuing fines.
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• In CALIFORNIA, health officials have warned that foods containing CBD will be considered illegal until the FDA provides guidance. A 2019 bill would have prohibited restrictions on the sale of products based solely on the inclusion of CBD, although similar bills failed to pass in the last legislative session.

• TEXAS has a new law legalizing hemp-derived CBD and creating a licensing and regulatory program for hemp and hemp-derived products. The law does not consider foods containing CBD to be adulterated or unsafe.

• WASHINGTON STATE amended its hemp laws to prohibit the use of CBD in foods.

*This is not a full list of state and local law or activity on this topic. This is a fast-changing issue. Consult with your legal counsel for the laws in the states and localities where you operate.

Is the FDA enforcing bans on CBD?

Yes. The FDA has issued a number of warning letters to manufacturers of foods and dietary supplements containing CBD, including 15 warning letters sent in November 2019 to companies marketing CBD products. These letters came at the same time the FDA issued a consumer update about products containing CBD.

Although the FDA’s letters have largely focused on products bearing egregious health claims — such as claims that CBD can cure or treat serious medical conditions like cancer and Alzheimer’s disease — one recent FDA warning letter to a CBD dietary-supplement manufacturer suggests the FDA’s approach may be widening. In this case, the FDA did not object to any claims made in connection with the manufacturer’s product; instead, the agency states that the product cannot be a dietary supplement because it contains CBD. The agency cited a provision in the federal Food, Drug, and Cosmetic Act that prohibits the use of a substance that has been studied or approved as a drug from being used in food or dietary supplements.
Are states enforcing bans on CBD in food?

The FDA’s minimalist approach to enforcement — targeting mostly sellers who make false health claims about CBD products — has caused some confusion, and effectively leaves enforcement action up to state and local officials.

At the state and local levels, many jurisdictions don’t have the time or inclination to enforce bans on CBD in food and drink. But as noted above, some states and cities are taking a stricter approach, including seizing or embargoing foods containing CBD.

IS CBD SAFE IN FOOD & BEVERAGE PRODUCTS?

Is CBD safe to put in food and beverages?

The FDA detailed its safety concerns about CBD in a November 2019 consumer update. The agency explains that it has only reviewed limited data about CBD safety, and says the data it has looked at so far points to real risks that need to be considered before taking CBD for any reason. These risks include the potential for liver toxicity, drug interactions, and other side effects.

The FDA identified gaps in the data and scientific literature that would need to be addressed to support the use of CBD in food and beverages. In a press release accompanying the consumer update, the FDA stated that, based on the evidence available today, it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts.

The agency is intensifying its efforts to study the health effects of CBD in food and is looking for data from the industry to support the safety of CBD as a food ingredient. The FDA has consistently maintained that CBD is not a risk-free substance, alluding to safety issues the agency identified as it reviewed and eventually approved CBD as a drug.
CBD IN FOOD & BEVERAGES

If I serve CBD, is there a particular amount (in milligrams) of CBD content I need to stay below?

There has been no FDA evaluation regarding proper dosage of CBD in food. Few, if any, states have established limits on the amount of CBD permitted in finished products for human consumption. Please check specific state regulations for more details.

WHAT’S NEXT?

Is the FDA going to make CBD legal for foods? When?

The FDA knows that public interest in marketing and accessing CBD in food is growing, and acknowledges its policies are causing confusion. So far, though, the agency hasn’t approved CBD as a food or beverage additive.

The agency is feeling pressure from Congress, industry and consumers to update its regulations, to keep pace with the marketplace and the increasing consumer demand for CBD. As noted above, the agency’s main concern appears to be that there’s little data to document the public health risks or benefits of including CBD in food and beverages.

The FDA in May 2019 established a high-level working group and held its first public hearing on CBD, asking for input on research to measure possible risks and benefits. The FDA noted in its November 2019 consumer update and press release that its review of safety data related to CBD is ongoing.

It is unclear when the agency will have more to say on a potential path forward for CBD in food, but the FDA has indicated that a rulemaking process to allow CBD in food could take two to five years.
Is Congress doing anything to clarify the rules?

Some lawmakers are asking the FDA to speed up its decisions on how to regulate foods and supplements containing CBD. They believe the 2018 farm bill cleared the way for a lawful pathway for foods containing CBD and want the FDA to begin moving.

Senate Majority Leader Mitch McConnell (R-Ky.) is among the lawmakers pressing the FDA to establish clearer guidance on how the FDA will use its discretion to enforce the law as the agency discusses longer-term regulations.

More than 20 bills have been introduced in Congress to legalize the use of marijuana and hemp in some form. However, Senate and House leaders haven’t said whether or when Congress will take up these bills. Most recently, a bipartisan bill was introduced in the U.S. House of Representatives by House Agriculture Chairman Collin Peterson to provide flexibility for CBD to be marketed as dietary supplement and remove some barriers for food companies to use CBD in food products.

What’s happening with the market for industrialized hemp?

Under the 2018 farm bill, the U.S. Department of Agriculture has taken on the new role of regulating industrialized hemp as an agriculture product. The USDA in October 2019 published an interim final rule to govern how hemp is grown and has begun to review state plans that have been submitted to the agency. Once the USDA approves a state plan, or begins issuing licenses under its own plan, the program to regulate the cultivation of hemp will be fully operational. As hemp production increases, the market for CBD is likely to get even bigger.
CONSIDERATIONS FOR RESTAURANTS

What are restaurants doing about CBD?

The confusing policy landscape hasn’t stopped some restaurants from selling CBD-infused products. Many of these restaurants focus on beverages — advertising CBD-infused lattes or smoothies, or offering CBD “mocktails,” for example. Most bartenders avoid mixing CBD and alcohol. Others are trying CBD in desserts, or in sauces for burgers.

Many other restaurant companies are staying away from adding CBD to the menu until regulatory issues are settled or CBD is approved as “food safe” by the FDA.

What is the National Restaurant Association’s position?

We filed comments with the FDA in July 2019 asking the agency to quickly answer questions about the health and safety of CBD products. We noted the challenges restaurants face with a patchwork of state and local rules, and the legal confusion our members face over serving any products with CBD. We asked for interim guidance as the FDA works to create a regulatory pathway for the safe use of CBD in food and beverages.

What should I think about before offering CBD foods or beverages at my restaurant?

If you are thinking about offering a CBD food or beverage on your menu, we recommend that you work with legal counsel to understand the implications under federal, state, and local law. Issues to consider include:

Diligence on the ingredient being sourced:

• What is the ingredient? For example, are you using a full or broad-spectrum hemp extract, which contains CBD but also other components of the plant, including THC? Or are you sourcing a CBD isolate which does not contain any other components of the hemp plant?

• Who is producing the ingredient? Where is the hemp used to make the ingredient sourced from? Is the hemp grower licensed by a state to cultivate hemp?
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• What is the THC content of the ingredient and does the ingredient supplier have certificates of analysis that show this content level? What controls are in place to ensure that the THC concentration is less than 0.3% (the legal standard for hemp)?

• Has the ingredient supplier conducted any safety evaluation of the CBD ingredient for use in foods? Did the ingredient supplier determine a safe dosage of CBD per serving for foods?

State and local law issues:

• What does the state I’m operating in say about the use of CBD in foods? Has the state taken enforcement actions? Has the state advised the public against consumption of CBD products?

• Does making a CBD food jeopardize any licenses, registrations or permits I have with the state or local government?

Safety considerations:

• What is an appropriate dosage of CBD? What type of food am I infusing with CBD? Are multiple ingredients in a single dish going to be infused with CBD, and if so, what is the overall exposure to CBD from the finished food?

• Should we take any measures to restrict who can order a CBD food, such as an age restriction?

• How do we make sure consumers are informed that the food contains CBD? What are our communications to customers when they inquire about CBD as a food ingredient? What do we say about CBD on our menu and other marketing materials?

ABOUT MARIJUANA EDIBLES

What’s an “edible”?

An “edible” typically refers to a food or beverage that has been infused with marijuana or THC. Although sometimes the term is used to refer to foods or beverages that have been infused with hemp or CBD derived from hemp, here we use the term “edibles” to refer to foods infused with marijuana or THC, not foods infused with CBD. Some states with recreational or medical marijuana laws refer specifically to marijuana-infused foods as “edibles” and regulate them differently than conventional foods under state law.
Can restaurants legally serve marijuana edibles?

Under federal law the sale of marijuana edibles is illegal even if authorized by state/local law. TEN STATES and WASHINGTON, D.C., have legalized marijuana for recreational purposes, but generally don’t allow restaurants to serve marijuana in food. All state recreational marijuana programs operate on a closed system. This means products can only be manufactured or sold by entities licensed with the state under the state’s marijuana laws.

- Currently, no state recreational marijuana laws allow the sale of marijuana edibles for consumption on public premises. CALIFORNIA’s recreational marijuana law allows local jurisdictions (cities, counties) to allow on-site consumption of marijuana edibles. West Hollywood, Calif., in 2019 took the first steps to authorize on-site consumption of marijuana edibles, licensing what some have referred to as the nation’s first ‘quasi-legal’ cannabis consumption lounge.

- Some local jurisdictions in states with recreational marijuana laws may be opening the door to restaurants or other types of “marijuana consumption lounges,” but these entities are highly regulated and limited by local jurisdictions. For example, West Hollywood is only granting a total of 15 licenses for consumption facilities. In addition, it’s important to note that the sale of marijuana edibles in any state would still be illegal under federal law, even if authorized by state or local law.

Good Resources

- FDA: What You Need to Know About CBD
- Best Food Facts: What Is CBD?