Regulations & the Manufacturing of Hemp Products

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Before the late 1950s, hemp in the US was considered an agricultural commodity, and the U.S. Department of Agriculture (USDA) supported its production. At that time, the Drug Enforcement Administration (DEA) was given the oversight and regulatory authority over all cannabis varieties, including hemp and marijuana. The DEA strictly controlled and regulated by these products as Schedule I controlled substances under the Controlled Substances Act.

The Agriculture Act of 2014 (2014 Farm Bill) brought some welcome changes that helped relax hemp production and marketing. The Agriculture Improvement Act of 2018, known as the Farm Bill of 2018, included more sections to expand the legal use of hemp. For instance, Section 7129 of the Bill describes hemp as a supplemental and alternative crop. The Bill also includes sections on the legitimacy of industrial hemp research (Section 7605), hemp production (Section 10113) and funds for more research of hemp as an alternative crop.

These changes also provided a better differentiation between hemp and marijuana in terms of farm policy and federal regulatory oversight. Under Section 297A Definitions, the term "hemp" means:

> ...the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.

Thus, *Cannabis sativa* L. with content below 0.3% of THC is considered hemp. Any plant with more than 0.3% of THC is considered marijuana. Any byproduct from a marijuana plant is still regulated, at the federal level, as a Schedule I controlled substances by the Drug Enforcement Administration.

When it comes to regulating marijuana products, states have been very active in the last decade and now in September 2021, the legality of marijuana varies by state. The different status by states encompasses terms such as: legalized, medical and decriminalized, medical, decriminalized, CBD only, and fully illegal let alone specific details on registration and compliance processes.

For instance, Alabama has approved a "medical cannabis bill" but the bill has many provisions that deter the use of these medical products. Thus, some states have mixed regulations in place. There are several websites that show maps or tables with all the states and the current statutes related to state regulations for marijuana.

Hemp and marijuana are distinct in several ways, including:

- The regulatory oversight and statutory definitions
- The chemical and genetic composition of the plants
- The different production and manufacturing practices used to create finished products

In both cases, hemp or marijuana products are harvested and dried and then used in further manufacturing activities. These manufacturing activities take place in what are called "facilities," which are regulated by states or the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act. These manufacturing facilities manufacture:

- Foods
- Dietary supplements
- Ingredients for use in body products and cosmetics
- Therapeutic products

Thus, there is a variety of products that can be manufactured and different regulatory guidelines according to the different products.

The Farm Bill of 2018 provided a series of guidance, mainly related to testing, to ensure that the product that is marketed as hemp are indeed products from pants with content below 0.3% of THC. Several states that have more "relaxed" regulations have also implemented several tests for quality purposes and are part of Quality Control Programs that states created in support of the hemp industry. Most of these tests aim at determining the potency of the crop (percentage of THC), and detecting any potential contaminants that may compromise the safety of the products.

However, there is a lack of standardized tests for cannabis and most laboratories determine their analytical methods based on specific regulations from states and borrow some microbiological screening test from other commodities, such as grain and food ingredients. Thus, it is important to recruit laboratories that have the experience and the certifications to perform tests that are reliable, meaning that they have the appropriate specificity and sensitivity for the analyte that will be tested.

Important Terms

There are important terms that are key to understanding how products from different *Cannabis sativa* L. plants are regulated. These terms include

Cannabis: This term refers to any part of the plant *Cannabis sativa* L. It is common so refer to marijuana as cannabis, but this term includes both hemp and marijuana.

> **Hemp:** This term, as already defined it, includes *Cannabis sativa* L. plant, or cannabis plants, with THC content less than 0.3%

Marijuana: This term includes *Cannabis sativa* L. plant, or cannabis plants, with THC content above 0.3%

Cannabinoids: This term is used to refer to the many related compounds that can be extracted from the in the plant. Some of these compounds include CBD and THC. There are more than 100 compounds, primarily in the flowering tops and mostly absent in seeds. Some of these products may have psychotropic effects.

Delta-9 tetrahydrocannabinol, or THC: This term refers exclusively to the cannabinoid that is responsible for psychotropic effects.

Cannabidiols: This is the term used to refer to those compounds from the *Cannabis sativa* L. plant without psychotropic effects.

CBD: This is a non- psychotropic compound and is the active therapeutic substance of an FDA-approved epileptic drug under the commercial name of Epidiolex.

Specific Regulations for Food Manufacturers

When it comes to food manufacturing, there are some key regulations to which all food manufactures must comply, at least to some extent, in order to engage in inter-state commerce of products. These key regulations are:

- Manufacture foods following Current Good Manufacturing Practice (21 CFR 117, Subpart B)
- Use only approved, safe food ingredients, color and additives (21 CFR 70, 172, etc.)
- Foods are packed in food approved containers (21 CFR 176-186, etc.)
- Food is "honestly" labeled. e.g., Nutrition Facts panel, serving sizes, etc.
- Be consistent with any nutrient claim (21 CFR 101)

The Current Good Manufacturing Practice (CGMP) include a series of guidelines to create an environment conducive to the manufacturing of wholesome food, meaning a food that is not adulterated or misbranded. Not all aspects of CGMP are applicable to all facilities, meaning that the personnel working at the facility will have to determine which areas are applicable to that particular facility. The following list contains the areas covered by CGMP:

§ 117.10 Personnel
§ 117.20 Plant and grounds
§ 117.35 Sanitary operations
§ 117.37 Sanitary facilities and controls
§ 117.40 Equipment and utensils
§ 117.80 Processes and controls
§ 117.93 Warehousing and distribution
§ 117.95 Holding and distribution of human food by-products for use as animal food

§ 117.110 Defect action levels

In the case of dietary supplements, the CGMP are codified under 21 CFR Part 111 and include many more provisions than the CGMP for foods. These provisions include process control systems related to batch production records, laboratory operations and packaging and labeling operations.

An important component of the manufacturing of food and dietary supplement includes the appropriate labeling of the finished products. The expectation from the regulatory agencies is that products will be "honestly" labeled, meaning that the description of the ingredients and total amount of the product will be accurate, such as the Nutrition Facts panel which requires serving sizes among other requirements. There is no pre-market approval of labels, but it is important that the labels are reviewed by someone with the knowledge to identify statements on the label that may be considered "misleading."

FDA has granted the status of GRAS (generally recognized as safe) for several Hemp-derived substances. All of these notices were sent on 2018 at the request of a company that requested a review by the Agency. These substances include

- Hemp seed protein powder (GRAS Notice 771)
- Hulled hemp seed (GRAS Notice 765)
- Hemp seed oil (GRAS Notice 778)

One of the questions that we frequently receive is: can THC or CBD products be sold as food ingredients or dietary supplements?

The answer to this question is "no" because the FDA has concluded that THC and CBD products are excluded from being considered food ingredients or dietary supplement ingredients. In addition, CBD is the active therapeutic substance of an FDA-approved drug and therefore any "interstate" commerce of any food to which a drug has been added is prohibited. California may be leading the way in a change in its new state legislation. See here California's new state law awaiting its Governor's signature. For comments and states' positions on industrial hemp, see the National Conference of State Legislatures and National Association of State Departments of Agriculture (NASDA).

The state regulations will continue to provide some new opportunities for the use of hemp derived products as food ingredients and dietary supplement ingredients. It is likely that what is passed and acceptable at the state level may eventually be adopted at the national level once we have more information on the safety of these products in the marketplace. Until then, it is important to continuously monitor the state regulations in the state where you are operating to ensure you are manufacturing food products or dietary ingredients that are wholesome and not considered adulterated of misbranded.

For up-to-date resources on industrial hemp in Vermont, see the Vermont Hemp Program