



# Department of Public Health and Human Services

Public Health & Safety Division ♦ Communicable Disease Control & Prevention Bureau  
Food & Consumer Safety ♦ PO Box 202951 ♦ 1400 Broadway ♦ Helena, MT 59620-2951  
Phone: (406) 444-2837 ♦ Fax: (406) 444-5055

Steve Bullock, Governor

Sheila Hogan, Director

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## Industrial Hemp and Cannabidiol Policy for Foods

### Purpose

The purpose of this policy is to address numerous inquiries from entrepreneurs who want to add industrial hemp ingredients or cannabidiol (CBD) to conventional food products or market such products as dietary supplements.

### Summary

The Montana Department of Public Health and Human Services (DPHHS) and FDA have determined that verifiable foodgrade industrial hulled hemp seeds and oil from such seeds will be allowed in food, including dietary supplements, if and only if, the food product is marketed without any and all health and health-related claims, and used in specific types of food categories detailed in the “ALLOWED” portion of the “Policy” section in this document.

Despite popular belief at the time this policy was written, CBD extracts are not allowed in food or dietary supplements, regardless of the *Cannabis* source, industrial hemp or otherwise. Specifically, CBD does not meet the legal definition of an ingredient allowed in conventional food or dietary supplements because CBD extracts are already federally regulated as a prescription drug and controlled substance.

There is no current Montana law that allows the introduction of CBD extracts into commerce as a conventional food or dietary supplement. Moreover, DPHHS believes that if CBD extracts were to be legalized in the state as edible products, such products would best be administered under the state’s existing Medical Marijuana Program, and not be allowed into the conventional food or dietary supplement supplies. Consumers are entitled to make informed choices about edible products in commerce and that information is best provided to consumers by participants in that program.

### Background

Under the Code of Federal Regulations (CFR), CBD and delta-9 tetrahydrocannabinol (THC) are Schedule One Controlled Substances (21 CFR 1308.11(d)(23)), and the federal Controlled Substances Act, regulates CBD as a chemical component of the *Cannabis* plant. Specifically, the December 14, 2016 Federal Register (FR) reads: “Although it might be theoretically possible to produce a CBD extract that contains absolutely no amounts of other cannabinoids, the DEA [Drug Enforcement Administration] is not aware of any industrially-utilized methods that have achieved this result” (FR v.81, No. 240).

The topic to which DEA refers is the seemingly evitable cross cross-contact activity that occurs when parts of the plant that have higher concentrations of THC or CBD come in contact with equipment or plant parts that have lesser concentrations of controlled substances that result in increasing the THC or CBD level in the final product than what may have been intended at the beginning of the manufacturing process.

Currently, Montana uses as a food standard parts 100-199 of the 2001 CFR, title 21, adopted under state rule 37.110.101 (1)(a)-(bl), ARM. Subsections (ax) and (bh) of that rule specify substances and additives that are allowed in foods and dietary supplements. CBD is not included in these regulations, nor should it be any more than aspirin or ibuprofen. Conventional foods and dietary supplements must not contain either over-the-counter drugs or prescription drugs to better ensure consumer safety and education.

This history is well detailed in public records that document the evolution of food safety laws on the federal and state levels, dating back to 1906 and 1911, respectively, when the national and Montana versions of the Pure Food and Drug Act became law. Prior to this time, it was not uncommon to have edible products contain ingredients such as morphine, opium, cocaine, heroin, chloroform, cannabis and other risky substances in foods and medicines. In fact, these substances are specifically named in Section 8 of the 1911 Montana food and drug law.

According to scientific publications from the National Institutes of Health, CBD has drug properties, and has been scientifically shown to have analgesic, anticonvulsant, muscle relaxant, anxiolytic, neuroprotective, anti-oxidant, and anti-psychotic activity. Also, the federal Food and Drug Administration (FDA) considers nearly all CBD products unapproved drugs. On June 25, 2018, FDA announced approval of CBD as the active ingredient in a drug to treat two rare and severe forms of epilepsy. Therefore, CBD does not meet the legal definition of a dietary supplement, nor is it an approved food additive or generally recognized as safe (GRAS) for use in regular food.

Dietary supplements are special types of food in which stricter production controls have been mandated because not all ingredients are required to be approved additives, generally recognized as safe, or conventional food ingredients. Active or primary ingredients in dietary supplements have known physical effects on the body beyond ordinary growth and maintenance of healthy bodily functions—some of which may be new to the United States. Their active ingredient inclusion into regular food would diminish certainty that their use in regular food would not be harmful under intended, common or usual conditions. In these situations, ingredients outside what is normally allowed in regular food are regulated as either dietary supplements or possibly new drugs.

Industrial hemp is legally defined in Montana law under the Alternative Agricultural Crops Act, which states that industrial hemp “means all parts and varieties of the plant *Cannabis sativa* L. containing no greater than 0.3% tetrahydrocannabinol” for the dry weight of the crop. The term is also defined in federal law in Section 7606 (b)(2) of the Agricultural Act of 2014, commonly known as the “Farm Bill” (Public Law 113-79). There appears to be a perception in the public realm that passage of the Farm Bill means all Cannabis and hemp-related products are now legal throughout the United States and this is simply not the case for sound reasons.

On December 20, 2018, FDA posted a “Constituent Update,” which indicates specific conditions in which industrial hulled hemp seeds and industrial hemp seed oil may be used in conventional foods. The conditions are described within Generally Recognized as Safe (GRAS) petition notices 765, 771 and 778. In response to these notices, FDA did not write any objections to the petitioner’s usage conditions, but also did not grant GRAS status to hulled hemp seeds. Specifically, FDA stated industrial hulled hemp seeds and industrial hemp seed oil may be used in food by adding them as a source of carbohydrates, nutrients, protein, and oil to baked goods, beverages (dairy alternative products, juices, protein drinks, smoothies), cereals, desserts, dips, dressings, meat alternative products, nutrition bars, sauces, snacks, spreads, and soups. FDA also indicated that only “trace amounts” of THC and CBD may be in the hulled seeds, which might possibly be acquired through inadvertent or perhaps intentional cross-contact activities with other parts of the plant or equipment during processing and packaging.

Prospective operators who want to use industrial hemp seeds and oil from such seeds in food or dietary supplements outside the scope detailed FDA GRAS notice petitions in 765, 771 and 778, are encouraged to submit their own GRAS petition notice to FDA for consideration.

FDA concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce, any food, including any animal food or feed, to which THC or CBD has been added, regardless of the source. Therefore, use of industrial hemp as the source of THC or CBD to be added to food products is prohibited. Stated differently, until the FDA and DEA rules that industrial hemp-derived CBD oil and CBD products can be used as food, CBD products are not an approved food, food ingredient, food additive, or dietary supplement.

## Policy

Food operators need to prove the applicable provisions below are being complied with during the pre-licensing and post-licensing inspection processes regarding approved food ingredient sourcing and non-adulteration status:

1. **SOURCE.** Source and non-adulteration status can be verified by providing the inspecting sanitarian with written documents that show the origin of the industrial hemp is from a verifiable and legal source. Participation in legally-allowed industrial hemp program would aid in this verification step. The Montana Department of Agriculture is one example of an agency that operates a legally-allowed industrial hemp program. If a food operator can prove they are a participant in such a program, this would provide a firm foundation upon which to conclude the foodgrade industrial hemp seed and industrial hemp seed oil is from an approved source.
2. **ALLOWED.** Verifiable foodgrade industrial hemp seeds and industrial hemp seed oil will be allowed in food and dietary supplements, if and only if, the food is marketed without any and all health and health-related claims. If health or health-related claims are made for such products, the product in question will be regulated as an unapproved drug, rather than food. Conditions in which industrial hulled hemp seeds and industrial hemp seed oil may be used are adding them as source of carbohydrates, nutrients, protein, and oil to:
  - a. baked goods
  - b. beverages (dairy alternative products, juices, protein drinks, smoothies)
  - c. cereals
  - d. desserts
  - e. dips
  - f. dressings
  - g. meat alternative products
  - h. nutrition bars
  - i. sauces
  - j. snacks
  - k. spreads, and
  - l. soups.
3. **UNALLOWED.** Hemp-related ingredients that will not be allowed in food:
  - a. Any and all CBD products derived from Cannabis plants; and
  - b. Any and all CBD products, including CBD oil, derived from industrial hemp; and
  - c. Hemp oil that is not derived from industrial hemp seeds; and
  - d. Industrial hemp seed oil with added CBD or other cannabinoids.
4. **PREPACKAGED CBD PRODUCTS.** Prepackaged CBD products manufactured outside Montana that are already in commerce:
  - a. CBD products marketed only as botanical substances, not as food, and do not make any health or health-related claims, should not be considered a workload obligation for the local health authority for possible enforcement action;
  - b. CBD products marketed as food and make any health or health-related claims, should be considered a workload obligation for the local health authority for enforcement actions under the Montana Food, Drug and Cosmetic Act. Local health authorities are encouraged to work with their local law enforcement authorities and county attorney to decide whether to create and implement an enforcement plan.
5. **PROPOSED CBD PRODUCTS.** Operators who propose to manufacture CBD products within Montana should be referred to the Montana Department of Agriculture Industrial Hemp Pilot Program to discuss options and legal status.
6. **ENFORCEMENT.** If there is probable cause to believe a food or dietary supplement in commerce, or is intended for introduction into commerce, may contain suspected illegal levels of THC or CBD, the sanitarian or authorized agent should contact their supervisor to decide whether to procure a sample for testing under provisions allowed under the Montana Food, Drug and Cosmetic Act. Local health authorities are encouraged to work with their local law enforcement authorities and county attorney to decide whether to create and implement an enforcement plan.