INDUSTRIAL HEMP ENROLLMENT AND OVERSIGHT

Food and Drug Branch

Industrial Hemp Enrollment and Oversight

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Frequently Asked Questions (FAQs)

This webpage addresses "Frequently Asked Questions" (FAQs) in response to inquiries regarding the implementation of Assembly Bill 45 (Aguiar-Curry, 2021), as well as provide information to both educate and help successfully navigate this new program. It is divided into four sections: 1. Background; 2. Licenses, Registration, and Fees; 3. Technical Information; and 4. Inhalable Industrial Hemp Products. This information will continue to be updated to address new questions submitted to the department and to clarify existing information as the implementation of this new law progresses.

This webpage does not convey any specific rights or obligations for either business or the California Department of Public Health (CDPH). It contains CDPH's current position on several aspects of a new regulatory program.

Background

Technical Information

Technical Information

What's the difference between marijuana (termed "cannabis" in California law) and industrial hemp?

Industrial hemp and marijuana are both Cannabis sativa L. However, they are differentiated by their variety of Cannabis sativa and their varying levels of cannabinoid composition. Marijuana contains tetrahydrocannabinol (THC), including, but not limited to, Delta-8-tetrahydrocannabinol, Delta-9-tetrahydrocannabinol, and Delta-10-tetrahydrocannabinol, that has a psychoactive effect on the user. Marijuana may have greater than 0.3% THC. On the other hand, industrial hemp must have 0.3% or less THC and has no psychoactive impact.

How much CBD may I add to the IH product I intend to manufacture?

IH products may contain up to 0.3% (dry weight basis) THC in the final form. There is not a specific limit on how much CBD may be present in the final form of the product; however, CDPH has the authority to limit the amount of CBD in allowable products through regulation, if needed.

Can you provide me a list of approved testing labs?

CDPH does not approve or recommend testing laboratories for industry. Firms manufacturing industrial hemp products which must be tested by an "independent testing laboratory" must ensure the selected laboratory aligns with the description of an "independent testing laboratory" given under "Chapter 9. Industrial Hemp" in the statute. AB 45 provides that an "independent testing laboratory" means one that:

- does not have a direct or indirect interest in the entity for which testing is being done,
- does not have a direct or indirect interest in a facility that cultivates, processes, distributes, dispenses, or sells raw hemp products,
- does not have a license issued by the Department of Cannabis Control, except as a licensed testing laboratory,
- and is either a testing laboratory licensed pursuant to Division 10 of the Business and Professions Code or is accredited by a third-party accrediting body as a competent testing laboratory pursuant to ISO/IEC 17025 of the International Organization of Standardization.

What testing is required for IH products?

Currently, AB 45 requires:

- THC concentration
- Any hemp derivatives identified on the label or associated advertising
- Contamination, as established in the California Business and Professions Code Section 26100 and associated regulations

Note that CDPH is authorized by law to additionally regulate any compound to be determined necessary through regulation.

Inhalable Industrial Hemp Products

- Who can manufacture inhalable industrial hemp products in California?
- What must a California inhalable industrial hemp manufacturer who sells out of California obtain from CDPH?
- How much does an IHEO Authorization cost?
- At this time, how does AB 45 apply to inhalable industrial hemp manufacturers?

Licenses, Registration and Fees

- What types of industrial hemp products may I manufacture, pack, or hold in California?
- Which licenses and registrations do I need to manufacture, pack, or hold industrial hemp products in California?
- What are the current requirements to manufacture and sell industrial hemp products in California?
- Is an IHEO Authorization mandatory for cosmetic manufacturers that include industrial hemp as an ingredient in their products? Current cosmetic manufacturers registration is voluntary.
- How much does an IHEO Authorization cost?
- May I make IH products from my home?
- Will my facility be inspected by CDPH?
- Once I submit my application, what is the process for me to receive my registration?
- How long is the IHEO Authorization valid for?
- Will an IHEO Authorization allow me to process or sell recreational or adult-use marijuana?
- I'm registered with the Department of Cannabis Control (DCC) to make cannabis edibles. May I also make industrial hemp edibles at my facility under the authority granted in AB 45?
- I want to grow industrial hemp plants. Will an IHEO Authorization allow me to operate a farm to grow the agricultural commodity?
- Do I need an IHEO Authorization to sell IH products at my retail store (e.g. grocery store, market, etc.)?
- I operate a café/restaurant. May I add IH extracts (e.g. CBD) to the food and beverages I advertise on my menu?
- I want to purchase industrial hemp and extract cannabinoids from the hemp biomass. Do I need an IHEO Authorization?
- If I manufacture industrial hemp products at multiple processing locations, do I need an IHEO Authorization for each location in California?
- Besides the specific requirements of AB 45, what laws apply to my IH food or cosmetic product business?
- What is the "current good manufacturing practice" (cGMP) for food?

Background

The California Department of Public Health (CDPH) has issued other Frequently Asked Questions (FAQ) and guidance documents related to industrial hemp. Do those still apply?

This document supersedes all previous FAQ and guidance documents issued by CDPH related to industrial hemp. It will be updated periodically throughout the implementation process of Assembly Bill 45 (AB 45), Chapter 576, Statutes of 2021, and corresponding regulations.

Where can I read the text of the new law?

You may read the law on the California Legislative Information website.

Who is the regulatory authority for industrial hemp products intended for human consumption or for pet food?

The California Department of Public Health (CDPH) has regulatory authority over industrial hemp PRODUCTS outlined in AB 45. Businesses engaged in the manufacturing, packing, or holding of industrial hemp products are required to register with CDPH. However, if you intend to grow industrial hemp as a CROP, you should contact the California Department of Food and Agriculture (CDFA). Please contact CDFA directly for information about their registration process.

How does recently passed legislation in California affect the industrial hemp industry?

California's AB 45 was passed by the Legislature and signed into law by the Governor on October 6, 2021. Among many provisions, the law defined industrial hemp products and created a framework for regulating the industry through CDPH. The CDPH is actively engaging with stakeholders to fully develop an effective program which protects consumers and enables industry to operate legally in California.

What is Industrial Hemp?

"Industrial hemp" or "hemp" means an agricultural product, whether growing or not, that is limited to types of the plant Cannabis sativa L. and any part of that plant, including the seeds of the plant and all derivatives, extracts, the resin extracted from any part of the plant, cannabinoids, isomers, acids, salts, and salts of isomers, with a delta-9 tetrahydrocannabinol concentration of no more than 0.3 percent on a dry weight basis. "Industrial hemp" does not include cannabinoids produced through chemical synthesis.

What is an "industrial hemp product" or "hemp product"?

It is a finished product such as cosmetic, food, food additive, pet food, dietary supplement, beverage, or herb product that contains industrial hemp that is for human or animal use. This excludes industrial hemp products that only contain industrial hemp that have received FDA GRAS designation for human food products. It also excludes cosmetics that only contain industrial hemp derivatives, substances, or compounds derived from the seed of industrial hemp. The product cannot include tetrahydrocannabinol (THC) isolate as an added ingredient and cannot include cannabinoids produced through chemical synthesis. THC includes delta-8, delta-9, delta-10 and any other type or cannabinoid that causes intoxication as defined by the department.

What is a "raw hemp product"?

It is a product that is derived from industrial hemp that is intended to be included in a food, beverage, pet food, dietary supplement, or cosmetic.

What is "raw extract" or "industrial hemp raw extract"?

It is an extract from industrial hemp not intended for consumer use and that contains a THC concentration of not more than an amount determined by the CDPH in regulation.

What are some uses of industrial hemp?

Industrial hemp has many potential uses including paper, ropes, linens and textiles for clothing and shoes, bioplastic alternatives to automotive and construction fiberglass, painting oils, soaps, nutritional supplementation, seed milk, and chemical extracts such as cannabidiol (CBD).

How can I get involved in the rulemaking process for this new industry?

The CDPH will solicit stakeholder input as we develop the Industrial Hemp Compliance Program. Please ensure you have signed up for our mailing list to receive updates.

If I obtain an Industrial Hemp Enrollment and Oversight (IHEO) Authorization from CDPH, will I be exempt from federal requirements regarding industrial hemp?

No. Federal agencies who have jurisdiction over the cultivation of industrial hemp, and/or the manufacturing of food, drugs, inhalables, and cosmetics may take regulatory and enforcement action independent of your status with the California Industrial Hemp Compliance Program.

Are industrial hemp and cannabis regulated differently in California?

Yes. AB 45 provided the regulatory framework for industrial hemp and its derivatives in specific products as noted above. The California Department of Public Health is developing the framework for the implementation of many of the requirements of the law. However, the Medicinal and Adult Use Cannabis Regulation and Safety Act is the law for cannabis businesses. It established the framework for the legal cannabis market. The Department of Cannabis Control has primary regulatory oversight authority of cannabis products. Cannabis does not include industrial hemp, and AB 45 does not apply to cannabis.

Can I start manufacturing and selling products now?

You may manufacture and sell industrial hemp products or raw hemp extract only after obtaining an IHEO Authorization. In order to get started on the process of applying, please click this link: https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/IHEOProcess.aspx

What if the federal government issues regulations later?

California laws and regulations will remain in effect until the federal government adopts regulations for industrial hemp products. At that time, CDPH will adopt new regulations if necessary.

Licenses, Registration and Fees

What types of industrial hemp products may I manufacture, pack, or hold in California?

- Shelf-stable food (e.g. baked goods, candy, confections, dried mixes, etc.)
- Dietary supplements taken by mouth (e.g. botanicals, herbs, powders, amino acids, etc.)
- Cosmetics (e.g. lotions, balms, makeup, salves, cleansers, etc.)
- Pet food (e.g. food for animals NOT including livestock)
- Beverages
- Inhalables ONLY for out-of-state sales
- Raw hemp extract

IH products which require refrigeration for safety are NOT allowed. You may NOT include industrial hemp in an alcoholic beverage, a product containing nicotine or tobacco, medical devices, or prescription or nonprescription drugs.

Which licenses and registrations do I need to manufacture, pack, or hold industrial hemp products in California?

You must apply for and maintain an IHEO Authorization issued by CDPH to manufacture, pack, or hold IH products in California.

You must also maintain and comply with laws for all other applicable registrations for your specific commodity. Other common licenses and registrations include the Processed Food Registration, cannery license, pet food registration (PDF), and cosmetic manufacturing registration. Applications and guidance documents for those programs are included at the links.

What are the current requirements to manufacture and sell industrial hemp products in California?

You must meet these requirements to sell in California:

- Possess a license or registration for your specific commodity (such as Processed Food Registration).
- Obtain an IHEO Authorization for each commodity.
- Comply with California law and federal law including but not limited to California Food and Agriculture (CDFA) law; California Department of Public Health (CDPH) law, such as the Sherman Food, Drug and Cosmetic Law; and the 2018 Farm Bill.
- Currently, inhalable industrial hemp products may not be sold in California.

Is an IHEO Authorization mandatory for cosmetic manufacturers that include industrial hemp as an ingredient in their products? Current cosmetic manufacturers registration is voluntary.

Yes. Under AB 45, cosmetic manufacturers that include industrial hemp must obtain an IHEO Authorization from the CDPH, as well as a mandatory cosmetic manufacturing registration that is referenced above.

However, cosmetic manufacturers registration is voluntary and does not require an IHEO Authorization under the following conditions:

- Cosmetics that do not contain any industrial hemp.
- Cosmetics that only contain industrial hemp that have received FDA GRAS designation for human food products.
- Cosmetics that only contain industrial hemp derivatives, substances, or compounds derived from the seed of industrial hemp.

The product cannot include tetrahydrocannabinol (THC) isolate as an added ingredient and cannot include cannabinoids produced through chemical synthesis. THC includes delta-8, delta-

9, delta-10 and any other type or cannabinoid that causes intoxication as defined by the department.

How much does an IHEO Authorization cost?

Authorization Fee Tier (Gross Annual Sales)	Extract Producer	Human Food Manufacturer	Processed Pet Food Manufacturer	Cosmetic Manufacturer
Tier 1 (</=$100,000)	$2,750	$1,900	$1,300	$1,600
Tier 2 ($100,001-$500,000)	$3,500	$2,800	$2,000	$2,400
Tier 3 ($500,001-$1,500,000)	$5,000	$3,700	$2,500	$3,000
Tier 4 ($1,500,001-$3,000,000)	$7,000	$4,700	$3,000	$3,600
Tier 5 ($3,000,001-$5,000,000)	$9,500	$5,900	$3,600	$4,300
Tier 6 ($5,000,001-$7,500,000)	$13,500	$7,100	$4,300	$5,200
Tier 7 ($7,500,001-$12,500,000)	$18,500	$8,500	$5,200	$6,200
Tier 8 ($12,500,001-$17,500,000)	$24,000	$9,900	$6,200	$7,400
Tier 9 ($17,500,001-$25,000,000)	$32,000	$11,500	$7,400	$8,800
Tier 10 (> $25,000,000)	$42,000	$14,000	$9,000	$10,500

May I make IH products from my home?

No. IH products must be made at a suitable, commercial location.

Will my facility be inspected by CDPH?

CDPH will evaluate your application and determine if a pre-registration, onsite inspection is necessary to protect public health and ensure compliance with applicable statutes. The California

Health and Safety Code grants the CDPH the authority to enter and inspect any establishment engaged in any covered activity, such as manufacturing, packing, or holding foods, drugs, medical devices, or cosmetics. Additionally, AB 45 specifies that CDPH may inspect financial data, sales data, and personnel data.

Once I submit my application, what is the process for me to receive my registration?

Your application will be reviewed, and an inspection may be assigned to field staff. If there are no significant violations of applicable laws and regulations observed, a supervisor will review your file and request that an IHEO Authorization is sent to the mailing address you included on your application.

How long is the IHEO Authorization valid for?

IHEO Authorizations are valid for one year from the date of issuance.

Will an IHEO Authorization allow me to process or sell recreational or adult-use marijuana?

No. This is not a license to sell cannabis. The Industrial Hemp Enrollment and Oversight Authorization only regulates products derived from industrial hemp.

I'm registered with the Department of Cannabis Control (DCC) to make cannabis edibles. May I also make industrial hemp edibles at my facility under the authority granted in AB 45?

No. At this time, industrial hemp food and cosmetic products may not be made at a facility which also manufactures cannabis products.

I want to grow industrial hemp plants. Will an IHEO Authorization allow me to operate a farm to grow the agricultural commodity?

No. Industrial hemp cultivation is under the regulatory authority of the California Department of Food and Agriculture (CDFA). Please contact CDFA directly for information about their registration process.

Do I need an IHEO Authorization to sell IH products at my retail store (e.g. grocery store, market, etc.)?

No. An IHEO Authorization is required for manufacturers of IH products and IH extracts. Retailers, subject to the California Retail Food Code, must ensure they obtain their packaged IH products from CDPH licensed sources.

I operate a café/restaurant. May I add IH extracts (e.g. CBD) to the food and beverages I advertise on my menu?

No. The law requires all IH products to be prepackaged and shelf stable. Manufacturing IH products at retail cafés and restaurants is not allowed.

I want to purchase industrial hemp and extract cannabinoids from the hemp biomass. Do I need an IHEO Authorization?

Yes. Extraction of cannabinoids must be done under the regulatory framework established by AB 45. Cannabinoid extraction businesses must obtain an IHEO Authorization.

If I manufacture industrial hemp products at multiple processing locations, do I need an IHEO Authorization for each location in California?

Yes. Each location where industrial hemp products are manufactured, packed or held must obtain an IHEO Authorization.

Besides the specific requirements of AB 45, what laws apply to my IH food or cosmetic product business?

Food manufacturers who include industrial hemp in their product must follow all food safety laws and regulations. Some of the applicable statutes include:

- California Health and Safety Code (HSC) Section 109875 et. Seq. (Sherman Food, Drug and Cosmetic Law).
- HSC Section 111950 – 112130 (California Food Sanitation Law)
- Title 21 Code of Federal Regulations (CFR), Part 117 (Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food).
- Title 21 CFR, Part 111 (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements).
- Title 21 CFR, Part 101 (Food Labeling)
- Title 21 CFR, Part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers)
- Title 21 CFR, Part 114 (Acidified Foods)
- Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Fair Packaging and Labeling Act (FPLA)

Cosmetics:

- California Health and Safety Code (HSC) Section 109875 et. Seq. (Sherman Food, Drug and Cosmetic Law)
- California Safe Cosmetics Act of 2005 (PDF)
- Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Fair Packaging and Labeling Act (FPLA)

What is the "current good manufacturing practice" (cGMP) for food?

The cGMPs for food are the foundational requirements for most businesses who manufacture, pack, or hold food in the United States. They are outlined in Title 21, Code of Federal

Regulations, Part 117, subpart B and apply to IHEO Authorization participants who manufacture food products for human consumption.

The labels I currently use for my IH products do not contain all required elements outlined in AB 45. May I continue to use my old labels until I run out?

Existing labeling requirements applicable to specific commodities must be followed. For example, food product labels must comply with Title 21, CFR Part 101 – Food Labeling. Required information on food labels include a statement of identity, ingredient list in descending order of predominance by weight, net quantity of product in the package, an address for the responsible party and a nutrition facts panel, when applicable.
New labeling requirements established pursuant to AB 45 for food and cosmetic products which contain industrial hemp (e.g. batch numbering, scannable QR code, cannabinoid concentration, warning statements, etc.) must be in place by January 7, 2022. Please refer to the text of the law for a list of the new labeling requirements.

I'm based outside of California and want to manufacture IH raw extracts and export them into California. Do I need to obtain an IHEO Authorization?

Yes. Extract manufacturers of industrial hemp both within California and outside of California must obtain an IHEO Authorization to lawfully ship their product into and out of California in compliance with AB 45. Out-of-state extract manufacturers must comply with federal law to address interstate commerce concerns pursuant to the 2018 Farm Bill.

Besides an IHEO Authorization, what do I need before I can distribute or sell my industrial hemp product in California?

Currently, AB 45 requires a certificate of analysis from an independent testing laboratory that confirms:

- The industrial hemp raw extract, in its final form, does not exceed THC concentration of an amount determined allowable by the Department in regulation, or the mass of the industrial hemp extract used in the final form product does not exceed a THC concentration of 0.3 percent.
- The industrial hemp product was tested for any hemp derivatives identified on the product label or in associated advertising following Section 111926.2.
- The industrial hemp product was produced from industrial hemp grown in compliance with Division 24 (commencing with Section 81000) of the Food and Agricultural Code if sourced from within California, or licensed in accordance with United States Department of Agriculture (USDA) requirements if sourced from outside the state.

I'm interested in manufacturing IH products. Where can I get help with the formulation of my product?

Currently, CDPH's Food and Drug Branch (FDB) has guidance documents published on our website related to food safety, cosmetic safety, and other licensing programs. We may publish

guidance documents related to the IHEO Authorization (e.g. labeling, registration steps, inspection expectations, etc.) as they are developed.

Since FDB is a regulatory agency and cannot offer consulting services for product development, you may want to contact a private consultant, trade association, or other qualified third-party for assistance with your product development and specific situation.

I'm based outside of California and want to manufacture IH products. Can I obtain an IHEO Authorization to sell my products in California?

California only requires an out-of-state industrial hemp extract manufacturer to be licensed and obtain an IHEO Authorization. California does not license or require an IHEO Authorization for out-of-state manufacturers of final form products to be sold in California.

How are manufacturers, both in-state and out-of-state, required to ensure the safety of IH products sold or distributed in California?

AB 45 requires that all IH products that are sold or distributed in California shall conform with all applicable state laws and regulations. Manufacturers must include a certificate of analysis to confirm approved THC concentration and product content and provide proof that the IH product was from an approved IH growing program.

CDPH may initiate an investigation to determine compliance with AB 45 or other law such as misbranding, adulteration, food manufacturing safety, etc. Enforcement may include:

- regulatory warnings
- public health advisories warnings
- civil penalties
- recall of IH final form products or extracts
- seizure and embargo of IH products

Also see FAQ titled, "Besides the specific requirements of AB 45, what laws apply to my IH food or cosmetic product business?"

Technical Information

What's the difference between marijuana (termed "cannabis" in California law) and industrial hemp?

Industrial hemp and marijuana are both Cannabis sativa L. However, they are differentiated by their variety of Cannabis sativa and their varying levels of cannabinoid composition. Marijuana contains tetrahydrocannabinol (THC), including, but not limited to, Delta-8-tetrahydrocannabinol, Delta-9-tetrahydrocannabinol, and Delta-10-tetrahydrocannabinol, that has a psychoactive effect on the user. Marijuana may have greater than 0.3% THC. On the other hand, industrial hemp must have 0.3% or less THC and has no psychoactive impact.

How much CBD may I add to the IH product I intend to manufacture?

IH products may contain up to 0.3% (dry weight basis) THC in the final form. There is not a specific limit on how much CBD may be present in the final form of the product; however, CDPH has the authority to limit the amount of CBD in allowable products through regulation, if needed.

Can you provide me a list of approved testing labs?

CDPH does not approve or recommend testing laboratories for industry. Firms manufacturing industrial hemp products which must be tested by an "independent testing laboratory" must ensure the selected laboratory aligns with the description of an "independent testing laboratory" given under "Chapter 9. Industrial Hemp" in the statute. AB 45 provides that an "independent testing laboratory" means one that:

- does not have a direct or indirect interest in the entity for which testing is being done,
- does not have a direct or indirect interest in a facility that cultivates, processes, distributes, dispenses, or sells raw hemp products,
- does not have a license issued by the Department of Cannabis Control, except as a licensed testing laboratory,
- and is either a testing laboratory licensed pursuant to Division 10 of the Business and Professions Code or is accredited by a third-party accrediting body as a competent testing laboratory pursuant to ISO/IEC 17025 of the International Organization of Standardization.

What testing is required for IH products?

Currently, AB 45 requires:

- THC concentration
- Any hemp derivatives identified on the label or associated advertising
- Contamination, as established in the California Business and Professions Code Section 26100 and associated regulations

Note that CDPH is authorized by law to additionally regulate any compound to be determined necessary through regulation.

Inhalable Industrial Hemp Products

Who can manufacture inhalable industrial hemp products in California?

Industrial hemp inhalables may be manufactured by California manufacturers. However, California-based manufacturers can only manufacture for sales outside California, as it is currently prohibited for sale in the state.

What must a California inhalable industrial hemp manufacturer who sells out of California obtain from CDPH?

At this time, an industrial hemp inhalable manufacturer shall obtain an Industrial Hemp Enrollment and Oversight (IHEO) Authorization from CDPH. The IHEO Authorization shall be renewed annually.

Authorization Fee Tier (Gross Annual Sales)	**Inhalable Product**
Tier 1 (</=$100,000)	$1,700
Tier 2 ($100,001-$500,000)	$2,600
Tier 3 ($500,001-$1,500,000)	$3,300
Tier 4 ($1,500,001-$3,000,000)	$4,000
Tier 5 ($3,000,001-$5,000,000)	$4,800
Tier 6 ($5,000,001-$7,500,000)	$5,700
Tier 7 ($7,500,001-$12,500,000)	$6,800
Tier 8 ($12,500,001-$17,500,000)	$8,100
Tier 9 ($17,500,001-$25,000,000)	$9,700
Tier 10 (> $25,000,000)	$12,000

How much does an IHEO Authorization cost?

At this time, how does AB 45 apply to inhalable industrial hemp manufacturers?

Manufacturers of inhalable industrial hemp are "hemp manufacturers".

Inhalable industrial hemp products meet the definition of "final form products".

Unless later approved by the FDA or other controlling law, industrial hemp inhalable products cannot contain any of the following:

- alcohol
- nicotine
- tobacco
- any drug whether prescription or non-prescription ("over-the-counter")

Note that the law also authorizes CDPH to restrict, via future regulation, any other substance that the department finds to be a danger to public health.

At this time, manufacturers of inhalable industrial hemp must follow all requirements for a "hemp manufacturer," such as testing requirements under applicable portions of the Sherman Food, Drug, and Cosmetic Law and restrictions on advertising or marketing to children or persons who are pregnant or breastfeeding.

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