INDUSTRIAL HEMP ENROLLMENT AND OVERSIGHT (IHEO) AUTHORIZATION FOR EXTRACT AND/OR HUMAN FOOD MANUFACTURERS

Incomplete applications will be returned.

Industrial Hemp (IH) Processed Food Registration (PFR) Type: (Check all that apply)

☐ **Extract Manufacturer (answer questions 1-5 and 9 below)**

☐ **Human Food Manufacturer (answer questions 6-9 on the second page)**

Extract Manufacturers (complete questions 1-5, and 9)

1. Provide information about the state or tribal agency that registered or licensed you and the registration/license information. Attach a copy of the registration/license and any additional licenses or certifications.

Approving State or Tribal Agency	Approver Contact Information	Registration/License Number	Expiration Date

2. List all current and proposed industrial hemp sources. Attach documents showing the industrial hemp is an approved source.

Business Name of Industrial Hemp Source (Must be Approved Source)	Business Address of Industrial Hemp Source	Registration/License Number of Industrial Hemp Source	Name of Entity that Issued the Registration/License

3. Extract Type: List extract types manufactured, packed or held at your facility. (Use separate sheet if necessary.)
(Check all that apply.) ☐ Full-Spectrum ☐ Broad-Spectrum ☐ Concentrate ☐ Crude Oil ☐ Other:
Attach up to three product labels if product is intended for distribution or sale.

4. Extraction Method: Check all extraction methods that will be conducted on premises.

Non-Volatile Solvent or Mechanical Extraction: ☐ Carbon Dioxide (CO_2) ☐ Ethanol ☐ Food-grade Butter or Oil ☐ Glycerin ☐ Mechanical ☐ Water or food grade dry ice ☐ Other:

Volatile Solvent Extraction: ☐ Butane ☐ Pentane ☐ Hexane ☐ Other:

5. Industrial Hemp Enrollment and Oversight (IHEO) Authorization Fee:

Tier	Check Which Applies	Gross Annual Revenue	Extract IHEO Authorization Fee	Tier	Check Which Applies	Gross Annual Revenue	Extract IHEO Authorization Fee
1	☐	Less than or equal to $100,000	$2,750	6	☐	$5,000,001 to $10,000,000	$13,500
2	☐	$100,001 to $500,000	$3,500	7	☐	$10,000,001 to $20,000,000	$18,500
3	☐	$500,001 to $1,500,000	$5,000	8	☐	$20,000,001 to $30,000,000	$24,000
4	☐	$1,500,001 to $3,000,000	$7,000	9	☐	$30,000,001 to 50,000,000	$32,000
5	☐	$3,000,001 to $5,000,000	$9,500	10	☐	More than $50,000,000	$42,000

Extract IHEO Authorization Fee to be entered on page two, Question 9(a).

--Continue to Next Page--

Human Food Manufacturers (complete questions 6-9)

6. Commodities/Products: Check all human food products containing industrial hemp that are manufactured, packed or held at your facility. (Check all that apply.) Attach up to three product labels.

☐ Food ☐ Beverage ☐ Fruit/Vegetable Juice ☐ Dietary Supplements ☐ Tincture ☐ Industrial Hemp Concentrate

7. List all current and proposed industrial hemp sources. Attach documents showing the industrial hemp is an approved source.

Business Name of Industrial Hemp Source (Must be Approved Source)	Business Address of Industrial Hemp Source	Registration/License Number of Industrial Hemp Source	Name of Entity that Issued the Registration/License

8. Industrial Hemp Enrollment and Oversight (IHEO) Authorization Fee:

Tier	Check Which Applies	Gross Annual Revenue	Human Food IHEO Authorization Fee	Tier	Check Which Applies	Gross Annual Revenue	Human Food IHEO Authorization Fee
1	☐	Less than or equal to $100,000	$1,900	6	☐	$5,000,001 to $7,500,000	$7,100
2	☐	$100,001 to $500,000	$2,800	7	☐	$7,500,001 to $12,500,000	$8,500
3	☐	$500,001 to $1,500,000	$3,700	8	☐	$12,500,001 to $17,500,000	$9,900
4	☐	$1,500,001 to $3,000,000	$4,700	9	☐	$17,500,001 to $25,000,000	$11,500
5	☐	$3,000,001 to $5,000,000	$5,900	10	☐	More than $25,000,000	$14,000

Human Food IHEO Authorization Fee to be entered on Question 9(b) below.

9. **Total IHEO Authorization Fees** *(to be transferred to Question 21(c) on CDPH 8610)*

a. Extract IHEO Authorization Fee: $ or ☐ N/A

b. Human Food IHEO Authorization Fee: $ or ☐ N/A

c. **Total IHEO Authorization Fees Due:** $
(transfer amount to Question 21(c) (CDPH 8610)

The Food and Drug Branch (FDB) **MUST BE NOTIFIED IMMEDIATELY** of any changes in the above information as provided by applicable laws under CA Health and Safety Code Division 104, Parts 5 and 6 (Sherman Law). Under penalty of perjury, I declare that the information included with this application and all attachments are true, correct, and complete. Misrepresentations or omissions may be grounds for denial, revocation or suspension. I give permission for the below authorized representatives and/or signatories to speak about the application with CDPH.

If I am an out-of-state manufacturer, I consent to applicable laws under Sherman Law for the product(s) of manufacture of this application. I also consent to inspection(s) including but not limited to manufacturing, holding, and distributing site(s), records, etc. by authorized agent(s) of CDPH FDB. I acknowledge that refusal to submit to inspection and commission of violations under Sherman Law may be grounds for denial, suspension and/or revocation of CDPH registration/licensure and may be subject to other penalties.

10. Owner's Signature	Owner's Printed Name	Title OWNER/	Date

Authorized representatives and/or signatories:

11. Business Operator Name	12. Telephone Number	13. Emergency Number	14. E-Mail Address
15. Correspondent Name	16. Telephone Number	17. Alternate Phone #	18. E-mail Address

-End of Application- All boxes must be completed. Incomplete applications will be returned.

Do Not Write Below This Line

License Number	Expiration Date	Date Received	Payment Type	Amount $

Instructions for Completing the Industrial Hemp Enrollment and Oversight (IHEO) Authorization for Extract and/or Human Food Manufacturers

IH Extract Manufacturer Applicant: Place an (X) in the box next to **Extract Manufacturer.**

1. **Approver and Registration/License:** Provide information about the approving state or tribal agency and registration/ license. Attach a copy of the registration/license and any additional applicable licenses or certifications.
2. **List Industrial Hemp Sources:** List all current and proposed industrial hemp sources used for manufacturing. Attach additional pages if you have more than three sources. Attach documents showing the industrial hemp is an approved source.
3. **Extract Type:** Check all boxes that apply to the type of extract being manufactured. If your choice is not listed, please check Other and indicate in the space what type of extract. Attach three product labels if the product is intended for distribution or sale. If there are fewer than three products, attach all product labels. You may attach a copy of the actual label. If you only are holding the product as a warehouser, you do not need to attach labels.
4. **Extraction Method:** Check all boxes that apply to extraction methods that will be conducted on premises. If your choice is not listed, please check Other and indicate in the space what type of extraction method will be used.
5. **Industrial Hemp Enrollment and Oversight (IHEO) Authorization Fee:** First, determine your current or estimated gross annual revenue (GAR) of industrial hemp extracts. If you have no revenue from extract manufacturing, GAR must be based on the product's fair market value if it were to be sold in an arm's length transaction at wholesale. Next, check the corresponding tier that applies. Finally, transfer the fee amount to Question 9(a).

IH Human Food Manufacturer Applicant: Place an (X) in the box next to **Human Food Manufacturer.**

6. **Commodities/Products:** Check all human food products containing industrial hemp that are manufactured, packed or held at your facility. Attach three product labels if the product is intended for distribution or sale. If there are fewer than three products, attach all product labels. You may attach a copy of the actual label. If you only are holding the product as a warehouser, you do not need to attach labels.
7. **List Industrial Hemp Sources:** List all current and proposed industrial hemp sources used for manufacturing. Attach additional pages if you have more than three sources. Attach documents showing the industrial hemp is an approved source.
8. **Industrial Hemp Enrollment and Oversight (IHEO) Authorization Fee:** First, determine your current or estimated gross annual revenue of industrial hemp human food Next, check the corresponding tier that applies. Finally, transfer the fee amount to Question 9(b).

For All Applicants:

9. **Total IHEO Authorization Fees:** This question determines the total IHEO Authorization Fee to be added to the CDPH 8610, Question 21(c).
    a. **Extract IHEO Authorization Fee:** Please input the amount from Question 5 in this field or check "N/A" if you are not manufacturing extracts.
    b. **Human Food IHEO Authorization Fee:** Please input the amount from Question 8 in this field or check "N/A" if you are only manufacturing extracts.
    c. **Total IHEO Authorization Fees Due:** Total the amount of 9(a) and 9(b). Transfer this sum to the CDPH 8610, Question 21(c).
10. **Owner's Signature, Printed Name, Title, Date:** This section **must** be signed by the majority owner of the business to authorize not only the application, but the representatives and/or signatories whom they authorize to speak on behalf of the firm.
11. **Business Operator:** Enter the full name of the person who manages the operations of your business and their title.
12. **Business Telephone Number:** Enter the daytime business telephone number for your business.
13. **24-Hour Emergency Contact Number:** Enter phone number where firm may be reached in the event of an emergency.
14. **Business Operator E-mail Address**: Enter e-mail address of the business operator, or the main company e-mail box.
15. **Correspondent:** Enter the name of the person to contact for information regarding this application and their title.
16. **Correspondent Telephone Number:** Enter the daytime business telephone number of the contact person.
17. **Correspondent Alternate Phone #:** Enter correspondent's alternate number or another number to call for information.
18. **Correspondent E-mail Address:** Enter the facility e-mail address.

Please ensure you sign this form and attach it along with the CDPH 8610 and associated payment. Please follow the instructions on the CDPH 8610 to remit payment to the California Department of Public Health.

Firm Name: **Phone Number:**

Address:

Industrial Hemp Self-Attestation

Must be submitted with appropriate applications

Instructions

The owner must do the following:

- **a)** Initial section A, which applies to all industrial hemp products.
- **b)** Do you manufacture extracts? If yes, initial section B and complete section G.
- **c)** Is your commodity a human food product (food, dietary supplements, beverages, canned food products)? If yes, initial C and complete section G.
- **d)** Is your commodity a processed pet food? If yes, initial section D and complete section G.
- **e)** Is your commodity a cosmetic (topicals, beauty products, patches, and pet topicals and pet oils)? If yes, initial section E and complete section G**.**
- **f)** Is your commodity an inhalable product? If yes, initial section F and complete section G.

A. ALL INDUSTRIAL HEMP PRODUCTS

1. Products and Manufacturing

- **a)** The products do not contain cannabinoids produced through chemical synthesis. HSC 111920(f).
- **b)** The final form hemp product does not contain THC isolate as an ingredient. HSC 111920(g)(1)(B)(iii).
- **c)** The industrial hemp product was produced from industrial hemp grown in compliance with Division 24 (commencing with Section 81000) of the Food and Agriculture Code if sourced from within California or licensed in accordance with United States Department of Agriculture requirements if sourced from outside the state. HSC 111921(b).
- **d)** The products are not medical devices or prescription drugs or non-prescription drugs. HSC 111921.5(a)(1), HSC 111921.5(a)(2).
- **e)** The products do not contain nicotine or tobacco, and the products are not alcoholic beverages. HSC 111921.5(a)(3), HSC 111921.5(a)(4).
- **f)** Manufacturing is in a commercial location. 17 CCR 23210(b).
- **g)** The extract in the products came from a firm registered by the Department. 17 CCR 23200(b)(4), 17 CCR 23200 (c)(4), 17 CCR 23200 (d)(4), 17 CCR 23200 (e)(3).

(initials)

2. Certificate of Analysis (COA)

a) Each required COA will be truthful and accurate.

b) Each required COA will be from an independent testing laboratory that confirms the mass of the industrial hemp extract used in the final form product does not exceed a THC concentration of 0.3%, which includes but is not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC. HSC 111921(a)(1), HSC 111920(l).

c) Each required COA will be from an independent testing laboratory that confirms no detectable amount of total THC in the final form food product. 17 CCR 23100(a)(1) and (c).

(initials)

3. Independent Testing Laboratory

a) The testing laboratory does not have a direct or indirect interest in the entity for which testing is being done. HSC 111920(e)(1).

b) The testing laboratory does not have a direct or indirect interest in a facility that cultivates, processes, distributes, dispenses, or sells raw hemp products in this state or in another jurisdiction. HSC 111920(e)(2).

c) The testing laboratory does not have a license from the California Department of Cannabis Control for anything other than as a licensed testing laboratory. HSC 111920(e)(3).

d) The testing laboratory is compliant with one of the following:

- Licensed by the California Department of Cannabis Control. HSC 111920(e)(4)(A).
- ISO 17025 accredited. HSC 111920(e)(4)(B).

(initials)

4. Labeling and Advertisement

a) There is no health-related statement that is untrue on the label of the products or published or disseminated in advertising or marketing. HSC 110407.

b) Advertising and marketing do not directly target children or persons who are pregnant or breastfeeding. HSC 111926(b).

c) Advertising or marketing placed in broadcast, cable, radio, print, or digital communications is only displayed where at least 70% of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience composition data. HSC 111926(c).

(initials)

B. EXTRACT MANUFACTURERS

1. Products are manufactured pursuant to good manufacturing practices. HSC 111922.3(a).
2. The raw extract final form was tested by an independent testing laboratory, to allow its use as an ingredient prior to being incorporated into a product. HSC 111925(a)(1), HSC 111925(a)(2).
3. The extract in its final form (ready to be included as an ingredient) has a total THC concentration, including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC, that does not exceed 0.3%, per testing by an independent testing laboratory. HSC 111925(a)(3), HSC 111920(l).
4. The raw hemp product has a certificate of analysis from an independent testing laboratory that confirms the raw hemp product is the product of a batch of industrial hemp that was tested by the independent testing laboratory. HSC 111952.2(a).
5. The raw hemp product has a certificate of analysis from an independent testing laboratory that confirms that a tested representative sample of the batch of industrial hemp contained a total THC concentration, including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC, that does not exceed 0.3% on a dry-weight basis. HSC 111952.2(b), HSC 111920(l).
6. The raw hemp product has a certificate of analysis from an independent testing laboratory that confirms that the tested sample of the batch did not contain contaminants that are unsafe for human or animal consumption. HSC 111952.2(c).
7. The raw hemp product complies with the same contaminant levels as those for cannabis. HSC 111925.4(a).

(initials)

C. HUMAN FOOD (Food, Dietary Supplements, Beverages, and Canned Food Products)

1. The final form food products intended for human consumption are not offered or sold to a person under 21 years of age. 17 CCR 23005.
2. Each serving in a package of final form food products intended for human consumption has no detectable amount of total THC. 17 CCR 23100(a)(1).
3. Each package of a final form food product intended for human consumption has no more than five servings. 17 CCR 23100(a)(2).
4. No final form food products intended for human consumption are manufactured, warehoused, distributed, offered, advertised, marketed, or sold that are above a non-detectable amount of total THC per serving. 17 CCR 23100(d).
5. The serving and package sizes for a final form food product intended for human consumption uses the same federal standards as non-industrial hemp food products. 17 CCR 23100(a)(3).
6. An independent testing laboratory calculated and established the limit of detection for chemical analyses according to 4 CCR 15371. 17 CCR 23100(b).

7. The food products were manufactured in compliance with good manufacturing practices. HSC 110469(a), 111922.3(a).
8. All parts of the hemp plant used in food products come from a state or country that has an established and approved industrial hemp program that inspects or regulates hemp under a food safety program or equivalent criteria. HSC 110469(b)(1).
9. The industrial hemp cultivator or grower is in good standing and in compliance with the governing laws of the state or country of origin. HSC 110469(b)(2).
10. The COA from an independent testing laboratory confirms the industrial hemp product was tested for any hemp derivatives identified on the product label or in associated advertising. HSC 111921(a)(2).
11. Food and beverage products are prepackaged and shelf stable. HSC 111922(b).
12. Packaging and labeling on the products include a label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis of the final form product batch by an independent testing laboratory. HSC 111926.2(a)(1).
13. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes all of the following:
    - The product name. HSC 111926.2(a)(1)(A).
    - The name of the product's manufacturer, packer, or distributor, and their address and telephone number. HSC 111926.2(a)(1)(B).
    - The batch number, which matches the batch number on the product. HSC 111926.2(a)(1)(C).
    - The concentration of cannabinoids presents in the product batch, including, at a minimum, total THC (including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC) and any marketed cannabinoids or ingredient. HSC 111926.2(a)(1)(D), HSC 111920(l).
    - The levels within the product batch of contaminants. HSC 111926.2(a)(1)(E).
14. Packaging and labeling on the products include the product expiration or best by date, if applicable. HSC 111926.2(a)(2).
15. Packaging and labeling on the products include a statement indicating that children or those who are pregnant or breastfeeding should avoid using the product prior to consulting with a health care professional about its safety. HSC 111926.2(a)(3).
16. Packaging and labeling on the products include a statement that products containing cannabinoids should be kept out of reach of children. HSC 111926.2(a)(4).
17. Packaging and labeling on the products include the following statement: "THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY." HSC 111926.2(a)(5).

(initials)

D. PROCESSED PET FOOD

1. Products are prepackaged and shelf stable. HSC 111922(b).
2. Products are manufactured pursuant to good manufacturing practices. HSC 111922.3(b).
3. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes all of the following:
   - The product name. HSC 111926.2(a)(1)(A).
   - The name of the product's manufacturer, packer, or distributor, and their address and telephone number. HSC 111926.2(a)(1)(B).
   - The batch number, which matches the batch number on the product. HSC 111926.2(a)(1)(C).
   - The concentration of cannabinoids presents in the product batch, including, at a minimum, total THC (including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC) and any marketed cannabinoids or ingredient. HSC 111926.2(a)(1)(D), HSC 111920(l).
   - The levels within the product batch of contaminants. HSC 111926.2(a)(1)(E).

   (initials)

E. COSMETICS

1. Packaging and labeling on the products include a label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis of the final form extract or the final form product batch by an independent testing laboratory. HSC 111926.3(a)(1).
2. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes all of the following:
   - The product name. HSC 111926.3(a)(1)(A).
   - The name of the product's manufacturer, packer, or distributor, and their address and telephone number. HSC 111926.3(a)(1)(B).
   - The batch number, which matches the batch number on the product. HSC 111926.3(a)(1)(C).
   - The concentration of cannabinoids presents in the product batch, including, at a minimum, total THC (including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC) and any marketed cannabinoids. HSC 111926.3(a)(1)(D), HSC 111920(l).
   - The levels within the product batch of contaminants. HSC 111926.3(a)(1)(E).
3. Packaging and labeling on the products include the product expiration or best by date, if applicable. HSC 111926.3(a)(2).
4. Packaging and labeling on the products include the following statement: "THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY." HSC 111926.3(a)(3).

   (initials)

F. INHALABLE PRODUCTS

1. The inhalable products manufactured are for the sole purpose of sale in other states. HSC 111921.6(a).
2. Inhalable products are not sold to consumers under 21 years of age. HSC 111929.
3. Inhalable products do not contain flavorings other than natural terpenes. HSC 111929.2(a).
4. Inhalable products do not contain polyethylene glycol (PEG). HSC 111929.2(b).
5. Inhalable products do not contain vitamin E acetate. HSC 111929.2(c).
6. Inhalable products do not contain medium chain triglycerides (MCT oil). HSC 111929.2(d).
7. Inhalable products do not contain squalene or squalene. HSC 111929.2(e).

(initials)

G. OWNER'S VERIFICATION SIGNATURE

Under penalty of perjury, I declare that the information included with this application and all attachments are true, correct, and complete. Misrepresentations or omissions may be grounds for denial, suspension, or revocation of CDPH registration/licensure and may be subject to other penalties.

If I am an out-of-state manufacturer, I consent to applicable laws under Sherman Law for the products of manufacture of this application. I also consent to inspections including but not limited to manufacturing, holding, and distributing sites, records, etc. by authorized agents of CDPH. I acknowledge that refusal to submit to inspection and commission of violations under Sherman Law may be grounds for denial, suspension or revocation of CDPH registration/licensure and may be subject to other penalties.

Owner's Signature Title

Owner's Printed Name Date