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State of California—Health and Human Services Agency
California Department of Public Health



GAVIN NEWSOM
Governor

August 12, 2022

Dear Industrial Hemp (IH) Product Manufacturers and Extractors:

The California Department of Public Health, Food and Drug Branch (FDB) finalized its regulations on July 5, 2022, and is accepting applications and fees for the manufacture of in-state industrial hemp products and extracts (both in-state and out-of-state extractors).

To lawfully manufacture, pack, or hold industrial hemp products and extracts, a manufacturer shall obtain both an Industrial Hemp Enrollment and Oversight (IHEO) Authorization and register with the department for the applicable food, processed pet food, or cosmetic product. Manufacturers of industrial hemp inhalable products need only obtain an IHEO Authorization.

In order to facilitate successful processing of your application(s) please be aware of the following:

1. All applicable laws and regulations (please refer to resources) for the safe production, testing, labeling, and warehousing of your commodity.
2. The California Health and Safety Code (H&SC) Section 110140 allows authorized agents of the Department to enter and inspect any regulated facility to assess compliance with laws and regulations of this State.
3. Application packets submitted to the FDB must include a signed and completed IHEO Authorization application, other applicable applications (e.g., food, processed pet food, cosmetic), supporting documentation, and appropriate fees. Operators who currently maintain a valid food, processed pet food, or cosmetic registration with FDB and are interested in adding industrial hemp to their products need to fill out and submit new applications with their IHEO Authorization application.
4. When submitting your application packet, you must demonstrate compliance with applicable requirements. An FDB representative will contact you to schedule an



initial inspection. After the initial IHEO Authorization is issued, subsequent inspections may be unannounced.

Resources



Food and Drug Branch

- Links to the Industrial Hemp Compliance Program and all other FDB licensing programs including applicable laws and regulations, consumer complaint portal and a variety of industry resources are available on our webpage.
- Website: Scan or click QR code
- Email for IH specific questions: FDBIH@cdph.ca.gov
- Phone: (800) 495-3232

The FDB has regulatory authority over industrial hemp products outlined in California Assembly Bill 45 (AB 45), Chapter 576, Statutes of 2021, and corresponding regulations. Industrial hemp as an agricultural product is regulated by the California Department of Food and Agriculture (CDFA). Their contact information is included below.



California Department of Food and Agriculture – Industrial Hemp Program

- Information about regulating hemp as an agricultural crop
- Website: Scan or click QR Code

If you have any questions or concerns, you may reach out to FDB at FDBIH@CDPH.CA.GOV or (916) 650-6500.

Sincerely,

A handwritten signature in blue ink, appearing to be 'BY'.

Benson Yee, Chief
Food and Drug Branch

INDUSTRIAL HEMP DERIVED PRODUCTS—Frequently Asked Questions

1. WHAT PRODUCTS AM I ALLOWED TO MANUFACTURE, PACK, AND HOLD IN CALIFORNIA WITH AN INDUSTRIAL HEMP ENROLLMENT AND OVERSIGHT (IHEO) AUTHORIZATION?

- Shelf-stable food (e.g., baked goods, candy, confections, dried mixes, etc.)
- Dietary supplements taken by mouth (e.g., botanical, 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
- Inhalers, ONLY for out-of-state sales
- Raw hemp extract

2. MAY I MAKE INDUSTRIAL HEMP PRODUCTS FROM MY HOME?

No. Industrial Hemp (IH) products must be made at a suitable, commercial location.

3. 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 Compliance program only regulates products derived from industrial hemp.

4. I AM 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 facility which also manufactures cannabis products.

5. DO I NEED AN IHEO AUTHORIZATION TO SELL INDUSTRIAL HEMP PRODUCTS AT MY STORE (E.G. GROCERY STORE, MARKETS, ETC.?)

No. An IHEO is required for manufacturers of Industrial Hemp (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. All IH products sold in stores must remain unopened and in their original IH Manufacturer package.

6. I OPERATE A CAFÉ /RESTAURANT. MAY I ADD INDUSTRIAL HEMP (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 restaurant is not allowed.

INDUSTRIAL HEMP DERIVED PRODUCTS—Frequently Asked Questions

Food facility operators may supply IH products separately if they are in their original package from the IH Manufacturer.

7. WHAT IS 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.

8. 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, inhaler industrial hemp products may not be sold in California
- Hemp products must be sold in unopened original packaging

9. THE LABELS I CURRENTLY USE FOR MY INDUSTRIAL HEMP 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. Food product labels must comply with Title 21, CFR part 101-Food Labelling. 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.

INDUSTRIAL HEMP DERIVED PRODUCTS—Frequently Asked Questions

10. WHAT IS INDUSTRIAL HEMP (IH)?

“Industrial Hemp” means an agricultural product, whether growing or not, that is limited to type of the plant *Cannabis sativa* L. and 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.

11. 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).

12. WHAT IS AN “INDUSTRIAL HEMP PRODUCT”?

It is a finished product (e.g., cosmetic, food, food additive, pet food dietary supplement, beverage, or herb) that is fit for human or animal consumption and contains industrial hemp. The finished product cannot include tetrahydrocannabinol (THC) isolate as an added ingredient.

13. WHAT IS “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.

14. 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).

The Los Angeles County Department of Public Health-Environmental Health Division (DPH-EH) serves as the local enforcement agency for 85 cities within the County of Los Angeles. DPH-EH is responsible for the enforcement of the California Retail Food Code (Cal Code) as well as applicable regulations pertaining to food.

15. WHERE CAN I FIND MORE INFORMATION?

Refer to [Industrial Hemp Compliance Program - FAQs](#) on the CDPH website for additional information. You may also contact the DPH-EH Industry Engagement Program at 626-430-5320.

HEALTH AND SAFETY CODE - HSC

DIVISION 104. ENVIRONMENTAL HEALTH [106500 - 119406]

(Division 104 added by Stats. 1995, Ch. 415, Sec. 6.)

PART 5. SHERMAN FOOD, DRUG, AND COSMETIC LAWS [109875 - 111929.4]

(Part 5 added by Stats. 1995, Ch. 415, Sec. 6.)

CHAPTER 9. Industrial Hemp [111920 - 111929.4]

(Chapter 9 added by Stats. 2021, Ch. 576, Sec. 10.)

ARTICLE 7. Labeling and Advertisement [111926 - 111926.3]

(Article 7 added by Stats. 2021, Ch. 576, Sec. 10.)

111926.

(a) A manufacturer, distributor, or seller of an industrial hemp product shall follow packaging, labeling, and advertising laws, including, but not limited to, Chapter 4 (commencing with Section 110290), and federal laws incorporated or applicable in this state, including, but not limited to, Sections 110100, 110340, 110371, 110380, 110382, and 110407 and shall not violate this part.

(b) A hemp manufacturer shall not directly target advertising or marketing to children or to persons who are pregnant or breastfeeding.

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

(Added by Stats. 2021, Ch. 576, Sec. 10. (AB 45) Effective October 6, 2021.)

111926.2.

(a) An industrial hemp product that is a dietary supplement, food, or beverage shall not be distributed or sold in the state without packaging and labeling on the product that includes all of the following information:

(1) 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 that provides all of the following information:

(A) The product name.

(B) The name of the product's manufacturer, packer, or distributor, and their address and telephone number.

(C) The batch number, which matches the batch number on the product.

(D) The concentration of cannabinoids present in the product batch, including, at minimum, total THC and any marketed cannabinoids or ingredient, as required by the department in regulation.

(E) The levels within the product batch of contaminants, as required in subdivision (c) of Section 111925.2.

(2) The product expiration or best by date, if applicable.

(3) 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.

(4) A statement that products containing cannabinoids should be kept out of reach of children.

(5) The following statement, "THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY."

(b) The requirements of this section shall apply to products manufactured 90 days or more after the enactment of this section.

(Added by Stats. 2021, Ch. 576, Sec. 10. (AB 45) Effective October 6, 2021.)

111926.3.

(a) An industrial hemp product that is a cosmetic shall not be distributed or sold in the state without packaging and labeling on the product that includes all of the following information:

(1) 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 that provides all of the following information:

(A) The product name.

(B) The name of the product's manufacturer, packer, or distributor, and their address and telephone number.

(C) The batch number, which matches the batch number on the product.

(D) The concentration of cannabinoids present in the product batch, including, at minimum, total THC and any marketed cannabinoids.

(E) The levels within the product batch of contaminants, as required in subdivision (c) of Section 111925.2.

(2) The product expiration or best by date, if applicable.

(3) The following statement, "THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY."

(b) The requirements of this section shall apply to products manufactured 90 days or more after the enactment of this section.

(Added by Stats. 2021, Ch. 576, Sec. 10. (AB 45) Effective October 6, 2021.)

Assembly Bill No. 45

CHAPTER 576

An act to add and repeal Section 26013.2 of the Business and Professions Code, to amend Sections 11018.5, 100425, and 110065 of, to add Sections 110036, 110407, 110469, 110611, 111691, and 113091 to, to add Chapter 9 (commencing with Section 111920) to Part 5 of Division 104 of, and to repeal Section 111921.6 of, the Health and Safety Code, relating to industrial hemp, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor October 6, 2021. Filed with Secretary of State October 6, 2021.]

LEGISLATIVE COUNSEL'S DIGEST

AB 45, Aguiar-Curry. Industrial hemp products.

(1) Existing law, the Sherman Food, Drug, and Cosmetic Law, prohibits the manufacture, sale, delivery, holding, or offer for sale of adulterated foods, beverages, or cosmetics. Existing law prescribes when a food or beverage is adulterated, including if it bears or contains any poisonous or deleterious substance that may render it injurious to the health of a person or other animal that may consume it. Existing law prescribes when a cosmetic is adulterated, including when it bears or contains a poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling or advertisement of the cosmetic, under customary or usual conditions.

The Sherman Food, Drug, and Cosmetic Law, among other things, regulates the labeling of food, beverages, and cosmetics and makes it a crime to distribute in commerce any food, drug, device, or cosmetic if its packaging or labeling does not conform to these provisions. Existing law also makes it unlawful for a person to disseminate any false advertisement of any food, drug, device, or cosmetic. Violation of the Sherman Food, Drug, and Cosmetic Law is a misdemeanor.

Existing law requires a person who manufactures pet food in California to obtain a license from the State Department of Public Health. Existing law also prohibits the manufacture, sale, or delivery of a pet food ingredient or processed pet food that is adulterated and defines "adulterated" for this purpose.

This bill would require a manufacturer of dietary supplements and food that includes industrial hemp to register with the State Department of Public Health and to be able to demonstrate that all parts of the plant used come from a state or country that has an established and approved industrial hemp program, as defined, that inspects or regulates hemp under a food safety program or equivalent criteria to ensure safety for human or animal consumption and that the industrial hemp cultivator or grower is in good

standing and compliance with the governing laws of the state or country of origin.

This bill would state that a dietary supplement, food, beverage, cosmetic, or pet food is not adulterated by the inclusion of industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp if those substances meet specified requirements, and would prohibit restrictions on the sale of dietary supplements, food, beverages, cosmetics, or pet food that include industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp based solely on the inclusion of those substances.

The bill would also prohibit a manufacturer, distributor, or seller of an industrial hemp product from including on the label, or publishing or disseminating in advertising or marketing, a health-related statement, as defined, that is untrue in any particular manner as to the effects on health of consuming products containing industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp. By creating a new crime, this bill would impose a state-mandated local program.

This bill would create a registration process, under the State Department of Public Health, for hemp manufacturers who produce specified products that include industrial hemp or who produce raw hemp extract, as defined, including requirements for testing and labeling on products. The bill would define “THC” for these purposes and would authorize the department to include or exclude comparable compounds from the definition of THC for purposes of regulation as industrial hemp based on the compound’s intoxicating effect, or lack thereof. The bill would authorize the department to collect specified fees, which would be used, upon appropriation, to implement the program. By creating a new crime, this bill would impose a state-mandated local program.

This bill, upon the enactment of a tax on inhalable products, would require the department to regulate those products, as specified, or enter into a memorandum of understanding or other interagency agreement with another state agency to do so. Until that tax is enacted, the bill would prohibit the manufacture and sale of inhalable products, except for the sole purpose of sale out of state.

This bill would require the Department of Cannabis Control to prepare a report to the Governor and the Legislature outlining the steps necessary for the incorporation of hemp products into the cannabis supply chain, as specified. The bill would also require the Department of Food and Agriculture and the State Department of Public Health, in consultation with the Department of Cannabis Control, if necessary, to develop a process to share license, registration, cultivar, and enforcement information to facilitate compliance and enforcement against unlicensed manufacturers or the sale of hemp that does not meet specified requirements. The bill would make communications shared between these agencies and local law enforcement for this purpose exempt from the California Public Records Act.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public

officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

Existing law provides that, except as otherwise provided by statute, all relevant evidence is admissible. The California Constitution provides for the Right to Truth-in-Evidence, which requires a $\frac{2}{3}$ vote of the Legislature to exclude any relevant evidence from any criminal proceeding, as specified.

This bill would make communications shared between agencies pursuant to the above provisions official information, which may be privileged and made inadmissible in an action or proceeding, thereby requiring a $\frac{2}{3}$ vote.

(2) Existing law, the Control, Regulate and Tax Adult Use of Marijuana Act (AUMA), added by Proposition 64 at the November 8, 2016, statewide general election, regulates the cultivation, distribution, transport, storage, manufacturing, testing, processing, sale, and use of marijuana for nonmedical purposes by people 21 years of age and older. The existing Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), among other things, consolidates the licensure and regulation of commercial medicinal and adult-use cannabis activities. Existing law, for purposes of commercial cannabis regulation, defines “cannabis” as derivatives of the cannabis plant, not including industrial hemp. Existing law defines industrial hemp, for this purpose, as cannabis plants having no more than 0.3% tetrahydrocannabinol (THC) contained in the dried flowering tops, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin produced therefrom. Industrial hemp is exempt from the provisions of MAUCRSA.

AUMA authorizes the Legislature to amend the act to further the purposes and intent of the act with a $\frac{2}{3}$ vote of the membership of both houses of the Legislature, except as provided.

This bill would amend AUMA by changing the definition of “industrial hemp” to include cannabis plants 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% on a dry weight basis.

(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

(4) This bill would declare that it is to take effect immediately as an urgency statute.

The people of the State of California do enact as follows:

SECTION 1. Section 26013.2 is added to the Business and Professions Code, to read:

26013.2. (a) On or before July 1, 2022, the department shall prepare a report to the Governor and the Legislature outlining the steps necessary to allow for the incorporation of hemp cannabinoids into the cannabis supply chain. The report shall include, but not be limited to, the incorporation of hemp cannabinoids into manufactured cannabis products and the sale of hemp products at cannabis retailers.

(b) (1) The report to be submitted pursuant to subdivision (a) shall be submitted in compliance with Section 9795 of the Government Code.

(2) Pursuant to Section 10231.5 of the Government Code, this section is repealed on January 1, 2025.

(c) It is the intent of the Legislature to consider, in light of the report submitted pursuant to subdivision (a), whether and how to take legislative action concerning the incorporation of hemp into the cannabis supply chain no later than the 2023–24 legislative session.

SEC. 2. Section 11018.5 of the Health and Safety Code is amended to read:

11018.5. (a) “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.

(b) Industrial hemp shall not be subject to the provisions of this division or of Division 10 (commencing with Section 26000) of the Business and Professions Code, but instead shall be regulated by the Department of Food and Agriculture in accordance with the provisions of Division 24 (commencing with Section 81000) of the Food and Agricultural Code, inclusive.

SEC. 3. Section 100425 of the Health and Safety Code is amended to read:

100425. (a) The fees or charges for the issuance or renewal of any permit, license, registration, or document pursuant to Sections 1639.5, 1676, 1677, 2805, 11839.25, 103625, 106700, 106890, 106925, 107080, 107090, 107095, 107160, 110210, 110470, 110471, 111130, 111140, 111630, 111923.5, 111923.6, 112405, 112510, 112750, 112755, 113060, 113065, 114065, 115035, 115065, 115080, 117923, 117995, 118045, 118210, and 118245 shall be adjusted annually by the percentage change printed in the Budget Act for those items appropriating funds to the state department. After the first annual adjustment of fees or charges pursuant to this section, the fees or charges subject to subsequent adjustment shall be the fees or charges for the prior calendar year. The percentage change shall be determined by the Department of Finance, and shall include at least the total

percentage change in salaries and operating expenses of the state department. However, the total increase in amounts collected under this section shall not exceed the total increased cost of the program or service provided.

(b) The state department shall publish annually a list of the actual numerical fee charges for each permit, license, certification, or registration governed by this section.

(c) This adjustment of fees and publication of the fee list shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(d) With respect to the fees or charges pursuant to Section 103625, the actual dollar fee or charge shall be rounded to the nearest whole dollar.

SEC. 4. Section 110036 is added to the Health and Safety Code, to read:

110036. All laws and regulations pertaining to industrial hemp products shall remain in effect until the adoption of regulations pursuant to the federal law that authorizes industrial hemp products. At that time, the department shall adopt new regulations either as necessary pursuant to the federal law or deemed necessary to protect consumers.

SEC. 5. Section 110065 of the Health and Safety Code is amended to read:

110065. (a) The department may adopt any regulations that it determines are necessary for the enforcement of this part. The regulations shall be adopted by the department in the manner prescribed by Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The department shall, insofar as practicable, make these regulations conform with those adopted under the federal act or by the United States Department of Agriculture or by the Internal Revenue Service of the United States Treasury Department.

(b) (1) The department may adopt emergency regulations to implement this division.

(2) The department may readopt any emergency regulation authorized by this section that is the same as, or substantially equivalent to, an emergency regulation previously adopted as authorized by this section. That readoption shall be limited to one time for each regulation.

(3) Notwithstanding any other law, the initial adoption of emergency regulations and the readoption of emergency regulations authorized by this section shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations and the readopted emergency regulations authorized by this section shall be each submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect for no more than 180 days, by which time final regulations shall be adopted.

(c) Initial regulations regarding industrial hemp shall be exempt from the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), except that the department shall post the proposed regulations on its internet website for public comment for 30 days. The comments received shall be considered

by the department and the final adopted regulations shall be filed with the Office of Administrative Law for publication in the California Code of Regulations. This exemption does not apply to regulations adopted pursuant to Section 111921.3 or 111922.

SEC. 6. Section 110407 is added to the Health and Safety Code, to read:

110407. (a) A manufacturer, distributor, or seller of an industrial hemp product shall not include on the label of the product, or publish or disseminate in advertising or marketing, any health-related statement that is untrue in any particular manner as to the health effects of consuming products containing industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp in violation of this part.

(b) For purposes of this section, “health-related statement” means a statement related to health, and includes a statement of a curative or therapeutic nature that, expressly or impliedly, suggests a relationship between the consumption of industrial hemp or industrial hemp products and health benefits or effects on health. However, “health-related statement” does not include statements required to be made pursuant to federal Food and Drug Administration regulations for active ingredients in prescription drugs, nonprescription over-the-counter drugs containing inactive ingredients, or structure-function claims allowed for dietary supplements made in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 343(r)(6)).

SEC. 7. Section 110469 is added to the Health and Safety Code, to read:

110469. (a) A wholesale food manufacturing facility that manufactures products that contain industrial hemp shall be registered in accordance with Section 110460 and shall comply with good manufacturing practices as defined in Section 110105 and as determined by the department in regulation.

(b) Industrial hemp shall not be used in dietary supplements or food products unless the manufacturer demonstrates both of the following:

(1) All parts of the hemp plant used in dietary supplements or 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 to ensure safety for human or animal consumption.

(2) The industrial hemp cultivator or grower is in good standing and in compliance with the governing laws of the state or country of origin.

SEC. 8. Section 110611 is added to the Health and Safety Code, to read:

110611. Except as provided in Section 25621.5 of the Business and Professions Code, a dietary supplement, food, or beverage is not adulterated by the inclusion of industrial hemp, as defined in Section 11018.5, as long as the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in Chapter 9 (commencing with Section 111920). The sale of a dietary supplement, food, or beverage that includes industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp shall not be restricted or prohibited based solely on the inclusion of industrial hemp provided that the cannabinoids, extracts, or derivatives from industrial

hemp meet the requirements of Chapter 9 (commencing with Section 111920).

SEC. 9. Section 111691 is added to the Health and Safety Code, to read:

111691. A cosmetic is not adulterated because it includes industrial hemp, as defined in Section 11018.5, as long as the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in Chapter 9 (commencing with Section 111920). The sale of a cosmetic that includes industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp shall not be restricted or prohibited based solely on the inclusion of industrial hemp provided that the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in Chapter 9 (commencing with Section 111920).

SEC. 10. Chapter 9 (commencing with Section 111920) is added to Part 5 of Division 104 of the Health and Safety Code, to read:

CHAPTER 9. INDUSTRIAL HEMP

Article 1. Definitions

111920. For purposes of this chapter, the following definitions apply:

- (a) “Department” means the State Department of Public Health.
- (b) “Established and approved industrial hemp program” means a program that meets any applicable requirements set forth in federal law regarding the lawful and safe cultivation of industrial hemp.
- (c) “Final form product” is a product intended for consumer use to be sold at a retail premise.
- (d) “Hemp manufacturer” means either of the following:
 - (1) A processor extracting cannabinoids from hemp biomass.
 - (2) A processor purchasing industrial hemp raw extract for the purpose of manufacturing a final form product.
- (e) “Independent testing laboratory” means a laboratory that meets all of the following requirements:
 - (1) Does not have a direct or indirect interest in the entity for which testing is being done.
 - (2) 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.
 - (3) Does not have a license issued pursuant to Division 10 (commencing with Section 26000) of the Business and Professions Code, other than as a licensed testing laboratory.
 - (4) Is either of the following:
 - (A) A testing laboratory licensed pursuant to Division 10 (commencing with Section 26000) of the Business and Professions Code, if the licensed testing lab has notified the Department of Cannabis Control.

(B) Accredited by a third-party accrediting body as a competent testing laboratory pursuant to ISO/IEC 17025 of the International Organization for Standardization.

(f) “Industrial hemp” has the same meaning as in Section 11018.5. “Industrial hemp” does not include cannabinoids produced through chemical synthesis.

(g) (1) “Industrial hemp product” or “hemp product” means a finished product containing industrial hemp that meets all of the following conditions:

(A) Is a cosmetic, food, food additive, dietary supplement, or herb.

(B) (i) Is for human or animal consumption.

(ii) “Animal” does not include livestock or a food animal as defined in Section 4825.1 of the Business and Professions Code.

(iii) Does not include THC isolate as an ingredient.

(2) “Industrial hemp product” does not include industrial hemp or a hemp product that has been approved by the United States Food and Drug Administration or a hemp product that includes industrial hemp or hemp that has received Generally Recognized As Safe (GRAS) designation. For purposes of nonfood applications, “industrial hemp product” does not include a hemp product that contains derivatives, substances, or compounds derived from the seed of industrial hemp.

(h) (1) “Manufacture” or “manufacturing” means to compound, blend, extract, infuse, or otherwise make or prepare an industrial hemp product.

(2) “Manufacturing” includes all aspects of the extraction process, infusion process, and packaging and labeling processes, including processing, preparing, holding, and storing of industrial hemp products.

(3) “Manufacturing” also includes processing, preparing, holding, or storing hemp components and ingredients.

(4) “Manufacturing” does not include planting, growing, harvesting, drying, curing, grading, or trimming a plant or part of a plant.

(i) “Raw extract” or “industrial hemp raw extract” means extract not intended for consumer use and that contains a THC concentration of not more than an amount determined by the department in regulation.

(j) “Raw hemp product” means a product that is derived from industrial hemp that is intended to be included in a food, beverage, dietary supplement, or cosmetic.

(k) “Retail” has the same meaning as in Section 113895.

(l) “THC” or “THC or comparable cannabinoid” means any of the following:

(1) Tetrahydrocannabinolic acid.

(2) Any tetrahydrocannabinol, including, but not limited to, Delta-8-tetrahydrocannabinol, Delta-9-tetrahydrocannabinol, and Delta-10-tetrahydrocannabinol, however derived, except that the department may exclude one or more isomers of tetrahydrocannabinol from this definition under subdivision (a) of Section 111921.7.

(3) Any other cannabinoid, except cannabidiol, that the department determines, under subdivision (b) of Section 111921.7, to cause intoxication.

(m) “THCA” means tetrahydrocannabinolic acid, CAS number 23978-85-0.

(n) “Total THC” means the sum of THC and THCA. Total THC shall be calculated using the following equation: total THC concentration (mg/g) +/- the measurement of uncertainty, as defined by the United States Department of Agriculture.

Article 2. General Provisions

111921. An industrial hemp product shall not be distributed or sold in the state except in conformity with all applicable state laws and regulations, including this chapter and any regulations promulgated thereunder, and with documentation that includes both of the following:

(a) A certificate of analysis from an independent testing laboratory that confirms both of the following:

(1) 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.

(2) The industrial hemp product was tested for any hemp derivatives identified on the product label or in associated advertising in accordance with Section 111926.2.

(b) 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.

111921.3. The department may adopt regulations imposing an age requirement for the sale of certain industrial hemp products upon a finding of a threat to public health.

111921.5. (a) Unless explicitly approved by the federal Food and Drug Administration, industrial hemp shall not be included in products in any of the following categories:

- (1) Medical devices.
- (2) Prescription drugs.
- (3) A product containing nicotine or tobacco.
- (4) An alcoholic beverage.

(b) The department may prohibit the inclusion of industrial hemp in other products when it poses a risk to human or animal health through regulation.

(c) Cannabis and cannabis products are not subject to this section.

111921.6. (a) Manufacture or sale of inhalable products is prohibited. Manufacture of inhalable products for the sole purpose of sale in other states is not prohibited.

(b) This section shall become inoperative and is repealed on the effective date of a measure passed by the Legislature that establishes a tax on inhalable

products and states the intent of the Legislature to fulfill the requirements of this section.

111921.7. (a) The department may exclude from the definition of “THC or Comparable Cannabinoid” one or more isomers of tetrahydrocannabinol if the department determines, consistent with subdivisions (c) and (d), that the tetrahydrocannabinol isomer does not cause intoxication.

(b) The department may include any other cannabinoid, in addition to those expressly listed in subdivision (l) of Section 111920, in the definition of “THC” if the department determines, consistent with subdivisions (c) and (d), that the cannabinoid causes intoxication.

(c) In making a determination under subdivision (a) or (b), the department shall consider scientific evidence concerning the pharmacological effects of the tetrahydrocannabinol or other cannabinoid in humans or other animals, if that evidence is available.

(d) Any initial determination under subdivision (a) or (b) shall not be subject to the administrative rulemaking requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, but the department, without being subject to those administrative rulemaking requirements, shall establish a process to receive public comment regarding those determinations, and shall publicly post all determinations on its internet website. However, any initial determination shall be confirmed subject to the administrative rulemaking requirements no later than 18 months following the date of the initial determination.

Article 3. Manufacture

111922. (a) The department, through regulation, may determine maximum serving sizes for hemp-derived cannabinoids, hemp extract, and products derived therefrom, active cannabinoid concentration per serving size, the number of servings per container, and any other requirements for foods and beverages.

(b) Food and beverages shall be prepackaged and shelf stable.

111922.3. (a) A hemp manufacturer who produces raw extract that will only be used for dietary supplements, foods, beverages, and cosmetics, or a hemp manufacturer who produces industrial hemp products shall comply with this chapter and, to the extent applicable, this part.

(b) A hemp manufacturer who produces processed pet food products shall comply with this chapter and Chapter 10 (commencing with Section 113025) of Part 6 and shall follow good manufacturing practices pursuant to those provisions.

Article 4. Registration and Fees

111923. The Industrial Hemp Enrollment and Oversight Fund is hereby established in the State Treasury. All money received by the department pursuant to Section 111923.5 shall be deposited into this fund and shall be

expended by the department, upon appropriation by the Legislature, to carry out and implement this chapter. Moneys in this fund shall not be redirected for any other purpose.

111923.3. (a) (1) A hemp manufacturer who produces an industrial hemp product that is a food or beverage shall register with the department pursuant to Article 2 (commencing with Section 110460) of Chapter 5.

(2) Sections 110473 and 110474 shall not apply to dietary supplements and food products that include industrial hemp.

(b) Notwithstanding the voluntary nature of registration provided in Section 111795, a hemp manufacturer who produces an industrial hemp product that is a cosmetic shall register pursuant to Article 4 (commencing with Section 111795) of Chapter 7.

(c) A hemp manufacturer who produces an industrial hemp product that is a processed pet food shall obtain a license pursuant to Article 2 (commencing with Section 113060) of Chapter 10 of Part 6.

(d) (1) An in-state hemp manufacturer who produces raw hemp extract and who does not produce an industrial hemp product, or an out-of-state hemp manufacturer who produces raw hemp extract with the intent to import that raw hemp extract into this state, shall register with the department pursuant to Article 2 (commencing with Section 110460) of Chapter 5.

(2) Sections 110473 and 110474 shall not apply to hemp manufacturers who register pursuant to this subdivision.

(e) All hemp manufacturers shall notify the department immediately of any change of information in their application for a license of registration.

111923.5. (a) In addition to licensing and registration requirements and fees required pursuant to other applicable laws, as specified in Section 111923.3, a hemp manufacturer shall obtain an industrial hemp enrollment and oversight authorization from the department. Authorization shall be renewed annually.

(b) The department shall assess an authorization fee and renewal fee to cover the actual reasonable costs of implementing the regulatory program in this chapter. Fees may be set at different amounts for different hemp manufacturer types, including food products, cosmetic products, and pet food products, based on the differing costs associated with regulatory requirements, including, but not limited to, the nature and scope of the authorization activities and oversight, inspection, and enforcement activities.

(c) The fee shall be adjusted pursuant to Section 100425.

(d) Fees may be prorated based upon the date of the renewal or issuance of the authorization.

111923.7. A hemp manufacturer located outside the state shall reimburse the department for travel and per diem required to perform necessary onsite inspections at the facility to ensure compliance with this chapter and related activities pursuant to this part.

111923.9. A hemp manufacturer or retailer who is operating in conformance with this part and in good faith compliance with their responsibilities under this chapter may manufacture or sell industrial hemp

products or raw hemp extract without authorization for three months after the effective date of the act that added this chapter.

Article 5. Recordkeeping

111924. The department may adopt regulations for recordkeeping standards that shall apply to transporters, manufacturers, and retailers of industrial hemp product and raw extract.

Article 6. Testing Requirements

111925. (a) A hemp manufacturer shall meet all of the following testing requirements:

(1) Industrial hemp shall be tested in raw extract final form, to allow its use as an ingredient, prior to being incorporated into a product.

(2) Testing shall be completed by an independent testing laboratory.

(3) The manufacturer of the hemp extract in its final form or the final form industrial hemp product shall be able to prove total THC concentration does not exceed 0.3 percent. A manufacturer of raw extract shall be able to prove that the THC concentration meets department requirements set forth pursuant to subdivision (a) of Section 111921.

(b) The department may regulate and restrict the cap on extract and may cap the amount of total THC concentration at the product level based on the product form, volume, number of servings, ratio of cannabinoids to THC in the product, or other factors, as needed.

111925.2. A raw hemp product shall not be distributed or sold in this state without a certificate of analysis from an independent testing laboratory that confirms all of the following:

(a) The raw hemp product is the product of a batch of industrial hemp that was tested by the independent testing laboratory.

(b) A tested representative sample of the batch of industrial hemp contained a total THC concentration that did not exceed 0.3 percent on a dry-weight basis.

(c) The tested sample of the batch did not contain contaminants that are unsafe for human or animal consumption.

111925.4. (a) As of the effective date of the act adding this chapter, testing requirements for contaminant levels shall be the same as those for cannabis, as established in paragraph (2) of subdivision (d) of Section 26100 of the Business and Professions Code and regulations adopted pursuant thereto.

(b) The department may adjust the specific contaminant levels for industrial hemp by regulation to protect consumers.

111925.6. (a) A product batch may be reprocessed or remediated after failed testing, but the batch shall not be distributed or sold unless the reprocessed or remediated batch has been retested and successfully passed all the analyses required pursuant to this article.

(b) If the batch cannot be reprocessed or remediated, the product batch shall be destroyed.

(c) If a failed product batch is not reprocessed or remediated in any way, it shall not be retested. Subsequent certificates of analysis produced without reprocessing or remediation of the failed product batch shall not supersede the initial regulatory compliance testing certificate of analysis.

(d) This section shall not prevent a product batch from being retested when the certificate of analysis was obtained 12 months prior or more.

(e) (1) Reprocessing or remediation shall be an available remedy for failed product batches in all industrial hemp product categories and raw extract.

(2) Remediation is not allowed once a product enters the retail market.

(f) A failed product batch that cannot be reprocessed or remediated shall be destroyed, at the expense of the owner, on video surveillance, as authorized by the department, or under the supervision of an authorized agent of the department.

Article 7. Labeling and Advertisement

111926. (a) A manufacturer, distributor, or seller of an industrial hemp product shall follow packaging, labeling, and advertising laws, including, but not limited to, Chapter 4 (commencing with Section 110290), and federal laws incorporated or applicable in this state, including, but not limited to, Sections 110100, 110340, 110371, 110380, 110382, and 110407 and shall not violate this part.

(b) A hemp manufacturer shall not directly target advertising or marketing to children or to persons who are pregnant or breastfeeding.

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

111926.2. (a) An industrial hemp product that is a dietary supplement, food, or beverage shall not be distributed or sold in the state without packaging and labeling on the product that includes all of the following information:

(1) 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 that provides all of the following information:

(A) The product name.

(B) The name of the product's manufacturer, packer, or distributor, and their address and telephone number.

(C) The batch number, which matches the batch number on the product.

(D) The concentration of cannabinoids present in the product batch, including, at minimum, total THC and any marketed cannabinoids or ingredient, as required by the department in regulation.

(E) The levels within the product batch of contaminants, as required in subdivision (c) of Section 111925.2.

(2) The product expiration or best by date, if applicable.

(3) 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.

(4) A statement that products containing cannabinoids should be kept out of reach of children.

(5) The following statement, “THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY.”

(b) The requirements of this section shall apply to products manufactured 90 days or more after the enactment of this section.

111926.3. (a) An industrial hemp product that is a cosmetic shall not be distributed or sold in the state without packaging and labeling on the product that includes all of the following information:

(1) 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 that provides all of the following information:

(A) The product name.

(B) The name of the product’s manufacturer, packer, or distributor, and their address and telephone number.

(C) The batch number, which matches the batch number on the product.

(D) The concentration of cannabinoids present in the product batch, including, at minimum, total THC and any marketed cannabinoids.

(E) The levels within the product batch of contaminants, as required in subdivision (c) of Section 111925.2.

(2) The product expiration or best by date, if applicable.

(3) The following statement, “THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY.”

(b) The requirements of this section shall apply to products manufactured 90 days or more after the enactment of this section.

Article 8. Enforcement

111927. (a) The department shall have the seizure and embargo powers provided for in Article 3 (commencing with Section 111860) of Chapter 7 with respect to industrial hemp products and raw extract.

(b) The department shall have the ability to recall industrial hemp products or raw extract that it determines to be dangerous to the public in the manner prescribed in Section 110806.

111927.2. (a) In addition to the inspection authority provided elsewhere in this part, the department may inspect financial data, sales data, and personnel data, as needed to enforce this chapter.

(b) State, local, or law enforcement officials may review paperwork from those handling or transporting industrial hemp plant material, raw extract,

intermediary industrial hemp product, or final finished product and take samples at any point along the supply chain to test that sample for verification.

(c) Upon inspection, if the industrial hemp plant material, raw extract, intermediary industrial hemp product, or final finished product does not meet the definition of industrial hemp, the state, local, or law enforcement official shall notify the department.

(d) (1) State, local, and law enforcement officials shall immediately notify the department of an arrest made for a violation over which the department has jurisdiction that involves a person authorized pursuant to this chapter.

(2) The department shall promptly investigate whether grounds exist for suspension or revocation of the authorization or if other actions are warranted under this part.

111927.4. Violations of this chapter are subject to the fines and penalties established in Article 1 (commencing with Section 111825) of Chapter 8.

Article 9. Agency Coordination

111928. (a) The Department of Food and Agriculture and the State Department of Public Health, in consultation with the Department of Cannabis Control, if necessary, shall develop a process to share license, registration, cultivar, and enforcement information to facilitate compliance and enforcement against unlicensed manufacturers or the sale of industrial hemp that does not meet the requirements of this part.

(b) Communications shared between state agencies and local and law enforcement officials regarding license, registration, cultivar, and enforcement information of manufacturers and retailers of industrial hemp products and raw extract shall not be subject to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code) and shall be considered “official information” pursuant to Section 1040 of the Evidence Code.

Article 10. Inhalable Products

111929. Inhalable products shall not be sold to consumers under 21 years of age.

111929.1. A hemp manufacturer who produces inhalable products shall comply with this chapter and, to the extent applicable, with the provisions of this part.

111929.2. An inhalable product shall not contain any of the following:

- (a) Flavorings other than natural terpenes.
- (b) Polyethylene glycol (PEG).
- (c) Vitamin E acetate.
- (d) Medium chain triglycerides (MCT oil).
- (e) Squalene or squalane.

(f) Any other substance that the department finds to be a danger to public health.

111929.3. The department may enter into a memorandum of understanding or other interagency agreement with another state agency to administer and enforce provisions of this chapter as they relate to inhalable products, including, but not limited to, testing provisions, advertising and labeling provisions, and the provisions relating to the manufacture and sale of inhalable products.

111929.4. This article shall become operative upon the effective date of a measure passed by the Legislature that establishes a tax on inhalable products and states the intent of the Legislature to fulfill the requirements of this section.

SEC. 11. Section 113091 is added to the Health and Safety Code, to read:

113091. A processed pet food is not adulterated because it includes industrial hemp, as defined in Section 11018.5, or cannabinoids, extracts, or derivatives from industrial hemp, if the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in Chapter 9 (commencing with Section 111920) of Part 5. The sale of processed pet food that includes industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp shall not be restricted or prohibited based solely on the inclusion of industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp, if the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in Chapter 9 (commencing with Section 111920) of Part 5.

SEC. 12. The Legislature finds and declares that Section 10 of this act, which adds Section 111928 to the Health and Safety Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

The Legislature finds that the information to be shared is proprietary business information.

SEC. 13. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 14. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to protect a rapidly expanding industry relating to derivatives from industrial hemp in California and to reduce inconsistency in implementation of state and federal law, it is necessary that this bill take effect immediately.

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