CALIFORNIA CODE OF REGULATIONS TITLE 17. PUBLIC HEALTH

DIVISION 1. STATE DEPARTMENT OF HEALTH SERVICES

CHAPTER 5. SANITATION (ENVIRONMENTAL)

SUBCHAPTER 2.6 INDUSTRIAL HEMP

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PROPOSED REGULATION TEXT

<u>ADOPT</u>

SUBCHAPTER 2.6 INDUSTRIAL HEMP

Article 4. Registration, License, Authorization, and Fees for Industrial Hemp Manufacturers

Section 23200. Industrial Hemp Manufacturer Requirements.

- (a) Every person in this state who manufactures only industrial hemp extract, and every person outside this state who manufactures industrial hemp extract for import into this state, must:
 - (1) Obtain a processed food registration and pay fees pursuant to section 23205(a),
 - (2) Obtain industrial hemp enrollment and oversight authorization pursuant to the requirements in sections 23210 and 23215, and
 - (3) Pay industrial hemp enrollment and oversight authorization fees pursuant to section 23230(b) for extract.
- (b) Every person in this state who is an industrial hemp manufacturer of human food, including but not limited to food, beverages, dietary supplements, and acidified and/or low-acid food, must:
 - (1) Obtain a processed food registration for food, beverage, or dietary supplements, or obtain a cannery license for acidified and/or low-acid food, and pay fees pursuant to section 23205(b),
 - (2) Obtain industrial hemp enrollment and oversight authorization pursuant to the requirements in sections 23210 and 23220,
 - (3) Pay industrial hemp enrollment and oversight authorization fees pursuant to section 23230(c) for human food, and
 - (4) Only use an extractor registered under section 23200(a).

- (c) Every person in this state who is an industrial hemp manufacturer of processed pet food must:
 - (1) Obtain a processed pet food license and pay fees pursuant to section 23205(c),
 - (2) Obtain industrial hemp enrollment and oversight authorization pursuant to the requirements in sections 23210 and 23220,
 - (3) Pay industrial hemp enrollment and oversight authorization fees pursuant to section 23230(c) for processed pet food, and
 - (4) Only use an extractor registered under section 23200(a).
- (d) Every person in this state who is an industrial hemp manufacturer of cosmetics must:
 - (1) Obtain a cosmetics registration and pay fees pursuant to section 23205(d),
 - (2) Obtain an industrial hemp enrollment and oversight authorization pursuant to the requirements in sections 23210 and 23220,
 - (3) Pay industrial hemp enrollment and oversight authorization fees pursuant to section 23230(c) for cosmetics, and
 - (4) Only use an extractor registered under section 23200(a).
- (e) Every person in this state who is an industrial hemp manufacturer of inhalable products must:
 - (1) Obtain industrial hemp enrollment and oversight authorization pursuant to the requirements in sections 23210 and 23225.
 - (2) Pay industrial hemp enrollment and oversight authorization fees pursuant to section 23230(c) for inhalable products, and
 - (3) Only use an extractor registered under section 23200(a).

Note: Authority cited: Sections 100275, 110065, 131000, 131050, 131051, 131052, and 131200, Health and Safety Code. Reference: Sections 111923.3 and 111923.5, Health and Safety Code.

<u>Section 23205.</u> Requirements for Registration or License for Extract, Human Food, <u>Processed Pet Food, and Cosmetics Industrial Hemp Manufacturers.</u>

- (a) Extract. Every person in this state who manufactures only industrial hemp extract, and every person outside this state who manufactures industrial hemp extract for import into this state, must obtain and maintain a valid processed food registration with the department, renew annually, and pay applicable nonrefundable fees pursuant to Health and Safety Code, Division 104, Part 5, Chapter 5, Article 2 (commencing with section 110460).
- (b) Human food. Every person in this state who manufactures industrial hemp human food must, according to food type, do as follows:
 - (1) For food, beverage, or dietary supplements:
 - (A) Obtain and maintain a valid processed food registration with the department, renew annually, and pay applicable nonrefundable fees pursuant to Health and Safety Code, Division 104, Part 5, Chapter 5, Article 2 (commencing with section 110460), and
 - (B) Pay all required additional fees pursuant to Health and Safety Code, Division 104, Part 5 and Part 6.
 - (2) For acidified and/or low-acid food:
 - (A) Obtain and maintain a valid cannery license with the department, renew annually, and pay applicable nonrefundable fees pursuant to Health and Safety Code, Division 104, Part 6, Chapter 8, Article 4 (commencing with section 112750), and
 - (B) Pay all required additional payments pursuant to Health and Safety Code, Division 104, Part 5 and Part 6.
- (c) Processed pet food. Every person in this state who manufactures industrial hemp processed pet food must obtain and maintain a valid processed pet food license with the department, renew annually, and pay applicable nonrefundable fees pursuant to Health and Safety Code, Division 104, Part 6, Chapter 10 (commencing with section 113025).
- (d) Cosmetics. Every person in this state who manufactures industrial hemp cosmetics must obtain and maintain a valid cosmetics registration with the department, renew Page 4 of 12

<u>annually, and pay applicable nonrefundable fees pursuant to Health and Safety</u>

<u>Code, Division 104, Part 5, Chapter 7, Article 4 (commencing with section 111795).</u>

Note: Authority cited: Sections 100275, 110065, 110466, 110471, 110485, 112765, 112770, 131000, 131050, 131051, 131052, and 131200, Health and Safety Code. Reference: Sections 111922.3 and 111923.3, Health and Safety Code.

Section 23210. Requirements for Industrial Hemp Enrollment and Oversight Authorization.

- (a) An industrial hemp enrollment and oversight authorization is the following:
 - (1) The registration or license pursuant to section 23205 is denied, expired, suspended, or revoked.
 - (2) The industrial hemp enrollment and oversight authorization is revoked or suspended.
- (b) An industrial hemp enrollment and oversight authorization application and industrial hemp enrollment and oversight authorization fee is required for each place of manufacturing, which must be in a separate commercial location.
- (c) An applicant must immediately notify the department of any changes to the industrial hemp enrollment and oversight authorization application and must:
 - (1) Submit applications pursuant to this article, and
 - (2) Pay full or pro-rated fees pursuant to this article.
- (d) An applicant must provide supporting documentation to verify information in the application.
- (e) An industrial hemp enrollment and oversight authorization is not transferable to, which includes but is not limited to, an entity, owner, address, or place.
- (f) New industrial hemp enrollment and oversight authorization.
 - (1) A new industrial hemp enrollment and oversight authorization application must be accompanied by full payment payable to the department of a nonrefundable industrial hemp enrollment and oversight authorization fee pursuant to section 23230.

- (2) An initial industrial hemp enrollment and oversight authorization is valid for one year from the date of approval subject to subpart (a) of this section.
- (g) Renewal industrial hemp enrollment and oversight authorization.
 - (1) A renewal industrial hemp enrollment and oversight authorization application must be accompanied by full payment payable to the department of a nonrefundable industrial hemp enrollment and oversight authorization fee pursuant to section 23230 and must be submitted annually prior to the expiration date.
 - (2) A renewal industrial hemp enrollment and oversight authorization is valid for one year from the prior date of issue of the industrial hemp enrollment and oversight authorization subject to subpart (a) of this section.

Note: Authority cited: Sections 100275, 110065, 131000, 131050, 131051, 131052, and 131200, Health and Safety Code. Reference: Section 111923.5, Health and Safety Code.

Section 23215. Industrial Hemp Enrollment and Oversight Authorization Application for Industrial Hemp Extract Manufacturers.

New or renewal applicants for industrial hemp extract manufacturers must provide all information on the application and must include supporting documentation as follows:

- (a) The processed food registration application and fees pursuant to Health and Safety Code, Division 104, Part 5, Chapter 5, Article 2 (commencing with section 110460), and
- (b) The industrial hemp enrollment and oversight authorization application that correctly provides all of the following for out-of-state and in-state industrial hemp extract manufacturers:
 - (1) The state or tribal agency that registered or licensed the manufacturer, the registration/license information, and any additional applicable licenses or certifications held by the manufacturer.

- (2) All current and proposed industrial hemp sources, including business information of industrial hemp source, location of industrial hemp source, approver information, and registration/license information.
- (3) Information for all products that contain industrial hemp that are manufactured at the facility.
- (4) Product labels.
- (5) An attestation that testing was completed by an independent testing laboratory.
- (6) Extraction methods.
- (7) Industrial hemp enrollment and oversight authorization fees.
- (8) Owner's signature under penalty of perjury for acknowledgments.
- (9) Owner's printed name, title of owner, and date.
- (10) An owner may authorize representatives and/or signatories to act on behalf of the firm. The representative information must include all of the following: names, telephone numbers, and email addresses.

Note: Authority cited: Sections 100275, 110065, 131000, 131050, 131051, 131052, and 131200, Health and Safety Code. Reference: Sections 111921, 111923.3, and 111923.5, Health and Safety Code.

Section 23220. Industrial Hemp Enrollment and Oversight Authorization Application for Industrial Hemp Human Food, Processed Pet Food, and Cosmetics Manufacturers.

New or renewal applicants for industrial hemp human food, processed pet food, or cosmetics manufacturers must provide all information on the application and must include supporting documentation as follows:

(a) The processed food registration application and fees pursuant to Health and Safety Code, Division 104, Part 5, Chapter 5, Article 2 (commencing with section 110460) for food, beverage, and dietary supplements; the cannery license application and fees pursuant to Health and Safety Code, Division 104, Part 6, Chapter 8, Article 4 (commencing with section 112750) for acidified and/or low-acid food; the processed pet food license application and fees pursuant to Health and Safety Code, Division 104, Part 6, Chapter 10 (commencing with section 113025) for processed pet food;

or the cosmetics registration application and fees pursuant to Health and Safety Code, Division 104, Part 5, Chapter 7, Article 4 (commencing with section 111795) for cosmetics; and

- (b) The industrial hemp enrollment and oversight authorization application that correctly provides all of the following:
 - (1) Information for all products that contain industrial hemp that are manufactured at the facility.
 - (2) Product labels.
 - (3) An attestation that testing was completed by an independent testing laboratory.
 - (4) All current and proposed industrial hemp sources, including business information of industrial hemp source, which must be an extractor registered under section 23200(a), and registration/license information.
 - (5) Industrial hemp enrollment and oversight authorization fees.
 - (6) Owner's signature under penalty of perjury for acknowledgments.
 - (7) Owner's printed name, title of owner, and date.
 - (8) An owner may authorize representatives and/or signatories to act on behalf of the firm. The representative information must include all of the following: names, telephone numbers, and email addresses.

Note: Authority cited: Sections 100275, 110065, 131000, 131050, 131051, 131052, and 131200, Health and Safety Code. Reference: Sections 110469, 111921, 111923.3, and 111923.5, Health and Safety Code.

Section 23225. Industrial Hemp Enrollment and Oversight Authorization Application for Industrial Hemp Inhalable Product Manufacturers.

New or renewal applicants for industrial hemp inhalable product manufacturers must provide all information on the application and must include supporting documentation as follows:

- (a) Type of applicant.
- (b) Previous address (if applicable).
- (c) Industrial hemp enrollment and oversight authorization number (if not new).

- (d) Name of firm.
- (e) Firm name doing business as.
- (f) Facility address.
- (g) Mailing address (if different or P.O. Box number).
- (h) Country (if other than United States).
- (i) Website (URL) (if applicable).
- (i) Type of ownership.
- (k) Owner's name or corporate name (if applicable)
- (I) State of incorporation or state of tax filing.
- (m) Owners' and officers' and board members' names and titles.
- (n) All current and proposed industrial hemp sources, including business information of industrial hemp source, which must be an extractor registered under section
 23200(a), and registration/license information.
- (o) Information for all products that contain industrial hemp that are manufactured at the facility.
- (p) Product labels.
- (q) An attestation that testing was completed by an independent testing laboratory.
- (r) Industrial hemp enrollment and oversight authorization fees.
- (s) Owner's signature under penalty of perjury for acknowledgements.
- (t) Owner's printed name, title of owner, and date.
- (u) An owner may authorize representatives and/or signatories to act on behalf of the firm. The representative information must include all of the following: names, telephone numbers, and email addresses.

Note: Authority cited: Sections 100275, 110065, 131000, 131050, 131051, 131052, and 131200, Health and Safety Code. Reference: Sections 111921 and 111923.5, Health and Safety Code.

Section 23230. Fees for the Industrial Hemp Enrollment and Oversight Authorization.

All industrial hemp manufacturers must pay industrial hemp enrollment and oversight authorization fees as follows:

(a) Calculating gross annual revenue.

The applicant must calculate gross annual revenue for the product category in subpart (b) and (c) for which industrial hemp enrollment and oversight authorization is sought. Gross annual revenue is based on the annual gross sales and revenue from manufacturing products containing industrial hemp for the 12 months preceding the date of the industrial hemp enrollment and oversight authorization application.

- (1) If a new applicant does not have prior sales and revenue, the new applicant must base gross annual revenue upon expected sales and revenue during the 12 months following the date of the industrial hemp enrollment and oversight authorization application.
- (2) For a manufacturer that sells or transfers products containing industrial hemp in a non-arm's length transaction, the gross annual revenue for such transactions must be based on the product's fair market value if it were to be sold in an arm's length transaction at wholesale.
- (3) For purposes of this section, an "arm's length transaction" means a sale entered into in good faith and for valuable consideration that reflects the fair market value in the open market between two informed and willing parties, neither under any compulsion to participate in the transaction.
- (b) Industrial hemp enrollment and oversight authorization fees for industrial hemp manufacturers of extract.

The industrial hemp enrollment and oversight authorization fee for a new or renewal authorization is in the charts below and is based on gross annual revenue as described in subpart (a).

INDUSTRIAL HEMP MANUFACTURERS OF EXTRACT

<u>Tier</u>	Gross Annual Revenue	<u>Extract</u>	
<u>1</u>	Less than or equal to \$100,000	<u>\$2,750</u>	

<u>2</u>	\$100,001 to \$500,000	<u>\$3,500</u>		
<u>3</u>	\$500,001 to \$1,500,000	<u>\$5,000</u>		
<u>4</u>	\$1,500,001 to \$3,000,000	<u>\$7,000</u>		
<u>5</u>	\$3,000,001 to \$5,000,000	<u>\$9,500</u>		
<u>6</u>	\$5,000,001 to \$10,000,000	<u>\$13,500</u>		
<u>7</u>	\$10,000,001 to \$20,000,000	<u>\$18,500</u>		
<u>8</u>	\$20,000,001 to \$30,000,000	<u>\$24,000</u>		
<u>9</u>	\$30,000,001 to 50,000,000	\$32,000		
<u>10</u>	More than \$50,000,000	<u>\$42,000</u>		

(c) Industrial hemp enrollment and oversight authorization fees for industrial hemp manufacturers of human food, processed pet food, cosmetics, and inhalable products.

The industrial hemp enrollment and oversight authorization fee for a new or renewal authorization is indicated in the charts below and is based on gross annual revenue as described in subpart (a).

INDUSTRIAL HEMP MANUFACTURERS OF HUMAN FOOD, PROCESSED PET FOOD, COSEMETICS, AND INHALABLE PRODUCTS

<u>Tier</u>	Gross Annual Revenue	<u>Human</u> <u>Food</u>	Processed Pet Food	Cosmetics	<u>Inhalable</u> <u>Product</u>
<u>1</u>	Less than or equal to \$100,000	<u>\$1,900</u>	<u>\$1,300</u>	<u>\$1,600</u>	<u>\$1,700</u>
<u>2</u>	\$100,001 to \$500,000	<u>\$2,800</u>	<u>\$2,000</u>	<u>\$2,400</u>	<u>\$2,600</u>
<u>3</u>	\$500,001 to \$1,500,000	<u>\$3,700</u>	<u>\$2,500</u>	<u>\$3,000</u>	<u>\$3,300</u>
<u>4</u>	\$1,500,001 to \$3,000,000	<u>\$4,700</u>	<u>\$3,000</u>	<u>\$3,600</u>	<u>\$4,000</u>
<u>5</u>	\$3,000,001 to \$5,000,000	<u>\$5,900</u>	<u>\$3,600</u>	<u>\$4,300</u>	<u>\$4,800</u>
<u>6</u>	\$5,000,001 to \$7,500,000	<u>\$7,100</u>	<u>\$4,300</u>	<u>\$5,200</u>	<u>\$5,700</u>
<u>7</u>	\$7,500,001 to \$12,500,000	<u>\$8,500</u>	<u>\$5,200</u>	\$6,200	<u>\$6,800</u>
<u>8</u>	\$12,500,001 to \$17,500,000	<u>\$9,900</u>	<u>\$6,200</u>	<u>\$7,400</u>	<u>\$8,100</u>

<u>9</u>	\$17,500,001 to \$25,000,000	\$11,500	<u>\$7,400</u>	\$8,800	<u>\$9,700</u>
<u>10</u>	More than \$25,000,000	<u>\$14,000</u>	<u>\$9,000</u>	<u>\$10,500</u>	<u>\$12,000</u>

Note: Authority cited: Sections 100275, 110065, 131000, 131050, 131051, 131052, and 131200, Health and Safety Code. Reference: Section 111923.5, Health and Safety Code.

<u>Section 23235. Withdrawal of Application for the Industrial Hemp Enrollment and Oversight Authorization.</u>

- (a) The applicant may withdraw an industrial hemp enrollment and oversight authorization application at any time prior to the department's issuance, denial, suspension, or revocation of registration/license.
- (b) Requests to withdraw an industrial hemp enrollment and oversight authorization application must be submitted to the department in writing, dated, and signed by the applicant.
- (c) Industrial hemp enrollment and oversight authorization fees for a withdrawn authorization application are nonrefundable.
- (d) The applicant may reapply and pay a new industrial hemp enrollment and oversight authorization fee following the withdrawal of an authorization application.

Note: Authority cited: Sections 100275, 110065, 131000, 131050, 131051, 131052, and 131200, Health and Safety Code. Reference: Section 111923.5, Health and Safety Code.