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## **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 2. Administration [110045 - 110243] (Chapter 2 added by Stats. 1995, Ch. 415, Sec. 6.)

ARTICLE 1. General [110045 - 110135] (Article 1 added by Stats. 1995, Ch. 415, Sec. 6.)

**110045.** The department shall administer and enforce this part.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110050. The Food Safety Fund is hereby created as a special fund in the State Treasury. All moneys collected by the department under subdivision (c) of Section 110466 and Sections 110470, 110471, 110485, 114365, 114365.6, 111130, and 113717, and under Article 7 (commencing with Section 110810) of Chapter 5, or awarded to the department pursuant to court orders or settlements for the use of food safety-related activities, shall be deposited in the fund, for use by the department, upon appropriation by the Legislature, for the purposes of providing funds necessary to carry out and implement the inspection provisions of this part relating to food, licensing, inspection, enforcement, and other provisions of Article 12 (commencing with Section 111070) of Chapter 5, relating to water, the provisions relating to education and training in the prevention of microbial contamination pursuant to Section 110485, and the registration provisions of Article 7 (commencing with Section 110810) of Chapter 5, and to carry out and implement the provisions of the California Retail Food Code (Part 7 (commencing with Section 113700) of Division 104).

(Amended by Stats. 2015, Ch. 18, Sec. 13. (SB 75) Effective June 24, 2015.)

110055. All money collected by the department under Sections 111830, 111885, and 111905 shall be deposited into the State Treasury to the credit of the General Fund.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110060. The director and authorized agents of the department shall have the powers set forth in Sections 100165 and 106500. (Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110061. For the purposes of administering this part, Part 6 (commencing with Section 111940) of Division 104 of the Health and Safety Code, Section 104559.5 of the Health and Safety Code, and Division 8.5 (commencing with Section 22950) of the Business and Professions Code, the following shall apply:

- (a) The department shall submit to the Department of Justice fingerprints and related information required by the Department of Justice for all employees, prospective employees, contractors, or subcontractors whose duties include access to criminal offender record information, as defined in Section 11075 of the Penal Code, pursuant to subdivision (u) of Section 11105 of the Penal Code. The Department of Justice shall provide a state- or federal-level response pursuant to subdivision (p) of Section 11105 of the Penal
- (b) The department Food and Drug Branch Chief, or the designee of the Food and Drug Branch Chief that is a peace officer employee, shall review the criminal history of all persons listed in this section in order to make a final determination of a person's fitness to perform duties.

(Added by Stats. 2024, Ch. 997, Sec. 16. (AB 179) Effective September 30, 2024.)

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.

(Amended by Stats. 2021, Ch. 576, Sec. 5. (AB 45) Effective October 6, 2021.)

**110070.** Whenever public health or other considerations in this state require, the department may adopt, upon its own motion, or upon the petition of any interested party, regulations that prescribe tolerances, included but not limited to zero tolerances, for poisonous or deleterious substances, food additives, pesticide chemicals, or color additives. The department may also prescribe the conditions under which a food additive or a color additive may be safely used and may grant exemptions for a food additive or color additive when it is to be used solely for investigational or experimental purposes.

A petitioner shall establish, by data submitted to the department, that a necessity exists for such regulations and that its effect will not be detrimental to the public health. If the data furnished by the petitioner is not sufficient to allow the department to determine whether such regulations should be adopted, the department may require additional data to be submitted. Failure to comply with this requirement shall be sufficient grounds to deny the request.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

<u>110075.</u> In adopting regulations, pursuant to Section 110070 of this part, the department shall consider all of the following factors that the petitioner shall furnish:

- (a) The name and all pertinent information concerning the poisonous or deleterious substance, food additive, pesticide chemical, or color additive, including its chemical identity and composition, its proposed use, including directions, recommendations, and suggestions, its proposed labeling, and all other relevant data bearing on its physical or other technical effect, and the quantity required to produce that effect.
- (b) The probable composition of any substance formed in or on a food, drug, device, or cosmetic resulting from the use of the substance.
- (c) The probable consumption and effect of the substance in the diet of man or any other animal.
- (d) Safety factors that, in the opinion of qualified experts, are generally recognized as appropriate for the use of animal experimentation data.
- (e) Practicable methods of analysis for determining the identity and quantity of all of the following:
  - (1) Any substance which is in or on the food, drug, device, or cosmetic.
  - (2) Any substance formed in or on the food, drug, device, or cosmetic because of the use of the substance.
  - (3) The pure substance and its anticipated breakdown products and impurities.
- (f) Facts supporting the contention that the use of the substance will serve a useful purpose. (Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

**110080.** (a) All pesticide regulations and any amendments to these regulations adopted pursuant to the federal act or the Food and Agricultural Code, in effect on November 23, 1970, or adopted on or after this date, are the pesticide regulations in this state. The department may, by regulation, prescribe tolerances for pesticides in processed foods in this state whether or not these tolerances are in accordance with the regulations adopted pursuant to the federal act or the Food and Agricultural Code.

- (b) Except as otherwise provided in this subdivision, the department shall evaluate the tolerance prescribed, or an exemption from a tolerance granted, for a pesticide in processed foods and make a determination whether or not the existing tolerance, or the exemption from a tolerance, is protective of the public health whenever any one of the following occurs:
  - (1) The Director of Food and Agriculture designates the pesticide as a restricted material pursuant to subdivisions (a) and (b) of Section 14004.5 of the Food and Agricultural Code.
  - (2) The Director of Food and Agriculture refuses to register or cancels the registration of the pesticide pursuant to Section 12825, or suspends the registration of the pesticide pursuant to Section 12826, of the Food and Agricultural Code, upon determining that the pesticide is detrimental to the public health and safety.
  - (3) The Director of Food and Agriculture adopts regulations restricting worker entry into areas treated with the pesticide pursuant to Section 12981 of the Food and Agricultural Code.
  - (4) The pesticide is the subject of a proceeding pursuant to a determination by the Environmental Protection Agency under paragraph (3)(i)(A), (3)(ii)(B), or (3)(iii) of subsection (a) of Section 162.11 of Title 40 of the Code of Federal Regulations.

The requirement to evaluate a tolerance prescribed, or an exemption from a tolerance granted, for a pesticide does not apply if the department finds that any of the actions described in paragraphs (1) to (4), inclusive, occurred for reasons that are not related to the question whether or not the existing tolerance, or the exemption from a tolerance, adequately protects the public health. If the department makes such a finding, the reasons for the finding shall be stated in writing.

- (c) The determination required by subdivision (b), and the reasons for the determination, shall be stated in writing. If the determination is required because any of the actions described in paragraphs (1) to (4), inclusive, of subdivision (b) occurs after January 1, 1985, the determination shall be completed within one year of the date of the action. If the determination is required because any of those actions occurred prior to January 1, 1985, the determination shall be completed by January 1, 1990.
- (d) In any case where the department, after consultation with the Department of Food and Agriculture, determines, pursuant to subdivision (b), that the tolerance prescribed, or an exemption from a tolerance granted, for a pesticide is not protective of the public health, the department shall, if it does not act immediately pursuant to subdivision (a), transmit notice of its determination to the responsible federal agencies and shall request that they take action, pursuant to the federal act, to modify the tolerance or an exemption from a tolerance. If, after one year from the date the notice is transmitted, the department finds that the responsible federal agencies have failed to take appropriate action to protect the public health, the department shall exercise its authority pursuant to subdivision (a) to prescribe a tolerance that is protective of the public health and shall notify the responsible federal agencies of its action.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996. Note: See Section 26205 (from which this section is derived) as modified on July 17, 1991, in Governor's Reorganization Plan No. 1 of 1991.)

**110085.** All food additive regulations and any amendments to the regulations adopted pursuant to the federal act in effect on November 23, 1970, or adopted on or after that date, are the food additive regulations of this state. The department may, by regulation, prescribe conditions under which a food additive may be used in this state whether or not these conditions are in accordance with the regulations adopted pursuant to the federal act.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

**110090.** All color additive regulations and any amendments to the regulations adopted pursuant to the federal act, in effect on November 23, 1970, or adopted on or after that date, are the color additive regulations of this state. The department may, by regulation, prescribe conditions under which a color additive may be used in this state whether or not those conditions are in accordance with regulations adopted pursuant to the federal act.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110095. All special dietary use regulations and any amendments to regulations adopted pursuant to the federal act, in effect on November 23, 1970, or adopted on or after that date, are the special dietary use regulations of this state. If the department finds that it is necessary to inform purchasers of the value of a food for special dietary use, it may adopt any special dietary use regulation, whether or not the regulation is in accordance with the regulations adopted pursuant to the federal act.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

- **110100.** (a) All food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food labeling regulations of this state.
- (b) The department may, by regulation, adopt additional food labeling regulations. Prior to the adoption of any food labeling regulation pursuant to this subdivision, the department shall seek comments from consumer groups and representatives of the food industry that have been identified by the department as being affected by the proposed regulation.

**110105.** All good manufacturing practices regulations for any food, drug, device, or cosmetic and any amendments to the regulations adopted pursuant to the federal act in effect on November 23, 1970, or adopted on or after such date, are the good manufacturing practices regulations of this state. If the department finds that it is necessary for the protection of consumers, it may adopt interpretative regulations as necessary to define "current good manufacturing practice" as used in this part.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

- 110110. (a) All regulations relating to (1) new drug applications, except for abbreviated new drug applications, adopted pursuant to Section 505 of the federal act (21 U.S.C. Sec. 355), (2) applications for premarket approval of new devices, adopted pursuant to Section 515 of the federal act (21 U.S.C. Sec. 360e), (3) postmarketing reports, recordkeeping, and other postapproval requirements for approved new drug applications or approved new device premarket approval applications, adopted pursuant to the federal act, that are in effect on January 1, 1993, or that are adopted on or after that date, shall be the new drug and new device application regulations of this state.
- (b) The department may, by regulation, adopt any new drug or new device application regulation that it determines is necessary for the administration and enforcement of this part, whether or not the regulation is in accordance with the regulations adopted pursuant to the federal act.

(Amended by Stats. 2000, Ch. 796, Sec. 4. Effective January 1, 2001.)

**110111.** All nonprescription drug regulations and any amendments to those regulations adopted pursuant to the federal act, that are in effect on January 1, 2000, or that are adopted on or after that date, shall be the nonprescription drug regulations of the state. The department may adopt any nonprescription drug regulation it deems necessary for the administration and enforcement of this part, provided that the regulation is not different from, or in addition to, any requirement for nonprescription drugs pursuant to Section 751 (21 U.S.C. Sec. 379r) of the federal act.

(Added by Stats. 2000, Ch. 796, Sec. 14. Effective January 1, 2001.)

110115. A federal regulation adopted pursuant to this part takes effect in this state 30 days after it becomes effective as a federal regulation. Any person who will be adversely affected by adoption of the federal regulation in this state may, within the 30 days prior to its becoming effective in this state, file with the department, in writing, objections and a request for a hearing. The timely filing of substantial objections to a regulation that has become effective under the federal act, stays the adoption of the regulation in this state.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

**110120.** If no substantial objections are received and no hearing is requested within 30 days after publication of a newly proposed state regulation, it shall take effect on the date set by the department. The effective date shall be at least 60 days after the time for filing objections has expired.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110125. If substantial objections are made to a federal regulation within 30 days prior to its becoming effective in this state or to a proposed regulation within 30 days after it is published, the department, after notice, shall conduct a public hearing to receive evidence on issues raised by the objections. Any interested person or his or her representative may be heard. The department shall act upon objections by order and shall mail the order to objectors by certified mail as soon after the hearing as practicable. The order shall be based on evidence contained in the record of the hearing. If the order concerns a federal regulation, the department may adopt, rescind, or modify it. If the order concerns a proposed regulation, the department may withdraw it or set an effective date for the regulation as published or as modified by the order. The effective date shall be at least 60 days after publication of the order.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

<u>110130.</u> Hearings authorized or required by this part shall be conducted by the department or agent as the department may designate for that purpose.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

**110135.** Before any alleged violation of this part is reported to the Attorney General, a district attorney, or a city attorney for the institution of a criminal proceeding, the person against whom this proceeding is contemplated may be given appropriate notice and an opportunity to show cause why he or she should not be prosecuted and to present additional facts that may mitigate the action. The showing may be presented either orally or in writing, in person, or by attorney.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)