



**California Health and Safety Code,
Division 104, Part 5**

**SHERMAN FOOD, DRUG, AND
COSMETIC LAW**

Effective January 1, 2018



**and Excerpts from the Health and Safety Code, Business
and Professions Code, and Penal Code**

TABLE OF CONTENTS

	<u>Page</u>	<u>Section Number</u>
CHAPTER 1. GENERAL PROVISIONS AND DEFINITIONS	4	<u>109875</u>
CHAPTER 2. ADMINISTRATION		
ARTICLE 1. General.....	9	<u>110045</u>
ARTICLE 2. Inspection and Sampling.....	13	<u>110140</u>
ARTICLE 3. Publicity.....	14	<u>110170</u>
ARTICLE 4. Export Documents.....	14	<u>110190</u>
ARTICLE 5. California Rx Prescription Drug Web Site Program.....	16	<u>110242</u>
CHAPTER 3. GUARANTEES.....	17	<u>110245</u>
CHAPTER 3.5 EXPIRATION DATES.....	18	<u>110286</u>
CHAPTER 4. PACKAGING, LABELING, AND ADVERTISING		
ARTICLE 1. General.....	18	<u>110290</u>
ARTICLE 2. Fair Packaging and Labeling.....	19	<u>110340</u>
ARTICLE 3. Advertising.....	22	<u>110390</u>
ARTICLE 4. Dietary Supplement Labeling and Advertising.....	24	<u>110422</u>
ARTICLE 4.5. Ephedrine Group Alkaloids.....	26	<u>110423.100</u>
CHAPTER 5. FOOD		
ARTICLE 1. Generally.....	26	<u>110425</u>
ARTICLE 2. Registration.....	28	<u>110460</u>
ARTICLE 3. Standard of Identity, Quality, and Fill.....	32	<u>110505</u>
ARTICLE 4. Enrichment of Food and Food Products.....	32	<u>110530</u>
ARTICLE 5. Adulterated Food.....	33	<u>110545</u>
ARTICLE 6. Misbranded Food.....	37	<u>110660</u>
ARTICLE 6.5. Recalled Food	40	<u>110806</u>
ARTICLE 7. California Organic Products Act of 2003.....	41	<u>110810</u>
ARTICLE 8. Potentially Hazardous Food.....	50	<u>110960</u>
ARTICLE 9. Frozen Foods.....	51	<u>110965</u>
ARTICLE 10. Ice.....	51	<u>110970</u>
ARTICLE 11. Local Enforcement.....	53	<u>111015</u>
ARTICLE 11.5. Local Enforcement: Live Food.....	54	<u>111067</u>
ARTICLE 12. Bottled, Vended, Hauled, and Processed Water.....	54	<u>111070</u>
ARTICLE 13. Hamburger and Imitation Hamburger.....	66	<u>111200</u>
ARTICLE 14. Asian Rice Noodles and Korean Rice Cakes.....	67	<u>111222</u>
CHAPTER 6. DRUGS AND DEVICES		
ARTICLE 1. General Provisions.....	68	<u>111225</u>
ARTICLE 2. Adulterated Drugs and Devices.....	69	<u>111250</u>
ARTICLE 3. Misbranded Drugs and Devices.....	70	<u>111330</u>
ARTICLE 4. Experimental Use of Drugs.....	76	<u>111515</u>
ARTICLE 4.5. Right to Try.....	76	<u>111548</u>
ARTICLE 5. New Drugs or Devices.....	79	<u>111550</u>

ARTICLE 6. Licenses.....	82	111615
CHAPTER 7. COSMETICS		
ARTICLE 1. General Provisions and Definitions.....	91	111660
ARTICLE 2. Adulterated Cosmetics	92	111670
ARTICLE 3. Misbranded Cosmetics.....	93	111730
ARTICLE 3.5. Chronic Health Effects of Cosmetics.....	94	111791
ARTICLE 4. Voluntary Registration.....	96	111795
CHAPTER 8. PENALTIES AND REMEDIES		
ARTICLE 1. Penalties.....	96	111825
ARTICLE 2. Proceedings.....	97	111840
ARTICLE 3. Seizure and Embargo.....	98	111860
ARTICLE 4. Injunctions.....	99	111900

Additional laws pertaining to the enforcement of Food, Drug, Medical Devices and Tobacco Products from the Health and Safety Code, Business and Professions Code, and Penal Code

Health and Safety Code		<u>H&SC</u>
Hazardous Substances Act	101	108100
Art or Craft Materials	110	108500
Toy Safety	112	108550
Poison Prevention Act	114	108675
Children’s Poison Protection Act	116	108750
Lead in Tableware	118	108850
Toxin-Free Infants and Toddlers Act.....	122	108940
Cancer Law	123	109250
Wholesale Foods	132	111940
California Food Sanitation Act	133	111950
Sanitary Control of Shellfish	138	112150
Cold Storage	143	112350
Frozen Foods	146	112500
Canneries	149	112650
Olive Oil	153	112875
Pure Pet Food Act	156	113025
Electronic Cigarettes.....	160	119405
Miscellaneous H&SC Sections Pertaining to:	161	
Food Drug Medical Device Cosmetic Safety, Including:		
H&SC Sections 100325, 106500, 131355, 131160, 131400, 131405, 131410, 131505, 131510		
Business and Professions Code		<u>B&PC</u>
STAKE Act	163	22950
Cigarette and Tobacco Products Licensing Act.....	170	22970
Penal Code Sections		<u>PC</u>
Tobacco Enforcement	178	308
Crimes Against Decency: Other Injuries to Persons	181	347
Crimes Against Public Health and Safety	182	382

CHAPTER 1. GENERAL PROVISIONS AND DEFINITIONS

109875. This part shall be known as the Sherman Food, Drug, and Cosmetic Law.

109880. Unless the context otherwise requires, the definitions set forth in this article govern the construction of this part.

109885. "Advertisement" means any representations, including, but not limited to, statements upon the products, its packages, cartons, and any other container, disseminated in any manner or by any means, for the purpose of inducing, or that is likely to induce, directly or indirectly, the purchase or use of any food, drug, device, or cosmetic.

109890. "Antibiotic drug" means any drug , except drugs for use in animals other than humans, composed in whole or in part of any form of penicillin, streptomycin, chlortetracycline chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance that is produced by micro-organisms, and that has the capacity to inhibit or destroy micro-organisms in dilute solution, including a chemically synthesized equivalent, or any derivative thereof.

109895. "Color additive" means a substance that satisfies both of the following requirements:

- (a) It is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source.
- (b) When added or applied to a food, drug, device, or cosmetic, or to the human body or any part of the body, it is capable, alone or through reaction with any other substance, of imparting color to the food, drug, device, or cosmetic, or to the human body or the part of the human body, to which it is added or applied.

The term "color additive" does not include any material that the department, by regulation, determines is used, or intended to be used, solely for a purpose or purposes other than coloring.

The term "color," as used in this section, includes black, white, and intermediate grays.

This section does not apply to any pesticide chemical, soil, or plant nutrient, or other agricultural chemical, solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

109900. "Cosmetic" means any article, or its components, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part of the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance.

The term "cosmetic" does not include soap.

109905. "Counterfeit", as used in respect to any food, drug, device, or cosmetic, means a food, drug, device, or cosmetic that bears or whose package or labeling bears, without authorization, the trademark, trade name, or other identifying mark, imprint, or device, or any likeness or trademark, trade name, or other identifying mark, imprint, or device of a manufacturer, processor, packer, or distributor, other than the actual manufacturer, processor, packer, or distributor, or that falsely purports or is represented to be the product of, or to have been packed or distributed by, the other manufacturer, processor, packer, or distributor.

109910. "Department" means the State Department of Health Services.

109915. "Director" means the State Director of Health Services.

109920. "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:

- (a) Recognized in the official National Formulary or the United States Pharmacopoeia, or any supplement to them.
- (b) Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease in humans or any other animal.
- (c) Intended to affect the structure or any function of the body of humans or any other animal and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and that is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

109925. "Drug" means any of the following:

- (a) Any article recognized in an official compendium.
- (b) Any article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or any other animal.
- (c) Any article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal.
- (d) Any article used or intended for use as a component of any article designated in subdivision (a), (b), or (c) of this section.

The term "drug" does not include any device.

Any food for which a claim (as described in Sections 403(r)(1)(B) (21 U.S.C. Sec. 343(r)(1)(B)) and 403(r)(3) (21 U.S.C. Sec. 343(r) (3)) or Sections 403(r)(1)(B) (21 U.S.C. Sec. 343(r)(1)(B)) and 403(r)(5)(D) (21 U.S.C. Sec. 343(r)(5)(D)) of the federal act), is made in accordance with the requirements set forth in Section 403(r) (21 U.S.C. Sec. 343(r)) of the federal act, is not a drug under subdivision (b) solely because the label or labeling contains such a claim.

109930. "Federal act" means the federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. Sec. 301 et seq.).

109935. "Food" means either of the following:

- (a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.
- (b) Any article used or intended for use as a component of any article designated in subdivision (a).

109940. "Food additive" means any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in the substance becoming a component of the food or otherwise affecting characteristics of the food. This includes any substance or radiation source intended for use in producing, manufacturing, packing, treating, packaging, transporting, or holding any food.

The term "food additive" does not include any of the following:

- (a) A pesticide chemical in or on a raw agricultural commodity.
- (b) A pesticide chemical that is used, or intended for use, in the production, storage, or transportation of any raw agricultural commodity.
- (c) A color additive.
- (d) Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 (72 Stat. 1784), pursuant to the federal act; the Poultry Products Inspection Act (71 Stat. 441; 21 U.S.C. Sec. 451 et seq.); the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. Sec. 71 et seq.); or the Food and Agricultural Code of this state.

109945. "Food and drug inspector" means any authorized agent of the Bureau of Food and Drug of the department, who shall have the powers set forth in Section 106500.

109947. "Food processing facility" means any facility operated for the purposes of manufacturing, packing, or holding processed food. Food processing facility does not include a food facility as defined in Section 113785, a cottage food operation that is registered or has a permit pursuant to Section 114365, or any facility exclusively storing, handling, or processing dried beans.

109948.

- (a) "Home medical device retail facility" is an area, place, or premises, other than a licensed pharmacy, in and from which prescription devices, home medical devices, or home medical device services are sold, fitted, or dispensed pursuant to prescription. "Home medical device retail facility" includes, but is not limited to, any area or place in which prescription devices, home medical devices, or home medical device services are stored, possessed, prepared, manufactured, or repackaged, and from which the prescription devices, home medical devices, and home medical device services are furnished, sold, or dispensed at retail.
- (b) "Home medical device retail facility" shall not include any area in a facility licensed by the department where floor supplies, ward supplies, operating room supplies, or emergency room supplies of prescription devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.
- (c) "Home medical device retail facility" shall not include any area of a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of Division 2 where the supplies specified in subdivision (c) of Section 4057 of the Business and Professions Code are stored or possessed solely for treatment of patients by a licensed home health agency or licensed hospice, as long as all prescription devices are furnished to these patients only upon the prescription or order of health care practitioners authorized to prescribe or order home medical devices or who use home medical devices or who use home medical devices to treat their patients.

109948.1

- (a) "Home medical device services" means the delivery, installation, maintenance, replacement of, or instruction in the use of, home medical devices used by a sick or disabled individual to allow the individual to be maintained in a residence.
- (b) "Home medical device" means a device intended for use in a home care setting including, but not limited to, all of the following:
 - (1) Oxygen delivery systems and prefilled cylinders.
 - (2) Ventilators.
 - (3) Continuous Positive Airway Pressure devices (CPAP).
 - (4) Respiratory disease management devices.
 - (5) Hospital beds and commodes.
 - (6) Electronic and computer driven wheelchairs and seating systems.
 - (7) Apnea monitors.
 - (8) Low air loss continuous pressure management devices.
 - (9) Transcutaneous Electrical Nerve Stimulator (TENS) units.
 - (10) Prescription devices.
 - (11) Disposable medical supplies including, but not limited to, incontinence supplies as defined in Section 14125.1 of the Welfare and Institutions Code.
 - (12) In vitro diagnostic tests.
 - (13) Any other similar device as defined in regulations adopted by the department.
- (c) The term "home medical device" does not include any of the following:
 - (1) Devices used or dispensed in the normal course of treating patients by hospitals and nursing facilities, other than devices delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical devices to an individual's residence.
 - (2) Prosthetics and orthotics.
 - (3) Automated external defibrillators (AEDs).
 - (4) Devices provided through a physician's office incident to a physician's service.

- (5) Devices provided by a licensed pharmacist that are used to administer drugs that can be dispensed only by a licensed pharmacist.
- (6) Enteral and parenteral devices provided by a licensed pharmacist.

109950. "Immediate container" does not include any package liner.

109951. "Infant formula" shall have the same definition as that term is used in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(z)). The department shall review all changes to the federal definition of "infant formula" before those changes are incorporated by reference pursuant to this section. Within six months after the effective date of any changes to the federal definition, the department shall complete its review of the changes, and submit a report to the Senate Health and Human Services Committee and the Assembly Health Committee that describes the changes and makes a recommendation as to whether it is appropriate to incorporate the changes by reference pursuant to this section. Any change to the federal definition shall take effect pursuant to this section one year after the effective date of the federal change, unless a law that specifically prohibits the change from taking effect is enacted and becomes effective.

109955. "Label" means a display of written, printed, or graphic matter upon a food, drug, device, or cosmetic or upon its immediate container.

109960. "Labeling" means any label or other written, printed, or graphic matter upon a food, drug, device, or cosmetic or upon its container or wrapper, or that accompanies any food, drug, device, or cosmetic.

109965. "Local health department" means the health department of a city, county, city and county, or local health district that qualifies for state assistance pursuant to Chapter 3 (commencing with Section 101175) of Part 3 of Division 101, or any city health department of a city that has had its own health department for 12 years or more.

109970. "Manufacture" means the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. The term "manufacture" includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic in furtherance of the distribution of the food, drug, device, or cosmetic. The term "manufacture" does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer.

109971. "Medical food" means any product that meets the definition of medical food in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360ee(b)(3)). The department shall review all changes to the federal definition of "medical food" before those changes are incorporated by reference pursuant to this section. Within six months after the effective date of any changes to the federal definition, the department shall complete its review of the changes, and submit a report to the Senate Health and Human Services Committee and the Assembly Health Committee that describes the changes and makes a recommendation as to whether it is appropriate to incorporate the changes by reference pursuant to this section. Any change to the federal definition shall take effect pursuant to this section one year after the effective date of the federal change, unless a law that specifically prohibits the change from taking effect is enacted and becomes effective.

109975. "New device" means any of the following:

- (a) Any device the composition, construction, or properties of which are such that the device is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of devices, as having been adequately shown, through scientific investigations to be safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling or advertising thereof.
- (b) Any device the composition, construction, or properties of which are such that the device, as a result of such investigation to determine its safety and effectiveness for use under these conditions, has

become so recognized, but which has not, otherwise than in the investigations, been used to a material extent or for a material time under the conditions.

109980. "New drug" means either of the following:

- (a) Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling or advertising thereof.
- (b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under these conditions, has become so recognized, but that has not, otherwise than in the investigations, been used to a material extent or for a material time under the conditions.

109985. "Official compendium" means the latest edition of the United States Pharmacopoeia, the latest edition of the Homeopathic Pharmacopoeia of the United States, or the latest edition of the National Formulary, or any supplement to any of these.

109990. "Package" means any container or wrapper that may be used by a manufacturer, producer, jobber, packer, or dealer for enclosing or containing any food, drug, device, or cosmetic.

The term "package" does not include any of the following:

- (a) Any shipping container or outer wrapping used solely for the transportation of a food, drug, device, or cosmetic in bulk quantity to any manufacturer, packer, processor, or wholesale or retail distributor.
- (b) Any shipping container or outer wrapping used by any retailer to ship or deliver any food, drug, device, or cosmetic to any retail consumer if the container or wrapping bears no printed matter pertaining to any food, drug, device, or cosmetic.

109992. "Pasteurized in-shell eggs" means shell eggs that have been pasteurized by any method approved by the federal Food and Drug Administration, the Department of Food and Agriculture, or the department.

109995. "Person" means any individual, firm, partnership, trust, corporation, limited liability company, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within the state, and any representative, agent, or agency of any of the foregoing.

110000. "Pesticide chemical" means any substance that alone, in chemical combination, or in formulation with one or more substances, is an "economic poison" within the meaning of Section 12753 of the Food and Agricultural Code of this state or the Federal Insecticide, Fungicide, and Rodenticide Act (61 Stat. 163; 7 U.S.C. Sec. 135 et seq.), and that is used in the production, storage, or transportation of any raw agricultural commodity.

110005. "Potentially hazardous food" means any food capable of supporting growth of infectious or toxigenic micro-organisms when held at temperatures above 45 degrees Fahrenheit.

110010. "Prescription" means an oral order given individually for the patient for whom prescribed directly from the prescriber to the furnisher or indirectly by means of a written order signed by the prescriber that bears the name and address of the prescriber, the license classification of the prescriber, the name and address of the patient, the name and quantity of drug or device prescribed, the directions for use, and the date of issue.

110010.1. "Prescription device" means any device limited to prescription use under Section 111470.

110010.2. "Prescription drug" means any drug limited to prescription use under Section 111470.

110015. "Principal display panel" means that part of a label most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.

110020. "Raw agricultural commodity" means any food in its raw or natural state. It includes, but is not limited to, any fruit that is washed, colored, or otherwise treated in its unpeeled natural form prior to marketing.

110025.

- (a) "Substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug or device involved, on the basis that it could be fairly and responsibly concluded by the experts that the drug or device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling, proposed labeling, or advertising of any drug or device.
- (b) If the department determines, based on relevant science, that data from one adequate and well-controlled clinical investigation, and confirming evidence, obtained prior to or after the investigation, sufficiently establish effectiveness, then the department may consider that data and evidence, to constitute substantial evidence for purposes of the preceding sentence.

110030. The provisions of this part regarding the selling of any food, drug, device, or cosmetic include, but are not limited to, all of the following:

- (a) The manufacture, production, processing, and packing of any food, drug, device, or cosmetic.
- (b) The exhibition, offer, possession, or holding of any food, drug, device, or cosmetic for sale, dispensing, giving, supplying, or applying in the conduct of any establishment.
- (c) The sale, dispensing, giving, supplying, or applying of any food, drug, device, or cosmetic in the conduct of any establishment.

110035. All regulations pertaining to any food, drug, device, or cosmetic adopted by the department that are in effect on the effective date of this part shall remain in effect until the department adopts regulations pursuant to this part which repeal the regulations.

110040. This part shall be so construed as to not be in conflict with the Food and Agricultural Code, or with the Alcoholic Beverage Control Act, Division 9 (commencing with Section 23000) of the Business and Professions Code, and the regulations adopted pursuant thereto.

CHAPTER 2. ADMINISTRATION

Article 1. General

110045. The department shall administer and enforce this part.

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).

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.

110060. The director and authorized agents of the department shall have the powers set forth in Sections 100165 and 106500.

110065. 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.

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.

110075. 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.

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)(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.

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.

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.

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.

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.

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.

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. 379(r)) of the federal act.

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.

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.

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.

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

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.

Article 2. Inspection and Sampling

110140. For purposes of enforcement of this part, any authorized agent of the department may, upon presenting appropriate credentials and at a reasonable time, do any of the following:

- (a) Enter any factory, warehouse, or establishment in which any food, drug, device, or cosmetic is manufactured, packed, or held; enter any vehicle that is being used to transport or hold the food, drug, device, or cosmetic; or enter any place where any food, drug, device, or cosmetic is suspected of being held in violation of this part.
- (b) Inspect any factory, warehouse, establishment, vehicle, or place, and all pertinent equipment, raw material, finished and unfinished materials, containers, and labeling in the factory, warehouse, establishment, vehicle, or place. In the case of any factory, warehouse, establishment, or consulting laboratory in which any food, drug, device, or cosmetic is manufactured, packed, or held, inspection shall include any record, file, paper, process, control, and facility that has a bearing on whether the food, drug, device, or cosmetic is adulterated or misbranded, or falsely advertised within the meaning of this part or whether it has been or is being manufactured, packed, transported, sold, or offered for sale in violation of this part.

110145. The inspection authorized by Section 110140 shall not include any of the following:

- (a) Financial data.
- (b) Sales data, other than shipment data.
- (c) Pricing data.
- (d) Personnel data, except data as to qualifications of technical and professional personnel.
- (e) Research data, except data relating to any new drug or antibiotic drug that is subject to reporting and inspection under this part or the federal act.

110150. An authorized agent of the department may secure any sample or specimen of any food, drug, device, or cosmetic. If the agent obtains any samples prior to leaving the premises, he or she shall leave a receipt describing any sample obtained.

110155. An authorized agent of the department shall have access to all records of carriers in commerce relating to the movement in commerce of any food, drug, device, or cosmetic, or the holding of that food, drug, device, or cosmetic during or after the movement, and the quantity, shipper, and consignee of the food, drug, device, or cosmetic. Evidence obtained under this section shall not be used in a criminal prosecution of the person from whom it is obtained. The carrier shall not be subject to the other provisions of this part by reason of their receipt, carriage, holding, or delivery of any food, drug, device, or cosmetic in the usual course of business as carriers.

110160. It is unlawful for any person to refuse to permit entry or inspection, the taking of samples or other evidence, or access to copying of any record as authorized by this part, or to conceal the samples or evidence, or withhold evidence concerning them.

110165. It is unlawful for any person to use to his or her own advantage, or to reveal to any person other than to the director, officers, employees, or authorized agents of this department, or to the courts when relevant in any judicial proceeding under this part, any information acquired under authority of this part concerning any method or process which as a trade secret is entitled to protection. However, the department may reveal trade secret information in connection with the responsibilities of the department under this part, to any employee of the federal Food and Drug Administration who is authorized in writing by the Chief of the Food and Drug Branch of the department or his or her designee to receive this type of information. The employee receiving this type of information shall be informed in writing of the prohibitions

under this section, shall be informed in writing that the information provided contains trade secrets, as defined under state and federal law, and shall agree in writing to keep the information confidential.

Article 3. Publicity

110170. The department may publish reports summarizing all judgments and court orders that have been rendered under this part, including the nature of the charge and the disposition of the charge.

110175. The department may distribute information regarding any food, drug, device, or cosmetic as the department considers necessary for the protection of the health and safety of the consumer or for his or her protection from fraud.

110180. The department may collect, report, or illustrate the results of any investigation of the department.

Article 4. Export Documents

110190. (a) Any person who ships to another state or country a food, drug, device, or cosmetic manufactured or produced in this state may request the department to issue an export document to reference the shipment of the food, drug, device, or cosmetic. The food, drug, device, or cosmetic shall be manufactured or produced in this state by a person who has a valid registration, license, certificate, or permit issued by the department under this part or the Miscellaneous Food, Food Facility, and Hazardous Substances Act (Section 27). For each request, the requesting person shall submit to the department, in hardcopy or the electronic formats described in subdivision (c), all of the following:

- (1) All labels, labeling, and advertising affixed to, accompanying, or relating to the food, drug, device, or cosmetic. The department shall accept electronic or paper copies of labels, labeling, or advertising.
 - (2) If not clearly evident from the materials submitted pursuant to paragraph (1), the requester shall submit both of the following:
 - (A) The name, place of business, and the type and number of the registration, license, certificate, or permit issued by the department to the manufacturer or producer of the food, drug, device, or cosmetic.
 - (B) The identity of the food, drug, device, or cosmetic being shipped.
 - (3) The name of the state or country to which the food, drug, device, or cosmetic is being shipped.
 - (4) The approximate date of shipment of the food, drug, device, or cosmetic.
 - (5) Additional statements the requesting person wishes to have incorporated into the export document.
 - (6) The name and telephone number of the requesting person to whom the department may refer questions or requests for additional information.
- (b) The person making the request shall also submit the one-time fee required by paragraph (1) of subdivision (a) of Section 110210, if the fee has not yet been paid, and the minimum charge required by paragraph (2) of subdivision (a) of Section 110210.
- (c) The department shall accept requests for an export document submitted by email or other electronic methods.
 - (1) For requests submitted by email or facsimile on or after January 1, 2014, payment of the fees described in subdivision (b) shall be provided to, and received by, the department within five business days after submittal of the request. The department shall suspend processing of a request if payment is not received within five business days, and shall resume processing once it receives the payment.
 - (2) For requests submitted using an electronic document request submittal process developed by the department and available on the department's Internet Web site, payment shall be submitted at the time of the request.
- (d) The department shall develop procedures to expedite approval of requests for an export document in which the labels, labeling, and advertising affixed to, accompanying, or relating to the food, drug,

device, or cosmetic remain unchanged from a previously approved request for an export document for that food, drug, device, or cosmetic.

110200.

- (a) Each export document issued by the department shall do all of the following:
 - (1) Identify either or both of the following:
 - (A) The name and place of business of the manufacturer or producer of the food, drug, device, or cosmetic.
 - (B) The name and place of business of the distributor of the food, drug, device, or cosmetic.
 - (2) Identify the food, drug, device, or cosmetic being shipped.
 - (3) Identify the state or country to which the food, drug, device, or cosmetic is being shipped.
 - (4) Identify the approximate date of shipment.
 - (5) Describe the department's authority over the food, drug, device, or cosmetic to be shipped and its manufacturer or producer.
 - (6) State that the department does not object to the sale of the food, drug, device, or cosmetic in this state or the shipment of the food, drug, device, or cosmetic to any other state or country.
- (b) Each export document issued by the department may, in the department's sole discretion, include additional statements requested by the person who requested the export document.
- (c) Each export document issued by the department shall be issued by the Chief of the Food and Drug Branch of the department, or his or her designee. The chief or his or her designee may issue an export document prepared by the department or by the requesting person.
- (d) The export document shall expire one year after its issue date.

110210.

- (a) Each person requesting the department to issue an export document shall pay nonreturnable fees as follows:
 - (1) A one-time fee of one hundred dollars (\$100).
 - (2) A fee for service charge at the rate of eighty dollars (\$80) per hour, at a minimum of twenty-five dollars (\$25) per request.
 - (3) Any attendant costs incurred by the department, including, but not limited to, the costs of additional inspection, priority mailing, or notary service necessitated by the request.
- (b) The fee amounts shall be adjusted annually pursuant to Section 100425.
- (c) In no case shall the fees exceed the reasonable costs of the department in administering this article.
- (d) The department shall provide to the person who pays the fees a statement or invoice that describes the costs paid from the fees.

110220.

- (a) The department may refuse to accept any request where the information required to be submitted by this article is incomplete.
- (b) The department may refuse to issue an export document, or may invalidate an export document, if it finds, or has probable cause to believe, any of the following:
 - (1) The food, drug, device, or cosmetic, or requesting person violated any provision of this part, the Miscellaneous Food, Food Facility, and Hazardous Substances Act (Section 27), or any regulation adopted pursuant to this part or that act.
 - (2) Any information required to be submitted by this article is incomplete or false.
 - (3) The requesting person has not paid all outstanding fees required by this article.
 - (4) The food, drug, device, or cosmetic is not manufactured or produced in this state.
 - (5) The food, drug, device, or cosmetic is intended to be exported under Section 110655, 110790, 111315, 111460, 111720, or 111785.
 - (6) The food is a raw agricultural commodity or dairy product regulated by the Department of Food and Agriculture or a poultry or meat product regulated by the United States Department of Agriculture.
- (c) If the department refuses to issue an export document, or invalidates an export document, the department shall inform the requesting person in writing of the reasons for the refusal or invalidation.

The requesting person may request reconsideration by forwarding a written request to the Chief of the Division of Environmental Health of the department. The request for reconsideration must be postmarked or received by the department no later than 30 days after the date of the department's refusal or invalidation, and shall include a complete statement of all arguments and evidence that support the request for reconsideration. The Chief of the Division of Environmental Health shall notify the requesting person of his or her decision within 30 days. The decision of the Chief of the Division of Environmental Health shall be final.

- (d) It is the intent of the Legislature that the department shall respond to each request for issuance of an export document within five working days of receipt of the request by the Food and Drug Branch of the department.

110225. It is unlawful for any person to knowingly supply the department with false material facts in a request for an export document or to falsely represent that the department has issued an export document.

110230. Any person who has a valid registration, license, certificate, or permit issued by the department to manufacture or produce a food, drug, device, or cosmetic in this state may request the department to issue an official copy of the valid registration, license, certificate, or permit.

110235.

- (a) Each person requesting the department to issue an official copy of a valid registration, license, certificate, or permit shall pay nonreturnable fees as follows:
 - (1) Fifteen dollars (\$15) per official copy.
 - (2) Any attendant costs incurred by the department, including, but not limited to, the costs of additional inspection, priority mailing, or notary service necessitated by the request.
- (b) The fee amount shall be adjusted annually pursuant to Section 100425.
- (c) The department shall provide to the person who pays the fees a statement or invoice that describes the costs paid from the fees.

110240. There is established an Export Document Program Fund within the General Fund. All fees collected pursuant to Sections 110210 and 110235 shall be deposited into the Export Document Program Fund and, upon appropriation, shall be expended by the department for the purpose of administering this article.

110241. All fees collected by the department pursuant to requests to conduct a voluntary medical device review shall be deposited into the Export Document Program Fund and, upon appropriation, shall be expended for the purpose of determining if the device is a new device or is substantially equivalent to a current or previously marked device.

Article 5. California Rx Prescription Drug Web Site Program

110242.

- (a) The California Rx Prescription Drug Web Site Program is hereby established.
- (b) The State Department of Health Services shall administer the program. The purpose of the program shall be to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.
- (c) The department shall establish a Web site on or before July 1, 2008, which shall, at a minimum, provide information about, and electronic links to, all of the following:
 - (1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program.
 - (2) State programs that provide drugs at discounted prices for California residents.
 - (3) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

- (4) Other Web sites as deemed appropriate by the department that help California residents to safely obtain prescription drugs at affordable prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.
- (d) The department's Web site shall include price comparisons of at least 150 commonly prescribed prescription drugs, including typical prices charged by licensed pharmacies in the state.
- (e) The department shall ensure that the Web site established pursuant to this section is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs.

110243.

- (a) Contracts and change orders entered into pursuant to this article and any project or systems development notice shall be exempt from all of the following:
 - (1) The competitive bidding requirements of State Administrative Manual Management Memo 03-10.
 - (2) The project authority requirements of Sections 4800 and following of the State Administrative Manual.
 - (3) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.
 - (4) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of the Government Code.
 - (5) Section 11.05 of, and Provision 6 of Item 4260-001-0001 of, Section 2.00 of the Budget Act of 2005 (Ch. 38, Stats. 2005).
- (b) Change orders entered into pursuant to this article shall not require a contract amendment.

CHAPTER 3. GUARANTEES

110245. No dealer shall be prosecuted under this part for a violation concerning any food, drug, device, or cosmetic that is contained in an original, unbroken, and undamaged package that bears the original labeling if all of the following requirements are satisfied:

- (a) He or she has used reasonable care in the storage and handling of the food, drug, device, or cosmetic.
- (b) He or she received the food, drug, device, or cosmetic in the usual channels of trade as first-class merchantable stock and not as seconds or damaged articles or job lots purchased under conditions that indicate that the food, drug, device, or cosmetic was not usual first-class merchandise.
- (c) He or she can produce a guarantee to the effect that the food, drug, device, or cosmetic is not adulterated, misbranded, or falsely advertised, within the meaning of this part, or that it is not a food, drug, device, or cosmetic which, pursuant to this part, may not be sold or offered for sale in this state.

110250. The guarantee shall be dated prior to the date of sale of the food, drug, device, or cosmetic and it shall be signed by the wholesaler, jobber, manufacturer, or other person located or residing in this state from whom the dealer received the food, drug, device, or cosmetic in good faith.

110255. A guarantee may be either a general guarantee or a special guarantee and shall be produced prior to the time of reporting an alleged violation to the Attorney General, the district attorney, or a city attorney for prosecution.

110260. A general guarantee shall guarantee without condition or restriction any food, drug, device, or cosmetic that is produced, prepared, compounded, packed, distributed, or sold by the guarantor as not adulterated, mislabeled, misbranded, falsely advertised, or that the article is not an article under this part that may not be sold or offered for sale.

110265. A special guarantee shall guarantee in the same manner as a general guarantee the particular food, drug, device, or cosmetic listed in an invoice of the food, drug, device, or cosmetic, and shall be attached to, or shall fully identify, the invoice.

110270. All guarantees shall contain the name and address of the guarantor making the sale of food, drug, device, or cosmetic. A guarantee shall protect the person only when the food, drug, device, or cosmetic covered by the guarantee remains identical, both as to composition and labeling, with the food, drug, device, or cosmetic as composed and labeled when originally received from the guarantor.

110275. It is unlawful for any person to give a guarantee or undertaking that is false.

110280. If the guarantee is to the effect that the food, drug, device, or cosmetic is not in violation within the meaning of the federal act, it shall be sufficient for all the purposes of this part, and shall have the same force and effect as though it referred to this part, unless, pursuant to this part, the standard for the food, drug, device, or cosmetic concerned is higher than the standard for a like food, drug, device, or cosmetic under the federal act. In that case, this part shall prevail over the federal act.

110285. In any case where the department has adopted a regulation prescribing a tolerance, including, but not limited to, a zero tolerance, for a poisonous or deleterious substance, food additive, pesticide chemical, or color additive in processed foods, the department may require manufacturers to guarantee that foods they market in the state comply with the tolerance. The department may require a guarantee periodically but in no case more often than once each calendar quarter.

CHAPTER 3.5. EXPIRATION DATES

110286.

(a) A retailer shall not sell or offer for sale after the expiration date an over-the-counter drug.

(b) Notwithstanding Section 111825, any retailer who violates this section is guilty of an infraction, punishable by a fine of not more than ten dollars (\$10) per day for each item sold or offered for sale after the expiration date. The fine shall be calculated based upon the number of days past the expiration date that the product is either found being offered for sale, or if the product is sold, the date of sale as established by evidence of proof of purchase, including, but not limited to, a sales receipt.

(c) The department may assess administrative penalties on a retailer who violates this section in the amount of ten dollars (\$10) per day for each item sold or offered for sale, in addition to other penalties authorized by law.

(d) For purposes of this section, "over-the-counter drug" means a nonprescription drug regulated by the federal Food and Drug Administration that is required to have an expiration date on its packaging pursuant to the federal act and federal regulations adopted pursuant to the federal act, including, but not limited to, Section 211.137 of Title 21 of the Code of Federal Regulations.

CHAPTER 4. PACKAGING, LABELING, AND ADVERTISING

Article 1. General

110290. In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered.

110295. The requirement that any word, statement, or other information appear on the label shall not be considered to be complied with unless the word, statement, or other information also appears on the outside container or wrapper of the retail package of any food, drug, device, or cosmetic, or is easily legible through the outside container or wrapper.

110300. It is unlawful for any person to forge, counterfeit, simulate, falsely represent, or without proper authority use, any mark, stamp, tag, label, or other identification device that is authorized or required by regulations adopted pursuant to this part or the federal act.

110310. It is unlawful for any manufacturer, packer, or distributor of a prescription drug or device offered for sale in this state to fail to maintain for transmittal or to fail to transmit to any practitioner licensed by applicable state law to administer the drug or device who makes written request for information as to the drug or device true and correct copies of all printed matter that is required to be included in any package in which that drug or device is distributed or sold. Nothing in this section shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this part.

110315. It is unlawful for any person, with the intent to deceive, to place, or cause to be placed upon any food, drug, device, or cosmetic, or its package, the trade name or other identifying mark or imprint of another person or any likeness of the trade name or other identifying mark or imprint of another person.

110320. It is unlawful for any person to sell, dispense, dispose of, hold, or conceal any food, drug, device, or cosmetic or its package, with knowledge that the trade name or other identifying marks, imprint, or likeness of the trade name or other identifying mark or imprint of another person has been placed on the food, drug, device, or cosmetic or its package in a manner prohibited by Section 110315.

110325. It is unlawful for any person to possess, make, sell, dispose of, cause to be made, or conceal any punch, die, plate, or other device that may be used to render a food, drug, device, or cosmetic or its package or labeling a counterfeit.

110330. It is unlawful for any person to do any act that causes any food, drug, device, or cosmetic to be a counterfeit, or to sell, dispense, or hold for sale or dispensing, the counterfeit food, drug, device, or cosmetic.

110335. The department may adopt regulations exempting from any labeling or packaging requirements of this part any food, drug, device, or cosmetic that is in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed and packed, on condition that the food, drug, device, or cosmetic is not adulterated or misbranded under the provisions of this part upon removal from the processing, labeling, or repacking establishment. Such food, drug, device, or cosmetic is subject to all other applicable provisions of this part.

All regulations relating to the exemptions that are in effect on the effective date of this part, or that are adopted on or after that date, pursuant to the federal act, are automatically effective in this state. The department may, however, adopt any additional regulations concerning exemptions.

Article 2. Fair Packaging and Labeling

110340. All labels of foods, drugs, devices, or cosmetics shall conform with the requirements of the declaration of net quantity of contents of Section 4 of the Fair Packaging and Labeling Act (80 Stat. 1296; 15 U.S.C., Sec. 1451) and the regulations adopted pursuant thereto. Foods, drugs, devices, and cosmetics exempted from the requirements of Section 4 of the Fair Packaging and Labeling Act, however, are also exempt from this article.

110345. The label of any package of a food, drug, device, or cosmetic that bears a representation as to the number of servings of the commodity contained in the package shall bear a statement of the net quantity, in terms of weight, measure, or numerical count, of each serving.

110350. It is unlawful for any person to distribute, or cause to be distributed, in commerce any packaged food, drug, device, or cosmetic if any qualifying words or phrases appear in conjunction with the separate

statement of the net quantity of contents required by Section 110340. This section, however, does not prohibit supplemental statements, at other places on the package, describing in nondeceptive terms the net quantity of contents. Such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the commodity contained in the package.

110355. Whenever the department determines that regulations containing prohibitions or requirements, other than those prescribed by Section 110340, are necessary to prevent the deception of consumers or to facilitate value comparisons as to any food, drug, device, or cosmetic, the department shall adopt regulations with respect to that commodity.

110360. The department may establish and define standards for the characterization of the size of a package that encloses any food, drug, device, or cosmetic, that may be used to supplement the label statement of net quantity of contents of packages containing the commodity. This section, however, does not authorize any limitation on the size, shape, weight, dimension, or number of packages that may be used to enclose any food, drug, device, or cosmetic.

110365. The department may regulate the placement upon any package that contains any food, drug, device, or cosmetic or upon any label affixed to the article, of any printed matter stating or representing by implication that the article is offered for retail sale at a price lower than the ordinary and customary retail sale price or that a retail sale price advantage is accorded to any purchaser of the article by reason of the size of that package or the quantity of its contents.

110370. The department may require that the label on each package of a food, drug, device, or cosmetic bear the common or usual name of the article, if any, and in case the article consists of two or more ingredients, the common or usual name of each ingredient listed in order of decreasing predominance by weight. This section, however, does not require that any trade secret be divulged.

110375.

- (a) No container wherein commodities are packed shall have a false bottom, false sidewalls, false lid or covering, or be otherwise so constructed or filled, wholly or partially, as to facilitate the perpetration of deception or fraud.
- (b) No container shall be made, formed, or filled as to be misleading. A container that does not allow the consumer to fully view its contents shall be considered to be filled as to be misleading if it contains nonfunctional slack fill. Slack fill is the difference between the actual capacity of a container and the volume of product contained therein. Nonfunctional slack fill is the empty space in a package that is filled to substantially less than its capacity for reasons other than any one or more of the following:
 - (1) Protection of the contents of the package.
 - (2) The requirements of machines used for enclosing the contents of the package.
 - (3) Unavoidable product settling during shipping and handling.
 - (4) The need to utilize a larger than required package or container to provide adequate space for the legible presentation of mandatory and necessary labeling information, such as those based on the regulations adopted by the United States Food and Drug Administration or state or federal agencies under federal or state law, laws or regulations adopted by foreign governments, or under an industrywide voluntary labeling program.
 - (5) The fact that the product consists of a commodity that is packaged in a decorative or representational container where the container is part of the presentation of the product and has value that is both significant in proportion to the value of the product and independent of its function to hold the product, such as a gift combined with a container that is intended for further use after the product is consumed, or durable commemorative or promotional packages.
 - (6) An inability to increase the level of fill or to further reduce the size of the package, such as where some minimum package size is necessary to accommodate required labeling, discourage pilfering, facilitate handling, or accommodate tamper-resistant devices.

- (7) The product container bears a reasonable relationship to the actual amount of product contained inside, and the dimensions of the actual product container, the product, or the amount of product therein is visible to the consumer at the point of sale, or where obvious secondary use packaging is involved.
 - (8) The dimensions of the product or immediate product container are visible through the exterior packaging, or where the actual size of the product or immediate product container is clearly and conspicuously depicted on any side of the exterior packaging excluding the bottom, accompanied by a clear and conspicuous disclosure that the representation is the "actual size" of the product or the immediate product container.
 - (9) The presence of any headspace within an immediate product container necessary to facilitate the mixing, adding, shaking, or dispensing of liquids or powders by consumers prior to use.
 - (10) The exterior packaging contains a product delivery or dosing device if the device is visible, or a clear and conspicuous depiction of the device appears on the exterior packaging, or it is readily apparent from the conspicuous exterior disclosures or the nature and name of the product that a delivery or dosing device is contained in the package.
 - (11) The exterior packaging or immediate product container is a kit that consists of a system, or multiple components, designed to produce a particular result that is not dependent upon the quantity of the contents, if the purpose of the kit is clearly and conspicuously disclosed on the exterior packaging.
 - (12) The exterior packaging of the product is routinely displayed using tester units or demonstrations to consumers in retail stores, so that customers can see the actual, immediate container of the product being sold, or a depiction of the actual size of the container prior to purchase.
 - (13) The exterior packaging consists of single or multiunit presentation boxes of holiday or gift packages if the purchaser can adequately determine the quantity and sizes of the immediate product container at the point of sale.
 - (14) The exterior packaging is for a combination of one purchased product, together with a free sample or gift, wherein the exterior packaging is necessarily larger than it would otherwise be due to the inclusion of the sample or gift, if the presence of both products and the quantity of each product are clearly and conspicuously disclosed on the exterior packaging.
- (c) Slack fill in a package shall not be used as grounds to allege a violation of this section based solely on its presence unless it is nonfunctional slack fill.
- (d) Any sealer may seize a container that facilitates the perpetration of deception or fraud and the contents of the container. By order of the superior court of the county within which a violation of this section occurs, the containers seized shall be condemned and destroyed or released upon any condition as the court may impose to ensure against their use in violation of this chapter. The contents of any condemned container shall be returned to the owner if the owner furnishes proper facilities for the return.

110380. All regulations and their amendments pertaining to foods, drugs, devices, and cosmetics that are in effect on the effective date of this part, or that are adopted on or after that date, pursuant to the Fair Packaging and Labeling Act (80 Stat. 1296; 15 U.S.C. Sec. 1451 et seq.) shall be the regulations of this state. The department may, when necessary, prescribe any packaging and labeling regulation for foods, drugs, devices, and cosmetics whether or not the regulation is in accordance with regulations adopted under the Fair Packaging and Labeling Act. No regulations shall be adopted that are contrary to the labeling requirements for the net quantity of contents required pursuant to Section 4 of the Federal Fair Packaging and Labeling Act and the regulations adopted pursuant to that section.

110385. It is unlawful for any person to distribute in commerce any food, drug, device, or cosmetic, if its packaging or labeling does not conform to the provisions of this article or to regulations adopted pursuant to this article. This section does not apply to persons engaged in business as wholesale or retail distributors of foods, drugs, devices, or cosmetics, except to the extent that they are engaged in the packaging or labeling of the commodities or they prescribe or specify the manner in which the commodities

are packaged or labeled. This section shall not be construed to repeal, invalidate, or supersede any other section of this part.

Article 3. Advertising

110390. It is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. An advertisement is false if it is false or misleading in any particular.

110395. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food, drug, device, or cosmetic that is falsely advertised.

110398. It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.

110400. It is unlawful for any person to receive in commerce any food, drug, device, or cosmetic that is falsely advertised or to deliver or proffer for delivery any such food, drug, device, or cosmetic.

110403. Except as otherwise provided in Section 110405, it is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:

- | | |
|--|---|
| (a) Appendicitis. | (v) Alcoholism. |
| (b) Blood disorders. | (w) Periodontal diseases. |
| (c) Bone or joint diseases. | (x) Epilepsy. |
| (d) Kidney diseases or disorders. | (y) Goiter. |
| (e) Cancer. | (z) Endocrine disorders. |
| (f) Carbuncles. | (aa) Sexual impotence. |
| (g) Diseases, disorders, or conditions of the eye. | (ab) Sinus infections. |
| (h) Diabetes. | (ac) Encephalitis. |
| (i) Diphtheria. | (ad) Tumors. |
| (j) Gallbladder diseases or disorders. | (ae) Venereal diseases. |
| (k) Heart and vascular diseases. | (af) Tuberculosis. |
| (l) High blood pressure. | (ag) Ulcers of the stomach |
| (m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness. | (ah) Varicose ulcers. |
| (n) Measles. | (ai) Scarlet fever. |
| (o) Meningitis. | (aj) Typhoid fever. |
| (p) Mental disease or mental retardation. | (ak) Whooping cough. |
| (q) Paralysis. | (al) Acquired immunodeficiency syndrome (AIDS). |
| (r) Pneumonia. | (am) AIDS-related complex (ARC). |
| (s) Poliomyelitis. | (an) Diseases, disorders, or conditions of the immune system. |
| (t) Prostate gland disorders. | |
| (u) Conditions of the scalp, affecting hair loss, or baldness. | |

110405. An advertisement that is not unlawful under Section 110390 is not unlawful under Section 110403 if it is either one of the following:

- (a) Disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of drugs or devices.

- (b) An advertisement that a drug or device has a specific curative or therapeutic effect on a condition, disorder, or disease listed in Section 110403 if the drug or device is approved or cleared for marketing for that specific curative or therapeutic effect through any of the following means:
- (1) A new drug application approved pursuant to Section 111500, or Section 505 of the federal act (21 U.S.C. Sec. 355).
 - (2) An abbreviated new drug application approved pursuant to Section 505 of the federal act (21 U.S.C. Sec. 355).
 - (3) A licensed biological product pursuant to Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262).
 - (4) A nonprescription drug that meets the requirements of Part 330 of Title 21 of the Code of Federal Regulations.
 - (5) A new animal drug application approved under Section 512 of the federal act (21 U.S.C. Sec. 360b).
 - (6) An abbreviated new animal drug application approved pursuant to Section 512 of the federal act (21 U.S.C. Sec. 360b).
 - (7) A new device application approved pursuant to Section 111550.
 - (8) A device premarket approval application approved under Section 515 of the federal act (21 U.S.C. Sec. 360e).
 - (9) A determination of substantial equivalence for a device pursuant to Section 513(f)(1) of the federal act (21 U.S.C. Sec. 360c (i)).

110410. Section 110403 shall not be construed as indicating that self-medication for conditions, disorders, or diseases other than those named is safe or efficacious.

110413. No publisher, radio or television broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the food, drug, device, or cosmetic to which a false advertisement relates, shall be liable under this article for the dissemination of the false advertisement, unless he or she has refused to furnish the department with the name and address of the manufacturer, packer, distributor, seller, or advertising agency, residing in this state who caused him or her to disseminate the advertisement.

110415. It shall be unlawful to advertise or otherwise represent chopped or ground beef or hamburger in violation of Section 110805.

110420.

- (a) Any fragrance advertising insert contained in a newspaper, magazine, mailing, or other periodically printed material shall contain only microencapsulated oils. Glue tabs or binders shall be used to prevent premature activation of the fragrance advertising insert.

“Fragrance advertising insert” means a printed piece with encapsulated fragrance applied to it that is activated by opening a flap or removing an overlying ply of paper.

Paperstocks employed in the manufacture of fragrance advertising inserts shall have a maximum porosity of 20 Sheffield units or 172 Gurley-Hill units.

- (b) Any person who distributes fragrance advertising inserts in violation of this section, is guilty of an infraction and shall, if convicted, be subject to a fine of one hundred dollars (\$100) for each distribution. The fine shall apply to each mass mailing or distribution, and to each mass publication of a magazine or newspaper in violation of this section. The fine shall not apply, however, to each individual letter, magazine, newspaper, or fragrance advertising insert so distributed. Section 111825 is not applicable to violations of this section.
- (c) This section shall become operative on January 1, 1992.

Article 4. Dietary Supplement Labeling and Advertising

110422.

- (a) Whenever a warning label is included on any product defined as a dietary supplement pursuant to Section 321(ff) of Title 21 of the United States Code, that is manufactured or distributed in this state, the label shall be clear and conspicuous.
- (b) Nothing in this section shall in any way limit or restrict any rights, remedies, or duties otherwise applicable by law.
- (c) This section shall be implemented to the extent permitted by federal law.

110423.(a)

- (1) The sale or distribution of any dietary supplement product containing ephedrine group alkaloids is prohibited unless the product label clearly and conspicuously contains the following statement:

“THIS PRODUCT HAS (INSERT THE AMOUNT OF PRODUCT) MILLIGRAMS OF CONCENTRATED EPHEDRINE GROUP ALKALOIDS PER SERVING IN THE FORM OF HERBAL EXTRACTS.”

- (2) The sale or distribution of any dietary supplement product containing ephedrine group alkaloids is prohibited unless the product label clearly and conspicuously contains the following warning:
 - (A) “WARNING: NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS. DO NOT USE IF PREGNANT OR NURSING. Consult a physician or licensed qualified health care professional before using this product if you have, or have a family history of, heart disease, thyroid disease, diabetes, high blood pressure, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, or if you are using a monoamine oxidase inhibitor (MAOI) or any other dietary supplement, prescription drug, or over-the-counter drug containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients found in certain allergy, asthma, cough or cold, and weight control products).”
 - (B) “Do not exceed recommended serving. Exceeding recommended serving may cause serious adverse health effects, including heart attack and stroke.”
 - (C) “Discontinue use and call a physician or licensed qualified health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms.”
 - (D) “Individuals who are sensitive to the effects of caffeine should consult a licensed health care professional before consuming this product.”
 - (E) “KEEP OUT OF REACH OF CHILDREN.”

- (b) The sale or distribution of dietary supplements containing steroid hormone precursors is prohibited unless the product label for these dietary supplements clearly and conspicuously contains the following warning:

“WARNING: NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS. DO NOT USE IF PREGNANT OR NURSING. Consult a physician or licensed qualified health care professional before using this product if you have, or have a family history of, prostate cancer, prostate enlargement, heart disease, low “good” cholesterol (HDL), or if you are using any other dietary supplement, prescription drug, or over-the-counter drug. Do not exceed recommended serving. Exceeding recommended serving may cause serious adverse health effects. Possible side effects include acne, hair loss, hair growth on the face (in women), aggressiveness, irritability, and increased levels of estrogen. Discontinue use and call a physician or licensed qualified health care professional immediately if you experience rapid heartbeat, dizziness, blurred vision, or other similar symptoms. KEEP OUT OF REACH OF CHILDREN.”

- (c) The product label for any dietary supplement product containing ephedrine group alkaloids or steroid hormone precursors shall clearly and conspicuously display the following statement: "To report any adverse events call 1-800-332-1088."

110423.2.

- (a) It is a misdemeanor for any manufacturer, wholesaler, retailer, or other person, to sell, transfer, or otherwise furnish any of the following to a person under 18 years of age:
 - (1) A dietary supplement containing an ephedrine group alkaloid.
 - (2) A dietary supplement containing any of the following:
 - (A) Androstenediol.
 - (B) Androstenedione.
 - (C) Androstenedione.
 - (D) Norandrostenediol.
 - (E) Norandrostenedione.
 - (F) Dehydroepiandrosterone.
- (b) A seller shall request valid identification from any individual who attempts to purchase a dietary supplement set forth in subdivision (a) if that individual reasonably appears to the seller to be under 18 years of age.
- (c) Notwithstanding subdivisions (a) and (b), a retail clerk who fails to request identification pursuant to subdivision (b) shall not be guilty of a misdemeanor pursuant to subdivision (a), subject to any civil penalties, or subject to any disciplinary action or discharge by his or her employer. This subdivision shall not apply to a retail clerk who is a willful participant in an ongoing criminal conspiracy to violate this article.

110423.4.

- (a) This article shall not apply to a licensed health care practitioner practicing within his or her scope of practice who prescribes, dispenses, or both, herbs in the course of treatment of patients under the care of the licensed practitioner.
- (b) This article shall not apply to herbal products that are sold or distributed directly to a licensed health care practitioner when the herbal product is used solely for the purpose of the treatment of patients under the care of the practitioner.

110423.6.

- (a) Except as provided in subdivision (b), a retail establishment that sells, transfers, or otherwise furnishes a dietary supplement product in violation of Section 110423.2 shall not be guilty of a misdemeanor pursuant to subdivision (a) of Section 110423.2 if all of the following conditions are met:
 - (1) Every checkout clerk at the retail establishment has completed standardized training that includes, but is not limited to, the law with respect to selling dietary supplement products subject to this article, methods of easily identifying dietary supplement products subject to this article when checking out customers, and procedures for requesting identification from any customer attempting to purchase dietary supplement products subject to this article who reasonably appears to the clerk to be a minor.
 - (2) Every checkout clerk at the retail establishment is provided with training updates that cover any changes in the law with respect to selling dietary supplement products subject to this article and any other responsibilities of the retail establishment under this article.
 - (3) Every programmable checkout scanner or computer used to check out customers with purchases is programmed to identify dietary supplement products subject to this article at the checkout station. A retail establishment that does not use programmable checkout scanners or computers is not required to satisfy this condition.
 - (4) Every checkout clerk has received a written list of dietary supplement products subject to this article that are sold by the retail establishment that may be posted at the checkout station for easy access.
- (b) Notwithstanding the fact that a retail establishment has met all of the conditions specified in subdivision (a), the retail establishment shall be guilty of a misdemeanor pursuant to subdivision (a) of Section 110423.2 if the retail establishment violates this article three or more times in a 12-month period.

110423.8. Nothing in this article limits or restricts any rights, remedies, or duties otherwise applicable by law.

Article 4.5. Ephedrine Group Alkaloids

110423.100. Notwithstanding Article 4 (commencing with Section 110423), the sale or distribution of any dietary supplement products containing ephedrine group alkaloids is prohibited.

110423.101. This article shall not apply, but Article 4 (commencing with Section 110423) shall apply, to any of the following:

- (a) A California licensed health care practitioner who is practicing within his or her scope of practice and who prescribes or dispenses, or both, dietary supplement products containing ephedrine group alkaloids in the course of the treatment of a patient under the direct care of that licensed health care practitioner, except that a licensed health care practitioner shall not prescribe or dispense dietary supplements containing ephedrine group alkaloids for purposes of weight loss, body building, or athletic performance enhancement.
- (b) Dietary supplement products containing ephedrine group alkaloids that are sold or distributed directly to a licensed health care practitioner when the dietary supplement product containing ephedrine group alkaloids is used solely for the purpose of the treatment of patients under the direct care of the health care practitioner.
- (c) Dietary supplement products containing ephedrine group alkaloids that are sold or distributed directly to a licensed pharmacist for resale to a patient for whom the products have been prescribed pursuant to subdivision (a).
- (d) Dietary supplement products containing ephedrine group alkaloids that are not for resale in California and that are sold or distributed directly to businesses not located in California.

110424. Violation of this article by any person, as defined in Section 109995, shall constitute an infraction, punishable by a fine not to exceed the following:

- (a) One thousand dollars (\$1,000) for the first violation.
- (b) Two thousand dollars (\$2,000) for the second violation.
- (c) Five thousand dollars (\$5,000) for the third and each subsequent violation.

CHAPTER 5. FOOD

Article 1. Generally

110425. Beer, that is subject to the Alcoholic Beverage Control Act, Division 9 (commencing with Section 23000) of the Business and Professions Code, shall only be subject to the provisions of this chapter that relate to adulteration and misbranding.

110430. Whenever the department finds that a class of food distributed in this state may, by reason of contamination with micro-organisms during manufacture, packing, or storage, be injurious to the health of any man or other animal that consumes it and that the injurious nature cannot be adequately determined after this food has entered commerce, the department shall adopt regulations providing for the issuance of permits to manufacturers, processors, or packers of the class of food. These permits shall establish conditions governing the manufacture, packing, or storage of the class of food for the period of time as may be necessary to protect the public health. The regulations shall prescribe a date after which no person shall introduce or deliver for introduction into commerce any food manufactured, packed, or stored by any manufacturer, processor, or packer, unless the person holds a permit issued by the department as provided by the regulations.

110435. The department may suspend immediately, upon written or oral notice, any permit issued pursuant to Section 110430 if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended may at any time apply for reinstatement of the permit. The department

shall, after prompt hearing and inspection of the establishment, reinstate the permit immediately, if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit.

110440. Any authorized agent of the department shall have access to any factory or establishment that operates under permit from the department for the purpose of ascertaining whether or not the conditions of the permit are being complied with. Denial of access for such inspection shall be grounds for suspension of the permit until the access is freely given by the holder of the permit or his or her agent.

110445. Any added poisonous or deleterious substance, or any food additive, pesticide chemical, preservative, or color additive, shall be considered unsafe for use with respect to any food unless there is in effect a regulation adopted pursuant to Section 110080, 110085, or 110090, that limits the quantity and the use, or intended use, of the substance to the terms prescribed by the regulation.

110450. On or before September 1, 1985, the department shall, within the limits of available resources, prepare and submit to the Legislature a program for detecting and monitoring chemical and pesticide residues in processed foods. In preparing the program, the department shall do all of the following:

- (a) Establish a list of chemical and pesticides developed from a knowledge of chemicals used in the food industry in processed foods and from the 96 pesticides on the Department of Food and Agriculture residue scan, for which analysis will be done by the department. The list shall include an explanation of why the listed chemicals and pesticides were selected. The Department of Food and Agriculture shall cooperate with the department in establishing the list required by this subdivision. In selecting the chemicals and pesticides to be placed on the list, the department shall make use of the following criteria:
 - (1) Chemicals that have been identified as having possible carcinogenic, reproductive, or mutagenic effects.
 - (2) Patterns of use in California.
 - (3) Quantities of use in California.
 - (4) Chemicals appearing as residues in processed food because of environmental persistence or resistance to degradation under conditions existing in the processing, manufacturing, milling, or shipping of processed foods sold in California.
 - (5) Chemicals that have the potential of chronic toxicity due to low continuous exposure. The department may revise the list and is authorized to add or remove chemicals or pesticides based on relevant information that becomes available to it after the list has been established and based on its experience in detecting the presence of chemical substances in processed foods under the sampling and testing program developed pursuant to subdivision (b).
- (b) The department shall design a sampling and testing program that does all of the following:
 - (1) Samples and tests processed food products that form a significant portion of the diet of the general population, and that may contain residues of the chemical substances on the list established pursuant to subdivision (a).
 - (2) Provides for specific testing of individual chemicals on the list established pursuant to subdivision (a) when a chemical cannot be detected using multiresidue testing procedures and when the department determines that the chemical may be the cause of chronic health effects.
 - (3) Lists the foods to be sampled, the stages of processing in which the foods will be sampled, the sampling frequency, and the techniques used in sampling.
 - (4) A description of plans for sampling processed imported foods from other states and countries.
- (c) As used in this section, "processed food" means any food chemically or physically altered from a raw agricultural commodity by chemical, mechanical, thermal, or other processes.

110455.

- (a) On or before July 1, 1990, the department shall commence and maintain a program for monitoring processed foods for pesticide residues, chemicals, microbes, and other contaminants. In designing the program, the department shall take into consideration any information developed pursuant to Section 110450.
- (b) The department shall consult with the Department of Food and Agriculture in designing the pesticide residue component of the monitoring program, to facilitate focusing the testing in areas of greatest

concern. Among the pesticides to be reviewed for possible monitoring shall be those contained in the lists of pesticides identified in Section 12535 of the Food and Agricultural Code.

- (c) In the development and ongoing operation of the department's monitoring program, the department shall consider, in establishing priorities:
- (1) Potential concentration effects that may occur during processing.
 - (2) Targeting foreign and domestic imported processed foods according to their estimated California market share.
 - (3) The extent to which processed foods are a part of the infant and child diet.

Article 2. Registration

110460. No person shall engage in the manufacture, packing, or holding of any processed food in this state unless the person has a valid registration from the department, except those engaged exclusively in the storing, handling, or processing of dried beans. The registration shall be valid for one calendar year from the date of issue, unless it is revoked. The registration shall not be transferable. This section shall not apply to a cottage food operation that is registered or has a permit pursuant to Section 114365.

110461. It is unlawful for any person to manufacture, pack, or hold processed food in this state unless in a food processing facility duly registered, as provided in this part.

110462. It is unlawful for any person to willfully make a false statement or representation, or knowingly fail to disclose a fact required to be disclosed in the application for registration or renewal of registration, as provided in this article.

110465. A separate registration is required for each place of manufacture, packing, or holding.

110466.

- (a) Commencing January 1, 2000, the department shall use the resources provided by the registration fees assessed by this article to inspect new and registered food processing facilities to determine compliance with this part. The department shall target the inspections and adjust their scope, depth, and frequency based on the department's statewide assessment of public health risk potential. In assessing public health risk potential, the department shall consider, at a minimum, the potential and actual health risks associated with processed foods manufactured, packed, or held in this state, and the food safety practices and compliance histories of persons who manufacture, pack, or hold processed foods in this state.
- (b) Commencing January 1, 2001, the department, pursuant to this chapter, shall conduct an annual inspection of each registered food processing facility and inspect each new food processing facility prior to issuing a new registration pursuant to Section 110460. This annual inspection requirement may be adjusted or waived based on an assessment of the food processing facility pursuant to subdivision (a).
- (c) The department may perform one or more reinspections of each new and registered food processing facility as necessary to prevent repeated or continuing violations of this part and for the purposes of approving the issuance of a new registration. The department shall charge a fee of one hundred dollars (\$100) per hour to cover the costs of performing the reinspections of the same food processing facility within any 12-month period.

110467. Any violation of any provision of this part or any regulation adopted pursuant to this part shall be grounds for denying a registration or for suspending or revoking a registration. Proceedings for the denial, suspension, or revocation of a registration shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the department shall have all the powers granted in that chapter.

110470. A registration application provided by the department shall be completed annually and accompanied by a nonreturnable registration fee.

The fee for a new or renewal registration for a food processing facility shall be as follows:

Holding Food Only:

Size of Facility	Fee Through 12/31/99	Fee Commencing 01/01/2000 Through 12/31/2000	Fee Commencing 01/01/2001 And on-going	Fee Commencing 01/01/2000 Los Angeles, San Bernardino Counties and the City of Vernon
0 – 5,000 sq.ft.	\$257.85	\$300	\$300	\$300
5,001–10,000 sq.ft.	257.85	350	400	350
Over 10,000 sq.ft.	386.77	500	600	500

Manufacturing or Packing Food

Number of Employees	Size of Facility	Fee	Fee	Fee	Fee
0 - 2		\$257.85	\$300	\$300	\$300
3 - 5	0 – 5,000 sq.ft.	257.85	350	400	350
6 - 20	0 – 5,000 sq.ft.	386.77	500	600	500
More than 20	0 – 5,000 sq.ft.	515.70	700	900	700
3 - 5	Over 5,000 sq.ft.	257.85	500	600	500
6 - 20	Over 5,000 sq.ft.	515.70	700	900	700
21 – 50	Over 5,000 sq.ft.	644..52	935	1,250	850
51 – 100	Over 5,000 sq.ft.	644..52	985	1,350	850
101 - 200	Over 5,000 sq.ft.	644..52	1,035	1,450	850
201 or more	Over 5,000 sq.ft.	644..52	1,085	1,550	850

A penalty of 1 percent per month shall be added to any registration fee not paid when due. The fee amount shall be adjusted annually pursuant to Section 100425.

110471.

- (a) Commencing January 1, 2006, the department shall make a one-time 15 percent cost-of-living adjustment to the registration fees established in Section 110470.
- (b) Commencing January 1, 2006, every person engaged in the manufacture, packing, or holding of processed food in this state that is subject to the requirements of Part 120 or 123 of Title 21 of the Code of Federal Regulations shall pay two hundred fifty dollars (\$250) in addition to their annual registration fee paid pursuant to Section 110470.
- (c) Revenue received pursuant to this section shall be deposited into the Food Safety Fund created by Section 110050.
- (d) Upon appropriation, the additional fee deposited in the FoodSafety Fund shall be used by the department to conduct inspections and reviews of those facilities required to have Hazard Analysis Critical Control Point (HACCP) plans or Standard Sanitation Operating Procedures (SSOPs).

110472. The department, in consultation with the California Conference of Directors of Environmental Health (CCDEH), representatives of the food processing industry, representatives of the local health departments of, Los Angeles, Orange, and San Bernardino Counties, and the City of Vernon, and any other person or entity deemed appropriate by the department shall develop, implement, and evaluate the processed food program in accordance with this chapter. In developing the processed food program, consideration shall be given to all aspects of the program provided for in this chapter.

110473. Notwithstanding the requirements of Section 110470, any person who is required to be registered under this chapter and is operating the food processing facility exclusively for charitable purposes, and meets the requirements of Section 214 of the Revenue and Taxation Code, shall not be required to submit any fees required by Section 110470.

110474. Nothing in this chapter shall relieve a person who has a valid registration to manufacture, pack, or hold processed food issued by the department from any other requirements for licensure, registration, or

certification under Article 7 (commencing with Section 110810), Article 12 (commencing with Section 111070), or Part 6 (commencing with Section 111940). The registration fee due to the department under this article from a person who holds one or more licenses, registrations, or certificates issued by the department pursuant to Article 12 (commencing with Section 111070) or Chapters 5 to 10, inclusive of Part 6 (commencing with Section 112150) shall be the fee for the single highest cost license, registration, or certificate only. Cannery inspection fees collected pursuant to Section 112730 and organic processed food registration fees collected pursuant to Section 110875 shall be in addition to any registration fees that may be collected under this article.

110475. Any person registered pursuant to this article shall immediately notify the department of any change in the information reported on the registration application.

110480. The registration provisions of this article shall not apply to any person whose manufacturing, packing, or holding of processed food is limited solely to temporarily holding processed foods for up to seven days for further transport if the foods are not potentially hazardous foods, as defined in Section 110005, or to any person whose manufacturing, packing, or holding of processed food is limited solely to activities authorized by any of the following:

- (a) A valid bottled water or water vending machine license issued pursuant to Article 12 (commencing with Section 111070).
- (b) A valid pet food license issued pursuant to Chapter 10 (commencing with Section 113025) of Part 6.
- (c) A valid permit issued pursuant to Chapter 4 (commencing with Section 113700) of Part 7 to a food facility including a food facility that manufactures, packs, or holds processed food for sale at wholesale, provided the food facility that manufactures, packs, or holds processed food for sale at wholesale does not meet any of the following conditions:
 - (1) Has gross annual wholesale sales of processed foods of more than 25 percent of total food sales.
 - (2) Sells processed foods outside the jurisdiction of the local health department.
 - (3) Sells processed foods that require labeling pursuant to this part.
 - (4) Processes or handles fresh seafood, frozen seafood held in bulk for further processing, or fresh or frozen raw shellfish.
 - (5) Salvages processed foods for sale other than at the retail food facility.
- (d) A valid cold storage license issued pursuant to Chapter 6 (commencing with Section 112350) of Part 6.
- (e) A valid cannery license issued pursuant to Chapter 8 (commencing with Section 112650) of Part 6.
- (f) A valid shellfish certificate issued pursuant to Chapter 5 (commencing with Section 112150) of Part 6.
- (g) A valid frozen food locker plant license issued pursuant to Chapter 7 (commencing with Section 112500) of Part 6.
- (h) A valid winegrower's license or wine blender's license pursuant to Division 9 (commencing with Section 23000) of the Business and Professions Code.
- (i) A valid milk products plant, margarine, imitation ice cream, imitation ice milk, or a products resembling milk products plant license, issued pursuant to Division 15 (commencing with Section 32501) of the Food and Agricultural Code.
- (j) A valid permit issued by a local health department to operate a processing establishment, as defined in Section 111955, that only holds or warehouses processed food, pursuant to Article 1 (commencing with Section 111950) of Chapter 4 of Part 6, provided that all of the following conditions are met:
 - (1) The warehouse does not manufacture or pack processed food.
 - (2) The warehouse does not hold fresh seafood, frozen seafood held in bulk for further processing, or fresh or frozen raw shellfish.
 - (3) The warehouse is not operated as an integral part of a food processing facility required to be registered pursuant to Section 110460.
 - (4) The warehouse facilities are located entirely within the area under the jurisdiction of the local health department.
 - (5) The warehouse does not salvage food as the primary business.
- (k) This section shall not be construed to limit the authority of Los Angeles, San Bernardino, and Orange Counties, or of the City of Vernon, to conduct any inspections otherwise authorized by Chapter 4 (commencing with Section 111950) of Part 6.

110485.

- (a) Every person who is engaged in the manufacture, packing, or holding of processed food in this state shall pay a food safety fee of one hundred dollars (\$100) to the department in addition to any fees paid pursuant to Section 110470.
- (b) Revenue received pursuant to this section shall be deposited in the Food Safety Fund created pursuant to Section 110050. A penalty of 10 percent per month shall be added to any food safety fee not paid when due.
- (c) Upon appropriation, the food safety fees deposited in the Food Safety Fund shall be used by the department to assist in developing and implementing education and training programs related to food safety. These programs shall be developed in consultation with representatives of the food processing industry. Implementation shall include education and training in the prevention of microbial contamination.
- (d) This section does not apply to companies exclusively involved in flour milling, dried bean processing, or in the drying or milling of rice, or to those individual registrants the director determines should not be assessed because substantial economic hardship would result to those registrants. For the purposes of this subdivision, the substantial hardship exemption shall be extended only to registrants whose wholesale gross annual income from the registered business is twenty thousand dollars (\$20,000) or less.

110490.

- (a) A laboratory that performs analyses of foods for pesticide chemical residues for other persons shall be accredited pursuant to Article 3 (commencing with Section 100825) of Chapter 4 of Part 1 of Division 101. This subdivision shall not apply to any of the following:
 - (1) A laboratory operated by a government agency.
 - (2) A laboratory not operated for commercial purposes that performs pesticide chemical residue analysis on foods for research or quality control for the internal use of the person initiating the analysis. For purposes of this section, "commercial purposes" means that the laboratory performs pesticide chemical residue analysis on the foods primarily for the purpose of making a profit.
- (b) A laboratory accredited pursuant to Section 12591 of the Food and Agricultural Code shall not be required to be accredited under this section until January 1, 1992.
- (c) A laboratory that performs analyses of foods for pesticide chemical residues, but that is not required by subdivision (a) to be accredited may apply for accreditation pursuant to Article 3 (commencing with Section 100825) of Chapter 4 of Part 1 of Division 101.
- (d) This section shall become operative on January 1, 1991, or 60 days after the initial set of regulations adopted pursuant to Sections 100830 and 100835 becomes effective, whichever is later.

110495.

- (a) Every laboratory or other person which performs or which brokers or otherwise arranges for the performance of pesticide chemical analysis on food shall report to the appropriate state agency any finding of pesticide chemical residues in a food for which no chemical residue tolerance has been established or that is in excess of federal or state residue tolerances or tolerances for a pesticide suspended, banned, or otherwise not permitted by the Department of Pesticide Regulation or the Environmental Protection Agency, if the food is in the channels of trade. The report shall be made as soon as possible, and in any event, not later than 24 hours after the analyzing laboratory makes the finding. Findings on raw agricultural commodities and dairy products shall be reported to the Department of Food and Agriculture. Findings on raw agricultural commodities shall also be reported to the Department of Pesticide Regulation. Findings on all other foods shall be made to the State Department of Health Services.
- (b) For the purpose of reporting findings regarding raw agricultural commodities, "in the channels of trade" means the point at which the raw agricultural commodities leave the farm, including raw agricultural commodities bound for processing up to the point that processing is initiated. For the purpose of reporting findings in processed foods, "in the channels of trade" means at the point the processed food leaves the direct control of the processor, which means either that the product is not

located on the premises owned by, or under the control of, the processor or a portion of the product has been released for sale or use.

Article 3. Standard of Identity, Quality, and Fill

110505. Definitions and standards of identity, quality, and fill of container, and any amendments to the definitions and standards, adopted pursuant to the federal act in effect on the effective date of this part, or adopted on or after that date, are the definitions and standards of identity, quality, and fill of container in this state. The department may, by regulation, establish definitions and standards of identity, quality, and fill of container for any food whether or not the definitions and standards are in accordance with the federal regulations, when in its judgment such action will promote honesty and fair dealing in the interest of consumers. This section shall not apply to wine.

110510. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the department shall designate the optional ingredients that shall be named on the label. This section shall not apply to wine.

110515. A temporary permit which is granted by the Food and Drug Administration of the Department of Health, Education and Welfare of the United States for interstate shipment of experimental packs of food that vary from the requirements of federal definitions and standards of identity is automatically effective in this state under the provisions provided in the permit. The department shall issue a permit when no federal permit exists and when the experimental packs are to be manufactured and tested only within this state. The permit is subject to any term or condition that the department may prescribe.

110520. Definitions and standards of identity and quality for distilled spirits and their amendments adopted by the Internal Revenue Service of the Treasury Department of the United States in effect on the effective date of this part, or adopted on or after that date, are the definitions and standards of identity and quality for distilled spirits in this state. The department may, by regulation, establish definitions and standards of identity and quality for any distilled spirit whether or not the definitions and standards are in accordance with regulations adopted by the Internal Revenue Service of the Treasury Department of the United States, when in its judgment the action will promote honesty and fair dealing in the interest of the consumers.

110525. The department may, by regulation, establish definitions and standards of identity and quality for wine. Such definitions and standards may incorporate in whole or in part, the regulations adopted by the Secretary of the Treasury pursuant to the Federal Alcohol Administration Act, pertaining to the standards of identity and quality for wine. Standards of identity and quality for wine adopted pursuant to this section may differ from or be inconsistent with the standards promulgated by the Secretary of the Treasury pursuant to the Federal Alcohol Administration Act. No standard of size, type, or fill of container for any wine subject to the provisions of the Alcoholic Beverage Control Act, Division 9 (commencing with Section 23000) of the Business and Professions Code, shall be adopted, but containers of wine sold in this state shall conform to the then current standards for the containers, including standards of fill, established by the Secretary of the Treasury pursuant to the Federal Alcohol Administration Act.

Article 4. Enrichment of Food and Food Products

110530. When a definition and standard of identity for an enriched food has been established pursuant to Section 110505, only the enriched form of the food shall be sold at retail in California.

110535. The nonenriched form of a food identified and standardized pursuant to Section 110505 may be used as an ingredient of another food only if it comprises less than 25 percent of the total ingredients, or it comprises 25 percent or more of the total ingredients and vitamins and minerals have been added to make it nutritionally equivalent to the enriched form of the ingredient.

Article 5. Adulterated Food

110545. Any food is adulterated if it bears or contains any poisonous or deleterious substance that may render it injurious to health of man or any other animal that may consume it. The food is not considered adulterated if the substance is a naturally occurring substance and if the quantity of the substance in the food does not render it injurious to health.

110550. Any food is adulterated if it bears or contains any added poisonous or deleterious substance that is unsafe within the meaning of Section 110445.

110552.

- (a) The department shall regulate candy to ensure that the candy is not adulterated.
- (b) For the purposes of this chapter, "candy" means any confectionary intended for individual consumption that contains chili, tamarind, or any other ingredient identified as posing a health risk in regulations adopted by the office or department.
- (c) For purposes of this section the following terms have the following meanings:
 - (1) "Office" means the Office of Environmental Health Hazard Assessment.
 - (2) "Adulterated candy" means any candy with lead in excess of the naturally occurring level. Moreover, candy is adulterated if its wrapper or the ink on the wrapper contains lead in excess of standards which the office, in consultation with the department and the Attorney General shall establish by July 1, 2006.
 - (3) "Naturally occurring level" of lead in candy shall be determined by regulations adopted by the office after consultation with the department and the Attorney General. For purposes of this section, the "naturally occurring level" of lead in candy is only naturally occurring to the extent that it is not avoidable by good agricultural, manufacturing, and procurement practices, or by other practices currently feasible. The producer and manufacturer of candy and candy ingredients shall at all times use quality control measures that reduce the natural chemical contaminants to the "lowest level currently feasible" as this term is used in subsection (c) of Section 110.110 of Title 21, Code of Federal Regulations. The "naturally occurring level" of lead shall not include any lead in an ingredient resulting from agricultural equipment, fuels used on or around soils or crops, fertilizers, pesticides or other materials that are applied to soils or crops or added to water used to irrigate soils or crops. The office shall determine the naturally occurring levels of lead in candy containing chili and tamarind no later than July 1, 2006. The office shall determine the naturally occurring levels of lead in candy containing other ingredients upon request by the department or the Attorney General, and in the absence of a request, when the office determines that the presence of the ingredient in candy may pose a health risk. Until the office adopts regulations determining the naturally occurring level of lead, the Attorney General's written determination, if any, including any determination set forth in a consent judgment entered into by the Attorney General, of the naturally occurring level of lead in candy or in a candy ingredient shall be binding for purposes of this section.
 - (4) "Wrapper" means all packaging materials in contact with the candy, including, but not limited to, the paper cellophane, plastic container, stick handle, spoon, small pot (olla), and squeeze tube, or similar devices. "Wrapper" does not include any part of the packaging from which lead will not leach, as demonstrated by the manufacturer, to the satisfaction of the office.
- (d) The standards adopted pursuant to paragraphs (2) and (3) of subdivision (c) shall be reviewed by the office every three-year to five-year period in order to determine whether advances in scientific knowledge, the development of better agricultural or manufacturing practices, or changes in detection limits require revision of the standards.
- (e) The department shall do all of the following:
 - (1) Ensure that the candy is not adulterated.
 - (2) Establish procedures for the testing of candy and the certification of unadulterated candy products. The procedures shall require candy manufacturers to certify candy as being unadulterated. The certification shall be based on appropriate sampling and testing protocols as determined by the office in consultation with the Attorney General's office.

- (3) Through its Food and Drug Branch, test the samples of candy collected pursuant to this article. The department may test any candy, including candy tested pursuant to paragraph (3) of subdivision (e) in order to ensure the candy is unadulterated.
 - (4) Adopt regulations necessary for the enforcement of this article.
 - (5) Evaluate the regulatory process, identify problems, and make changes or report to the Legislature, as necessary.
- (f) If the candy tested pursuant paragraphs (2) or (3) of subdivision (e) is found to be adulterated, the department shall do both of the following:
- (1) Issue health advisory notices to county health departments alerting them to the danger posed by consumption of the candy.
 - (2) Notify the manufacturer and the distributor of the candy that the candy is adulterated, and that the candy may not be sold or distributed in the state until further testing proves that the candy is unadulterated.
- (g) (1) For any candy found to be adulterated, the manufacturer or distributor may request that the department test a subsequent sample of candy. The department shall select the candy to be tested. The cost of any subsequent sampling and testing shall be borne by the manufacturer or distributor requesting the additional testing.
- (2) If the candy is found to be unadulterated when it is retested, the department shall provide the manufacturer or distributor and the county health department with a letter stating that the candy has been retested and determined to be unadulterated, and that the sale and distribution of the candy in the state may resume.
 - (3) If the candy is found to remain adulterated when retested, the manufacturer or distributor may take corrective measures and continue to resubmit samples for testing until tests prove the candy unadulterated.
- (h) The department shall convene an interagency collaborative which is hereby established to serve as an oversight committee for the implementation of this section and to work with the office in establishing and revising the required standards. The interagency collaborative shall be composed of the following members:
- (1) The department.
 - (2) The Childhood Lead Poisoning Branch of the department.
 - (3) The Food and Drug Branch of the department.
 - (4) The office.
 - (5) The office of the Attorney General.
- (i) The interagency collaborative may confer with the United States Consumer Product Safety Commission, the United States Food and Drug Administration, recognized experts in the field, representatives of California community environmental justice organizations and candy manufacturers.
- (j) (1) The sale of adulterated candy to California consumers is a violation of this section. Any person knowingly and intentionally selling adulterated candy shall be subject to a civil penalty of up to five hundred dollars (\$500) per violation. The regulations adopted shall provide that funding for this section shall be met in part or in whole by those penalties, upon appropriation by the Legislature.
- (2) In the event that a candy product is found to be adulterated, the department may recover the costs incurred in the chemical analysis of that product from the manufacturer or distributor.
 - (3) Except as expressly set forth in this section, nothing in this section shall alter or diminish any legal obligation otherwise required in common law or by statute or regulation, and nothing in this section shall create or enlarge any defense in any action to enforce that legal obligation. Penalties imposed under this section shall be in addition to any penalties otherwise prescribed by law.
 - (4) This section shall not be the basis for any stay of proceedings or other order limiting or delaying the prosecution of any action to enforce Section 25249.6.

110555. Any food is adulterated if it is, bears, or contains any food additive that is unsafe within the meaning of Section 110445. If, however, a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under this part or the Food and Agricultural Code and the raw agricultural commodity has been subject to processing, such as

canning, cooking, freezing, dehydrating, or milling, the residue of a pesticide chemical remaining in or on the processed food shall not be deemed unsafe if the residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity.

110560. Any food is adulterated if it consists in whole or in part of any diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.

110565. Any food is adulterated if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered unwholesome, diseased, or injurious to health.

110570. Any food is adulterated if it is, in whole or in part, the product of any diseased animal, any animal that has died otherwise than by slaughter, or any animal that has been fed on the uncooked offal from a slaughterhouse.

110575. Any food is adulterated if its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

110580. Any food is adulterated if it has been intentionally subjected to ionizing radiation unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to Section 110070.

110585. Any food is adulterated if any one of the following conditions exist:

- (a) If any valuable constituent has been in whole or in part omitted or abstracted therefrom.
- (b) If any substance has been substituted wholly or in part therefor.
- (c) If damage or inferiority has been concealed in any manner.
- (d) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight or reduce its quality or strength or make it appear better or of greater value than it is.

110590. Any food is adulterated if it is confectionery and any one of the following conditions exist:

- (a) It has partially or completely embedded therein any nonnutritive object, provided that this subdivision shall not apply in the case of any nonnutritive object if, in the judgment of the department as provided by regulation, the object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health.
- (b) It bears or contains any alcohol in excess of 5 percent by weight.
- (c) It bears or contains any nonnutritive substance, provided that this subdivision shall not apply to a safe nonnutritive substance that is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of the confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this act; and provided further that the department may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

110595. Any food is adulterated if it bears or contains any color additive that is unsafe within the meaning of Section 110445.

110597. Any food is adulterated if it is wine and any one of the following conditions exists:

- (a) It contains lead in concentrations exceeding 150 parts per billion, or in excess of a more stringent tolerance as may be established by federal law or regulation, unless it can be shown by the producer, or if not produced in California, by the licensed importer, that the wine was bottled before January 1, 1994.
- (b) A metal foil capsule containing lead in excess of 0.3 percent by dry weight is affixed or attached to its container, unless it can be shown by the producer, or if not produced in California, by the licensed importer, that the wine was bottled before January 1, 1994.

(c) Notwithstanding any other rule or principle of law that may afford a private right of action to bring claims based on alleged violations of laws or standards, the right to commence and pursue civil or administrative actions to impose or collect fines, penalties, damages, or other remedies based on an alleged violation of the Wine Safety Act established pursuant to Senate Bill 1022 of the 1993-94 Regular Session shall be vested exclusively in the state, through the Food and Drug Branch of the State Department of Health Services and the Office of the Attorney General, and with local health officers or city attorneys or district attorneys otherwise empowered to prosecute violations of this division. Retailers of wine, including, but not limited to, "retailers" as defined in Section 23023 of the Business and Professions Code, or food facilities as defined in Section 113785, shall be entitled to all of the same protections for any violations of the Wine Safety Act established pursuant to Senate Bill 1022 of the 1993-94 Regular Session, as are afforded to food dealers pursuant to Chapter 3 (commencing with Section 110245). This subdivision does not apply to, limit, alter, or restrict any action for personal injury or wrongful death, or any action based upon a failure to warn.

110600. Any food is adulterated if it is fresh meat and it contains any preservative or other chemical substance not approved for use in fresh meat by the department, the United States Department of Agriculture, or the Department of Food and Agriculture of this state.

110605. Any food is adulterated if it is chopped or ground beef or hamburger unless it is composed of voluntary striated muscle of fresh beef that does not contain any substance that is not approved by the department and unless it has a total fat content that is not in excess of 30 percent by weight.

110610. Any food is adulterated if it is pork sausage or breakfast sausage and it has a total fat content that is in excess of 50 percent by weight.

110615. The methods of analysis used in determining the fat content of products described in Sections 110605 and 110610 shall be those prescribed by the current issue of "Official and Tentative Methods of Analysis of the Association of Official Analytical Chemists," and the supplements thereto.

110620. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is adulterated.

110625. It is unlawful for any person to adulterate any food.

110630. It is unlawful for any person to receive in commerce any food that is adulterated or to deliver or proffer for delivery any such food.

110635. While any regulation relating to a substance referred to in Section 110080, 110085, or 110090 is in effect, any food bearing or containing a substance in accordance with the regulation shall not be considered to be adulterated.

110640. The director, with the assistance of the Department of Food and Agriculture, and in cooperation with the federal Food and Drug Administration and Environmental Protection Agency, shall identify those pesticides most likely to leave residue in processed foods.

110645. Whenever the director has been notified by the Director of Food and Agriculture pursuant to Section 12582 of the Food and Agricultural Code, the director shall immediately notify the processor, if known, by telephone, with immediate written confirmation, and take appropriate action pursuant to Section 110045.

110650. This article does not prohibit the addition of fluorine or fluorine compounds to water intended for sale to the public as bottled water for domestic use in the manner and to the extent as may be approved by the department. The label of the bottled water shall, however, satisfy all of the labeling requirements prescribed by this part.

110655. Any food intended for export shall not be deemed to be adulterated within the provisions of this part if it satisfies all of the following requirements:

- (a) It accords to the specifications of the foreign purchaser.
- (b) It is not in conflict with the laws of the importing country.
- (c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

Article 6. Misbranded Food

110660. Any food is misbranded if its labeling is false or misleading in any particular.

110661. Any food is misbranded if it is manufactured, packed, or held in this state in a food processing facility not duly registered as provided in this part, except for food from facilities exclusively storing, handling, or processing dry beans.

110665. Any food is misbranded if its labeling does not conform with the requirements for nutrition labeling as set forth in Section 403(q) (21 U.S.C. Sec. 343(q)) of the federal act and the regulations adopted pursuant thereto. Any food exempted from those requirements under the federal act shall also be exempt under this section.

110670. Any food is misbranded if its labeling does not conform with the requirements for nutrient content or health claims as set forth in Section 403(r) (21 U.S.C. Sec. 343(r)) of the federal act and the regulations adopted pursuant thereto. Any food exempted from those requirements under the federal act shall also be exempt under this section.

110673. Any food is misbranded if its labeling does not conform with the requirements for food allergen labeling as set forth in Section 403(w) of the federal act (21 U.S.C. Sec. 343(w)) and the regulations adopted pursuant thereto. Any food exempted from those requirements under the federal act, shall also be exempt under this section.

110674. Any food is misbranded if its labeling does not conform with the requirements for pasteurized in-shell egg labeling as set forth in Section 27644.5 of the Food and Agricultural Code, and the regulations adopted pursuant thereto.

110675. Any food is misbranded if it is in package form, unless it bears a label containing all of the following information:

- (a) The name and place of business of the manufacturer, packer, or distributor.
- (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information required by subdivision (b), and exemptions as to small packages, shall be established in accordance with regulations adopted pursuant to Sections 110100 and 110380.

110680. Any food is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

110685. Any food is misbranded if it is offered for sale under the name of another food, or if it is an imitation of another food for which a definition and standard of identity has been established by regulation and its label does not bear, in type of uniform size and prominence the word "imitation," and immediately following, the name of the food imitated.

110690. Any food is misbranded if its container is so made, formed, or filled as to be misleading.

110695. Any food is misbranded if it is a confectionery and contains alcohol in excess of ½ of 1 percent by weight and that fact does not appear on the label for the food.

110700. Any food is misbranded if it is a potentially hazardous processed food that is preserved by refrigeration at temperatures of 45 degrees Fahrenheit or lower and it is not conspicuously labeled "Perishable Keep Refrigerated."

110705. Any food is misbranded if any word, statement, or other information required pursuant to this part to appear on the label or labeling is not prominently placed upon the label or labeling with conspicuousness, as compared with other words, statements, designs, or devices in the labeling and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

110710. Any food is misbranded if it purports to be, or is represented as, a food for which a definition and standard of identity has been established under Section 110505 and the label fails to bear the name of the food specified in the standard or otherwise fails to conform to the definition and standard.

110715. Any food is misbranded if it purports to be, or is represented as, a food for which a standard of quality or fill has been prescribed by regulation under Section 110505 and its quality or fill is below the standard unless its label bears, in a manner and form as specified by regulation, a statement that it is below the standard.

110720. Any food for which no standard of identity exists is misbranded unless it bears a label clearly stating the common or usual name of the food.

110725.

- (a) Any food fabricated from two or more ingredients is misbranded unless it bears a label clearly stating the common or usual name of each ingredient, and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of fruit or vegetable juice contained in the food. Any spice, flavoring, or color not required to be certified under Section 110090, except any spice, flavoring, or color sold as such, may be designated as spice, flavoring, or color without naming each.
- (b) Exemptions may be established by the department, when compliance with any requirement of this section is impractical or results in deception or unfair competition.
- (c) In adopting any regulations relating to this section, the department shall take into consideration the current regulations established by the Secretary of Health and Human Services under authority contained in the federal act.
- (d) Notwithstanding Section 110040 or any other provision of law, as used in this section, the term "food" includes, but is not limited to, meat. The term "food" does not, however, include any alcoholic beverage.
- (e) This section shall not apply to any food sold for consumption on or off the premises of any restaurant in the course of its business as a restaurant, or to any milk or dairy product.

110730. The requirements of Sections 110720 and 110725 do not apply to any food that is packaged at the direction of retail purchasers at the time of sale if the ingredients are disclosed to the purchasers by other means in accordance with the regulations adopted by the department.

110735. Any food is misbranded if it purports to be, or is represented, for special dietary uses as prescribed by regulation under Section 110095 and its label does not bear information concerning any vitamin or mineral content, or other dietary property as the department prescribes, by regulation, as necessary to fully inform purchasers as to the food's value for that use.

110740. Any food is misbranded if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless its labeling states that fact. Exemptions may be established by the department.

110745. Any food is misbranded if it is intended as a component of another food and when used in accordance with the directions of the purveyor, it will result in the final food being adulterated or misbranded.

110750. Any food is misbranded if it is a color additive and it is not in conformity with the requirements for color additives prescribed under the provisions of Section 110090.

110755. Any food is misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 108685 or 108700.

110760. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is misbranded.

110765. It is unlawful for any person to misbrand any food.

110770. It is unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for delivery any such food.

110775. It is unlawful for any person to alter, mutilate, destroy, obliterate, or remove the label, or any part of the labeling, of any food if the act results in the food being misbranded.

110790. Any food intended for export shall not be deemed to be misbranded under this part if it satisfies all of the following requirements:

- (a) It accords to the specifications of the foreign purchaser.
- (b) It is not in conflict with the laws of the importing country.
- (c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

110795.

- (a) The department may adopt regulations that name and describe the characteristics of salmon and any other fish or other seafood it considers appropriate. The department shall consult with the Department of Fish and Game, the Joint Committee on Fisheries and Aquaculture, consumers, commercial fishermen, aquaculturists, and seafood processors, wholesalers, restaurateurs, and other retailers before adopting these regulations. The department shall not adopt any regulation that conflicts with the common name of any fish designated by the Department of Fish and Game pursuant to Section 8023 of the Fish and Game Code.
- (b) In addition to the consultations required by subdivision (a), the department shall consult and seek the recommendations of the groups named in that subdivision concerning the possible need for, or desirability of, any further legislation or regulations affecting seafood labeling.
- (c) No regulation adopted pursuant to this section shall deviate from a pertinent United States standard where the fish or seafood product specified is packed or processed as a standardized product under a United States standard.
- (d) Nothing in this section or in regulations adopted pursuant to this section shall be construed to require the use of more than the common family name of any fish or seafood by any restaurant in menus or advertisements.

110800.

- (a) Any label of any retail cut of beef, veal, lamb, or pork held for sale in a retail food production and marketing establishment or a frozen food locker plant shall clearly identify the species (beef, veal, lamb, or pork) and the primal cut from which it is derived, and the retail name.

This section shall not apply to ground beef or hamburger, boneless stewing meat, cubed steaks, sausage, or soupbones.

(b) "Primal cuts" include only the following in the various species:

Beef Veal Lamb Pork

Chuck	Shoulder	Shoulder	Shoulder
Rib	Rib	Rib	--
Loin	Loin	Loin	--
Shank	Shank	Shank	--
Brisket	Breast	Breast	--
Plate	Breast	Breast	--
Flank	Flank	--	--
Round	Round or Leg	Leg	Leg or Ham

Cuts derived from other than the above primal cuts need only show species and the retail name.

(c) It is unlawful and constitutes misbranding for any person to sell or offer for sale in a retail food production and marketing establishment or frozen food locker plant any retail cut of beef that is labeled in violation of this section.

110805.

- (a) Except as otherwise provided in this section, no chopped or ground beef or hamburger that is offered for sale in any retail food production and marketing establishment or frozen food locker plant shall be advertised, labeled, or otherwise held out in any manner to describe or suggest its quality or relative leanness or fat content unless the label, advertisement, or other representation accurately discloses the maximum fat content thereof by the designation "Does not exceed __ percent fat". However, in no case shall the fat content of any chopped or ground beef or hamburger exceed 30 percent fat, except in no case shall the fat content exceed 26 percent in the case of chopped or ground beef or hamburger processed from the primal cut of chuck when the primal cut designation is being used.
- (b) No designation such as, but not limited to, "lean," "super lean," "premium," "deluxe" or similar terms descriptive of quality, leanness, or fat content shall be included on the label unless the label also contains a fat-weight designation as specified in subdivision (a). However, as an alternative to including the fat-weight designation on the label, the fat-weight designation required by this section may be disclosed by means of a sign placed immediately adjacent to the counter on which the chopped or ground beef or hamburger is displayed. This sign shall be within plain view of prospective purchasers and shall display the appropriate designation specified in subdivision (a) in boldface print.
- (c) Chopped or ground beef or hamburger that is processed from primal cuts of round or sirloin shall not be required to disclose the maximum fat content if there is no reference to leanness or other quality designation relating to fat content other than the primal cut from which the product is derived. If there is a reference to leanness or any other quality designation relating to fat content, the maximum fat designation shall be a fat-weight designation as specified in subdivision (a).
- (d) It is unlawful and constitutes misbranding for any person to sell or offer for sale in a retail food production and marketing establishment or frozen food locker plant any chopped or ground beef or hamburger that is labeled in violation of this section.

Article 6.5. Recalled Food

110806.

- (a) A meat or poultry supplier, distributor, broker, or processor that sells a meat- or poultry-related product in California that meets the criteria for a Class I or Class II recall according to the United States Department of Agriculture guidelines shall immediately notify the State Department of Health Services and shall provide the department with a list of all customers, including a firm name, address, contact person's name, telephone number, fax, and e-mail address, that have received or will receive any product subject to recall that the supplier, distributor, broker, or processor has handled or anticipates handling. The list shall include all pertinent identifying codes, including establishment numbers, package codes, product codes, pack dates, and lot numbers, if any, received or to be received, and any other relevant information. The information shall be

electronically submitted to the department in a spreadsheet format specified by the department, and shall include, but not be limited to, a complete product distribution list of the recalled product, for each customer, including product ship date, amount of product shipped and amount of any product returned. The supplier, distributor, broker, or processor shall immediately notify each of its customers that received or may receive those products of the recall in a standardized format. The supplier, distributor, broker, or processor shall document this notification process, including who was notified, the date and time of the notification, and by what method they were notified. This information shall be maintained by the supplier, distributor, broker, or processor and shall be provided to the department upon request.

- (b) The department may, after receiving the information required by subdivision (a), notify appropriate local health officers and environmental health directors, as soon as practicable, that a business in the local jurisdiction has handled or received, or anticipates handling or receiving, a recalled meat- or poultry-related product. The department shall, if it makes the notification authorized by this subdivision, provide appropriate local health officers and environmental health directors with each supplier's, distributor's, broker's, processor's, or retailer's name, address, contact information, affected product identifying codes, including establishment numbers, package codes, product codes, pack dates, and lot numbers, if any, and all other supply chain information available.
- (c)
 - (1) If the department makes the notification authorized by subdivision (b), the department, local health officers, and environmental health directors may notify the public in a manner local health officers, in consultation with the department and environmental health directors, deem appropriate regarding recalled meat- and poultry-related products based on their determination that the retailer is present within the local jurisdiction and has received or made the product available to the public.
 - (2) If the retailer is a restaurant, and a determination has been made by a local health officer or environmental health officer that the contaminated product has not been served, sold, or otherwise offered to the public for consumption, and the contaminated product has been permanently removed from the restaurant's food supply, then the public notification shall exclude the name or any other identifying feature of the restaurant.

110807. This article shall become operative on July 1, 2007.

Article 7. The California Organic Products Act of 2003

110810. This article shall be known, and may be cited as, the California Organic Products Act of 2003.

110811. This article shall be interpreted in conjunction with Chapter 10 (commencing with Section 46000) of Division 17 of the Food and Agricultural Code and the regulations promulgated by the National Organic Program (NOP) (Section 6517 of the federal Organic Foods Production Act of 1990 (7 U.S.C. Sec. 6501 et seq.)).

110812. The director shall enforce regulations promulgated by the National Organic Program (Section 6517 of the federal Organic Foods Production Act of 1990 (7 U.S.C. Sec. 6501 et seq.)), provisions of this article, and Chapter 10 (commencing with Section 46000) of Division 17 of the Food and Agricultural Code.

110815. Unless otherwise defined pursuant to the National Organic Program, the following words and phrases, when used in this article, shall have the following meanings:

- (a) "Animal food" means any food intended to be fed to any household animal, including, but not limited to, cats, or dogs and other carnivores. It does not include "feed" intended for livestock as defined in Section 205.2 of Title 7 of the Code of Federal Regulations.
- (b) "Director" means the Director of the Department of Health Services.
- (c) "Enforcement authority" means the governmental unit with primary enforcement jurisdiction, as provided in Section 110930.
- (d) "Handle" means to sell, process, or package agricultural products.
- (e) "Handler" means any person engaged in the business of handling agricultural products, but does not include final retailers of agricultural products that do not process agricultural products.

- (f) "Handling operation" means any operation or portion of an operation, except final retailers of agricultural products that do not process agricultural products, that (1) receives or otherwise acquires agricultural products and (2) processes, packages, or stores agricultural products.
- (g) "NOP" means the National Organic Program established pursuant to the Organic Foods Production Act of 1990 (7 U.S.C. Sec. 6501 et seq.) and the regulations adopted for implementation.
- (h) "Processing" means cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, or otherwise manufacturing, and includes packaging, canning, jarring, or otherwise enclosing food in a container.
- (i) "Prohibited materials" means any materials prohibited under regulations adopted by (Section 6517 of the federal Organic Foods Production Act of 1990 (7 U.S.C. Sec. 6501 et seq.)). For products not covered by the National Organic Program, prohibited materials are anything not on the approved list.
- (j) "Secretary" means the Secretary of the California Department of Food and Agriculture.
- (k) "Sold as organic" means any use of the terms "organic," "organically grown," or grammatical variations of those terms, whether orally or in writing, in connection with any product grown, handled, processed, sold, or offered for sale in this state, including, but not limited to, any use of these terms in labeling or advertising of any product and any ingredient in a multi-ingredient product.
- (l) "USDA" means the United States Department of Agriculture.

110818. Water, including substances dissolved in water, shall not be a prohibited material, even if it contains incidental contamination from a prohibited material, if the prohibited material was not added by, or under the direction or control of, the person in control of the product.

110820. Except as otherwise provided in this article, no product shall be sold as organic pursuant to this article unless it is produced according to regulations promulgated by the NOP, and consists entirely of products manufactured only from raw or processed agricultural products except as follows:

- (a) Water, air, and salt may be added to the product.
- (b) Ingredients other than raw or processed agricultural products may be added to the product if these ingredients include nonagricultural substances or nonorganically produced agricultural products produced in a manner consistent with, or which are on the national list adopted by the United States Secretary of Agriculture pursuant to Section 6517 of the NOP and do not represent more than 5 percent of the weight of the total finished product, excluding salt and water.

110825. Materials acceptable in this state are those outlined by regulations promulgated by the NOP and the provisions of this article.

110827. No aquaculture, fish, or seafood product, including, but not limited to, farmed and wild caught species, shall be labeled or represented as "organic" until formal organic certification standards have been developed and implemented by the United States Department of Agriculture's National Organic Program or the California Department of Food and Agriculture.

110830.

- (a) No product handled, processed, sold, advertised, represented, or offered for sale in this state, shall be sold as organic unless it also is prominently labeled and invoiced with similar terminology as set forth by regulations promulgated by the NOP.
- (b) No product may be advertised or labeled as "organic when available" or similar terminology that leaves in doubt whether the food is being sold as organic.

110835. The director may adopt regulations allowing or prohibiting the use of substances in the processing of products that are exempt or excluded from certification under the NOP, and animal food and cosmetics sold as organic.

110838.

- (a) Cosmetic products sold, labeled, or represented as organic or made with organic ingredients shall contain, at least 70 percent organically produced ingredients.

- (b) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as “organic” or “100 percent organic,” or sold, labeled, or represented as being made with organic ingredients or food groups, or as inclusive of organic ingredients, shall be calculated as follows:
 - (1) For products containing organically produced ingredients in solid form, by dividing the total net weight of combined organic ingredients at formulation, excluding water and salt, by the total weight of the finished product, excluding water and salt.
 - (2) For products containing organically produced ingredients in liquid form, by dividing the fluid volume of all organic ingredients, excluding water and salt, by the fluid volume of the finished product, excluding water and salt. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.
 - (3) For products containing organically produced ingredients in both solid and liquid form, by dividing the combined weight of the solid ingredients and the weight of the liquid ingredients, excluding water and salt, by the total weight of the finished product, excluding water and salt.
- (c) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.
- (d) The percentage of all organically produced ingredients in an agricultural product must be determined by the handler who affixes the label to the consumer package and verified by the handler’s certifying agent. The handler may use information provided by the certified operation in determining the percentage.

110839. Multi-ingredient cosmetic products sold as organic in California with less than 70 percent organically produced ingredients, by weight or by fluid volume, excluding water and salt, may only identify the organic content as follows:

- (a) By identifying each organically produced ingredient in the ingredient statement with the word “organic” or with an asterisk or other reference mark that is defined below the ingredient statement to indicate the ingredient is organically produced.
- (b) If the organically produced ingredients are identified in the ingredient statement, by displaying the product’s percentage of organic contents on the information panel.

110840.

- (a) All persons who handle products sold as organic shall keep accurate and specific records of the following:
 - (1) Except when sold to the consumer, the name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all persons, to whom or from whom the product is sold, purchased, or otherwise transferred, the quantity of product sold or otherwise transferred, and the date of the transaction.
 - (2) Invoices, bills of lading, or other documents that show transfer of title of certified organic products must indicate the product is “organic” or “certified organic” and, if applicable, the California registration number of the person transferring the product.
 - (3) Any person selling a product which is exempt or excluded from certification under NOP rules, shall follow the requirements of Section 205.101 of Title 7 of the Code of Federal Regulations.
 - (4) All substances applied to the product or used in or around any area where product is kept, including the quantity applied and the date of each application. All pesticide chemicals shall be identified by brand name, if any, and by source.
- (b) All persons who sell, at retail, products sold as organic shall keep accurate and specific records of the following:
 - (1) Except when sold to the consumer, the name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all suppliers of persons, to whom or from whom the product is sold, purchased, or otherwise transferred, the quantity of product purchased or otherwise transferred, and the date of the transaction.

- (2) Invoices, bills of lading or other documents that show transfer of title of certified organic products must indicate the product is “organic” or “certified organic” and, if applicable, the California registration number of the person transferring the product.
 - (3) Any person selling a product that is exempt or excluded from certification under NOP rules, shall follow the requirements of Section 205.101 of Title 7 of the Code of Federal Regulations.
 - (4) All substances applied to the product or used in or around any area where product is kept, including the quantity applied and the date of each application. All pesticide chemicals shall be identified by brand name, if any, and by source.
- (c) All records required to be kept under this section shall be maintained as set forth by regulations promulgated by the NOP, when applicable, or as follows: by producers for not less than three years and by handlers for not less than two years from the date that the product is sold, and shall be maintained by retailers for not less than one year from the date that the product is sold, and shall be maintained by the retailers for not less than one year from the date that the product is received by the retailer. These records shall be made available for inspection at any time by the director or the secretary and by each certification organization that certifies the product, if any, for purposes of carrying out this article and Chapter 10 (commencing with Section 46000) of Division 17 of the Food and Agricultural Code.

110845.

- (a) Notwithstanding any other provision of law, any producer, handler, processor, or retailer of products sold as organic shall immediately make available for inspection by, and shall upon request, within 72 hours of the request, provide a copy to, the director, the Attorney General, any prosecuting attorney, any governmental agency responsible for enforcing laws related to the production or handling of products sold as organic, or the secretary of any record required to be kept under this section for purposes of carrying out this article and Chapter 10 (commencing with Section 46000) of Division 17 of the Food and Agricultural Code. Records acquired pursuant to this subdivision shall not be public records as that term is defined in Section 6252 of the Government Code and shall not be subject to Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code.
- (b) Upon written request of any person that establishes cause for the request, the director and the secretary shall obtain and provide to the requesting party within 10 working days of the request a copy of any of the following records required to be kept under this article that pertain to a specific product sold or offered for sale, and that identify substances applied, administered, or added to that product, except that financial information about an operation or transaction, information regarding the quantity of a substance administered or applied, the date of each administration or application, information regarding the identity of suppliers or customers, and the quantity or price of supplies purchased or products sold shall be removed before disclosure and shall not be released to any person other than persons and agencies authorized to acquire records under subdivision (a):
- (1) Records of a handler, as described in paragraph (4) of subdivision (a) of Section 110840, records of previous handlers, if any, without identifying the previous handlers or producers, and, if applicable, records obtained as required in subdivision (b).
 - (2) Records of a retailer, as described in paragraph (4) of subdivision (b) of Section 110840, records of previous handlers, if any, as described in paragraph (4) of subdivision (a) of, Section 110840, without identifying the previous handlers, and, if applicable, records obtained as required in subdivision (b).

This subdivision shall be the exclusive means of public access to records required to be kept by handlers and retailers under this article.

A person required to provide records pursuant to a request under this subdivision, may petition the director or the secretary to deny the request based on a finding that the request is of a frivolous or harassing nature. The secretary or director may, upon the issuance of this finding, waive the information production requirements of this subdivision for the specific request for information that was the subject of the petition.

- (c) Information specified in subdivision (b) that is required to be released upon request shall not be considered a “trade secret” under Section 110165, Section 1060 of the Evidence Code, or the

Uniform Trade Secrets Act (Title 5 (commencing with Section 3426) of Part 1 of Division 4 of the Civil Code).

- (d) The director or the secretary may charge the person requesting records a reasonable fee to reimburse him or her self or the source of the records for the cost of reproducing the records requested.
- (e) Any person who first imports into this state, for resale, products sold as organic shall obtain and provide to the enforcement authority, upon request, proof that the products being sold have been certified by an accredited certifying organization or have otherwise been produced in compliance with this article.
- (f) The director shall not be required to obtain records not in his or her possession in response to a subpoena. Prior to releasing records required to be kept pursuant to this chapter in response to a subpoena, the director shall delete any information regarding the identity of suppliers or customers and the quantity or price of supplies purchased or products sold.

110850.

- (a) Following initial United States Department of Agriculture accreditation of certifying agents as provided in Section 6514 of Title 7 of the United States Code and upon implementation of the federal organic certification requirement pursuant to the federal Organic Foods Production Act of 1990 (7 U.S.C. Sec. 6501 et seq., Sec. 2101, P.L. 101-624), all products sold as organic in California shall be certified by a federally accredited certifying agent, if they are required to be certified under the federal act. In addition products shall be sold as organic only in accordance with this section, Sections 110855 to 110870, inclusive, and Section 46009 of the Food and Agricultural Code. The secretary, director, and the county agricultural commissioners shall carry out this subdivision to the extent that adequate funds are made available for that purpose.
- (b) Products sold as organic may be certified only by a certification organization registered pursuant to Section 46014.1 of the Food and Agricultural Code or a federally accredited certification organization.
- (c) In order to be registered, a certification organization shall be accredited by the USDA, if required.
- (d) A certification organization that certifies processed products sold as organic shall register with the secretary.
- (e) The director may audit the organization's certification procedures and records at any time. Records of certification organizations not otherwise required to be released upon request or made publicly available shall not be released by the director except to other employees of the department, the Department of Food and Agriculture, a county agricultural commissioner, the Attorney General, any prosecuting attorney, or any government agency responsible for enforcing laws related to the activities of the person subject to this part.

110855. Prior to initial certification of a producer, a registered certification organization shall conduct at least one initial physical inspection of the premises where the food to be certified is produced. This inspection shall include the recordkeeping system necessary for compliance with Section 110840 and the area or facility at which the food is produced.

110860.

- (a) A registered certification organization shall no less often than, at the end of each calendar quarter, prepare a list by name of all persons whose production or processing of food is certified or pending certification by the certification organization.

This list shall be filed with the department or the Department of Food and Agriculture, as applicable, by the certification organization and made publicly available within 30 days after the end of each quarter.

- (b) A registered certification organization or a federally accredited certification organization shall, at least annually, physically inspect the premises where the food to be certified is produced and processed. The inspection shall include an examination of recordkeeping.

110865. A registered certification organization shall adopt and adhere to a certification plan filed annually and made publicly available. Except in the case of a certification program established pursuant to subdivision (e) of Section 110850, a certification plan shall be filed as part of the registration required pursuant to subdivision (d) of Section 110850. A certification plan shall at minimum include a detailed description of all of the following elements of the certification organization's program:

- (a) Minimum information required from producers or processors regarding growing or processing practices and methods for verifying that information.
- (b) Qualifications of and training requirements for all inspectors.
- (c) Procedures for inspection, including frequency and items covered.
- (d) Procedures for soil and tissue sampling and analysis.
- (e) Criteria for certification.
- (f) Process for certification decisionmaking, including identification of persons with decisionmaking authority.

110870. Only products that have been handled and processed in accordance with this article may be certified by a registered certification organization.

110875.

- (a) Every person engaged in this state in the processing or handling of processed products for human consumption, including dietary supplements, alcoholic beverages, and fish or seafood sold as organic (except for processors and handlers of processed meat, fowl, or dairy products and retailers that are engaged in the processing or handling of products sold as organic), and every person engaged in the processing or handling of animal food and cosmetics sold as organic, shall register with the director, and shall thereafter annually renew the registration unless no longer so engaged. Handlers of processed food products that are registered with the department pursuant to Article 2 (commencing with Section 110460) shall register under this section in conjunction with the annual renewal of their registration pursuant to that article. Handlers of organic products that are required to be registered to manufacture, pack, or hold processed food pursuant to Article 2 (commencing with Section 110460) of Chapter 5 of Part 5 of Division 104, licensed to bottle, vend, haul, or process water pursuant to Article 12 (commencing with Section 11070) of Chapter 5 of Part 5 of Division 104, certified to process or handle fresh or frozen seafood or fresh or frozen raw shellfish pursuant to Chapter 5 (commencing with Section 112150) of Part 6 of Division 104, licensed to operate a cold storage facility pursuant to Chapter 6 (commencing with Section 112350) of Part 6 of Division 104, licensed to process low acid canned foods pursuant to Chapter 8 (commencing with Section 112650) of Part 6 of Division 104, licensed to manufacture olive oil pursuant to Chapter 9 (commencing with Section 112875) of Part 6 of Division 104, and licensed or registered to process or hold pet food in California pursuant to Chapter 10 (commencing with Section 113025) of Part 6 of Division 104, shall possess a valid registration or license in order to obtain a valid organic registration for the same facility under this section. All others required to register under this subdivision shall register within 30 days of forms being made available for this purpose. Any processor or handler of processed products required to register under this subdivision that does not pay the registration fee required by subdivision (c) within 30 days of the date on which the fee is due and payable shall pay a penalty of 11/2 percent per month on the unpaid balance.
- (b) Registration shall be on a form provided by the director and shall be valid for a period of one calendar year from the date of validation of the completed registration form. The director shall make registration forms available for this purpose. The information provided on the registration form shall include all of the following:
 - (1) The nature of the registrant's business, including the specific commodities and quantities of each commodity that is handled and sold as organic.
 - (2) The total current annual organic gross sales, or if not selling the product, the total current gross annual revenue received from processing, packaging, repackaging, labeling, or otherwise handling organic products for others, in dollars.
 - (3) The names of all certification organizations and governmental entities, if any, providing certification to the registrant pursuant to this article and the regulations adopted by the NOP.
 - (4) Sufficient information, under penalty of perjury, to enable the director to verify the amount of the registration fee to be paid in accordance with subdivision (c).

- (c) To the extent feasible, the director shall coordinate the registration and fee collection procedures of this section with similar licensing or registration procedures applicable to registrants. When coordinating the organic registration with other required registrations or licenses identified in subdivision (a), the expiration date shall be the same expiration date as the valid license or registration. For persons that hold two-year licenses or registrations pursuant to subdivision (a), the organic registration shall be renewed annually using the same expiration month and day as the two-year license or registration.
- (d) A registration form shall be accompanied by payment of a nonrefundable registration fee payable to the department by handlers which shall be based on annual gross sales of organic product or annual revenue received from processing, packaging, repackaging, labeling, or otherwise handling organic product for others, by the registrant in the calendar year that precedes the date of registration. If no sales or revenue were made in the preceding year, then based on the expected sales or revenue during the 12 calendar months following the date of registration.

Unless specified elsewhere, the fee is based according to the following schedule:

Gross Annual Sales or Revenue	Annual Registration Fee
\$0-\$5,000	\$ 50
\$5,001-\$50,000	\$100
\$50,001-\$125,000	\$200
\$125,001-\$250,000	\$300
\$250,001-\$500,000	\$400
\$500,001-\$1,500,000	\$500
\$1,500,001-\$2,500,000	\$600
\$2,500,001-and above	\$700

- (1) Any handler that does not take possession or title of the product but arranges for the sale of the product shall register and pay one hundred dollars (\$100) per year.
- (2) Any person that only provides temporary storage for seven days or less, or only provides transportation for organic product and does not handle the processed packaged product, does not have to register.
- (3) Any person that hires any other person to custom pack, repack, or label organic products shall register and pay a fee based on the total annual sales of products custom packed, repacked, or labeled for them as outlined in the chart above.
- (e) Revenue received pursuant to this section shall be deposited in the Food Safety Fund created pursuant to Section 110050.
- (f) The director shall reject a registration submission that is incomplete or not in compliance with this article and regulations promulgated by the NOP.
- (g) The director shall provide a validated certificate to the registrant.
- (h) Registration forms shall be made available to the public for inspection and copying at the main office of the department. Copies of registration forms shall also be made available by mail, upon written request and payment of a reasonable fee, as determined by the director. Registration information regarding quantity of products sold and gross sales volume in dollars shall be deleted prior to public inspection and copying and shall not be released to any person except other employees of the department, the Department of Food and Agriculture, a county agricultural commissioner, the Attorney General, any prosecuting attorney, or any government agency responsible for enforcing laws related to the activities of the person subject to this part.
- (i) A registrant shall immediately notify the director of any change in the information reported on the registration form and shall pay any additional fee owed if that change results in a higher fee owed than previously paid.
- (j) The director in consultation with the California Organic Products Advisory Committee, may suspend the registration program set forth in this section if the director determines that income derived from registration fees is insufficient to support a registration enforcement program.
- (k) A registration is considered legal and valid until revoked, suspended, or until the expiration of the registration.

- (l) The registration revocation process must be in conjunction with other provisions of this article. The director can initiate the revocation process for failure to comply with this article or any part of the regulations adopted pursuant to the NOP. Any person against whom the action is being taken shall have the opportunity to appeal the action and be afforded the opportunity to be heard in an administrative appeal. This appeal can be administered by either the state or county agricultural commissioner's office.
- (m) When the registration fee is not paid within 60 days from the expiration date the account may be considered closed and the registration voided. A notification will be sent to the registrant and the certifier will notify them that they are no longer able to market products as organic until the account is paid in full.
- (n) Any registration that is more than 60 days late will be considered invalid and it is a violation if product is sold as organic.

110880. This article shall apply to all products sold as organic within the state, wherever produced, handled, or processed, and to all products produced, that are handled or processed in the state, wherever sold as organic.

110885. This article shall not apply to the term "natural" when used in the labeling or advertising of a product.

110890.

- (a) It is unlawful for any person to sell, offer for sale, advertise, or label any product in violation of this article.
- (b) Notwithstanding subdivision (a), a person engaged in business as a distributor or retailer of products who in good faith sells, offers for sale, labels, or advertises any product in reliance on the representations of a producer, handler, or other distributor that the product may be sold as organic, shall not be found to violate this article unless the distributor either: (1) knew or should have known that the product could not be sold as organic; (2) was engaged in producing or processing the product; or (3) prescribed or specified the manner in which the product was produced or processed.

110895.

- (a) It is unlawful for any person to certify products in violation of this article.
- (b) It is unlawful for any person to certify products as organic unless duly registered or accredited as a certification organization pursuant to Section 110850.
- (c) It is unlawful for any person to willfully make a false statement or representation, or knowingly fail to disclose a fact required to be disclosed, in registration for a certification organization pursuant to Section 110850.

110900.

- (a) It is unlawful for any person to produce, handle, or process products sold as organic unless duly registered pursuant to Section 110875.
- (b) It is unlawful for any person to willfully make a false statement or representation, or knowingly fail to disclose a fact required to be disclosed, in registration pursuant to Section 110875.

110905. It is unlawful for any person to forge, falsify, fail to retain, fail to obtain, or fail to disclose records pursuant to Sections 110840 and 110845.

110910. It is unlawful for any person to do any of the following:

- (a) Advertise, label, or otherwise represent that any fertilizer or pesticide chemical may be used in connection with the production, processing, or distribution of products sold as organic if that fertilizer or pesticide chemical contains a prohibited material.
- (b) Alter any organic registration form.
- (c) Alter any certification document.
- (d) Falsify any document.
- (e) Use the term "transitional organic" in this state to represent a product for sale.

110915.

- (a) In lieu of prosecution, the director may levy a civil penalty against any person who violates this article, any regulation adopted pursuant to this article, or any regulation promulgated by the NOP in an amount not more than five thousand dollars (\$5,000) for each violation. The amount of the penalty assessed for each violation shall be based upon the nature of the violation, the seriousness of the effect of the violation upon effectuation of the purposes and provisions of this article, and the impact of the penalty on the violator, including the deterrent effect on future violations.
- (b) Notwithstanding the penalties prescribed in subdivision (a), if the director finds that a violation was not intentional, the director may levy a civil penalty of not more than two thousand five hundred dollars (\$2,500) for each violation.
- (c) For a first offense, in lieu of a civil penalty as prescribed in subdivisions (a) and (b), the director may issue a notice of violation, if he or she finds that the violation is minor.
- (d) A person against whom a civil penalty is levied shall be afforded an opportunity for a hearing before the director, upon request made within 30 days after the date of issuance of the notice of penalty. At the hearing, the person shall be given the right to review the director's evidence of the violation and the right to present evidence on his or her own behalf. If no hearing is requested, the civil penalty shall constitute a final and nonreviewable order.
- (e) If a hearing is held, review of the decision of the director may be sought by any person within 30 days of the date of the final order of the director pursuant to Section 1094.5 of the Code of Civil Procedure.
- (f) A civil penalty levied by the director pursuant to this section may be recovered in a civil action brought in the name of the state.

110920. No fee established and collected pursuant to this article shall exceed the department's costs of regulating and enforcing the provisions of this article related to the function for which the fee is established.

110925. Any fees and civil penalties collected pursuant to this article shall be deposited in the General Fund and, upon appropriation by the Legislature, shall be expended to fulfill the responsibilities of the director as specified in this article.

110930. The director shall, to the extent funds are available, enforce this article applicable to all processors and handlers of processed products sold as organic, including handlers and processors of fish and seafood, cosmetics, and animal food products sold as organic, except for processors and handlers of processed meat, fowl, and dairy products.

110935. The director shall maintain in a central location, and make publicly available for inspection and copying, upon request, a list of all penalties levied within the past five years, including the amount of each penalty, the party against whom the penalty was levied, and the nature of the violation. The list also shall be available by mail, upon written request and payment of a reasonable fee, as determined by the director.

110940.

- (a) Any person may file a complaint with the director concerning suspected noncompliance with this article by a person over whom the director has responsibility as provided in this article or regulations adopted by the NOP.
- (b) The director shall, to the extent funds are available, establish a procedure for handling complaints, including, provision of a written complaint form, and procedures for commencing an investigation within three working days of receiving a written complaint regarding fresh food, and within seven working days for other product, and completing an investigation and reporting findings and enforcement action taken, if any, to the complainant within 90 days thereafter.
- (c) The director may establish minimum information requirements to determine the verifiability of a complaint and may provide for rejection of a complaint that does not meet the requirements. The director shall provide written notice of the reasons for rejection to the person filing the complaint.
- (d) The responsibilities of the director under this section shall be carried out to the extent funds are available.
- (e) The complaint process in this state shall also meet all the complaint processes outlined in regulations promulgated by the NOP.

110945. This article shall apply notwithstanding any other provision of law that is inconsistent with this article. Nothing in this article is intended to repeal any other provision of law not inconsistent with this article.

110950. The director may adopt any regulations as are reasonably necessary to assist in the implementation of, or to make more specific, the provisions of, this article.

110955. Any reference in law to former Section 26569.11, whether existing or hereinafter enacted, shall be interpreted to refer to this article and Chapter 10 (commencing with Section 46000) of Division 17 of the Food and Agricultural Code as the successor section.

110956.

- (a) All organic product regulations and any amendments to those regulations adopted pursuant to the NOP, that are in effect on the date this bill is enacted or that are adopted after that date shall be the organic product regulations of this state.
- (b) The director may, by regulation, prescribe conditions under which organic products not addressed by the National Organic Program may be sold in this state.

110957. It shall be unlawful for a person to represent in advertising or labeling that the person or the products of the person are registered pursuant to this article.

110958. Annually, the director shall compile and publish and submit to the California Organic Products Advisory Committee a summary of information collected under Section 110875, including, but not limited to, the following:

- (a) The total number of registrations received under this section.
- (b) The total number and quantity of each type of product sold as organic by all registrants combined.
- (c) The total annual organic gross sales volume or revenue of all registrants combined, and the median gross annual organic sales or revenue of all registrants.
- (d) The names of all registrants.
- (e) The number of registrants in each of the following ranges of annual gross sales volume:
 - (1) \$0-\$5,000
 - (2) \$5,001-\$25,000
 - (3) \$25,001-\$50,000
 - (4) \$50,001-\$125,000
 - (5) \$125,001-\$250,000
 - (6) \$250,001-\$500,000
 - (7) \$500,001-\$750,000
 - (8) \$750,001-\$1,000,000
 - (9) \$1,000,001-\$1,500,000
 - (10) \$1,500,001-\$2,500,000
 - (11) \$2,500,001-\$10,000,000
 - (12) \$10,000,001-\$30,000,000
 - (13) \$30,000,001 and above.
- (f) The report published pursuant to this section shall present the required information in an aggregate form that preserves the confidentiality of the proprietary information of individual registrants.

110959. Beginning January 1, 2003, the director shall conduct a program of spot inspections of persons required to register pursuant to Section 110875 to verify continuing compliance with this article and the regulations adopted by the NOP according to uniform procedures established by the director and regulations promulgated by the NOP.

Article 8. Potentially Hazardous Food

110960. Except as provided in Section 113995, it is unlawful for any person to transport, hold, or display any potentially hazardous refrigerated food at any temperature above 45 degrees Fahrenheit.

Article 9. Frozen Foods

110965.

- (a) No retail food production and marketing establishment shall advertise, label, or otherwise hold out as fresh any meat or fish that has been previously frozen.
- (b) For purposes of this section:
 - (1) "Frozen" means any meat or fish stored in a room or compartment in which the temperature is plus five degrees Fahrenheit or lower.
 - (2) "Retail food production and marketing establishment" means any room, building, or place, or portion thereof, maintained, used, or operated for, or in conjunction with, the retail sale of food, or preparation of food. "Retail food production and marketing establishment" does not include any food facility, such as any "mobile food preparation unit" any "vehicle," and any "vending machine" as defined in Chapter 4 (commencing with Section 113700) of Part 7; any wholesale food manufacturing, distributing, or storage establishment, including, but not limited to, the licensed premises or branch office of any winegrower, any brandy manufacturer, or any wine blender, subject to Chapter 4 (commencing with Section 111950) of Part 6; any frozen food locker plant subject to Chapter 7 (commencing with Section 112500) of Part 6; any health facility subject to Chapter 2 (commencing with Section 1250) of Division 2 and Section 127050; any community care facility subject to Chapter 3 (commencing with Section 1500) of Division 2; or any "official establishment" subject to Chapter 4 (commencing with Section 18650) of Part 3 of Division 9 of the Food and Agricultural Code.
- (c) On and after the effective date of the act that added this subdivision to this section during the 1993-94 Regular Session, Section 26661 of the Food and Agricultural Code shall apply, to the exclusion of any provision of this section, with respect to the advertising, labeling, or otherwise holding out, of poultry.

Article 10. Ice

110970. This article applies only to ice that is intended for human consumption and is sold in packaged form. This article shall not apply to persons, hotels, restaurants, caterers, food service contractors, and theaters that manufacture, sell, or furnish ice solely to, or for, their customers in a manner that is incidental to the manufacturing, furnishing, or sale of other goods or services. This article shall not apply to ice dispensing or vending machines, except those that dispense or vend packaged ice, or to the icing of vehicles used to transport food.

110975. The following definitions apply to this article:

- (a) "Ice" means the product obtained as the result of freezing water by natural, mechanical, or artificial means.
- (b) "Natural ice" means the product obtained as the result of freezing water by natural means.

110980. In addition to the requirements of this article, unless ice is otherwise specifically excluded, regulations specifying good manufacturing practices applicable to food generally pursuant to Section 110105 shall be applicable to the manufacture of ice.

110985. No person shall make ice from, or cut natural ice from, water that does not comply with primary drinking water standards adopted by the department pursuant to Section 116365. No person shall sell or offer for sale for human consumption or food preservation ice made or cut in violation of this article.

110990. Unless water from a public water system, as defined in Section 116275, is used in the manufacture of ice, the manufacturer shall, on a quarterly basis, obtain from an approved laboratory, a bacterial analysis of the water used. The analysis shall be submitted to the department, indicating whether the water is pure and wholesome.

110995. Any person or entity who manufactures, transports, stores, or sells ice shall comply with all of the following:

- (a) A room in which ice is manufactured shall be used for no other purpose than the manufacture of ice and the production of refrigeration, and may contain refrigeration equipment and machinery. This subdivision shall not apply to any food facility as defined in Section 113785.
- (b) Ice storage or processing areas shall be maintained in a clean and sanitary condition and no noxious or offensive odors, smoking, or other air pollution shall be permitted therein.
- (c) Cover tops for tank cans shall have a smooth, painted, or treated surface, and shall be cleaned daily. Water used for cleaning shall not be permitted to drip into freezing cans. Only potable water shall be used in sprays and in the thaw tanks for the removal of ice from cans. Water coverage tanks shall be covered and provided with filtered vents.
- (d) Crushed, cubed, or shaved ice, intended for human consumption, shall be stored in a manner that prevents its pollution or contamination.
- (e) Soil, waste, or drain pipes shall not be installed or maintained above any ice platform, loading space, ice container, ice storage room, dip tank or any place where leakage from the pipes may drop into, or upon any ice or upon any area or equipment used in the manufacture of ice, unless a safety device shall be installed under the pipes drained to an open receptacle or drain so as to prevent pollution of ice, water, or equipment used in the manufacture of the ice.
- (f) Block ice-loading platforms shall be washed with water as often as necessary to keep them in a clean and sanitary condition, but not less than once each day.
- (g) Block ice pullers and block ice storage-room employees shall wear rubber overshoes while on duty. The rubber overshoes shall be removed when the employee leaves the storage or tank room, except that if the rubber overshoes are not removed, they shall be cleaned and disinfected before reentering the storage or tank room. The use of street shoes without rubber overshoes in these areas is prohibited.
- (h) All frozen unpackaged ice blocks intended for sale for human consumption or for the refrigeration of food products shall be washed thoroughly with potable water. Ice manufactured for industrial purposes need not be washed prior to shipping but shall be handled and stored separately from ice intended for human consumption.
- (i) Ice shall be handled only with clean tongs, ice-carrying bags, scoops, or other sanitary containers, and shall not be directly handled with bare hands.
- (j) Single service supplies shall be stored, dispensed, and handled in a sanitary manner and shall be used only once.
- (k) Persons not directly involved in the manufacture, processing, packaging, or storing of ice, in the maintenance of facilities and equipment used therefore, or in the management, supervision, or inspection thereof, shall not be permitted in any area where ice is manufactured, processed, packaged, or stored, unless personal cleanliness and hygienic practices are taken to prevent contamination of the product. These areas shall have signs posted to this effect.
- (l) Bacteriological tests of the finished ice shall be conducted not less than biannually, chemical and physical tests annually, and radiological tests every four years, to insure that ice manufactured for human consumption or for the refrigeration of food products complies with the primary drinking water standards adopted by the department pursuant to Section 116365.
- (m) No ice produced out of state shall be sold or distributed within this state unless it complies with this article.

111000.

- (a) Filter beds and any filtering equipment shall be designed to protect ice from contamination and shall be subject to periodic treatment and cleaning.
- (b) All equipment and utensils used in ice production areas shall be of easily cleanable construction, shall be kept clean and in good repair, and shall be handled and stored in a sanitary manner. Materials used as ice contact surfaces shall be smooth, nontoxic, and nonabsorbent. Ice cans shall be leakproof and the inner surfaces of the containers shall be free of corrosion.
- (c) Freezing tank covers shall be designed and constructed to protect ice containers from splash, drip, and other contamination, shall be easily cleanable, and shall be kept clean and in good repair. The covers shall be equipped with rings or similar devices when hooks are used for pulling. Can or tank covers, and the ledges or sides of the tank upon which the cover rests, shall be cleaned as often as necessary to keep them in a sanitary condition.

- (d) Conveyor surfaces shall be of impervious material and shall protect ice from contaminants that may result from shredding, flaking, peeling, or fragmentation of the conveyor surface.
- (e) Equipment lubrication shall not contaminate the ice and only food grade lubricants shall be used.
- (f) All product storage and holding areas to be refrigerated shall be cleaned as often as necessary to keep them free of contamination.
- (g) Air used for water agitation shall be filtered or otherwise treated to remove dust, dirt, insects, and extraneous material. Filters shall be placed upstream from the compressor and shall be easily removable for cleaning or replacement.
- (h) The compressor or blower used to supply air or water agitation shall be designed to deliver oil-free air.
- (i) Air lines and core or vacuum devices shall be used as needed to produce ice free of rust or other foreign materials.

111005. In addition to the requirements of this article, ice shall be considered a food subject to all the sanitation requirements applicable to food generally pursuant to Article 1 (commencing with Section 110425), except those provisions that specifically exclude ice.

111010. Any truck, vehicle, or other equipment used for delivery, distribution, or selling ice, shall comply with all of the following:

- (a) It shall be constructed and maintained to provide adequate and reasonable protection to the ice transported therein. Care shall be taken to prevent its contact with any contaminants, or other substances that would take the ice out of compliance with the drinking water standards prescribed by this article.
- (b) All cubed, crushed, or shaved ice shall be kept in clean receptacles or containers that shall be kept covered while the vehicle is in motion.

Article 11. Local Enforcement

111015. "Health officer," as used in this article, means the health officer appointed by a county board of supervisors pursuant to Section 101000, by the governing body of a city pursuant to Section 101460, by the governing body of a city and county, or by a local health district board pursuant to former Section 940, that is continued in effect as to any existing district by Section 3 of Chapter 380 of the Statutes of 1959.

111020. The department, upon the request of a health officer, may authorize the local health department of a city, county, city and county, or local health district to enforce this part, and the regulations adopted pursuant to this part that pertain to retail food establishments, as defined by regulation, if the department determines that the local health department has sufficient personnel with adequate training to do so. The enforcement shall be limited to the area under the jurisdiction of the local health department.

111025. The department may revoke any authorization made pursuant to this article, if it determines, after a hearing conducted pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code that the local health department authorized pursuant to this article is not enforcing this part or the regulations adopted pursuant to this part, or no longer has an adequate staff qualified to do so.

111030. A local health department that is authorized by the department to enforce this part may make inspections, take samples, make laboratory examinations, impose and remove embargoes, hold informal hearings, certify facts to the district attorney, and institute proceedings for the forfeiture, condemnation, and destruction of food found to be adulterated or misbranded. The action shall be instituted in the name of the city, county, city and county, or district of which the local health department is a part, and shall conform to the requirements of this part and the regulations adopted by the department pursuant to this part.

111035. For the purposes of this article, the health officer and his or her deputies shall have the same powers and authority as an inspector of the Bureau of Food and Drug of the department.

111040. When an examination or analysis made pursuant to this part shows that any provision of this chapter has been violated, written notice of that fact together with a copy of the findings shall be furnished to each party from whom the sample was obtained, or who issued the product guarantee.

111045. The health officer shall set a time for an informal hearing, at which the parties may be heard before him or her or his or her representatives. A notice in writing shall be served upon the interested parties at least 15 days prior to the hearing. The informal hearing shall be private and limited to questions of fact. Appearances may be made in person or by attorney. Testimony may be taken and evidence introduced as to the correctness of the findings made by the person making the examination or performing the analysis.

111050. If the examination or analysis is found to be correct, or if any party fails to appear after notice has been duly given, the health officer may certify the facts found to the district attorney of the county. No publication shall be made until after the hearing is concluded.

111055. This article shall not be construed as repealing, either directly or by implication, any of the existing sections of this chapter, but shall be construed as constituting an alternative method of enforcing this part.

111060. This article shall not affect any previous authorization by the department to a local health department of a county, city, or city and county to enforce this part.

111065. The department may adopt regulations relating to the operation of a local health department as it considers necessary to fully effect this article, including, but not limited to, requirements relating to reporting of activities and the numbers and qualification of personnel.

Article 11.5. Local Enforcement: Live Food

111067.

- (a) Any city, county, or city and county may adopt an ordinance that provides for the regulation of the disposition of bullfrogs and turtles imported for sale in live animal markets for use as food. The ordinances may provide for all of the following:
- (1) The designation of a local agency to carry out this article.
 - (2) Require a permit, issued by an agency designated by the city, county, or city and county to issue permits, for the sale of bullfrogs and turtles imported for sale in live animal markets for use as food.
 - (3) Establish a fee for the permit in an amount determined sufficient to offset the administrative cost of issuing the permit and enforcing the provisions of the ordinance.
 - (4) Require that animals sold pursuant to the permit be dispatched at the time of sale.
 - (5) Require that signs be posted at the permittee's place of business, stating that animals must be properly dispatched and that release into the wild in a live state is unlawful.
 - (6) Authorize the local agency, after notice and opportunity for a hearing, to suspend or revoke a permit issued pursuant to paragraph (1) for violation of any provision of the ordinance adopted pursuant to this article.
- (b) The State Department of Health Services and the Department of Fish and Game may consult with a city, county, or city and county for purposes related to this article.

111068. Nothing in this article is intended to limit or preempt the jurisdiction of any state agency or commission, or any other state entity, from adopting any regulation or taking any action it deems necessary and appropriate regardless of any local ordinance adopted pursuant to this article.

Article 12. Bottled, Vended, Hauled, and Processed Water

111070.

- (a) "Bottled water," means any water that is placed in a sealed container at a water-bottling plant to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by

humans. Bottled water shall not include water packaged with the approval of the department for use in a public emergency.

- (b) "Vended water" means any water that is dispensed by a water-vending machine, retail water facility, or water from a private water source, or other water as defined in Section 111170 that is not placed by a bottler in sealed containers, and that is dispensed by a water-vending machine, retail water facility, water hauler, or any other person or facility for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. "Vended water," does not include water from a public water system that has not undergone additional treatment. Water sold without further treatment is not "vended water" and shall be labeled in accordance with Section 111170.
- (c) "Water-bottling plant" means any facility in which bottled water is produced.
- (d) A "water-vending machine" means a water-connected vending machine designed to dispense drinking water, or purified or other water products. The machines shall be designed to reduce or remove turbidity, off-tastes, and odors and to provide disinfection treatment. Processes for dissolved solids reduction or removal shall also be used.
- (e) "Water hauler," means any person who hauls water in bulk by any means of transportation if the water is to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. "In bulk," as used in this subdivision, means containers having capacities of 250 gallons or greater.
- (f) "Retail water facility" means any commercial establishment where vended water is sold, and placed in customer's containers, or placed in containers sold or given to customers who come to the establishment to obtain water.
- (g) "Private water source," means a privately owned source of water, other than a public water system, that is used for bottled or vended water and meets the requirements of an approved source for bottled water as defined in Section 129.3 of Title 21 of the Code of Federal Regulations.
- (h) "Bottled water distributor" means any person, other than an employee or representative of a bottled water plant, who delivers bottled water directly to customers.

111070.5. (a) "Advanced purified demonstration water" means product water from an advanced water purification facility that satisfies both of the following requirements:

- (1) The product water is treated by all of the following treatment processes:
 - (A) Microfiltration, ultrafiltration, or other filtration process that removes particulates before reverse osmosis.
 - (B) Reverse osmosis.
 - (C) Advanced oxidation.
 - (2) The product water meets or exceeds all federal and state drinking water standards and is produced in accordance with the advanced treatment criteria for purified water specified in Section 60320.201 of Title 22 of the California Code of Regulations.
- (b) A bottler of advanced purified demonstration water shall do all of the following:
- (1) Submit sample labels to the department for review at least 30 days before bottling advanced purified demonstration water.
 - (2) Submit the analyses of the advanced purified demonstration water required under subdivision (e) of Section 13570 of the Water Code to the department at least seven days before bottling advanced purified demonstration water.
 - (3) Conduct a full sanitation of the bottling and filling equipment immediately after bottling advanced purified demonstration water.

111071.

- (a) As a condition of licensure, each bottled water plant, as defined in subdivision (c) of Section 111070, shall annually prepare a bottled water report and shall, upon request, make that report available to each customer.
- (b) The report shall be prepared in English, Spanish, and in the appropriate languages for each non-English-speaking group other than Spanish that exceeds 10 percent of the state's population.
- (c) For purposes of complying with this section, when bottled water comes from a municipal source, the relevant information from the consumer confidence report or water quality report prepared for that year by the public water system pursuant to Section 116470, may be used.
- (d) The bottled water report shall include, but not be limited to, all of the following:

- (1) The source of the bottled water, consistent with applicable state and federal regulations.
- (2) A brief and plainly worded definition of the terms “statement of quality,” “maximum contaminant level,” “primary drinking water standard,” and “public health goal.”
- (3) A brief description of the treatment process.
- (4) A reference to the United States Food and Drug Administration Web site that provides product recall information.
- (5) The bottled water company’s address and telephone number that enables customers to obtain further information concerning contaminants and potential health effects.
- (6) Information on the levels of unregulated substances, if any, for which water bottlers are required to monitor pursuant to state or federal law or regulation.
- (7) (A) The following statement:

“Drinking water, including bottled water, may reasonably be expected to contain at least small amounts of some contaminants. The presence of contaminants does not necessarily indicate that water poses a health risk. More information about contaminants and potential health effects can be obtained by calling the United States Food and Drug Administration, Food and Cosmetic Hotline (1-888-723-3366).”

(B) If the telephone number for the United States Food and Drug Administration, Food and Cosmetic Hotline changes, the statement shall be updated to reflect the new telephone number.
- (8) The following statement:

“Some persons may be more vulnerable to contaminants in drinking water than the general population. Immuno-compromised persons, including, but not limited to, persons with cancer who are undergoing chemotherapy, persons who have undergone organ transplants, persons with HIV/AIDS or other immune system disorders, some elderly persons, and infants can be particularly at risk from infections. These persons should seek advice about drinking water from their health care providers. The United States Environmental Protection Agency and the Centers for Disease Control and Prevention guidelines on appropriate means to lessen the risk of infection by cryptosporidium and other microbial contaminants are available from the Safe Drinking Water Hotline (1-800-426-4791).”
- (9) The following statement:

“The sources of bottled water include rivers, lakes, streams, ponds, reservoirs, springs, and wells. As water naturally travels over the surface of the land or through the ground, it can pick up naturally occurring substances as well as substances that are present due to animal and human activity. Substances that may be present in the source water include any of the following:

 - (1) Inorganic substances, including, but not limited to, salts and metals, that can be naturally occurring or result from farming, urban stormwater runoff, industrial or domestic wastewater discharges, or oil and gas production.
 - (2) Pesticides and herbicides that may come from a variety of sources, including, but not limited to, agriculture, urban stormwater runoff, and residential uses.
 - (3) Organic substances that are byproducts of industrial processes and petroleum production and can also come from gas stations, urban stormwater runoff, agricultural application, and septic systems.
 - (4) Microbial organisms that may come from wildlife, agricultural livestock operations, sewage treatment plants, and septic systems.
 - (5) Substances with radioactive properties that can be naturally occurring or be the result of oil and gas production and mining activities.”
- (10) The following statement:

“In order to ensure that bottled water is safe to drink, the United States Food and Drug Administration and the State Department of Public Health prescribe regulations that limit the amount of certain contaminants in water provided by bottled water companies.”
- (11) (A) The following statement, if nitrate (NO₃) levels above 23 ppm but below 45 ppm (the Maximum Contaminant Level for nitrate (NO₃)) are detected:

“Nitrate in drinking water at levels above 45 mg/L is a health risk for infants of less than six months of age. These nitrate levels in drinking water can interfere with the capacity of the infant’s blood to carry oxygen, resulting in a serious illness. Symptoms include shortness of breath and blueness of the skin. Nitrate levels above 45 mg/L may also affect the ability

of the blood to carry oxygen in other individuals, including, but not limited to, pregnant women and those with certain specific enzyme deficiencies. If you are caring for an infant, or you are pregnant, you should ask advice from your health care provider.”

- (B) If the nitrate disclosure requirements for municipal water suppliers are revised by the State Department of Public Health, this statement shall be updated to reflect the revision.
- (12) (A) The following statement, if arsenic levels above 5 ppb, but below 10 ppb (the Maximum Contaminant Level for arsenic), are detected:

“Arsenic levels above 5 ppb and up to 10 ppb are present in your drinking water. While your drinking water meets the current EPA standard for arsenic, it does contain low levels of arsenic. The standard balances the current understanding of arsenic’s possible health effects against the costs of removing arsenic from drinking water. The State Department of Public Health continues to research the health effects of low levels of arsenic, which is a mineral known to cause cancer in humans at high concentrations and is linked to other health effects, including, but not limited to, skin damage and circulatory problems.”

- (B) If the arsenic disclosure requirements for municipal water suppliers are revised by the State Department of Public Health, this statement shall be updated to reflect the revision.
- (13) A full disclosure of any exemption or variance that have been granted to the bottler by the State Department of Public Health, including an explanation of reasons for each exemption or variance and the date of the exemption or variance.

111075.

- (a) Any person who processes, packages, distributes, transfers, or stores bottled water or vended water shall comply with the good manufacturing practices described in Part 129 of Title 21 of the Code of Federal Regulations.
- (b) Prior to bottling or vending water, the water shall be subjected to filtration and effective germicidal treatment by ozone, ultraviolet, carbon dioxide, or an equivalent disinfection process approved by the department, except that the requirements for filtration and germicidal treatment shall not apply to mineral water as defined in and from a source that is subject to the council directive of the European Economic Community pertaining to natural mineral waters, dated July 15, 1980, or that is subject to any other natural mineral water standard in the country of origin that prohibits filtration and germicidal treatment, so long as both of the following conditions are met:
 - (1) The source and product are certified by the responsible authority in the country of origin as complying with microbiological standards at least equal to the standards of this article.
 - (2) The product complies with microbiological standards of this article.
- (c) Bottled or vended water that originates from a surface water source that is not protected from surface contamination shall be subjected to ozonation, filtration, or another effective process that removes or destroys the cysts of the parasite *Giardia lamblia*. For the purposes of this section, a spring house, catchment basin, storage tank, or bore hole adjacent to a natural spring water source as defined in paragraphs (3) and (8) of subdivision (e) of Section 111170, is not a surface water source.
- (d) Ollas or other water-holding dispensers, both refrigerated and nonrefrigerated, water-vending machines, and water dispensers in retail water facilities, shall be examined for cleanliness each time they are serviced by the distributor, bottler, retail water facility, or water-vending machine operator. When necessary, these dispensers shall be sanitized according to the methods described in Part 129 of Title 21 of the Code of Federal Regulations.
- (e) Sanitary operations, equipment procedures, and process controls used in the treatment, storage, transport, or dispensing of water at a retail water facility shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivisions (a) to (c), inclusive, of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), and (h) of Section 129.80.
- (f) Sanitary operations, equipment, procedures, and process controls used in the treatment, storage, transfer, transport, or dispensing of water by water haulers, shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivisions (a) and (b) of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), and (h) of Section 129.89.

- (g) The design and construction of wells, bore holes, catchment basins, spring houses, storage tanks, or other water-contact equipment used by private water sources shall comply with the requirements of the local regulatory authority. Sanitary operations, equipment procedures, and transfer controls used in the treatment, storage, transfer, or dispensing of water by private water source operators shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivision (a) of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), (g), and (h) of Section 129.80.
- (h) Bottled water may be processed through lines used also for other food products under the following conditions:
 - (1) Process lines, including storage tanks and associated equipment, shall be used exclusively for the production of bottled water, except for filling equipment, that may be used also for filling other food products.
 - (2) Before being used for the bottling of water, filling equipment that is designed to be cleaned in-place and that is used for filling other food products shall be thoroughly cleansed and sanitized in-place in accordance with the manufacturer's specifications and in compliance with Section 129.80 of Title 21 of the Code of Federal Regulations and the supplementary procedures that follow in paragraphs (3) to (7), inclusive, of this section.
 - (3) Immediately following completion of filling operations for any other food product other than water, the filler shall be thoroughly rinsed internally and externally with potable water.
 - (4) In accordance with filler manufacturer's instructions, any parts that are not designed to be cleaned in-place shall be disassembled and removed. All of these parts shall be cleansed and sanitized prior to reassembly using appropriate cleansing and sanitizing procedures, as specified in subdivisions (c) and (d) of Section 129.80 of Title 21 of the Code of Federal Regulations.
 - (5) All surfaces of the filler that do not contact food products shall be cleaned manually so as to render all surfaces clean and free of any residues.
 - (6) The filler shall be prepared and all appropriate connections made in accordance with the filler manufacturer's instructions to place the filler in the clean-in-place mode. The following procedures shall be followed:
 - (A) An alkaline cleaning solution of appropriate strength shall be recirculated through the filler to provide effective cleaning of all product contact surfaces, with a minimum recirculation time of 20 minutes at a temperature between 140 and 170 degrees Fahrenheit.
 - (B) The cleaning solution shall be drained and followed with a potable water rinse-to-drain for the removal of all residual cleaner alkalinity. This step may be supplemented by the application of an acidified rinse prior to the potable water rinse in order to neutralize any residual alkalinity on product contact surfaces.
 - (7) Following reassembly of all parts to place the filler into the product mode and just prior to bottling water, the filler shall be sanitized in-place in accordance with procedures specified in subdivision (d) of Section 129.80 of Title 21 of the Code of Federal Regulations.
 - (8) Any alternate cleaning, rinsing, or sanitizing operations or processes not described in this section shall be approved in writing by the department.
- (i) Bottled water and bulk waters sold at retail shall not contact equipment, lines, tanks, or vehicles used for processing, packaging, holding, or hauling of any nonfood product.

111080. The quality and labeling standards requirements for bottled water and vended water, including mineral water, shall include all standards prescribed by Section 165.110 of Title 21 of the Code of Federal Regulations. In addition, bottled water and vended water, when bottled, shall comply with the following quality standards and any additional quality standards adopted by regulation that the department determines are reasonably necessary to protect the public health:

- (a) Bottled water and vended water shall meet all maximum contaminant levels set for public drinking water that the department determines are necessary or appropriate so that bottled water may present no adverse effect on public health. New or revised allowable levels or monitoring provisions adopted for bottled water by the United States Food and Drug Administration under the federal Food, Drug and Cosmetic Act that are more stringent than the state requirements for bottled water

are incorporated into this chapter and are effective on the date established by the federal provisions unless otherwise established by regulations of the department.

- (b) Bottled and vended water shall not exceed 10 parts per billion of total trihalomethanes or five parts per billion of lead unless the department establishes a lower level by regulation.
- (c) Bottled and vended water shall contain no chemicals in concentrations that the United States Food and Drug Administration or the state department has determined may have an adverse effect on public health.

111085. Polycarbonate resins manufactured after January 1, 1988, and intended for use in fabricating containers for water products defined in this article shall not contain in excess of three parts per million residual methylene chloride or in excess of 200 parts per million residual monochlorobenzene unless the department establishes a lower level by regulation. For the purpose of monitoring compliance with this section, the concentration of methylene chloride and monochlorobenzene shall not exceed one part per billion in water. "Polycarbonate resins" means the substances defined by Section 177.1580 of Title 21 of the Code of Federal Regulations except as modified by this section.

111090. Any owner or operator of a water-vending machine or other device from which any operator or customer dispenses vended water shall comply with the following standards of design, construction and sanitation and any additional standards adopted by regulation that the department determines are reasonably necessary to protect the public health. The water-vending machines or devices shall do all of the following:

- (a) Comply with the construction and performance standards established by the department or by an independent authority approved by the department.
- (b) Be designed and constructed to permit easy cleaning and maintenance of all exterior and interior surfaces.
- (c) Have all parts and surfaces that come into contact with the water constructed of approved, corrosive-resistant and nonabsorbent material capable of withstanding repeated cleaning and sanitizing treatment.
- (d) Have a recessed or guarded corrosion-resistant dispensing spout.
- (e) Be designed so that all treatment of the vended water by distillation, ion exchange, filtration, ultraviolet light, reverse osmosis, mineral addition, or any other acceptable process is done in an effective manner.
- (f) Have an effective system of handling drip, spillage, and overflow of water.
- (g) Have a backflow prevention device approved by the department for all connections with the water supply.
- (h) Dispense water disinfected by ultraviolet light or other method approved by the department prior to delivery into the customer's container.
- (i) Be equipped with monitoring devices designed to shutdown operation of the machine when the disinfection unit fails to function, or shall be monitored daily at startup and manually shutdown whenever the unit fails to function.
- (j) Be equipped with a self-closing, tight-fitting door on the vending compartment, or enclosing the vending spout to protect the vending spout when the water-vending machine is not in use. As an alternative, water-vending machines or other water-dispensing devices may be enclosed in a room with tight-fitting walls, ceilings, and one of the following: a self-closing door, an effective air screen device, or an alternative effective device approved by the department.
- (k) Comply with the American Water Works Association (AWWA) specifications for granular activated carbon if used in the treatment of potable water (AWWA B604-74).
- (l) Be maintained in a clean and sanitary condition, free from dirt and vermin.
- (m) Use a state approved and regulated public water supply or private water source.
- (n) Be located in an area that can be maintained in a clean condition and in a manner that avoids insect and rodent harborage.
- (o) Be equipped with monitoring devices designed to shut down the labeled purified water delivery system if treatment of water by the machine does not result in a total dissolved solids content of less than 10 milligrams per liter in the purified water. Alternatively, machines shall be monitored daily at startup and manually shutdown whenever the total dissolved solids content exceeds 10 milligrams per liter in the purified water.

111095. It shall be unlawful to operate a bottled water plant, water-vending machine, retail water facility, or private water source in violation of the minimum health standards of this article.

111100. It is unlawful for any person to operate a water vending machine in this state that does not satisfy the minimum standards prescribed by this article for the design, construction, and sanitation of water-vending machines.

111105. The department, upon the request of a local health officer, may authorize the local health officer to implement and enforce those provisions of this article that relate to water-vending machines, retail water facilities, and water haulers under the terms and conditions specified by the department.

111110. No water-vending machine shall be used in this state that does not at least satisfy the minimum standards adopted by the department.

111115.

- (a) Each water-vending machine, retail water treatment plant, water hauler vehicle and facility, and private water source shall be maintained in a clean and sanitary condition at all times.
- (b)
 - (1) The department shall require that water-vending machines be cleaned, serviced, and sanitized in accordance with the manufacturer's specifications, but at least once every 31 days.
 - (2) Inspection records shall be kept for every visit made by either the operator or the maintenance personnel pursuant to this subdivision. These records shall show the date and time of the visit, any tests performed, any maintenance performed, and the signature or electronic signature of the operator or maintenance personnel. The records shall be kept by the owner of the water-vending machine for a minimum of two years and shall be made available to the department upon request.
- (c) A record of any consumer complaints shall be kept on file with the owner of the water-vending machine for a minimum of two years, and shall be made available to the department upon request.
- (d) If the department determines that there is a violation of this article, the department may do either or both of the following:
 - (1) Embargo the machine pursuant to Section 111860.
 - (2) Impose a fine, as determined appropriate by the department.
- (e)
 - (1) The department shall, annually, conduct inspections of not less than 20 percent of the licensed water-vending machines in the state and shall include both rural and urban counties. The selection of these machines shall be dependent on the state of the machine and the quality of the water source, and any other factors as determined by the department.
 - (2) The department may perform, within 12 months of the initial violation, one or more reinspections of each water-vending machine or water retailer that is found to be in violation of this section as necessary to prevent repeated or continuing violations. The department shall charge a fee to the owner to cover the costs of performing the reinspections. The fee shall not exceed the full cost of performing the reinspections up to a maximum of one hundred dollars (\$100) per hour.
- (f) Subdivisions (b) to (e), inclusive, shall become operative January 1, 2009.

111120.

- (a) No person shall operate a water-bottling plant, a private water source, or be a bottled water distributor in this state except pursuant to a license issued by the department. If a person has a valid water-bottling plant license issued by the department, additional license fees for a private water source operator, a retail water facility, a water hauler, or a bottled water distributor based and operating at the same address, shall not be required.
- (b) No person shall own or operate a water-vending machine or a retail water facility or be a water hauler, except pursuant to a license issued by the department or to a permit issued by a local health department.
- (c) It shall be unlawful for any person to bottle, collect, treat, hold, distribute, haul, vend, or sell bottled water, vended water, operate a retail water facility, or operate a private water source without the license as required by this article. Any bottled water or vended water dispensed by a retail water

facility or a private water source that is not licensed in compliance with this article is misbranded and may be embargoed pursuant to subdivision (e) of Section 111120.

- (d) It shall be unlawful for a water bottler, distributor, vendor, retail water facility operator, or private water source operator to sell or otherwise distribute water that is adulterated, as defined in Section 110445, 110545, 110560, or 110565, or that is misbranded as defined in Article 6 (commencing with Section 110660) of Chapter 5.
- (e) For the purposes of enforcing this section, water may be embargoed pursuant to Section 111860 in its immediate container, well, spring, spring vault, holding tank, water hauling vehicle, retail water treatment system, spigot, or pipe if there is reasonable cause to believe that it is adulterated.
- (f) Any retail water facility, water vendor, or water hauler that violates this article may be subjected to the same penalty and enforcement procedure provided for violation of this article by a water bottling facility.

111125. No bottled water produced in an out-of-state bottling plant shall be sold or distributed within this state unless either the out-of-state bottler or the distributor shall have first obtained a bottler's or distributor's license.

111130.

- (a) The department shall charge and collect a fee for each license application submitted in accordance with the fee schedule in Table 1, that shall be an amount reasonably necessary to produce sufficient revenue to enforce this article. The fees collected shall be adjusted annually as required by Section 100425. New applicants for a water bottling plant license shall pay Category 2 fees for the first license year.
- (b) The water-bottling plant and bottled water distributor categories shall be determined by dividing by 52 the number of gallons produced or shipped into California during the previous year. If the result is an average of 5,000 gallons or less per week, the firm is Category 1. If the average exceeds 5,000 gallons per week, the firm is Category 2.

Table 1

Table 1	
License Fees	
License Class	Annual Fee
Water Bottling Plant	
Category 1	\$310
Category 2	875
Water-Vending Machine	40
Water Hauler	310
Retail Water Facility	310
Private Water Source Operator	310
Bottled Water Distributor	310

- (c) The owners or operators of each water-bottling plant, retail water facility, private water source, each water hauler in California and bottlers or distributors of water bottled out-of-state shall make application for a license on forms provided by the department. Applications and license fees shall be submitted annually. Applicants shall provide to the department, in electronic format, the serial number of each machine, and the street address, city, ZIP Code, and county where the machine is located.
- (d) Each water-vending machine owner or operator shall make application annually for a license for all machines on forms provided by the department. A decal or seal provided by the department indicating a license fee has been paid shall be affixed in a prominent place to each water-vending machine in service. The duty to display the decal or seal shall apply only on and after the decal has been received by the operator.

111135. The department may deny any license application or revoke or suspend any license issued for cause. The department shall inform the person of any denial, revocation, or suspension in writing, stating with particularity reasons for the denial, revocation, or suspension. "Cause," as used in this section, means a violation of any provision of this chapter or any regulation adopted pursuant thereto.

111140. The department shall charge and collect a fee for each department evaluation required to issue a new license for a water-vending machine model or a retail water facility to determine compliance with standards established by this article. The fee shall be three hundred dollars (\$300) and shall be adjusted annually as required by Section 100425.

111145.

- (a) The department shall require each bottler, distributor, or vendor of bottled water, each owner or operator of any water-vending machine, each water hauler, each retail water facility operator, each private water source operator, and each applicant for a license, to test for all substances necessary to establish conformance to standards adopted pursuant to Section 111080 at the times and frequencies the department may reasonably establish.
- (b) Each product dispensed by a water-vending machine or a retail water facility shall be sampled and analyzed for coliform bacteria at least once every six months. The analysis shall be submitted to the department indicating whether the water is pure and wholesome. Analysis of vended water or water from retail water facilities shall be submitted to the local health officers if the local health officers are authorized by the department pursuant to subdivision (b) of Section 111105.
- (c) Purified waters from retail water facilities shall be analyzed by the operator for dissolved solids by conductivity measurement not less frequently than once every seven days.
- (d) Purified water from vending machines shall be analyzed by the operator for the dissolved solids by conductivity measurement each time the vending machine is serviced.

111150.

- (a) All sources of bottled water, vended water, and water dispensed by a retail water facility shall be monitored annually for the presence of volatile organic compounds of potential public health concern, as specified by the United States Environmental Protection Agency in Tables 2 and 14 contained in Volume 50 of the Federal Register on pages 46904, 46923, and 46924 on November 13, 1985, or as reasonably specified by the department as a condition of licensure.
- (b) In lieu of source water monitoring required by this section, a water bottler, water vendor, or a retail water facility may document that the source monitoring required by this section is conducted by another entity approved by the department, or may comply with the treatment requirements of subdivision (c).
- (c) Detection in the source water of a volatile organic compound, except trihalomethanes, for which source monitoring is required pursuant to this section shall be followed immediately by a program of periodic monitoring by the water bottler, water vendor, or retail water facility to confirm the presence or absence in the source water of the volatile organic compound. If the volatile organic compound is confirmed to be present in the source water it shall be treated using granular activated carbon treatment or an equivalent treatment operated in accordance with good manufacturing practices as provided in Section 129.80 of Title 21 of the Code of Federal Regulations until the time that the concentration of the volatile organic compound does not exceed either one part per billion, or any United States Environmental Protection Agency or United States Food and Drug Administration level for drinking water, or a maximum contaminant level established by the department for bottled water.
- (d) The department may exempt any water bottler, water vendor, or retail water facility from the monitoring requirements of this section for any source based on a showing satisfactory to the department that the source (1) does not contain the volatile organic compound for which monitoring is required and (2) is not vulnerable to contamination by the volatile organic compound because for surface water sources the compounds are not applied, manufactured, stored, disposed or shipped upstream, and for groundwater sources, the compounds are not applied, manufactured, stored, disposed, or shipped in the groundwater recharge basin.

111155. Notwithstanding any other provisions of this article, the department may require any bottler, distributor, or vendor of bottled water, any owner or operator of a water-vending machine, any water hauler, any retail water facility operator, any private water source operator, or any applicant for a license to test and submit results to the department for any substance, including organic chemical contaminants, at any time that the department believes the substance may be present in the water source and threaten the public health.

111160.

- (a) Upon a determination by the department that a particular water source is subject to potential contamination, the department shall notify the bottler, distributor, or vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator of the specific contaminants or class of contaminants that pose a potential health risk.
- (b) Within 90 days after notification by the department, the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator shall conduct an analysis of the water source and submit the results of the analysis to the department.
- (c) If evidence of contamination is found, the department may, by order, require the bottler, distributor, vendor of bottled water, or the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator to conduct a source and product water analysis for the contaminants of concern in accordance with conditions specified by the department. The water analysis shall be conducted and reported on an annual basis, unless the department finds that reasonable action requires either more frequent or less frequent analysis.
- (d) The department may, by order, require the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator to reduce or eliminate the concentration of any chemical that the department determines may have an adverse effect on public health. Until an enforceable standard has been established for a chemical that may have an adverse effect on human health, the department may require treatment techniques to reduce the concentration of the contaminants that require treatment, in the department's judgment, to prevent known or anticipated adverse effects on the health of persons. The treatment system shall be designed to meet criteria designated by the department or by an independent authority approved by the department.
- (e) The department may grant variances from the requirements of subdivision (d), if the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator demonstrates either of the following:
 - (1) That the prescribed treatment technique is not necessary to protect the health of consumers because its water source is not subject to, nor is it likely to be subject to, significant chemical contamination.
 - (2) An alternative treatment technique is at least as efficient in lowering the level of contaminants to be controlled.

111165. All testing of bottled water, bottled water sources, water distributed by water haulers, water from retail water facility, and water from vending machines shall be done by laboratories approved by the department, laboratories certified by the United States Environmental Protection Agency, laboratories certified by the primary enforcement authority in states that have been granted primacy by the United States Environmental Protection Agency, or laboratories certified (accredited) by a third-party organization acceptable to a primacy state.

111170.

- (a) Labeling and advertising of bottled water and vended water shall conform with this section, Chapter 4 (commencing with Section 110290), and applicable portions of Part 101 of Title 21 of the Code of Federal Regulations.
- (b) Each container of bottled water sold in this state, each water-vending machine, and each container provided by retail water facilities located in this state shall be clearly labeled in an easily readable format. Retail water facilities that do not provide labeled containers shall post, in a location readily visible to consumers, a sign conveying required label information.
- (c) Water-vending machines, retail water facilities, and private water sources that sell water at retail shall display in a position clearly visible to customers the following information:
 - (1) The name and address of the operator.
 - (2) The fact that the water is obtained from an approved public water supply or licensed private water source.

- (3) A statement describing the treatment process used.
 - (4) If no treatment process is utilized, a statement to that effect.
 - (5) A toll-free telephone number or a local telephone number within the area code in which the machine is located that may be called for further information, service, or complaints, and the toll-free telephone number of the department's food and drug branch that may be called for complaints or questions.
 - (6) A sign or label indicating the date on which the water-vending machine was last sanitized and serviced by the operator or maintenance personnel as required pursuant to paragraph (1) of subdivision (b) of Section 111115.
 - (7) A notice to consumers listing the industry's recommendations for the type and condition of container suitable for use with the water-vending machine.
 - (8) A valid decal or seal received from the department indicating that a license fee has been paid and a license issued for the water-vending machine as set forth in subdivision (d) of Section 111130.
- (d) The information required pursuant to subdivision (c) shall be displayed in both English and Spanish.
 - (e) Bottled water may be labeled "drinking water," notwithstanding the source or characteristics of the water, only if it is processed pursuant to the Food and Drug Administration Good Manufacturing Practices contained in Section 165.110 and Parts 110 and 129 of Title 21 of the Code of Federal Regulations, Sections 12235 to 12285, inclusive, of Title 17 of the California Code of Regulations, and any other requirements established by the department pursuant to Sections 111145, 111150, and 111155. Any vended water and any water from a retail water facility may be labeled "drinking water," notwithstanding the source or characteristics of the water, only if it is processed pursuant to Article 10 (commencing with Section 114200) of Chapter 4 of Part 7 and any other requirements established by the department pursuant to Sections 111145, 111150, and 111155.
 - (f) Each container of bottled water sold at retail or wholesale in this state in a beverage container shall include on its label, or on an additional label affixed to the bottle, or on a package insert or attachment, all the following:
 - (1) The name and contact information for the bottler or brand owner.
 - (2) The source of the bottled water, in compliance with applicable state and federal regulations.
 - (3) A clear and conspicuous statement that informs consumers about how to access water quality information contained in the bottled water report required by Section 111071.
 - (A) The statement shall contain all of the following:
 - (i) It shall include the term "water quality and information" appropriately, while informing customers about methods of gaining access to the full bottled water report.
 - (ii) It shall provide a telephone number, where information can be requested from the bottled water company and one other means of contact for the bottled water company, including, but not limited to, a mailing address, e-mail address, or the bottled water company's Web site.
 - (B) The following statement may be used to fulfill the requirements of this paragraph:

"For more information and to obtain additional consumer information relating to water quality, including a bottled water report, contact (name of bottled water company) at (telephone number or toll-free telephone number) and (at least one of the following: mailing address, e-mail address, or the bottled water company's Web site)."
- (g) Bottlers that distribute bottled or vended water directly to consumers shall provide a statement on each billing statement that includes both of the following:
 - (1) A telephone number and mailing address of the bottler or brand owner.
 - (2) The means by which a consumer may obtain consumer information relating to water quality, including a bottled water report, as described in Section 111071.
 - (h) Amendments made to this section by SB 220 of the 2007-08 Regular Session shall only apply to bottled water that was bottled on or after January 1, 2009.

111172.

- (a) The labeling on bottled water sold in nonreturnable (one-way) packages in this state shall include one of the following:
 - (1) A telephone number of the bottler or brand owner.
 - (2) The bottler's or brand owner's mailing address.
- (b) Bottlers or brand owners may also include other forms of contact, including, but not limited to, the bottler's or brand owner's E-mail address or website.
- (c) This section shall become operative on January 1, 2002.

111175.

- (a) In addition to the requirements of Section 111170, if a bottler, distributor, water hauler, retail water facility operator, or vending machine operator provides information in the labeling or advertising stating or implying that this water is of a specific water type (for example, "spring water") or treated in a specific manner (for example, "purified"), the type or treatment shall be clearly labeled in an easily readable format. In order to be so labeled, the source or treatment shall conform to the definitions established in Section 165.110 of Title 21 of the Code of Federal Regulations, or, if not defined in that section, with the following criteria:
 - (1) "Mineralized water" means bottled or vended water that meets the requirements of "mineral water" except that the water contains added minerals.
 - (2) "Natural water" means bottled or vended spring, artesian well, or well water that is unmodified by mineral addition or deletion, except "natural water" may be filtered and shall be sanitized with ozone or an equivalent disinfection process and treated to reduce the concentration of any substance that exceeds safety standards established by the department.
 - (3) "Naturally sparkling water" means bottled water or vended water with a carbon dioxide content from the same source as the water. "Sparkling," "carbonated," or "carbonation added" means bottled water or vended water that contains carbon dioxide.
 - (4) Notwithstanding any other provision of this section, water from a public water system that is unprocessed by the bottler or vendor shall be in compliance with Section 165.110(a)(3)(ii) of Title 21 of the Code of Federal Regulations.

111180. Except as provided in Section 111080, any bottled water or vended water, the quality of which is below the quality required by this article, shall be labeled with a statement of substandard quality, as prescribed by subsection (b) of Section 165.110 of Subpart B of Part 165 of Title 21 of the Code of Federal Regulations.

111185. Any bottler, distributor, vendor of bottled water, or owner or operator of any water-vending machine or retail water facility, whose corporate name or trademark contains the words "spring" or "springs," or any derivative of either of these words, or "well," "artesian well," or "natural" shall label each bottle or vending machine with the source of the water in typeface at least equal to the size of the typeface of the corporate name or trademark, if the source of the bottled or vended water is different from the source stated in the corporate name or trademark. Retail water facilities that do not provide labeled containers shall post, in a location readily visible to consumers, a sign conveying required label information.

111190.

- (a) A bottled water, as defined in Section 111170, with natural or added carbonation, may be prepared with added flavors, extracts, essences, or fruit juice concentrates derived from a spice or fruit and comprising less than 1 percent by weight of the final product. The final product shall contain no sweeteners, or additives other than the flavors, extracts, essences, or fruit juice concentrates and carbon dioxide and shall be designated on labels and in advertising as follows:
 - (1) The common or usual name of the characterizing flavor shall accompany the designation of the bottled water product type as defined in subdivision (b) of Section 111170.
 - (2) The product may be designated as "natural" only if it meets the requirements for the designation as defined in paragraphs (5) and (6) of subdivision (b) of Section 111170, and naturally derived flavors, extracts, or essences are used.

- (b) Products labeled pursuant to this section shall comply with all other provisions of this article. Products with one type or one source of bottled water that are labeled pursuant to this section shall not be blended with water that is not bottled water or that is of another bottled water type.

111192.

- (a) Bottlers and water haulers that distribute directly to consumers shall provide a sentence on each billing statement that includes one of the following:
- (1) A telephone number of the bottler or brand owner.
 - (2) The bottler's or brand owner's mailing address.
- (b) Bottlers or brand owners may also include other forms of contact, including, but not limited to, the bottler's or brand owner's E-mail address or website.
- (c) Bottlers and water haulers that distribute directly to consumers shall, in the billing statement, provide to new customers, and to existing customers once per year thereafter, the following statement:

"As a food product, bottled water is subject to rules and regulations promulgated by the federal Food and Drug Administration (FDA). For further information, please contact (insert the name of the bottler or brand owner) at (insert the bottler's or brand owner's telephone number or mailing address)."

- (d) Water vending machines shall display the same information on the machines that is required under subdivisions (a) and (c).
- (e) Retail water facilities shall provide new customers the same information that is required under subdivisions (a) and (c). These facilities shall also display this information in a take-home format.
- (f) This section shall become operative on January 1, 2002.

111193.

- (a) The department may by written permission allow a person to package water for use in public emergencies without obtaining a water bottling license, where the emergency has resulted in the interruption of, or has compromised the quality of, the public drinking water supply. This permission may authorize the suspension of any provision of this chapter and related regulations.
- (b) (1) The department may at any time change or impose on the permittee any requirements such as testing, equipment, and documentation that the department deems necessary to protect public health but in doing so shall consider the effect of those requirements in light of the urgency of the situation. The department may grant or withdraw this permission at any time.
- (2) Packing, distribution, and use of water under this permit shall only be allowed during the emergency period and shall end upon the restoration of adequate public drinking supplies as determined by the department. Distribution shall be limited to the area affected. Water so packaged shall be prominently labeled "drinking water", "for emergency use only", and "not for sale", or similar wording approved by the department.
- (c) This section shall not be construed to restrict licensed water bottling plants from providing water processed in accordance with this chapter in emergency situations.

111195. The department, prior to issuing a license, shall review all labels prepared pursuant to this article, and may require any changes in order to comply with this article.

111198. The department shall post annually on its Internet Web site, in connection to the entities it regulates under this article, all of the following information:

- (a) The total number of licenses, by type and county, issued in the prior calendar year.
- (b) The number of inspections performed by the department in the previous calendar year, broken down by county and license type.
- (c) The number and type of major violations, and the actions taken to correct those violations.
- (d) The number and dollar value of fines levied under subdivision (c).

Article 13. Hamburger and Imitation Hamburger

111200. As used in this article, the following definitions shall apply:

- (a) "Hamburger" means chopped fresh or frozen beef, or a combination of both fresh or frozen beef, with or without the addition of beef fat as such, and with or without the addition of seasoning. Hamburger shall not contain more than 30-percent fat, and shall not contain added water, binders, or extenders. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of hamburger to the extent of 25 percent, and if in excess of natural proportions, its presence shall be declared on the label in the ingredient statement, if any, and otherwise contiguous to the name of the product.
- (b) "Imitation hamburger" means chopped fresh or frozen beef, or a combination of both fresh or frozen beef, with or without the addition of beef fat as such, and with or without the addition of seasoning. Imitation hamburger may contain binders and extenders, with or without the addition of partially defatted beef tissue, without added water or with added water only in amounts that the products' characteristics are essentially that of a meat pattie.
- (c) "Restaurant" means restaurants, itinerant restaurants, vehicles, vending machines, or institutions including hospitals, schools, asylums, eleemosynaries, and all other places where food is served to the public for consumption on the premises of sale that are not included within the definitions of the terms restaurants, itinerant restaurants, vehicles, and vending machines.

111205.

- (a) If imitation hamburger is sold or served in restaurant a list of ingredients thereof shall appear on the menu, or, if there is no menu, the information shall be posted as state department shall by regulations require. No list of ingredients, however, shall be required for imitation hamburger that contains not more than 10 percent added protein and water, and that does not contain other binders or extenders.
- (b) No restaurant shall use the terms "hamburger," "burger," or any other cognate thereof in any advertisement, or menu to refer to any imitation hamburger. A restaurant selling or serving imitation hamburger may refer to the product as imitation hamburger or by any other term that accurately informs the customer of the nature of the food product that he or she is sold or served.

111210. It is unlawful and constitutes misbranding for any person to advertise, offer for sale, sell, or serve as hamburger or imitation hamburger in any restaurant any product that does not come within the definitions of those terms contained in Section 111200. It is unlawful and constitutes misbranding for any person to violate any provision of this article or any regulation adopted pursuant thereto.

111215. It is the public policy of this state to require restaurants selling hamburger and imitation hamburger to accurately inform the consumer public of the contents of foods.

111220. This article shall be enforced by the same persons and in the same manner as provided in Article 7 (commencing with Section 28690) of Chapter 11 of Division 22.

Article 14. Asian Rice Noodles and Korean Rice Cakes

111222. For purposes of this article the following definitions shall apply:

- (a) "Asian rice-based noodle" is defined as a rice-based pasta that contains rice powder, water, wheat starch, vegetable cooking oil, and optional ingredients to modify the pH or water activity, or to provide a preservative effect. The ingredients shall not include any animal fats or any other products derived from animals. An Asian rice-based noodle is prepared by using a traditional method that includes cooking by steaming at not less than 130 degrees Fahrenheit, for not less than four minutes.
- (b) "Korean rice cake" is defined as a confection that contains rice powder, salt, sugar, various edible seeds, oil, dried beans, nuts, dried fruits, and dried pumpkin. The ingredients may not include any animal fats or any other products derived from animals. A Korean rice cake is prepared by using a traditional Korean method that includes cooking by steaming at not less than 275 degrees Fahrenheit, for not less than five minutes, nor more than 15 minutes.
- (c) "Vietnamese rice cake," also known as Bánh Tét or Bánh Chưng, is defined as a confection that contains a combination of rice, beans, and meat or fruit wrapped tightly in banana leaves for cooking. Bánh Tét is a rice cake in a cylindrical shape, and Bánh Chưng is a rice cake in a square shape. A Vietnamese rice cake is prepared using a traditional Vietnamese method that includes cooking by boiling in water for not less than 10 hours. Vietnamese rice cakes are required to be

handled, prepared, and stored under sanitary conditions both when they are kept at no more than 70 degrees Fahrenheit upon completion of cooking and after the rice cakes have been cooled to below 70 degrees Fahrenheit. Any Vietnamese rice cakes that are unwrapped from the banana leaves after cooking shall be refrigerated.

111223.

- (a) (1) All manufacturers of Asian rice-based noodles shall place a label on the packaging of Asian rice-based noodles that indicates the date and time that the product first came out of hot holding at temperatures above 135 degrees Fahrenheit and includes a statement that the Asian rice-based noodles are perishable.
- (2) The product packaging shall only be labeled once.
- (3) Notwithstanding paragraphs (1) and (2), this section shall not apply to Asian rice-based noodles that have a pH of 4.6 or below, have a water activity of 0.85 or below, or have been determined by the department to be nonpotentially hazardous foods based on formulation and supporting laboratory documentation submitted to the department by the manufacturer.
- (b) All manufacturers of Korean rice cakes shall place a label issued by the Korean Rice Cake Association Corporation on the Korean rice cake that indicates the date of manufacture. The Korean rice cakes label shall include a statement that the rice cake must be consumed within one day of manufacture.
- (c) (1) All manufacturers of Vietnamese rice cakes shall place a label, designed by the Vietnamese Rice Cake Association, Inc., on the Vietnamese rice cake that indicates the date and time the cooking process was completed. The Vietnamese rice cakes label shall include a statement that the rice cake must be consumed within 24 hours of the date and time printed on the label.
- (2) Notwithstanding paragraph (1), this section does not apply to Vietnamese rice cakes that have been determined by the department to be nonpotentially hazardous foods based on formulation and supporting laboratory documentation submitted to the department by the manufacturer.

CHAPTER 6. DRUGS AND DEVICES

Article 1. General Provisions

111225. As used in this chapter, with respect to a drug or drug ingredient, “established name” means either of the following:

- (a) The name designated pursuant to Section 508 of the federal act (21 U.S.C. Sec. 358).
- (b) If there is no such name and the drug or ingredient is an article recognized in an official compendium, then the official title in the compendium is the established name. If neither subdivision (a) or (b) of this section applies, the common or usual name, if any, of the drug or of the ingredient is the established name. When an article is recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug. If it is labeled and offered for sale as a homeopathic drug, the official title used in the Homeopathic Pharmacopoeia shall apply.

111230. Any drug represented in its labeling or advertisement as an antiseptic shall be considered to be represented as a germicide, except in the case of a drug that is purported to be or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use involving prolonged contact with the body.

111235. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug. If it is labeled and offered for sale as a homeopathic drug, it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

111240. Any added poisonous or deleterious substance, or color additive, shall be considered unsafe for use with respect to any drug or device unless there is in effect a regulation adopted pursuant to Section 110090 that prescribes its use in or on drugs or devices.

111245. The department may establish performance standards for devices, that shall be designed to provide reasonable assurance of safe and effective performance and, where appropriate, requiring the use and prescribing the form and content of labeling for the proper installation, maintenance, operation, or use of the device. However, if a performance standard is established for a device pursuant to Section 514 of the federal act (21 U.S.C. Sec. 360d) or Section 521 of the federal act (21 U.S.C. Sec. 360k), it shall be the performance standard of this state for device.

111246. Commencing January 1, 2002, any product used for the treatment of lice or scabies in human beings that contains the pesticide Lindane shall not be used or sold in the state.

Article 2. Adulterated Drugs and Devices

111250. Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

111255. Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

111260. Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

111265. Any drug or device is adulterated if it is packaged and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

111270. Any drug or device is adulterated if it bears or contains for the purpose of coloring only a color additive that is unsafe within the meaning of Section 111240.

111275. Any drug or device is adulterated if it is a color additive, the intended use of which in or on drugs or devices is for the purpose of coloring only, and it is unsafe within the meaning of Section 111240.

111280. Any drug is adulterated if it purports to be, or is represented as, a drug that is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in the compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of the tests or methods of assay, those prescribed under authority of this part. No drug defined in an official compendium shall be deemed to be adulterated under this section because it differs from the standard of strength, quality, or purity set forth in the compendium, if its difference in strength, quality, or purity from the standard is plainly stated on the label.

111285. Any drug or device is adulterated if its strength differs from, or its purity or quality is below, that which it is represented to possess.

111290. Any drug or device is adulterated if any substance has been mixed or packed with it so as to reduce its quality or strength or if any substance has been substituted, wholly or in part, for the drug or device.

111295. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

111300. It is unlawful for any person to adulterate any drug or device.

111305. It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device.

111310. While any regulation described in Section 110090 relating to any color additive is in effect, any drug or device that bears or contains the color additive in accordance with the regulation shall not be considered adulterated.

111315. Any drug or device intended for export shall not be deemed to be adulterated under this part if it satisfies all of the following requirements:

- (a) It accords to the specifications of the foreign purchaser.
- (b) It is not in conflict with the laws of the importing country
- (c) It is labeled on the outside of the shipping package to show that it is intended for export. If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

111320. Any device is adulterated that fails to meet the applicable performance standard, if any, as provided in Section 111245.

111325. A drug or device is deemed adulterated under the laws of this state if it is subject to regulations issued by the United States Food and Drug Administration as set forth in Parts 200, 211, 314, and 800 of Volume 21 of the Code of Federal Regulations, as amended, relating to tamper-resistant packaging, but is not in compliance therewith.

Article 3. Misbranded Drugs and Devices

111330. Any drug or device is misbranded if its labeling is false or misleading in any particular.

111335. Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

111340. Any drug or device is misbranded unless it bears a label containing all of the following information:

- (a) The name and place of business of the manufacturer, packer, or distributor.
- (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

111345. Any drug or device is misbranded if any word, statement, or other information required by or under this part to appear on the label or labeling is not prominently placed on the label or labeling with conspicuousness, as compared with other words, statements, designs, or devices in the labeling, and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

111355.

(a) Any drug is misbranded unless its label bears, to the exclusion of any other nonproprietary name except the applicable, systematic chemical name or the chemical formula, all of the following information:

- (1) The established name of the drug, if any.
- (2) If it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any

bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein.

- (3) For nonprescription drugs, the quantity or proportion of each active ingredient and the established name of each inactive ingredient in accordance with Sections 502(e)(1)(A)(ii) and (iii) of the federal act (21 U.S.C. 352(e)(1)(A)(ii) and (iii)).
- (b) The requirement for stating the quantity of the active ingredients of any drug, including the quantity or proportion of any alcohol, and also including, whether active or not, the quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein, shall apply to all drugs, including prescription drugs and nonprescription drugs. However, the requirement for declaration of quantity shall not apply to nonprescription drugs that are also cosmetics, as defined in Section 201(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(i)) and that are labeled in compliance with federal labeling requirements concerning declaration of ingredients including active ingredients and also the quantity and proportion of any alcohol, except that the quantity or proportion of the following ingredients, whether active or not, shall be declared: bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein. The department may exempt any nonprescription drug from the requirement of stating the quantity of the active ingredients, other than those specifically named in this subdivision, upon a showing by the applicant through evidence satisfactory to the department that the granting of the exemption will not endanger the public health. For any prescription drug the established name of the drug or ingredient, as the case may be, on the label and on any labeling on which a name for the drug or ingredient is used shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for the drug or ingredient.

The changes made in this section by Chapter 943 of the Statutes of 1978 shall not apply to any drug shipped by a manufacturer or packer to a retailer or wholesaler before January 1, 1980. Any such drugs so shipped shall comply with this section on and after January 1, 1981.

111360. Any drug subject to Section 111470 is misbranded unless the manufacturer, packer, or distributor of the drug includes, in all advertisements and other descriptive matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug, a true statement of all of the following:

- (a) The established name, printed prominently and in a type at least half as large as that used for any proprietary name of the drug.
- (b) The formula showing quantitatively each ingredient of the drug to the extent required for labels under Section 111355.
- (c) The name and place of business of the manufacturer that produced the finished dosage form of the drug, as prescribed by regulations issued by the department. This subdivision applies only to advertisements or descriptive matter issued for drugs manufactured in finished dosage form on or after April 1, 1973.
- (d) Such other information, in brief summary relating to side effects, contraindications, and effectiveness as shall be required by regulations promulgated by the department.

Regulations relating to side effects, contraindications, and effectiveness issued pursuant to Section 502(n) of the federal act (21 U.S.C. Sec. 352(n)) are the regulations establishing information requirements relating to side effects, contraindications and effectiveness in this state. The department may, by regulation, make other requirements relating to side effects, contraindications, and effectiveness whether or not in accordance with the regulations adopted under the federal act.

111365. Any drug subject to Section 111470 is misbranded unless the established name of the prescription drug or prescription drug ingredient is printed on the label prominently and in type at least half as large as that used for the proprietary name or designation on the label, labeling, or advertising.

The department may, by regulation, establish exemptions from the requirements of this section when compliance with this section is not considered necessary for the protection of health and safety.

111375. Any drug or device is misbranded unless its labeling bears all of the following information:

- (a) Adequate directions for use.
- (b) Such adequate warnings against use in pathological conditions or by children where its use may be dangerous to health.
- (c) Adequate warning against unsafe dosage or methods or duration of administration or application.

Warnings shall be in a manner and form as are necessary for the protection of users.

If the department determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

Any drug or device exempted under Section 502(f) of the federal act (21 U.S.C. Sec. 352(f)) is exempt from the requirement of this section. The department, however, may adopt any regulation including a drug or device within, or excluding a drug or device from the requirements of this section, whether or not the inclusion or exclusion of the drug or device is in accord with the federal act.

111380. Any drug is misbranded if it purports to be a drug that is recognized in an official compendium and it is not packaged and labeled as prescribed in the official compendium. The method of packaging, however, may be modified with the consent of the department.

111385. Any drug or device is misbranded if the department determines that the drug or device is liable to deterioration, unless it is packaged in that form and manner and its label bears a statement of the precautions, as the department, by regulation, may require as necessary for the protection of public health. Such regulations shall not be established for any drug or device recognized in an official compendium, unless the department has informed the appropriate body, charged with the revision of the official compendium, of the need for that packaging or labeling requirements and that body has not prescribed the requirements in a reasonable length of time.

111390. Any drug or device is misbranded if its container is so made, formed, or filled as to be misleading.

111395. Any drug is misbranded in any of the following cases:

- (a) It is an imitation of another drug.
- (b) It is offered for sale under the name of another drug.
- (c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package.

111397.

- (a) Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded.
- (b) Any foreign dangerous drug that is imported lawfully under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or pursuant to an announcement by the United States Food and Drug Administration of the exercise of enforcement discretion for instances including, but not limited to, clinical research purposes, drug shortages, development of countermeasures against chemical, biological, radiological, and nuclear terrorism agents, or pandemic influenza preparedness and response is not misbranded.

111400. Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

111415. Any drug is misbranded if it is a color additive, intended for use in or on drugs for the purpose of coloring only and its packaging and labeling fail to conform to the packaging and labeling requirements adopted pursuant to Section 110090.

111420. A drug or device is misbranded if a trademark, trade name, or other identifying mark, imprint, or device of another person, or any likeness of the trademark, trade name, or other identifying mark, imprint, or device of another person, has been placed on the drug or device, or upon its container.

111425. A drug or device is misbranded if it was manufactured in this state in an establishment not duly licensed as provided in this part.

111430. A drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States.

111435. Any drug is misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 108685 or 108700.

111440. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

111445. It is unlawful for any person to misbrand any drug or device.

111450. It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

111455. It is unlawful for any person to alter, mutilate, destroy, obliterate, or remove the label or any part of the labeling of any drug or device if the act results in the drug or device being misbranded.

111460. Any drug or device intended for export shall not be deemed to be misbranded under this part if it satisfies all of the following requirements:

- (a) It accords to the specifications of the foreign purchaser.
- (b) It is not in conflict with the laws of the importing country.
- (c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

111465. A drug or device is deemed misbranded under the laws of this state if it is subject to regulations issued by the United States Food and Drug Administration relating to tamper-resistant packaging, as set forth in Parts 200, 211, 314, and 800 of Volume 21 of the Code of Federal Regulations, as amended, but is not in compliance therewith.

111470. The following drugs or devices, that are intended for use by man, shall be sold only upon a written prescription of a practitioner licensed by law to prescribe the drug or device, or upon an oral prescription of the licensee that is reduced promptly to writing and filed by the pharmacist, or by refilling the written or oral prescription if the refilling is authorized by the prescriber either in the original prescription or by oral order that is reduced promptly to writing and filed by the pharmacist:

- (a) A habit forming drug to which Section 111350 applies.
- (b) A drug or device that, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the drug or device.
- (c) A drug or device for which adequate directions cannot be written for persons, who are not practitioners licensed by law to prescribe the drug or device, for safe and effective self-medication or treatment by those persons, who are not practitioners licensed by law to prescribe the drug or device.

- (d) A drug or device that is limited by an effective application under Section 505 of the federal act (21 U.S.C. Sec. 355) or Section 111550 to use under the professional supervision of a practitioner licensed by law to administer the drug or device.

If any prescription for the drug does not indicate the number of times it may be refilled, if any, the prescription may not be refilled unless the pharmacist obtains a new order from the practitioner.

111475. The act of selling a drug or device contrary to Section 111470 shall be deemed to be an act that results in the drug or device being misbranded while held for sale.

111480. Any drug or device sold by filling or refilling a written or oral prescription of a practitioner licensed to prescribe the drug or device shall be exempt from the labeling requirements of Sections 111335, 111340, 111350, 111355, 111360, 111365, 111375, 111380, 111385, 111395, 111415, and 111420, if the drug or device bears a label displaying all the following:

- (a) Except where the prescriber orders otherwise, either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.
- (b) The directions for the use of the drug or device.
- (c) The name of the patient(s).
- (d) The name of the prescriber.
- (e) The date of issue.
- (f) The name, address of the furnisher, and prescription number or other means of identifying the prescription.
- (g) The strength of the drug or drugs dispensed.
- (h) The quantity of the drug or drugs dispensed.
- (i) The expiration date of the effectiveness of the drug or device if the information is included on the original label of the manufacturer of the drug or device.

If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

The exemption shall not apply to any drug or device dispensed in the course of the conduct of a business of dispensing drugs or devices pursuant to diagnosis by mail, or to a drug or device dispensed in violation of Section 111470.

111485. The department may, by regulation, remove any drug or device subject to Sections 111350 and 111550 from the requirements of Section 111470, when the requirements are not necessary for the protection of the public health. Any drug removed from the prescription requirements of the federal act by regulations adopted pursuant to the federal act is removed from the requirements of Section 111470. The department may, however, by regulation, continue the applicability of Section 111470 for any drug or device, or make these sections inapplicable to any drug or device, whether or not the inclusion or exclusion of the drug or device is in accordance with the regulations adopted pursuant to the federal act.

111490.

- (a) A drug or device that is subject to Section 111470 is misbranded if at any time prior to dispensing, its label fails to bear the statement "Caution: federal law prohibits dispensing without prescription," or "Caution: state law prohibits dispensing without prescription," or "Rx only." A drug or device to which Section 111470 does not apply is misbranded if at any time prior to dispensing its label bears the caution statement or "Rx only" quoted in the preceding sentence.
- (b) A device that is subject to Section 111470 is misbranded if, at any time prior to dispensing, its label fails to bear the statement "Caution: federal law restricts this device to sale by or on the order of a _____," the blank to be filled in with the designation of the practitioner licensed to use or order use of

the device. A device to which Section 111470 does not apply is misbranded if, at any time prior to dispensing, its label bears the caution statement quoted in the preceding sentence.

111495. Nothing in this article shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or that may hereafter be included within the classification stated in Division 10 (commencing with Section 11000) or in the applicable federal law relating to controlled substances.

111500. A physician, dentist, podiatrist, or veterinarian may personally furnish his or her own patient with drugs as are necessary in the treatment of the condition for which he or she attends the patient provided that the drug is properly labeled to show all the information required in Section 111480 except the prescription number.

111505. For purposes of Section 111510, the following definitions shall apply:

- (a) "Distributor" means any corporation, person, or other entity, not engaged in the manufacture of a legend drug product, who distributes for resale and distribution a legend drug product under the label of the corporation, person, or entity.
- (b) "Legend drug" means any controlled substance subject to the Federal Controlled Substances Act (Title II, P.L. 91-513) or subject to the Uniform Controlled Substances Act, Division 10 (commencing with Section 11000), and any drug described in Section 4211 of the Business and Professions Code or Section 111470.
- (c) "Solid dosage forms" means capsules or tablets intended for oral administration.
- (d) "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, or marks or monograms unique to the manufacturer, distributor, or both. The National Drug Code may be used as a code imprint.

111510.

- (a) No legend drug in solid dosage form may be manufactured or distributed for sale in this state unless it is clearly marked or imprinted with a code imprint identifying the drug and the manufacturer or distributor of the drug. Manufacturers or distributors who only repack an already finished dosage form of a legend drug shall not have the responsibility to do the imprint.
- (b) On or before July 1, 1982, manufacturers or distributors of legend drugs, depending on whether the manufacturer's or distributor's code imprint will appear on the surface of the solid dosage form, shall provide to the department a list of their legend drugs and the intended code imprints. The department shall provide for the distribution of the information required to be submitted under this subdivision to all poison control centers in the state. Manufacturers, distributors, and the department shall provide to any licensed health care provider, upon request, lists of legend drugs and code imprints provided to the department under this section, but may charge a reasonable fee to cover copying and postage costs. Updated lists shall be provided to the department annually or as changes or revisions occur.
- (c) The department may grant exemptions from the requirements of this section upon application of a manufacturer or distributor indicating size or other characteristics that render the product impractical for the imprinting required by this section.
- (d) A legend drug that does not meet the requirements is misbranded.
- (e) It is the intent of the Legislature that all legend drugs having solid dosage forms be imprinted regardless of by whom they are distributed.
- (f) This section shall apply to all legend drugs sold in California on or after January 1, 1983.
- (g) Pharmacists, pharmacies, and licensed wholesalers shall only be liable for knowing and willful violations of this section, except that no liability shall accrue if the pharmacist acts pursuant to Section 4229.5 of the Business and Professions Code.
- (h) The provisions of subdivisions (a) to (g), inclusive, shall not apply to any of the following:
 - (1) Drugs purchased by a pharmacy, pharmacist, or licensed wholesaler prior to January 1, 1983, and held in stock for resale.
 - (2) Drugs that are the subject of an investigation pursuant to Section 111590 or 111595.
 - (3) Drugs that are manufactured by or upon the order of a practitioner licensed by law to prescribe or administer drugs and that are to be used solely by the patient for whom prescribed.

Article 4. Experimental Use of Drugs

111515. As used in this article, “experimental drug” means any of the following:
A drug intended for investigational use under Section 111595.

111520. No person shall prescribe or knowingly administer an experimental drug to another person in violation of this article.

111525. Prior to prescribing or administering an experimental drug, consent to the use of the drug shall be obtained in the method and manner specified in Chapter 1.3 (commencing with Section 24170) of Division 20.

111530.

- (a) Notwithstanding the provisions of Section 24175, if the subject is a minor, consent shall be provided by a parent or guardian of the subject and shall also be provided by the subject if the subject is seven years of age or older.
- (b) Consent given pursuant to this section shall only be for the prescribing or administering of an experimental drug that is related to maintaining or improving the health of the subject or related to obtaining information about a pathological condition of the subject.

111535. Consent given pursuant to Section 111525 may be revoked at any time by either verbal or written communication to the practitioner supervising the administration of the experimental drug.

111540. Prior to administering an experimental drug, the experimental activity as a whole, including the consent procedures required by Section 111525, shall be reviewed and approved by a committee for the protection of human subjects that is acceptable, as determined by the department. A committee for the protection of human subjects that operates under a general or special assurance approved by the federal Department of Health, Education, and Welfare pursuant to Part 46 of Title 45 of the Code of Federal Regulations shall be an acceptable committee for purposes of this section. A copy of the consent procedures approved by a committee for the protection of human subjects shall be filed with the department prior to the commencement of the experiment.

111545. A person having an ownership interest in a skilled nursing facility or intermediate care facility, as those terms are defined in Section 1250, may not prescribe an experimental drug for a patient in the facility.

Article 4.5. Right to Try Act

111548. This article shall be known and may be cited as the Right to Try Act.

111548.1. For purposes of this article, unless the context otherwise requires, the following definitions shall apply:

- (a) “Consulting physician” means a physician and surgeon licensed under the Medical Practice Act or an osteopathic physician and surgeon licensed under the Osteopathic Act who performs all of the following:
 - (1) Examines the qualified individual and his or her relevant medical records.
 - (2) Confirms, in writing, the primary physician’s diagnosis and prognosis.
 - (3) Verifies, in the opinion of the consulting physician, that the eligible patient is competent, acting voluntarily, and has made an informed decision.
- (b) “Eligible patient” means a person who meets all of the following conditions:
 - (1) Has an immediately life-threatening disease or condition.
 - (2) Has considered all other treatment options currently approved by the United States Food and Drug Administration.

- (3) Has not been accepted to participate in the nearest clinical trial to his or her home for the immediately life-threatening disease or condition identified in paragraph (1) within one week of completion of the clinical trial application process, or, in the treating physician's medical judgment, it is unreasonable for the patient to participate in that clinical trial due to the patient's current condition and stage of disease.
 - (4) Has received a recommendation from his or her primary physician and a consulting physician for an investigational drug, biological product, or device.
 - (5) Has given written informed consent for the use of the investigational drug, biological product, or device, or, if he or she lacks the capacity to consent, his or her legally authorized representative has given written informed consent on his or her behalf.
 - (6) Has documentation from his or her primary physician and a consulting physician attesting that the patient has met the requirements of this subdivision.
- (c) "Health benefit plan" means a plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. "Health benefit plan" includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in Section 1345, and a policy of health insurance, as defined in Section 106 of the Insurance Code, issued by a health insurer.
- (d) "Immediately life-threatening disease or condition" means a stage of disease in which there is a reasonable likelihood that death will occur within a matter of months.
- (e) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial approved by the United States Food and Drug Administration, but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.
- (f) "Primary physician" means a physician and surgeon licensed under the Medical Practice Act or an osteopathic physician and surgeon licensed under the Osteopathic Act.
- (g) "State regulatory board" means the Medical Board of California or the Osteopathic Medical Board of California.
- (h) (1) "Written, informed consent" means a written document that has been approved by the primary physician's institutional review board or an accredited independent institutional review board, is signed by an eligible patient, or his or her legally authorized representative when the patient lacks the capacity to consent, and attested to by the patient's primary physician and a witness that, at a minimum, does all of the following:
- (A) Explains the currently approved products and treatments for the immediately life-threatening disease or condition from which the patient suffers.
 - (B) Attests to the fact that the patient, or when the patient lacks the capacity to consent his or her legally authorized representative, concurs with the patient's primary physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.
 - (C) Clearly identifies the specific proposed investigational drug, biological product, or device that the patient is seeking to use.
 - (D) Describes the potentially best and worst outcomes of using the investigational drug, biological product, or device and describes the most likely outcome. This description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the primary physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.
 - (E) Clearly states that the patient's health benefit plan, if any, and health care provider are not obligated to pay for the investigational drug, biological product, or device or any care or treatments consequent to use of the investigational drug, biological product, or device.

(F) Clearly states that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and that care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements.

(G) Clearly states that in-home health care may be denied if treatment begins.

(H) States that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device, and that this liability extends to the patient's estate, except as otherwise provided in the patient's health benefit plan or a contract between the patient and the manufacturer of the drug, biological product, or device.

(2) Written, informed consent for purposes of this article shall be consistent with the informed consent requirements of the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).

111548.2. (a) Notwithstanding Section 110280, 111520, or 111550, a manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to an eligible patient pursuant to this article. This article does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(b) A manufacturer may do both of the following:

(1) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

(2) Require an eligible patient to pay the costs of, or associated with, the manufacture of the investigational drug, biological product, or device.

(c) (1) This article does not expand the coverage provided under Sections 1370.4 and 1370.6 of this code, Sections 10145.3 and 10145.4 of the Insurance Code, or Sections 14087.11 and 14132.98 of the Welfare and Institutions Code.

(2) This article does not require a health benefit plan to provide coverage for the cost of any investigational drug, biological product, or device, or the costs of services related to the use of an investigational drug, biological product, or device under this article. A health benefit plan may provide coverage for an investigational drug, biological product, or device made available pursuant to this section.

(d) If the clinical trial for an investigational drug, biological product, or device is closed due to the lack of efficacy or for toxicity, the investigational drug, biological product, or device shall not be offered. If notice of closure of a clinical trial is given for an investigational drug, biological product, or device taken by a patient outside of a clinical trial, the manufacturer and the patient's primary physician shall notify the patient of the information from the safety committee of the clinical trial.

(e) If an eligible patient dies while being treated by an investigational drug, biological product, or device made available pursuant to this article, the patient's heirs and health benefit plan, except to the extent the plan provided coverage pursuant to paragraph (2) of subdivision (c), are not liable for any outstanding debt related to the treatment or lack of insurance for the treatment.

111548.3. (a) Notwithstanding any other law, a state regulatory board shall not revoke, fail to renew, or take any other disciplinary action against a physician's license based on the physician's recommendation to an eligible patient regarding, or prescription for or treatment with, an investigational drug, biological product, or device if the recommendation or prescription is consistent with protocol approved by the physician's institutional review board or an accredited independent institutional review board.

(b) The physician's institutional review board or an accredited institutional review board shall biannually report the following information to the State Department of Public Health, the Medical Board of California, and the Osteopathic Medical Board of California:

(1) The number of requests made for an investigational drug, biological product, or device.

(2) The status of the requests made.

(3) The duration of the treatment.

- (4) The costs of the treatment paid by eligible patients.
 - (5) The success or failure of the investigational drug, biological product, or device in treating the immediately life-threatening disease or condition from which the patient suffers.
 - (6) Any adverse event for each investigational drug, biological product, or device.
- (c) A state agency shall not alter any recommendation made to the federal Centers for Medicare and Medicaid Services regarding a health care provider's certification to participate in the Medicare or Medicaid program based solely on the recommendation from an individual health care provider that a patient have access to an investigational drug, biological product, or device.
- (d) A violation of this section shall not be subject to Chapter 8 (commencing with Section 111825).

111548.5. This article does not create a private cause of action, and actions taken pursuant to this article shall not serve as a basis for a civil, criminal, or disciplinary claim or cause of action, including, but not limited to, product liability, medical negligence, or wrongful death, against a manufacturer of an investigational drug, biological product, or device, or against any other person or entity involved in the care of an eligible patient for harm done to the eligible patient or his or her heirs resulting from the investigational drug, biological product, or device, or the use or nonuse thereof, if the manufacturer or other person or entity has complied with the terms of this article in relation to the eligible patient, unless there was a failure to exercise reasonable care.

Article 5. New Drugs or Devices

111550. No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

- (a) It is one of the following:
 - (1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).
 - (2) A new biologic product for which a license has been issued as required by the federal Public Health Service Act (42 U.S.C. Sec. 262).
 - (3) A device that is reported under Section 510(k) of the federal act (21 U.S.C. or 360(k)), or is a device exempted pursuant to subsection (l) or (m) of Section 360 of Title 21 of the United States Code, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under Section 515 of the federal act (21 U.S.C. Sec. 360e).
- (b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information:
 - (1) Full reports of investigations that have been made to show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.
 - (2) A full list of the articles used as components of the new drug or device.
 - (3) A full statement of the composition of the new drug or device.
 - (4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new drug, or in the case of a new device, a full statement of its composition, properties, and construction, and the principles of its operation.
 - (5) Samples of the new drug or device and of the articles used as components of the drug or device as the department may require.
 - (6) Specimens of the labeling and advertisements proposed to be used for the new drug or device.

111555. Within 180 days after the filing of an application provided for in Section 111550, or an additional period as shall be agreed upon by the department and the applicant, the department shall do either of the following:

- (a) Approve the application, if it finds that none of the grounds for denying approval specified in Section 111550 apply.
- (b) Give the applicant written notice for an opportunity for a hearing before the department on the question of whether the application is approvable. If the applicant elects to accept the opportunity for hearing by written request within 30 days after the notice, the hearing shall commence not more than 90 days after the expiration of the 30 days unless the department and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the department's order thereon shall be issued within 90 days after the date fixed by the department for filing final briefs.

111560. The department shall issue an order refusing to approve an application if, after written notice to the applicant and after giving him or her an opportunity for a hearing, the department makes any of the following findings:

- (a) That the reports of investigation, that are required to be submitted to the department pursuant to Section 111550, do not include adequate tests by all methods reasonably applicable to show whether or not the new drug or device is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling and advertisement of the new drug or device.
- (b) That the results of the tests submitted pursuant to Section 111550 to show whether or not the new drug or device is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling and advertisement of the new drug or device show that the drug or device is unsafe for use under these conditions or do not show that the new drug or device is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling and advertisement.
- (c) That the methods, facilities, and controls used in the manufacture, processing, or packing of the new drug or device are inadequate to preserve its identity, strength, quality, purity, composition, or other characteristics.
- (d) That upon the basis of information submitted as part of the application, or upon the basis of any other information before it with respect to the new drug or device, that the department has insufficient information to determine whether the drug or device is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling and advertisement.
- (e) That evaluated on the basis of the information submitted as part of the application and any other information before it with respect to the new drug or device, that there is a lack of substantial evidence that the new drug or device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling or advertisement of the new drug or device.
- (f) That based on an evaluation by the department of all material facts, that the proposed labeling or advertising of the new drug or device is false or misleading in any particular.

111565. An order pursuant to Section 111560 refusing approval of a new drug application or a new device application shall be revoked whenever the department finds that the facts justify the action.

111570. In the case of any new drug or device for which an approval of an application filed pursuant to Section 111550 is in effect, the applicant shall establish and maintain records, and make reports to the department, of data relating to clinical experience and other data or information, received or otherwise obtained by the applicant with respect to the new drug or device, as the department may by general regulation, or by order with respect to the application, prescribe. Any regulation or order issued pursuant to this section or pursuant to Section 111595 shall have due regard for the professional ethics of the medical profession and the interest of patients and shall provide, where the department determines that it is reasonably necessary, for the examination upon request, by the persons to whom the regulation or order is applicable, of similar information received or otherwise obtained by the department. Every person required pursuant to this section to maintain records, and every person in charge or in custody of the records, shall, upon request of an authorized agent of the department, permit the agent at all reasonable time to have access to, and copy and verify, the records.

111575. The department shall issue an order withdrawing approval of an application concerning any new drug or device if, after giving written notice to the applicant and an opportunity for a hearing, the department makes any of the following findings:

- (a) That clinical or other experience, tests, or other scientific data show that the new drug or device is unsafe for use under the conditions of use upon the basis of which the application was approved.
- (b) That new evidence of clinical experience, not contained in the application or not available to the department until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available to the department when the application was approved, shows that the new drug or device is not shown to be safe for use under the conditions of use upon the basis of which the application was approved.
- (c) On the basis of new information with respect to the new drug or device, evaluated together with the evidence available to the department when the application was approved, that there is a lack of substantial evidence that the new drug or device will have the effect it purports or is represented to have, under the conditions of use prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.
- (d) That the application contains any untrue statement of a material fact.
- (e) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain the records or to make required reports, or the applicant has refused to permit access to, or copying or verification of, the records.
- (f) That on the basis of new information before the department, evaluated together with the evidence before it when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the new drug or device are inadequate to assure and preserve its identity, strength, quality, purity, composition, and characteristics as determined by qualified experts selected by the department, and were not made adequate within a reasonable time after receipt of written notice from the department specifying the matter complained of.
- (g) That on the basis of new information before it, evaluated together with the evidence before it when the application was approved, the labeling or advertisement of the new drug or device, based on an evaluation of all material facts, is false or misleading in any particular and is not corrected within a reasonable time after receipt of written notice from the department specifying the matter complained of.

111580. When the department finds that there is an imminent hazard to the public health, it may suspend the approval for the application immediately.

111585. An order pursuant to Section 111575 or 111580 withdrawing approval of an application concerning any new drug or device shall be revoked whenever the department finds that the facts justify the action.

111590. Section 111550 does not apply to a drug or device intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Secs. 352 and 360) and the regulations adopted pursuant to the federal act.

111595. Section 111550 does not apply to any drug or device intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if all the following conditions are complied with:

- (a) The submission to the department, before any clinical testing of a drug or device is undertaken, of reports, by the manufacturer or the sponsor of the investigation of the drug or device, of preclinical tests including tests on animals, of the drug or device adequate to justify the proposed clinical testing.
- (b) The manufacturer or the sponsor of the investigation of a drug or a device proposed to be distributed to investigators for clinical testing obtaining a signed, notarized agreement from each of the investigators that patients to whom the drug or device is administered will be under his or her personal supervision, or under the supervision of investigators responsible to him or her, and that he

or she will not supply the drug or device to any other investigator, or to clinics, for administration to human beings.

- (c) The establishment and maintenance of the records, and the making of the reports to the department, by the manufacturer or the sponsor of the investigation of the drug or device, of data, including but not limited to, analytical reports by investigators, obtained as a result of the investigational use of the drug or device, as the department finds will enable it to evaluate the safety and effectiveness of the drug or device in the event of the filing of an application pursuant to Section 111550.
- (d) The manufacturer, or the sponsor of the investigation, require experts using the drugs or devices for investigational purposes to certify to the manufacturer or sponsor that they will comply with the requirements of Article 4 (commencing with Section 111515).
- (e) Any other conditions as the department shall adopt as regulations necessary for the protection of the public health. The federal regulations adopted pursuant to Section 505(i) of the federal act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Secs. 352 and 360) shall be the regulations for exemptions from Section 111550 in this state. However, the department may prescribe, by regulation, any condition for exemption from Section 111550 whether or not the condition is in accordance with regulations adopted under the federal act.

111605.

- (a) In making determinations on requests for approval of AIDS-related drugs, as defined in subdivision (b), in accordance with Section 111550, or for exemptions from these requirements, for purposes of investigations of these drugs, pursuant to Section 111595, the department shall employ persons to conduct reviews of requests for drug marketing approval for AIDS-related drugs, or exemptions from the approval requirements as specified in that section. The AIDS Vaccine Research and Development Advisory Committee shall review and advise the department in its actions under this section.

Where necessary, the department shall enter into contracts with appropriate and qualified persons or entities for the review of these requests, including persons with significant experience in conducting or reviewing clinical trials of drugs or physicians with significant experience in treating AIDS patients.

No person may contract with the department for the review of a request under this subdivision if the person has a financial interest or a conflict of interest involving the drug being evaluated.

- (b) "AIDS-related drug" means either of the following:
 - (1) A vaccine to protect against human immunodeficiency virus (HIV) infection.
 - (2) Antiviral agent, immune modulator, or other agent to be administered to persons who have been infected with HIV, to counteract the effects of this infection, or any drug to treat opportunistic infections associated with AIDS.
- (c) The immunities provided for in Sections 818.4 and 821.6 of the Government Code shall apply whenever the department grants approval pursuant to Section 111550 or an exemption from the approval requirements pursuant to Section 111595, for an AIDS-related drug.

111610. Section 111550 does not apply to any of the following:

- (a) A drug or device that is sold in this state, or introduced into interstate commerce, at any time prior to the enactment of the federal act, if its labeling and advertising contained the same representations concerning the conditions of its use.
- (b) Any drug that is licensed under the Public Health Service Act of July 1, 1944 (58 Stats. 682, as amended; 42 U.S.C. Sec. 201 et seq.) or under the eighth paragraph of the heading of Bureau of Animal Industry of the act of March 4, 1913 (37 Stat. 832-833; 21 U.S.C. Sec. 151 et seq.), commonly known as the "Virus-Serum-Toxin Act."

Article 6. Licenses

111615. No person shall manufacture any drug or device in this state unless he or she has a valid license from the department. The license is valid for two calendar years from the date of issue, unless it is revoked. The license is not transferable.

The department may require any manufacturer, wholesaler, or importer of any prescription ophthalmic device in this state to obtain a license.

111620. A separate license is required for each place of manufacture.

111625. A license application shall be completed biennially and accompanied by an application fee as prescribed in Section 111630. This fee is not refundable if the license is refused.

111630. The department shall by regulation establish the application form and set the fee for licensure and renewal of a license. The penalty for failure to apply for renewal of a license within 30 days after its expiration is ten dollars (\$10) and shall be added to the renewal fee and be paid by the applicant before the renewal license may be issued. All moneys collected as fees shall be expended when appropriated by the Legislature in the carrying out of the provisions of this part and the regulations adopted pursuant to this part.

Any person licensed pursuant to this section shall immediately notify the department of any change in the information reported in the license application.

111635.

- (a) Prior to issuing a license required by Section 111615 to any place of business where a drug or device is manufactured, the department shall receive from each place of business documentation that evidences ownership and any of the following:
- (1) The place of business is operating pursuant to a valid biologics license issued by the United States Food and Drug Administration in compliance with Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262).
 - (2) The place of business is operating with a valid establishment registration pursuant to Section 510 of the federal act (21 U.S.C. Sec. 360). This documentation shall include an attestation from an officer of the place of business that a federal inspection was completed within the two years prior to the date of the attestation.
 - (3) The place of business is operating in compliance with audits conducted pursuant to the International Standards Organization (ISO) 9000 series, ISO 13485:2003 quality management systems standards, ISO 15378:2006 quality management systems standards, pursuant to Parts 210 and 211 of Title 21 of the Code of Federal Regulations, or pursuant to Part 820 of Title 21 of the Code of Federal Regulations.
 - (4) The place of business is operating pursuant to an approved investigational new drug issued by the federal Food and Drug Administration pursuant to Section 312.20 of Title 21 of the Code of Federal Regulations or pursuant to an approved investigational device exemption issued by the federal Food and Drug Administration pursuant to Section 812.20 of Title 21 of the Code of Federal Regulations.
- (b) If the department receives documentation that satisfies the requirements of subdivision (a), the department shall not inspect the place of business prior to issuing a license required by Section 111615. If the department does not receive the documentation required, the department shall inspect the place of business prior to issuing a license required by Section 111615.
- (c) Upon request by a place of business licensed under Section 111615, the department shall provide an official copy of the valid license to the place of business in accordance with Sections 110230 and 110235.
- (d) Notwithstanding Section 111640, for any place of business where a drug or device is manufactured and the manufacturer has received a license pursuant to this section, the department shall make investigations or inspections authorized by Article 2 (commencing with Section 110140) of Chapter 2 only when any of the following occur:
- (1) The department becomes aware of an issue and makes a determination that the health and safety of the public is at risk.
 - (2) A complaint has been registered with the department and the department makes a determination that the health and safety of the public is at risk.
 - (3) A notification has been sent by the United States Food and Drug Administration to the department that requests assistance regarding any Class I or II recall action memorandum.

- (4) The United States Food and Drug Administration has requested assistance for enforcement activities, including, but not limited to, embargoes, seizures, or injunctions.
- (e) Inspections made pursuant to subdivision (d) shall be limited to inspections for compliance with, or violations of, Chapter 4 (commencing with Section 110290) or this chapter.

111640. The department shall make investigations or inspections authorized by Article 2 (commencing with Section 110410) of Chapter 2 as it deems necessary to carry out this chapter.

111645. Any violation of any provision of this part or any regulation adopted pursuant to this part shall be grounds for denying a license or for suspending or revoking a license. Proceedings for the denial, suspension, or revocation of a license shall be conducted pursuant to Section 100171.

111650. Drug manufacturers who have obtained a license or who are applying for a license pursuant to this article shall submit to the California State Board of Pharmacy information as the Board of Pharmacy deems reasonably necessary to carry out its drug distribution responsibilities including, but not limited to, information on drug inventories or restricted dangerous drugs. Failure of any manufacturer to report the information to the Board of Pharmacy in a timely fashion shall be grounds for the department to deny, suspend, or revoke the manufacturer's license. The California State Board of Pharmacy may adopt regulations that are reasonably necessary to implement this section.

111655. The licensing provisions of this chapter shall not apply to any of the following:

- (a) Any pharmacy that maintains establishments in conformance with provisions of the Pharmacy Law, Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, regulating the practice of pharmacy, and that is regularly engaged in dispensing prescription drugs or devices, upon prescriptions of any person licensed to administer the drugs or devices to patients under the care of the person in the course of his or her professional practice, and that does not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of his or her business of dispensing or selling drugs or devices at retail.
- (b) Any pharmacy that solely engages in providing drugs or devices to a person licensed by law to administer the drug or device for his or her use in the course of his or her professional practice.
- (c) Any pharmacy that solely provides drugs or devices to another pharmacy in order to meet a temporary inventory shortage.
- (d) Any person who is licensed by law to prescribe or administer drugs or devices and who manufactures, prepares, propagates, compounds, or processes drugs or devices solely for use in the course of his or her professional practice.
- (e) Any person who manufactures, prepares, propagates, compounds, or processes any drug or device solely for use in nonclinical research, teaching, or chemical analysis and not for sale.
- (f) Any wholesaler, as defined in Section 4038 of the Business and Professions Code.
- (g) Any such other class of persons as the department may by regulation exempt from the application of this article upon a finding that licensing by a class of persons in accordance with this article is not necessary for the protection of the public health.
- (h) Any registered dispensing optician licensed pursuant to the provisions of Chapter 5.5 (commencing with Section 2550) of Division 2 of the Business and Professions Code, who is regularly engaged in dispensing or selling prescription lenses and frames, and not engaged in the manufacture, preparation, processing or assembling of lenses or frames for sale other than in the regular course of his or her business of dispensing or selling lenses or frames at retail.

111656.

- (a) No person shall conduct a home medical device retail facility business in the State of California unless he or she has obtained a license from the department. A license shall be required for each home medical device retail facility owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a home medical device retail facility in more than one location. The license shall be renewed annually and shall not be transferable. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to home medical device retail facilities.

- (b) Applications for a home medical device retail facility license shall be made on a form furnished by the department. The department may require any information it deems reasonably necessary to carry out the purposes of this section.
- (c) A warehouse owned by a home medical device retail facility the primary purpose of which is storage, not dispensing of home medical devices to patients, shall be licensed at a fee one-half of that for a home medical device retail facility. There shall be no separate or additional license fee for warehouse premises owned by a home medical device retail facility that are physically connected to the retail premises or that share common access.
- (d) The department may, at its discretion, issue a temporary license when the ownership of a home medical device retail facility is transferred from one person to another upon any conditions and for the periods of time as the department determines to be in the public interest. A temporary license fee shall be established by the department at an amount not to exceed the annual fee for renewal of a license to conduct a home medical device retail facility.
- (e) Notwithstanding any other provision of law, a licensed home medical device retail facility may furnish a prescription device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Health Services set forth in Title 22 of the California Code of Regulations.
- (f) The licensure requirements of this section shall not apply to the following entities or practitioners, unless the entities or practitioners furnish home medical devices or home medical device services through a separate entity including, but not limited to, a corporate entity, division, or other business entity:
 - (1) Home health agencies that do not have a Part B Medicare supplier number.
 - (2) Hospitals, excluding providers of home medical devices that are owned or related to a hospital.
 - (3) Manufacturers and wholesale distributors, if not selling directly to the patient.
 - (4) Health care practitioners authorized to prescribe or order home medical devices or who use home medical devices or who use home medical devices to treat their patients.
 - (5) Licensed pharmacists and pharmacies. Pharmacies that sell or rent home medical devices shall be governed by the provisions of Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code and any rules and regulations adopted by the California State Board of Pharmacy.
 - (6) Licensed hospice programs.
 - (7) Licensed nursing homes.
 - (8) Licensed veterinarians.
 - (9) Licensed dentists.
 - (10) Emergency medical services provider.
 - (11) Breast feeding support programs.

111656.1.

- (a)
 - (1) After January 1, 2002, prior to issuing a license required by Section 111656, the department shall inspect each place of business to determine ownership, adequacy of facilities, and personnel qualifications. Nothing in this section shall prohibit the department from inspecting any medical device retail facility prior to January 1, 2002.
 - (2)
 - (A) After the initial inspection pursuant to paragraph (1), the department shall inspect a licensee that is accredited by an accreditation organization approved by the federal Centers for Medicare and Medicaid Services, or its successor entity, only upon a complaint made to the department regarding the licensee.
 - (B) A licensee shall only be deemed to be accredited and subject to inspection pursuant to subparagraph (A) if all of the following conditions exist:
 - (i) The licensee is accredited by the accrediting organization at least every three years.
 - (ii) The licensee is subject to unannounced onsite midcycle surveys by the accrediting organization to validate ongoing compliance.
 - (iii) Within 30 days following an inspection by the accrediting organization, the accrediting organization notifies the department regarding the status of the licensee's accreditation.

- (iv) If the licensee is less than fully accredited, the accrediting organization notifies the department of the reasons for the lack of full accreditation and any corrective action plan recommended to the licensee.
- (C) The department shall inspect a licensee that ceased to be accredited in compliance with subparagraph (B) pursuant to paragraph (3).
- (3) The department shall inspect a licensee that is not accredited by an accreditation organization approved by the federal Centers for Medicare and Medicaid Services, or its successor entity, at least annually.
- (b) The annual license fee for a home medical device retail facility shall be eight hundred fifty dollars (\$850) until adjusted pursuant to subdivision (c).
- (c) The annual license fee required by Sections 111656 and 111630 shall be adjusted annually, commencing July 1, 2003, by the department so that license fee revenues cover the estimated licensing program costs. Adjusted fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.
- (d) Commencing July 1, 2003, the department shall by July 30 of each year, publish the amount of fees to be charged as adjusted pursuant to this section. This adjustment of fees 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.
- (e) Commencing January 1, 2003, the department shall, on or before January 10 of each year, provide the Legislature with a report recommending fee rates. The report shall describe the estimated licensing program costs for the next fiscal year to carry out the licensing, regulating, inspecting, and other duties and responsibilities of the department in carrying out the provisions of this article. The department shall describe the projected license fee amount so that license fee revenues cover the estimated licensing program costs. Projected fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.
- (f) The Drug and Device Safety Fund is hereby created as a special fund in the State Treasury. All moneys collected by the department under this section and Sections 111656.7, 111656.8, 111656.12, and 111630, and fines and penalties collected by the department in the enforcement of this article, 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 provisions of this article relating to drugs and devices.
- (g) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

111656.1

- (a) Prior to issuing a license required by Section 111656, the department shall inspect each place of business to determine ownership, adequacy of facilities, and personnel qualifications. The department shall inspect each licensee at least annually thereafter.
- (b) The annual license fee for a home medical device retail facility shall be eight hundred fifty dollars (\$850) until adjusted pursuant to subdivision (c).
- (c) The annual license fee required by Sections 111656 and 111630 shall be adjusted annually, commencing July 1, 2003, by the department so that license fee revenues cover the estimated licensing program costs. Adjusted fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.
- (d) The department shall by July 30 of each year publish the amount of fees to be charged as adjusted pursuant to this section. This adjustment of fees 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.
- (e) The department shall, on or before January 10 of each year, provide the Legislature with a report recommending fee rates. The report shall describe the estimated licensing program costs for the next fiscal year to carry out the licensing, regulating, inspecting, and other duties and responsibilities of the department in carrying out the provisions of this article. The department shall describe the projected license fee amount so that license fee revenues cover the estimated licensing program costs. Projected fee amounts shall take into account the resources required for inspections and other

activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.

- (f) The Drug and Device Safety Fund is hereby created as a special fund in the State Treasury. All moneys collected by the department under this section and Sections 111656.7, 111656.8, 111656.12, and 111630, and fines and penalties collected by the department in the enforcement of this article, 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 provisions of this article relating to drugs and devices.
- (g) This section shall become operative on January 1, 2023.

1

111656.2.

- (a) The following standards shall apply to all home medical device retail facilities:
 - (1) Each retail facility shall store prescription devices in a manner that does not allow a customer direct access or self-service.
 - (2) Each retail facility shall maintain the premises, fixtures, and equipment in a clean and orderly condition.
 - (3) Each retail facility shall maintain the premises in a dry, well-ventilated condition, free from contamination or other conditions that may render home medical devices unfit for their intended use.
- (b) The department may by regulation impose any other standards pertaining to the acquisition, storage, and maintenance of prescription devices or other goods or to the maintenance or condition of the licensed premises of any home medical device retail facility as the department determines are reasonably necessary.

111656.3.

- (a) Each home medical device retail facility shall have written policies and procedures related to home medical device handling and, if authorized by the department pursuant to Section 111656.4, the dispensing of prescription devices. Those written policies and procedures shall be adequate to assure compliance with this article and shall include, but not be limited to:
 - (1) Training of staff, patients, and caregivers.
 - (2) Cleaning, storage, and maintenance of home medical devices necessary to prevent damage or contamination and to assure their operation in accordance with manufacturer specifications.
 - (3) Emergency services. If home medical device malfunction may threaten a patient's health, access to emergency services 24 hours per day, 365 days per year shall be available for device maintenance or replacement.
 - (4) Maintaining all records required by this article and any regulations adopted pursuant to the provisions of this article.
 - (5) Storage and security requirements to assure that prescription devices are dispensed in accordance with this article.
 - (6) Quality assurance.
- (b) The home medical device retail facility shall make consultation available to the patient or primary caregiver about the proper use of devices and related supplies furnished by the home medical device retail facility. The home medical device retail facility shall notify the patient or primary caregiver that this consultation is available.
- (c) Each home medical device retail facility shall ensure all personnel who engage in the taking of orders for, the selling of, or the fitting of prescription devices, if authorized by the department pursuant to Section 111656.4, shall have training and demonstrate initial and continuing competence in the order-taking, fitting, and sale of prescription devices that the home medical device retail facility furnishes pursuant to Section 111656.4.
- (d) Each home medical device retail facility shall prepare and maintain records of training and demonstrated employee competence required under this article for employees of the home medical device retail facility. The records shall be maintained for three years from and after the last date of employment.

¹ Chapter 213, Statutes of 2017

- (e) Each home medical device retail facility shall have an ongoing, documented quality assurance program that includes, but is not limited to, the following:
 - (1) Monitoring personnel performance to assure compliance with this article.
 - (2) Storage, maintenance, and dispensing of prescription devices to assure that prescription devices are dispensed in accordance with this article.
- (f) The records and documents specified in subdivisions (a) and (e) shall be maintained for three years from the date of making. The records and documents described in subdivisions (a), (d), and (e), shall be open to inspection at all times during business hours by authorized agents of the department or an inspector from the California State Board of Pharmacy for the purpose of investigating a pharmacist.

111656.4. Section 4051 of the Business and Professions Code shall not prohibit a home medical device retail facility from selling or dispensing prescription devices if the department finds that sufficient qualified supervision is employed by the home medical device retail facility to adequately safeguard and protect the public health. Each person applying to the department for this exemption shall meet the following requirements to obtain and maintain the exemption:

- (a) A licensed pharmacist or an exemptee who meets the requirements set forth in paragraphs (1) to (5), inclusive, and whose license of exemption is currently valid, shall be in charge of the home medical device retail facility.
 - (1) He or she shall be a high school graduate or possess a general education development equivalent.
 - (2) He or she shall have a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices.
 - (3) He or she shall complete a training program that addresses each of the following subjects that are applicable to his or her duties:
 - (A) Knowledge and understanding of state and federal laws relating to the distribution of dangerous drugs and dangerous devices.
 - (B) Knowledge and understanding of state and federal laws relating the distribution of controlled substances.
 - (C) Knowledge and understanding of quality control systems.
 - (D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
 - (E) Knowledge and understanding relating to the safe storage and handling of home medical devices.
 - (F) Knowledge and understanding of prescription terminology, abbreviations, and format.
 - (4) The department may, by regulation, require training programs that include additional material.
 - (5) The department shall not issue an exemptee a license until the applicant provides proof of completion of the required training that the department determines is adequate to fulfill these requirements.
- (b) The licensed pharmacist or exemptee shall be on the premises at all times that prescription devices are available for sale or fitting unless the prescription devices are stored separately from other merchandise and are under the exclusive control of the licensed pharmacist or exemptee. A licensed pharmacist or an exemptee need not be present in the warehouse facility of a home medical device retail facility unless the department establishes that requirement by regulation based upon the need to protect the public.
- (c) The department may require an exemptee to complete a designated number of hours of coursework in department-approved courses of home health education in the disposition of any disciplinary action taken against the exemptee.
- (d) Each premises maintained by a home medical device retail facility shall have a license issued by the department and shall have a licensed pharmacist or exemptee on the premises if prescription devices are furnished, sold, or dispensed.
- (e) A home medical device retail facility may establish locked storage (a lock box or locked area) for emergency or after working hours furnishing of prescription devices. Locked storage may be installed or placed in a service vehicle of the home medical device retail facility for emergency or after hours service to patients having prescriptions for prescription devices.

- (f) The department may by regulation authorize a licensed pharmacist or exemptee to direct an employee of the home medical device retail facility who operates the service vehicle equipped with locked storage described in subdivision (e) to deliver a prescription device from the locked storage to patients having prescriptions for prescription devices. These regulations shall establish inventory requirements for the locked storage by a licensed pharmacist or exemptee to take place shortly after a prescription device has been delivered from the locked storage to a patient.

111656.5.

- (a) A person other than a licensed pharmacist, an intern pharmacist, an exemptee, as specified in Section 111656.4, or an authorized agent of the department or a person authorized to prescribe, may not be permitted in that area, place, or premises described in the license issued by the department wherein prescription devices are stored, possessed, prepared, manufactured, or repacked, except that a licensed pharmacist or exemptee shall be responsible for any individual who enters the medical device retail facility for the purposes of receiving, fitting, or consultation from the licensed pharmacist or exemptee or any person performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the home medical device retail facility. The licensed pharmacist or exemptee shall remain present in the home medical device retail facility any time an individual is present who is seeking a fitting or consultation. However, a licensed pharmacist or an exemptee need not be present on the premises of a home medical device retail facility at all times of its operation and need not be present in a warehouse facility owned by a home medical device retail facility unless the department establishes that requirement by regulation based upon the need to protect the public. The exemptee need not be present if the prescription devices are stored in a secure locked area under the exclusive control of the exemptee and unavailable for dispensing. This subdivision shall apply only to prescription devices.
- (b) A “warehouse” as used in this section, is a facility owned by a home medical device retail facility that is used for storage only. There may not be fitting, display, or sales at that location. A licensed pharmacist or exemptee shall be designated as “in charge” of a warehouse but need not be present during its operation. The licensed pharmacist or exemptee may permit others to possess a key to the warehouse.
- (c) Notwithstanding the remainder of this section, a home medical device retail facility may establish a locked facility, meeting the requirements of Section 111656.4, for furnishing prescription devices to patients having prescriptions for prescription devices in emergencies or after working hours.
- (d) The department may establish reasonable security measures consistent with this section as a condition of licensing in order to prevent unauthorized persons from gaining access to the area, place, or premises, or to the prescription devices therein.
- (e) The department may by regulation establish labeling requirements for prescription devices sold, fitted, or dispensed by a home medical device retail facility as it deems necessary for the protection of the public.

111656.6. Home medical devices for rental purposes shall at all times while under the control of the home medical device retail facility, be maintained in a clean and sanitary condition and in good working order following, where available, manufacturer specifications.

111656.7.

- (a) Without registering as an out-of-state home medical device retail facility, an out-of-state home medical device retail facility shall not sell or distribute prescription devices in this state through any person or media other than a wholesaler who is licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code.
- (b) Applications for an out-of-state home medical device retail facility registration shall be made on a form furnished by the department. The department may require any information it deems reasonably necessary to carry out the purposes of this section.
- (c) The Legislature by enacting this section does not intend a registration issued to any out-of-state home medical device retail facility pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state home medical device retail facility.

- (d) The Legislature by enacting this section does not intend a registration issued to any out-of-state home medical device retail facility pursuant to this section to serve as any evidence that the out-of-state home medical device retail facility is doing business within this state.

111656.8.

- (a) No person acting as principal or agent for any out-of-state home medical device retail facility who has not obtained a registration from the department pursuant to this article and who sells or distributes prescription devices in this state that are not obtained through a wholesaler who has obtained a license pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, shall conduct the business of selling or distributing prescription devices within this state without registering with the department pursuant to this article.
- (b) Registration of persons under this section shall be made on a form furnished by the department. The department may require any information as the department deems reasonably necessary to carry out the purposes of this section including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose prescription devices he or she is selling or distributing.
- (c) The department may deny, revoke, or suspend the registration of persons registered under this article for any violation of this article or Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code or for any violation of Part 5 (commencing with Section 109875) of Division 104. The department may deny, revoke, or suspend the person's registration if the manufacturer whose prescription devices he or she is selling or distributing violates this article or Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code or Part 5 (commencing with Section 109875) of Division 104.
- (d) Registration under this section shall be renewed annually.

111656.9. When, in the opinion of the department, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a home medical device retail facility that does not meet all of the requirements for licensure as a home medical device retail facility, the department may waive any licensing requirements for that medical device retail facility.

111656.10.

- (a) The department may void the license of a home medical device retail facility, if the licensed premises remain closed, as defined in subdivision (e), other than by order of the department. For good cause shown, the department may void a license after a shorter period of closure. To void a license pursuant to this subdivision, the department shall make a diligent, good faith effort to give notice by personal service on the licensee. If no written objection is received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the department may void the license without the necessity of a hearing. If the licensee files a written objection, the department shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the department shall have all the powers granted in that chapter.
- (b) In the event that the license of a home medical device retail facility is voided pursuant to subdivision (a) or revoked or a home medical device retail facility notifies the department of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all prescription devices to another licensee authorized to possess the prescription devices. The licensee transferring the prescription devices shall immediately confirm in writing to the department that the transfer has taken place.
- (c) If a home medical device retail facility fails to comply with subdivision (b), the department may seek and obtain an order from the superior court in the county in which the home medical device retail facility is located, authorizing the department to enter the home medical device retail facility and inventory and store, transfer, sell, or arrange for the sale of, prescription devices found in the home medical device retail facility.

- (d) In the event that the department sells or arranges for the sale of any prescription devices pursuant to subdivision (c), the department may retain from the proceeds of the sale an amount equal to the cost to the department of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the prescription devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the prescription devices were removed.
 - (1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.
 - (2) Where a statute or regulation requires the licensee to file with the department his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the department, and service of notice in this manner shall be deemed completed on the 10th day after the mailing.
 - (3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the department for the remaining proceeds within 30 calendar days after the personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the department into the Drug and Device Safety Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.
- (e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.
- (f) Nothing in this section shall be construed as requiring a home medical device retail facility to be open seven days a week.

111656.11.

- (a) It is unlawful for any person who is neither a licensed pharmacist nor an exemptee to take charge of a home medical device retail facility or to furnish prescription devices except as otherwise provided in this article.
- (b) It is unlawful for any person who has obtained a license to conduct a home medical device retail facility to fail to place a licensed pharmacist or exemptee in charge of that home medical device retail facility or for any person to, by himself or herself, or by any other person, permit the compounding or dispensing of prescriptions, except by a licensed pharmacist or exemptee or as otherwise provided in this article.

111656.12.

- (a) The fee for examination and investigation for an exemptee license under Section 111656.4 shall be one hundred dollars (\$100).
- (b) The fee for an exemptee license and annual renewal under Section 111656.4 shall be one hundred fifty dollars (\$150).
- (c) The fee for registration as an out-of-state home medical device retail facility or as the principal or agent of an out-of-state home medical device retail facility shall be one hundred fifty dollars (\$150).

111656.13.

- (a) Any entity that prior to July 1, 2001, held a current, valid license as a medical device retailer pursuant to Section 4130 of the Business and Professions Code, shall be deemed to be a licensed home medical device retail facility until the expiration of that license if the entity is in compliance with all applicable criteria for obtaining a license as a home medical device retail facility.
- (b) Any entity that was not required to obtain a license as a medical device retailer in order to provide equipment or services prior to July 1, 2001, and that is required to obtain a license as a home medical device retail facility pursuant to Section 111656, shall apply for a license as a home medical device retail facility by July 1, 2001; however, the requirement for licensure shall only apply to those entities on and after January 1, 2002.

CHAPTER 7. COSMETICS

Article 1. General Provisions and Definitions

111660. As used in this chapter, “hair dye” does not include any eyelash dye or eyebrow dye.

111665. Any color additive shall be considered unsafe for use with respect to any cosmetic unless there is in effect a regulation adopted pursuant to Section 110090 that prescribes its use in cosmetics.

Article 2. Adulterated Cosmetics

111670. A cosmetic is adulterated if it bears or contains any 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, or under conditions of use as are customary or usual.

111675. Section 111670 shall not apply to coal tar hair dye, that is conspicuously labeled as follows: “Caution—this product contains ingredients that may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.” The labeling shall also bear adequate directions for such preliminary testing.

111680. Any cosmetic is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance.

111685. Any cosmetic is adulterated if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

111690. Any cosmetic is adulterated if its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

111695. Any cosmetic is adulterated if it is not a hair dye and it is, or it bears or contains, a color additive that is unsafe within the meaning of Section 111665.

111700. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any cosmetic that is adulterated.

111705. It is unlawful for any person to adulterate any cosmetic.

111710. It is unlawful for any person to receive in commerce any cosmetic that is adulterated or to deliver or proffer for delivery any such cosmetic.

111715. While any regulation relating to any color additive referred to in Section 111665 is in effect, any cosmetic that bears or contains a color additive in accordance with these regulations shall not be considered adulterated.

111720. Any cosmetic intended for export shall not be deemed to be adulterated under this part if it satisfies all of the following requirements:

- (a) It accords to the specifications of the foreign purchaser.
- (b) It is not in conflict with the laws of the importing country.
- (c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

111725. A cosmetic is deemed adulterated under the laws of this state if it is subject to regulations issued by the United States Food and Drug Administration relating to tamper-resistant packaging, as set forth in Part 700 of Volume 21 of the Code of Federal Regulations, as amended, but is not in compliance therewith.

Article 3. Misbranded Cosmetics

111730. Any cosmetic is misbranded if its labeling is false or misleading in any particular.

111735. Any cosmetic is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

111740. Any cosmetic is misbranded if it is in package form and it does not bear a label containing all of the following information:

- (a) The name and place of business of the manufacturer, packer, or distributor.
- (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations shall be permitted from the requirements of subdivision (b) of this section. Requirements for placement and prominence of the information and exemptions as to small packages shall be established by regulations adopted pursuant to Section 110380.

111745. A cosmetic is misbranded if any word, statement, or other information required pursuant to this part to appear on the label or labeling is not prominently placed upon the label or labeling with conspicuousness, as compared with other words, statements, designs, or devices, in the labeling, and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

111750. Any cosmetic is misbranded if its container is so made, formed, or filled as to be misleading.

111755. A cosmetic is misbranded if it is a color additive, unless its packaging and labeling are in conformity with the packaging and labeling requirements applicable to color additives prescribed under the provisions of Section 110090. This section does not apply to packages of color additives that, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes.

111760. Any cosmetic is misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 108685 or 108700.

111765. It is unlawful for any person to manufacture, or sell any cosmetic that is misbranded.

111770. It is unlawful for any person to misbrand any cosmetic.

111775. It is unlawful for any person to receive in commerce any cosmetic that is misbranded, or to deliver or proffer for delivery any cosmetic.

111780. It is unlawful for any person to alter, mutilate, destroy, obliterate, or remove the label or any part of the labeling of any cosmetic if the act results in the cosmetic being misbranded, while held for sale.

111785. Any cosmetic intended for export shall not be deemed to be misbranded under this part if it satisfies all of the following requirements:

- (a) It accords to the specifications of the foreign purchaser.
- (b) It is not in conflict with the laws of the country to which it is intended for export.
- (c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

111790. A cosmetic is deemed misbranded under the laws of this state if it is subject to regulations issued by the United States Food and Drug Administration relating to tamper-resistant packaging, as set forth in Part 700 of Volume 21 of the Code of Federal Regulations, as amended, but is not in compliance therewith.

Article 3.5. Chronic Health Effects of Cosmetics

111791. This article shall be known, and may be cited, as the California Safe Cosmetics Act of 2005.

111791.5. For purposes of this article, the following terms have the following meanings:

- (a) "Authoritative body" means any agency or formally organized program or group recognized pursuant to Section 12306 of Title 22 of the California Code of Regulations as being authoritative for the purpose of identifying chemicals that cause cancer or reproductive toxicity.
- (b) "Chemical identified as causing cancer or reproductive toxicity" means a chemical identified pursuant to Section 25249.8 or identified by an authoritative body as any of the following:
 - (1) A substance listed as known or reasonably anticipated to be a human carcinogen in a National Toxicology Report on carcinogens.
 - (2) A substance given an overall carcinogenicity evaluation of Group 1, Group 2A, or Group 2B by the International Agency for Research on Cancer.
 - (3) A substance identified as a Group A, Group B1, or Group B2 carcinogen, or as a known or likely carcinogen by the United States Environmental Protection Agency.
 - (4) A substance identified as having some or clear evidence of adverse developmental, male reproductive, or female reproductive toxicity effects in a report by an expert panel of the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction.
- (c) "Division" means the Division of Environmental and Occupational Disease Control within the State Department of Health Services.
- (d) "Ingredient" has the same meaning as that term is defined in subdivision (e) of Section 700.3 of Part 700 of Chapter 1 of Title 21 of the Code of Federal Regulations and does not include any incidental ingredient as defined in subdivision (l) of Section 701.3 of Part 701 of Chapter 1 of Title 21 of the Code of Federal Regulations.
- (e) "Manufacturer" means any person whose name appears on the label of a cosmetic product pursuant to the requirements of Section 701.12 of Title 21 of the Code of Federal Regulations.

111792.

- (a) Commencing January 1, 2007, the manufacturer of any cosmetic product subject to regulation by the federal Food and Drug Administration that is sold in this state shall, on a schedule and in electronic or other format, as determined by the division, provide the division with a complete and accurate list of its cosmetic products that, as of the date of submission, are sold in the state and that contain any ingredient that is a chemical identified as causing cancer or reproductive toxicity, including any chemical that meets either of the following conditions:
 - (1) A chemical contained in the product for purposes of fragrance or flavoring.
 - (2) A chemical identified by the phrase "and other ingredients" and determined to be a trade secret pursuant to the procedure established in Part 20 and Section 720.8 of Part 720 of Title 21 of the Code of Federal Regulations. Any ingredient identified pursuant to this paragraph shall be considered to be a trade secret and shall be treated by the division in a manner consistent with the requirements of Part 20 and Part 720 of Title 21 of the Code of Federal Regulations. Any ingredients considered to be a trade secret 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) for the purposes of this section.
- (b) Any information submitted pursuant to subdivision (a) shall identify each chemical both by name and Chemical Abstract Service number and shall specify the product or products in which the chemical is contained.
- (c) If an ingredient identified pursuant to this section subsequently is removed from the product in which it was contained, is removed from the list of chemicals known to cause cancer or reproductive toxicity published under Section 25249.8, or is no longer a chemical identified as causing cancer or reproductive toxicity by an authoritative body, the manufacturer of the product containing the ingredient shall submit the new information to the division. Upon receipt of new information, the division, after verifying the accuracy of that information, shall revise the manufacturer's information on record with the division to reflect the new information. The manufacturer shall not be under

obligation to submit subsequent information on the presence of the ingredient in the product unless subsequent changes require submittal of the information.

- (d) This section shall not apply to any manufacturer of cosmetic products with annual aggregate sales of cosmetic products, both within and outside of California, of less than one million dollars (\$1,000,000), based on the manufacturer's most recent tax year filing.

111792.5.

- (a) In order to determine potential health effects of exposure to ingredients in cosmetics sold in the state, the division may conduct an investigation of one or more cosmetic products that contain chemicals identified as causing cancer or reproductive toxicity or other ingredients of concern to the division.
- (b) An investigation conducted pursuant to subdivision (a) may include, but not be limited to, a review of available health effects data and studies, worksite health hazard evaluations, epidemiological studies to determine the health effects of exposures to chemicals in various subpopulations, and exposure assessments to determine total exposures to individuals in various settings.
- (c) If an investigation is conducted pursuant to subdivision (a), the manufacturer of any product subject to the investigation may submit relevant health effects data and studies to the division.
- (d) In order to further the purposes of an investigation, the division may require manufacturers of products subject to the investigation to submit to the division relevant health effects data and studies available to the manufacturer and other available information as requested by the division, including, but not limited to, the concentration of the chemical in the product, the amount by volume or weight of the product that comprises the average daily application or use, and sales and use data necessary to determine where the product is used in the occupational setting.
- (e) The division shall establish reasonable deadlines for the submittal of information required pursuant to subdivision (d). Failure by a manufacturer to submit the information in compliance with the requirements of the division shall constitute a violation of this part.

111793.

- (a) If the division determines pursuant to an investigation that an ingredient in a cosmetic product is potentially toxic at the concentrations present in the product or under the conditions used, the division shall immediately refer the results of its investigation to the Division of Occupational Safety and Health in the Department of Industrial Relations and the Office of Environmental Health Hazard Assessment.
- (b) Within 180 days after it receives the results of an investigation pursuant to subdivision (b), the Division of Occupational Safety and Health shall, pursuant to Section 147.1 of the Labor Code, develop and present one or more proposed occupational health standards to the Occupational Safety and Health Standards Board in the Department of Industrial Relations, unless the Division of Occupational Safety and Health affirmatively determines, in a written finding within 90 days, that a standard is not necessary to protect the health of an employee who has regular exposure to the hazard for the period of his or her working life. The written finding shall identify the reasons for determining the standard is not necessary and the factual basis for the finding.

111793.5.

- (a) The Legislature finds and declares the following:
 - (1) The Cosmetic Ingredient Review (CIR) panel is a nongovernmental body established and funded by the cosmetics industry to review the safety of cosmetic ingredients.
 - (2) According to a 2004 analysis of the 2003 CIR Compendium by the Environmental Working Group, 54 cosmetic products violate the CIR's own safe use recommendations to manufacturers by containing an ingredient that the CIR has found is not safe for the specific use indicated on the product's label.
 - (3) Federal regulations (21 C.F.R. 740.10) require every ingredient in a cosmetic product and every finished cosmetic product to be adequately substantiated for safety prior to marketing, and state that any ingredient or product whose safety has not been adequately substantiated prior to marketing is misbranded unless it displays a warning statement declaring, "The safety of this product has not been determined."

- (b) The division may, as early as feasible within existing resources, determine whether the products identified in paragraph (2) of subdivision (a) have been adequately substantiated for safety pursuant to Section 740.10 of Title 21 of the Code of Federal Regulations. For any product adequately substantiated for safety, the division shall determine if the product contains any ingredient that the CIR has found is not safe for the specific use indicated on the product's label.
- (c) If the division finds that a product has been adequately substantiated for safety despite containing an ingredient that the CIR has found is not safe for the specific use indicated on the product's label, the division shall refer its findings to the Attorney General and the federal Food and Drug Administration for possible enforcement action pursuant to this part and the federal Food, Drug and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

Article 4. Voluntary Registration

111795.

- (a) Any person who manufactures a cosmetic in this state may register with the department. Any registration issued under this article shall be valid for one calendar year from the date of issue, unless it is suspended or revoked. The registration shall not be transferable.
- (b) A separate registration shall be required for each place of manufacture.

111800. A registration application form provided by the department shall be completed annually and accompanied by an application fee of three hundred fifty dollars (\$350). This fee shall not be returnable if the registration is denied. The fee amount shall be adjusted annually pursuant to Section 100425. All fees collected pursuant to this section shall be deposited into the Export Document Program Fund established by Section 110240.

111805. Any person registered pursuant to this article shall immediately notify the department of any change in the information reported in the registration application.

111810.

- (a) Prior to issuing a registration under Section 111795, the department shall inspect each place of business to determine ownership, adequacy of facilities, personnel qualifications, and compliance with this part. The department shall annually inspect each registrant.
- (b) The department shall provide to each registrant a validated copy of the completed registration application form, sent to the mailing address shown on the form, as evidence of valid registration.

111815. The department shall make any investigations or inspections authorized by Article 2 (commencing with Section 110410) of Chapter 2 as it deems necessary to carry out this article.

111820. Any violation of this part or any regulation adopted pursuant to this part shall be grounds for denying a registration or for suspending or revoking a registration. Proceedings for the denial, suspension, or revocation of the registration shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the department shall have all the powers granted in that chapter.

CHAPTER 8. PENALTIES AND REMEDIES

Article 1. Penalties

111825.

- (a) Any person who violates any provision of this part or any regulation adopted pursuant to this part shall, if convicted, be subject to imprisonment for not more than one year in the county jail or a fine of not more than one thousand dollars (\$1,000), or both the imprisonment and fine.
- (b) Notwithstanding subdivision (a), any person who violates Section 111865 by removing, selling, or disposing of an embargoed food, drug, device, or cosmetic without the permission of an authorized agent of the department or court shall, if convicted, be subject to imprisonment for not more than

one year in the county jail or a fine of not more than ten thousand dollars (\$10,000), or both the fine and imprisonment.

- (c) (1) Notwithstanding subdivision (a), any person who purchases or sells a foreign dangerous drug or medical device, an illegitimate product, as defined in Section 360eee(8) of Title 21 of the United States Code, that is not approved or otherwise authorized by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is guilty of a misdemeanor and subject to imprisonment for not more than one year in a county jail, a fine of not more than ten thousand dollars (\$10,000) per occurrence, or both the imprisonment and fine.
(2) This subdivision does not apply to those individuals determined by the United States Food and Drug Administration to have acted in compliance with the requirements under Part H (commencing with Section 360eee) of Subchapter V of Chapter 9 of Title 21 of the United States Code with regard to the illegitimate or suspect products.
- (d) If the violation is committed after a previous conviction under this section that has become final, or if the violation is committed with intent to defraud or mislead, or if the person committed a violation of Section 110625 or 111300 that was intentional or that was intended to cause injury, the person shall be subject to imprisonment for not more than one year in the county jail, imprisonment in the state prison, or a fine of not more than ten thousand dollars (\$10,000), or both the imprisonment and fine.
- (e) This section does not preclude punishment under any other law that provides for a greater punishment.

111830. Upon conviction of any violation of this part, or any regulation adopted pursuant to this part, the court may require, as a condition of probation under Section 1203.1 of the Penal Code, that the defendant pay to the department the reasonable costs incurred by the department in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing. This payment shall be in addition to any other costs that a court is authorized to require a defendant to pay under Section 1203.1 of the Penal Code.

111835. One-half of all fines collected by any court or judge for any violation of any provision of this part shall be paid into the State Treasury to the credit of the General Fund.

Article 2. Proceedings

111840. The Attorney General, any district attorney, or any city attorney to whom the department reports any violation of this part shall begin appropriate proceedings in the proper court.

111845. The department is not required to institute proceedings under this part for minor violations of this part, if the department believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

111850. When the state asserts a violation of this part, the state need not negative any exemption or exception from the requirements of this part in any pleading or in any trial, hearing, or other proceeding. The burden of proof with respect to any exemption or exception rests upon the person claiming its benefit.

111855.

- (a) If any person violates any provision of this part, or any regulation adopted pursuant to this part, the department may assess a civil penalty against that person as provided by this section.
- (b) The penalty may be in an amount not to exceed one thousand dollars (\$1,000) per day unless the penalty is for a violation of Section 111825, in which case the penalty may be in an amount not to exceed ten thousand dollars (\$10,000) per day. Each day a violation continues shall be considered a separate violation.
- (c) If, after examination of a possible violation and the facts surrounding that possible violation, the department concludes that a violation has occurred, the department may issue a complaint to the person charged with the violation. The complaint shall allege the acts or failures to act that constitute

the basis for the violation and the amount of the penalty. The complaint shall be served by personal service or by certified mail and shall inform the person so served of the right to a hearing.

- (d) Any person served with a complaint pursuant to subdivision (c) of this section may, within 20 days after service of the complaint, request a hearing by filing with the department a notice of defense. A notice of defense is deemed to have been filed within the 20-day period if it is postmarked within the 20-day period. If a hearing is requested by the person, it shall be conducted within 90 days after the receipt by the department of the notice of defense. If no notice of defense is filed within 20 days after service of the complaint, the department shall issue an order setting the penalty as proposed in the complaint unless the department and the person have entered into a settlement agreement, in which case the department shall issue an order setting the penalty in the amount specified in the settlement agreement. When the person has not filed a notice of defense or where the department and the person have entered into a settlement agreement, the order shall not be subject to review by any court or agency.
- (e) Any hearing required under this section shall be conducted pursuant to the procedures specified in Section 100171, except to the extent they are inconsistent with the specific requirements of this section.
- (f) Orders setting civil penalties under this section shall become effective and final upon issuance thereof, and payment shall be made within 30 days of issuance. A copy of the order shall be served by personal service or by certified mail upon the person served with the complaint.
- (g) Within 30 days after service of a copy of a decision issued by the director after a hearing, any person so served may file with the superior court a petition for writ of mandate for review of the decision. Any person who fails to file the petition within this 30-day period may not challenge the reasonableness or validity of the decision or order of the director in any judicial proceeding brought to enforce the decision or order or for other remedies. Section 1094.5 of the Code of Civil Procedure shall govern any proceedings conducted pursuant to this subdivision. In all proceedings pursuant to this subdivision, the court shall uphold the decision of the director if the decision is based upon substantial evidence in the whole record. The filing of a petition for writ of mandate shall not stay any corrective action required pursuant to this part or the accrual of any penalties assessed pursuant to this section. This subdivision does not prohibit the court from granting any appropriate relief within its jurisdiction.
- (h) The remedies under this section are in addition to, and do not supersede, or limit, any and all other remedies, civil or criminal.

Article 3. Seizure and Embargo

111860. Whenever an authorized agent of the department finds, or has probable cause to believe, that any food, drug, device, or cosmetic is adulterated, misbranded, or falsely advertised within the meaning of this part, or the sale of any food, drug, device, or cosmetic would be in violation of this part, that agent shall affix to the food, drug, device, cosmetic, or component thereof, a tag or other appropriate marking. He or she shall give notice that the food, drug, device, or cosmetic is, or is suspected of being, adulterated, misbranded, falsely advertised, or the sale of which would be in violation of this part and has been embargoed, and that no person shall remove or dispose of the food, drug, device, or cosmetic by sale or otherwise until permission for removal or disposal is given by an authorized agent of the department or the court.

111865. It is unlawful for any person to remove, sell, or dispose of a detained or embargoed food, drug, device, or cosmetic without permission of an authorized agent of the department or the court.

111870. When an authorized agent of the department has found that a food, drug, device, or cosmetic that is embargoed, is not adulterated, misbranded, falsely advertised, or the sale of which is not otherwise in violation of this part, that agent shall remove the tag or other marking.

111875. When an authorized agent of the department finds, or has reasonable cause to believe, that the embargo will be violated, that agent may remove the embargoed food, drug, device, or cosmetic to a place of safekeeping.

111880. If a food, drug, device, or cosmetic is alleged to be adulterated, misbranded, falsely advertised, or the sale of which is otherwise in violation of this part, the department shall commence proceedings in the superior court in whose jurisdiction the food, drug, device, or cosmetic is located, for condemnation of the article.

111885. If the court finds that an embargoed food, drug, device, or cosmetic is adulterated, misbranded, falsely advertised, or the sale of which is otherwise in violation of this part, the food, drug, device, or cosmetic shall, after entry of the judgment, be destroyed at the expense of the claimant or owner, under the supervision of an authorized agent of the department. All court costs and fees and all reasonable costs incurred by the department in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing, shall be taxed against the claimant or owner of the food, drug, device, or cosmetic or his or her agent. When the adulteration or misbranding can be corrected by proper labeling or processing of the food, drug, device, or cosmetic, or when the false advertisement can be corrected and when all provisions of this part can be complied with, then, after entry of the judgment and after costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that the food, drug, device, or cosmetic will be brought into compliance, the court may, by order, direct that the food, drug, device, or cosmetic be delivered to the claimant or owner to be brought into compliance by labeling, processing, or other means under the supervision of an authorized agent of the department. The expense of the supervision shall be paid by the claimant or owner. The bond shall be discharged when the court finds that the food, drug, device, or cosmetic is no longer held for sale in violation of this part and that all of the expenses of supervision have been paid.

111890. Whenever an authorized agent of the department finds any meat, meat products, seafood, poultry, vegetable, fruit, or other food that is unsound, or that contains any filthy, decomposed, or putrid substance, or that may be poisonous or deleterious to health, or otherwise unsafe, that agent may declare the food to be a nuisance and the department, or its authorized agent, shall condemn or destroy it, or render it unsalable as human food by decharacterization.

111895. Any superior court of this state may condemn any food, drug, device, or cosmetic under provisions of this part. In the absence of an order, the food, drug, device, or cosmetic may be destroyed under the supervision of an authorized agent of the department who has the written consent of the owner, his or her attorney, or authorized representative.

Article 4. Injunctions

111900. The Attorney General or any district attorney, on behalf of the department, may bring an action in superior court and the court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of this part. Any proceeding under the provisions of this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the department shall not be required to allege facts necessary to show, or tending to show, lack of adequate remedy at law, or to show, or tending to show, irreparable damage or loss.

111905. In addition to the injunctive relief provided in Section 111900, or as a nonpunitive alternative to Section 111915, the court, after finding any person has violated this part, shall award to the department all reasonable costs incurred by the department in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing, as determined by the court. The award shall be paid to the department by the person found by the court to have violated this part.

111910.

(a) Notwithstanding the provisions of Section 111900 or any other provision of law, any person may bring an action in superior court pursuant to this section and the court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of Article 7 (commencing with Section 110810) of Chapter 5. Any proceeding under this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the person shall not be required to allege

facts necessary to show, or tending to show, lack of adequate remedy at law, or to show, or tending to show, irreparable damage or loss, or to show, or tending to show, unique or special individual injury or damages.

- (b) In addition to the injunctive relief provided in subdivision (a), the court may award to that person, organization, or entity reasonable attorney's fees as determined by the court.
- (c) This section shall not be construed to limit or alter the powers of the department and its authorized agents to bring an action to enforce this chapter pursuant to Section 111900 or any other provision of law.

111912. Notwithstanding any provision of this part, or any other provision of law, the department shall have no affirmative obligation to administer, regulate, or enforce state law relating to organic foods except Section 110850, relating to the registration of persons who certify processors of organic foods, and Section 110875, relating to the registration of processors of organic foods.

111915. In addition to injunctive relief, the court may impose as a civil penalty, damages in the maximum sum of one thousand dollars (\$1,000) for each day the violation is continued. Damages shall be paid one-half to this state and one-half to the county in which the action is brought if brought by the Attorney General, or entirely to the county if brought by a district attorney.

**Hazardous Substances Act
HEALTH AND SAFETY CODE
SECTION 108100-108225**

108100. This chapter shall be known as the California Hazardous Substances Act.

108105. Unless the provisions or the context otherwise requires, these definitions, rules of construction, and general provisions shall govern the construction of this chapter.

108110. The term "art or craft material" means any raw or processed material or manufactured product marketed or being represented by the manufacturer, repackager or retailer as being suitable for use in any phase of the creation of any work of visual or graphic art of any medium. These mediums may include, but shall not be limited to, paintings, drawings, prints, sculpture, ceramics, enamels, jewelry, stained glass, plastic sculpture, photographs, and leather and textile goods. The term shall not include economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act (61 Stats. 163) or Chapter 2 (commencing with Section 12751) of Division 7 of the Food and Agricultural Code; or to drugs, devices, or cosmetics, that are subject to the Federal Food, Drug and Cosmetics Act (52 Stats. 1040) or Part 5 (commencing with Section 109875).

108115. "Department" means the State Department of Health Services.

108120. As used in this chapter, "federal act" means the Federal Hazardous Substances Act (74 Stats. 372; 15 U.S.C., Sec. 1261, et seq.).

108125. The term "hazardous substance" means:

- (a) Any substance or mixture of substances that (1) is toxic, (2) is corrosive, (3) is an irritant, (4) is a strong sensitizer, (5) is flammable or combustible, or (6) generates pressure through decomposition, heat, or other means; if the substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.
- (b) Any substances that the department by regulation finds pursuant to the provisions of Section 108320 meet the requirements of subdivision (a) of this section.
- (c) Any radioactive substance, if, with respect to the substance as used in a particular class of article or as packaged, the department determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with this chapter in order to protect the public health.
- (d) Any toy or other article intended for use by children that the department determines, by regulation, pursuant to the provisions of Section 108320, presents an electrical, mechanical, or thermal hazard.

108130. The term "hazardous substance" shall not apply to any of the following:

- (a) Foods, drugs, or cosmetics subject to the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040) or Part 5 (commencing with Section 109875).
- (b) Substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house.
- (c) Source material, special nuclear material, or byproduct material, as defined in the Atomic Energy Act of 1954 (68 Stat. 919), as amended, and regulations issued pursuant thereto by the Atomic Energy Commission.
- (d) Fertilizing materials regulated by Chapter 5 (commencing with Section 14501) of Division 7 of the Food and Agricultural Code.
- (e) Livestock remedies regulated by Chapter 4 (commencing with Section 14200) of Division 7 of the Food and Agricultural Code.
- (f) Economic poisons regulated by Chapter 2 (commencing with Section 12751) of Division 7 of the Food and Agricultural Code, except as provided in Section 108135.
- (g) Economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act (61 Stat. 163), except as provided in Section 108135.
- (h) Injurious substances as defined and regulated by Article 112 (commencing with Section 5225) of Group 16 of Subchapter 7 of Chapter 4 of Title 8 of the California Code of Regulations.

108135. The term “hazardous substance” shall apply to any article that is not itself an economic poison within the meaning of the Federal Insecticide, Fungicide and Rodenticide Act or Chapter 2 (commencing with Section 12751) of Division 7, of the Food and Agricultural Code, but that is a hazardous substance within the meaning of Section 108125 by reason of bearing or containing an economic poison.

108140. The term “human carcinogen” means any substance listed as a human carcinogen by the International Agency for Research on Cancer.

The term “potential human carcinogen” means one of the following:

- (1) Any substance that does not meet the definition of human carcinogen, but for which there exists sufficient evidence of carcinogenicity in animals, as determined by the International Agency for Research on Cancer.
- (2) Any chemical shown to be changed by the human body into a human carcinogen.

108145. The term “toxic” shall apply to any substance, other than a radioactive substance, that has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.

108150. The term “toxic substance causing chronic illness” means any of the following:

- (1) Human carcinogens.
- (2) Potential human carcinogens.
- (3) Any substance included in the list of hazardous substances prepared by the Director of Industrial Relations, pursuant to Section 6382 of the Labor Code, notwithstanding exemptions made for substances on the list that are used in particular forms, circumstances, or concentrations, if the health hazard presented by the substance is not the subject of label statements required by federal law.

108155. “Highly toxic” means any substance that falls within any of the following categories:

- (a) Produces death within 14 days in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, at a single dose of 50 milligrams or less per kilogram of body weight, when orally administered.
- (b) Produces death within 14 days in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, when inhaled continuously for a period of one hour or less at an atmospheric concentration of 200 parts per million by volume or less of gas or vapor or two milligrams per liter by volume or less of mist or dust, provided the concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner.
- (c) Produces death within 14 days in half or more than half of a group of 10 or more rabbits tested in a dosage of 200 milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for 24 hours or less.

108160. If the department finds that available data on human experience with any substance indicate results different from those obtained on animals with the dosages or concentrations stated in Section 108155, the human data shall take precedence.

108165. “Corrosive” means any substance which in contact with living tissue will cause destruction of tissue by chemical action; but shall not refer to action on inanimate surfaces.

108170. “Irritant” means any substance not corrosive within the meaning of Section 108165 that on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction.

108175. “Strong sensitizer” means a substance that will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity that becomes evident on reapplication of the same substance and that is designated by the department. Before designating any substance as a strong sensitizer, the department, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity.

108180. The term “extremely flammable” shall apply to any substance that has a flashpoint at or below 20 degrees Fahrenheit, as determined by the Tagliabue open-cup tester, the term “flammable” or “combustible” shall apply to any substance that has a flashpoint of above 20 degrees to and including 80 degrees Fahrenheit, as determined by the Tagliabue open-cup tester, and the term “combustible” shall apply to any substance that has a flashpoint above 80 degrees Fahrenheit to and including 150 degrees, as determined by the Tagliabue open-cup tester; except that the flammability or combustibility of solids and of the contents of self-pressurized containers shall be determined by methods found by the department to be generally applicable to the materials or containers, respectively, and established by regulations issued by it, which regulations shall also define the terms “flammable” and “combustible” and “extremely flammable” in accord with those methods.

108185. “Radioactive substance” means a substance that emits ionizing radiation.

108190. “Label” means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the case of an article that is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of the matter directly upon the article involved, or upon a tag or other suitable material affixed thereto, and a requirement made by, or pursuant to, this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless the word, statement, or other information also appears (a) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (b) on all accompanying literature where there are directions for use, written or otherwise.

108195. The term “immediate container” does not include package liners.

108200. The term “misbranded hazardous substance” means a hazardous substance (including a toy or other article intended for use by children, that is a hazardous substance, or that bears or contains a hazardous substance in the manner as to be susceptible of access by a child to whom the toy or other article is entrusted) intended, or packaged in a form suitable for use in the household or by children if the packaging or labeling of the substance is in violation of an applicable regulation issued pursuant to Section 108685 or 108700, or if the substance, except as otherwise provided by, or pursuant to, Section 108320, 108355, or 108360, fails to bear a label that states conspicuously, as prescribed in Chapter 8 (commencing with Section 108800):

- (1) the name and place of business of the manufacturer, packer, distributor, or seller;
- (2) the common or usual name or the chemical name, if there be no common or usual name, of the hazardous substance or of each component that contributes substantially to its hazard, unless the department by regulation permits or requires the use of a recognized generic name;
- (3) the signal word “DANGER” on substances that are extremely flammable, corrosive, or highly toxic;
- (4) the signal word “WARNING” or “CAUTION” on all other hazardous substances;
- (5) an affirmative statement of the principal hazard or hazards, such as “Flammable,” “Combustible,” “Vapor harmful,” “Causes burns,” “Absorbed through skin,” or similar wording descriptive of the hazard;
- (6) precautionary measures describing the action to be followed or avoided, except when modified by the department pursuant to Section 108320, 108325, 108330, 108355, or 108360;
- (7) instructions, when necessary or appropriate, for first aid treatment;
- (8) the word “Poison” for any hazardous substance that is defined as “highly toxic” by Section 108155; (9) instructions for handling and storage of packages that require special care in handling or storage; and
- (10) the statement “Keep out of the reach of children,” or its practical equivalent, or if the article is intended for use by children and is not a banned hazardous substance, adequate direction for the protection of children from the hazard. The term “misbranded hazardous substance” also includes a household substance as defined in subdivision (b) of Section 108680 if it is a substance described in Section 108125 and its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 108685 or 108700.

108205. The term “banned hazardous substance” means either:

- (a) Any toy, or other article intended for use by children, that is a hazardous substance, or that bears or contains a hazardous substance in the manner as to be susceptible of access by a child to whom the toy or other article is entrusted.
- (b) Any hazardous substance intended or packaged in a form suitable, for use in the household, that the department by regulation classifies as a “banned hazardous substance” on the basis of a finding that, notwithstanding the cautionary labeling as is or may be required under this chapter for that substance, the degree or nature of the hazard involved in the presence or use of that substance in households is that the objective of the protection of the public health and safety can be adequately served only by keeping that substance, when so intended or packaged, out of the channels of intrastate commerce.

108210.

- (a) An article may be determined to present an electrical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture may cause personal injury or illness by electric shock.
- (b) An article may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness from any of the following:
 - (1) Fracture, fragmentation, or disassembly of the article.
 - (2) Propulsion of the article or any part or accessory thereof.
 - (3) Points or other protrusions, surfaces, edges, openings, or closures.
 - (4) Moving parts.
 - (5) Lack or insufficiency of controls to reduce or stop motion.
 - (6) As a result of self-adhering characteristics of the article.
 - (7) Because the article, or any part or accessory thereof, may be aspirated or ingested.
 - (8) Because of instability.
 - (9) Because of any other aspect of the article’s design or manufacture.
- (c) An article may be determined to present a thermal hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness because of heat as from heated parts, substances, or surfaces.

108215. The department, by regulation, shall exempt from subdivision (a) of Section 108205

- (1) articles such as chemical sets, that by reason of their functional purpose require the inclusion of the hazardous substance involved or necessarily present an electrical, mechanical, or thermal hazard and that bear labeling giving adequate directions and warnings for safe use and are intended for use by children who have attained sufficient maturity, and may reasonably be expected to read and heed the directions and warnings and
- (2) fireworks subject to control under Part 2 (commencing with Section 12500) of Division 11.

108220. Proceedings for the issuance, amendment, or repeal of regulations pursuant to subdivision (b) of Section 108205 and Section 108215 shall be in the manner prescribed in Section 108335. If the department, however, finds that the distribution for household use of the hazardous substance involved presents an imminent hazard to the public health, it may by order publish a notice of the findings, and thereupon the substance when intended or offered for household use or when so packaged as to be suitable for that use shall be deemed to be a “banned hazardous substance” pending the completion of proceedings relating to the issuance of the regulations.

108225. Notwithstanding any other provision of this chapter, no substance or article shall be deemed to violate any provision of this chapter except Article 6 (commencing with Section 108500), if the substance or article complies with federal law.

108230. A determination by the department that a toy or other article intended for use by children presents an electrical, mechanical, or thermal hazard shall be made by regulation.

108235. If, before or during the making of a determination pursuant to Section 108230, the department finds that, because of an electrical, mechanical, or thermal hazard, distribution of the toy or other article involved presents an imminent hazard to the public health and the department by regulation gives notice of

the finding, the toy or other article shall be deemed to be a banned hazardous substance for purposes of this chapter until the proceeding has been completed. If not yet initiated when the regulation is adopted, a proceeding shall be initiated as promptly as possible.

108240. The manufacture, production, preparation, compounding, packing, selling, offering for sale, or keeping for sale within the State of California, or the introduction into this state from any other state, territory, or the District of Columbia, or from any foreign country, of any package of a misbranded hazardous substance or banned hazardous substance is prohibited.

108245. Any person who imports or receives from any other state or territory or the District of Columbia or from any foreign country, or who having so received delivers for pay or otherwise or offers to deliver to any other person, any misbranded hazardous substance or banned hazardous substance or any person who shall manufacture or produce, prepare or compound, or pack or sell, or offer for sale, or keep for sale in the State of California any misbranded hazardous substance or banned hazardous substance, shall be guilty of a misdemeanor punishable as provided in Section 108295.

108250. The packing, selling, offering for sale, or keeping for sale of a hazardous substance in a reused food, drug, or cosmetic container or in a container that, though not a reused container, is identifiable as a food, drug, or cosmetic container by its labeling or by other identification, is unlawful. Such an act shall result in the hazardous substance being in a misbranded package. As used in this section, the terms "cosmetic," "drug" and "food" shall have the same meaning as in Chapter 1 (commencing with Section 109875) of Part 5.

108255. The department may by regulation prohibit the use of any other container for hazardous substances if it determines that the container may be mistaken for a food, drug, or cosmetic container and has a closure that presents a health hazard due to ease of opening.

108260. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a hazardous substance is unlawful if the act results in the article being a misbranded hazardous substance or banned hazardous substance.

108265. It shall be unlawful to refuse to permit entry or inspection authorized by Section 108370 or to permit access to and copying of any record as authorized by Section 108300.

108270. No person shall be prosecuted under this chapter if, after receipt of a hazardous substance, he or she can establish a guarantee or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he or she received in good faith the hazardous substance, to the effect that the hazardous substance is not a misbranded hazardous substance or a banned hazardous substance within the meaning of these terms, as defined by this chapter.

108275. If the guarantee is to the effect that the article is not misbranded or banned within the meaning of the Federal Hazardous Substances Act (Public Law 86-813, 74 Stat. 372), it shall be sufficient for all the purposes of this chapter and have the same force and effect as though it referred to this chapter whether given by a person residing in the United States or elsewhere.

108280. The giving of a guarantee referred to in Section 108270 that is false, is prohibited, except by a person who relied upon a guarantee to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he or she received in good faith the hazardous substance.

108285. No person shall be prosecuted under this chapter if the hazardous substance is shipped or delivered for shipment for export to any foreign country, in a package marked for export on the outside of the shipping container and labeled in accordance with the specifications of the foreign purchaser and in accordance with the laws of the foreign country, but if the hazardous substance is sold or offered for sale in domestic commerce, this section shall not apply.

108290. The use by any person to his or her own advantage, or revealing other than to the department or any agent of the department or to the courts when relevant in any judicial proceeding under this chapter, of any information acquired under authority of this chapter concerning any method of process that as a trade secret is entitled to protection is prohibited.

108295. Any person who violates any of the provisions of this chapter is guilty of a misdemeanor, and upon conviction shall be punished by a fine of not less than fifty dollars (\$50) or more than one thousand dollars (\$1,000), or by imprisonment in the county jail for a term not exceeding six months, or by both fine and imprisonment.

If the violation is committed with intent to defraud or mislead, or after a conviction of the person under this section has become final, the person shall be subject to imprisonment for not more than one year in the county jail, or a fine of not more than two thousand dollars (\$2,000), or both the imprisonment and fine.

108300. For the purpose of enforcing this chapter, carriers engaged in commerce, and persons receiving or holding hazardous substances shall upon the request of an agent of the department, permit the agent, at reasonable times, to have access to and to copy all records showing the movement of any hazardous substance, or the holding thereof during or after the movement, and the quantity, shipper, and consignee thereof, provided, that evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained, provided, further, that carriers shall not be subject to this chapter by reason of their receipt, carriage, holding, or delivery of hazardous substances in the usual course of business as carriers. As used in this section, "carrier" means a person engaged in transporting property from one place to another and who has no other interest in the ownership of the property.

108305. Before any violation of this chapter is reported to the district attorney of the county, or the prosecuting officer of the city, for institution of a criminal proceeding the person against whom the proceeding is contemplated may be given appropriate notice and an opportunity to present his or her view, either orally or in writing, with regard to each contemplated proceeding. 108310. For the purposes of this article, the following terms have the following meanings:

- (a) "Manufacturer" includes an importer for resale.
- (b) A dealer who sells at wholesale an article or substance shall, with respect to that sale, be considered the distributor of that article or substance.

108315. In the case of any article or substance sold on or after the effective date of this section by its manufacturer, distributor, or dealer that is a banned hazardous substance, whether or not it was at the time of its sale, the article or substance shall, in accordance with regulations of the department, be repurchased as follows:

- (a) The manufacturer of any such article or substance shall repurchase it from the person to whom he or she sold it, and shall do the following:
 - (1) Refund that person the purchase price paid for the article or substance.
 - (2) If that person has repurchased the article or substance pursuant to subdivision (b) or (c) reimburse him or her for any amounts paid in accordance with subdivision (b) or (c) for the return of the article or substance in connection with its repurchase.
 - (3) If the manufacturer requires the return of the article or substance in connection with his or her repurchase of it in accordance with this subdivision, reimburse that person for any reasonable and necessary expenses incurred in returning it to the manufacturer.
- (b) The distributor of any article or substance shall repurchase it from the person to whom he or she sold it, and shall do the following:
 - (1) Refund that person the purchase price paid for the article or substance.
 - (2) If that person has repurchased the article or substance pursuant to subdivision (c), reimburse him or her for any amounts paid in accordance with that subdivision for the return of the article or substance in connection with its repurchase.
 - (3) If the distributor requires the return of the article or substance in connection with his or her repurchase of it in accordance with this subdivision, reimburse that person for any reasonable and necessary expenses incurred in returning it to the distributor.
- (c) In the case of any article or substance sold at retail by a dealer, if the person who purchased it from the dealer returns it to him or her, the dealer shall refund the purchaser the purchase price paid for it

and reimburse him or her for any reasonable and necessary transportation charges incurred in its return. 108320. The department may adopt regulations regarding hazardous substances as it determines are necessary to adequately enforce and administer this chapter. Any violation of the regulations shall be deemed to be a violation of this chapter.

108325. Whenever in the judgment of the department the action will promote the objectives of this chapter by avoiding or resolving uncertainty as to its application, the department may by regulation declare to be a hazardous substance, for the purpose of this chapter, any substance or mixture of substances that it finds meet the requirements of Section 108125.

108330. If the department finds that the requirements of Section 108200 are not adequate for the protection of the public health and safety in view of the special hazard presented by any particular hazardous substance, it may by regulation establish reasonable variations or additional label requirements as it finds necessary for the protection of the public health and safety; and any hazardous substance intended, or packaged in a form suitable, for use in the household or by children, that fails to bear a label in accordance with regulations shall be deemed to be a misbranded hazardous substance.

108335. 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 regulations shall conform as nearly as practicable with regulations promulgated by the United States Department of Health, Education, and Welfare, Food and Drug Administration.

108340. To the extent that the requirements of this chapter are identical with the federal act, all regulations and any amendments to regulations adopted pursuant to the federal act that are in effect on the effective date of this section or that are adopted on or after the date are the hazardous substances regulations of this state.

108345. A federal regulation adopted pursuant to this chapter 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 a federal regulation in this state may, within the 30 days prior to its becoming effective in this state, file with the state 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.

108350. 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 state department, after notice, shall conduct a public hearing to receive evidence on issues raised by the objections. Any interested person or his or her representatives shall be heard. The state 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 state department may adopt, rescind, or modify it. If the order concerns a proposed regulation, the state 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.

108355. If the department finds that, because of the size of the package involved or because of the minor hazard presented by the substance contained therein, or for other good and sufficient reasons, full compliance with the labeling requirements otherwise applicable under this chapter is impracticable or is not necessary for the adequate protection of the public health and safety, the department may exempt the substance from these requirements to the extent it determines to be consistent with adequate protection of the public health and safety. 108360. The department may exempt from the requirements established by, or pursuant to, this chapter any container of a hazardous substance with respect to which it finds that adequate requirements satisfying the purposes of this chapter have been established by, or pursuant to, any other law enacted by the Legislature.

108365. The department may appoint agents as it may deem necessary. 108370. The department or its duly authorized agent shall have free access to all reasonable hours to any factory, warehouse, or

establishment in which hazardous substances are manufactured, processed, packed, or held for introduction into commerce, or to enter any vehicle being used to transport or hold hazardous substances, in commerce, for either of the following purposes:

- (a) Inspecting the factory, warehouse, establishment, or vehicle to determine if any of the provisions of this chapter are being violated.
- (b) To secure samples or specimens of any hazardous substances. If the agent obtains any sample, prior to leaving the premises, he or she shall give to the owner, operator, or agent in charge a receipt describing the samples obtained. If an analysis is made of the sample, a copy of the results of the analysis shall be furnished promptly to the owner, operator, or agent in charge.

108375. Whenever a duly authorized agent of the department finds, or has probable cause to believe, that any hazardous substance is so misbranded as to be dangerous or fraudulent or is a banned hazardous substance, he or she shall affix to the article a tag or other appropriate marking, giving notice that the article is, or is suspected of being, misbranded and has been detained or quarantined, and warning all persons not to remove or dispose of the article by sale or otherwise until permission for removal or disposal is given by the department or the court.

108380. Whenever the findings of the department show, after investigation and examination, that any hazardous substance found in the possession of any person is misbranded, or banned, the hazardous substance may be seized and quarantined.

108385. A hazardous substance found to be misbranded, or to be a banned hazardous substance may, by order of a court or judge, or in the absence of the order, with the written consent of the owner thereof, be seized or destroyed.

108390. When a misbranded hazardous substance or a banned hazardous substance is detained or quarantined under this article, the department shall commence proceedings in the name of the people of the State of California against the article in the superior court of the county or city and county in which the article is detained or quarantined by petitioning the court for a judgment to forfeit, condemn, and destroy the article. Upon the filing of the petition, the clerk of the court shall fix a time and place for the hearing thereof, and cause notices thereof to be prepared notifying all persons who may claim an interest in the article of the time and place of the hearing. A copy of the petition and notice shall be posted for 14 days in at least three public places in the city or city and county where the court is held, and in a conspicuous place where the article is detained or quarantined. A copy of the petition and notice shall also be served upon each person in possession of the article and on each owner or claimant whose name and address is known. The service may be made by personal service or by registered mail by mailing a copy of the notice and petition by registered mail to the last known address of the person. At any time prior to the date of the hearing any person in possession of the article, or owner thereof or claimant thereto, may file an answer that may include a prayer for a judgment of release of the article or relief in accordance with Sections 108400 and 108405. At the time set for the hearing, the court shall commence to hear and determine the proceeding, but may, for good cause shown, continue the hearing to a day certain; provided, the court shall finally determine all the issues presented by the petition.

108395. If the court finds that a detained or quarantined article is misbranded, after entry of the decree the article shall be destroyed at the expense of the claimant thereof, under the supervision of the agent of the department. All court costs and fees, and storage and other proper expenses, shall be taxed against the claimant of the article or his or her agent.

108400. If the misbranding can be corrected by proper labeling or processing of the article, after entry of the decree and after costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that the article shall be so labeled or processed, has been executed, the court may by order direct that the article be delivered to the claimant thereof for the labeling or processing under the supervision of an agent of the department. The expense of the supervision shall be paid by the claimant.

108405. The bond shall be returned to the claimant of the article on representation to the court by the department that the article is no longer in violation of this chapter, and that the expenses of the supervision have been paid.

108410. The department shall cause to be published from time to time reports summarizing any judgments, decrees, or court orders that have been rendered under this chapter, including the nature of the charge and the disposition thereof. The department shall also cause to be disseminated information regarding hazardous substances in situations involving, in the opinion of the department, imminent danger to health. Nothing in this section shall be construed to prohibit the department from collecting, reporting, and illustrating the results of the investigations of the department.

108415. In addition to the remedies heretofore provided, the department is hereby authorized to bring an action in superior court and the court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of this chapter. Any proceeding under this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the department shall not be required to allege facts necessary to show or tending to show lack of adequate remedy at law or to show or tending to show irreparable damage or loss.

108420. If any provision of this chapter is declared unconstitutional, or the applicability thereof to any person or circumstance is held invalid, the constitutionality of the remainder of the chapter and the applicability thereof to other persons and circumstances shall not be affected thereby. 108500. For the purposes of this article, an art or craft material shall be presumed to contain an ingredient that is a toxic substance causing chronic illness if the ingredient, whether an intentional ingredient or an impurity, is 1 percent or more by weight of the mixture or product, or if the department determines that the toxic or carcinogenic properties of the art or craft material are such that labeling is necessary for the adequate protection of the public health and safety.

HEALTH AND SAFETY CODE
SECTION 108500-108515
Art or Craft Materials

108500. For the purposes of this article, an art or craft material shall be presumed to contain an ingredient that is a toxic substance causing chronic illness if the ingredient, whether an intentional ingredient or an impurity, is 1 percent or more by weight of the mixture or product, or if the department determines that the toxic or carcinogenic properties of the art or craft material are such that labeling is necessary for the adequate protection of the public health and safety.

108505. The Legislature finds and declares that there exists a significant danger to the public health and safety from exposure to art or craft material that contains toxic chemicals. This health risk threatens not only professional artists and craftspersons, but art teachers, students at every educational level, hobbyists, and children. Toxic substances may be employed during the course and scope of creating art or craft objects of all varieties. The Legislature additionally finds and declares that present labeling of ingredients and hazards of art or craft material is insufficient to adequately protect the consumers of this state from chronic adverse health effects. Because many persons do not know what toxic chemical substances they work with, proper precautionary actions cannot be taken. Disclosure of toxic ingredients, their possible adverse effects on health, and instructions for safe handling, will substantially minimize unnecessary exposure to excessive risk.

Additionally, the Legislature finds and declares that it is consistent to impose upon those who manufacture, repackage, distribute, and sell art or craft material a duty to convey to consumers information about the potential health hazards of the products they manufacture.

Therefore, the Legislature intends by this article to ensure that consumers be provided information concerning the nature of the toxic substances with which they are working and the known and suspected health hazards of these substances, and to ensure the uniformity of labeling standards, so that materials with similar hazards also have essentially similar labels.

108510. No person shall distribute, sell, offer for sale, or expose for sale any art or craft material containing toxic substances causing chronic illness on which the person:

- (a) Has failed to affix a conspicuous label containing the signal word "WARNING," to alert users of potential adverse health effects.
- (b) Has failed to affix a conspicuous label warning of the health-related dangers of the art or craft material.
 - (1) If the product contains a human carcinogen, the warning shall contain the statement: "CANCER HAZARD! Overexposure may create cancer risk."
 - (2) If the product contains a potential human carcinogen, and does not contain a human carcinogen, the warning shall contain the statement: "POSSIBLE CANCER HAZARD! Overexposure might create cancer risk."
 - (3) If the product contains a toxic substance causing chronic illness, the warning shall contain, but not be limited to, the following statement or statements where applicable:
 - (A) May cause sterility or damage to reproductive organs.
 - (B) May cause birth defects or harm to developing fetus.
 - (C) May be excreted in human milk causing harm to nursing infant.
 - (D) May cause central nervous system depression or injury.
 - (E) May cause numbness or weakness in the extremities.
 - (F) Overexposure may cause damage to (specify organ).
 - (G) Heating above (specify degrees) may cause hazardous decomposition products.
 - (4) If a product contains more than one chronically toxic substance, or if a single substance can cause more than one chronic health effect, the required statements may be combined into one warning statement.
- (c) Has failed to affix on the label a list of ingredients that are toxic substances causing chronic illness.

- (d) Has failed to affix on the label a statement or statements of safe use and storage instructions, conforming to the following list. The label shall contain, but not be limited to, as many of the following risk statements as are applicable:
- (1) Keep out of reach of children.
 - (2) When using, do not eat, drink, or smoke.
 - (3) Wash hands after use and before eating, drinking, or smoking.
 - (4) Keep container tightly closed.
 - (5) Store in well ventilated area.
 - (6) Avoid contact with skin.
 - (7) Wear protective clothing (specify type).
 - (8) Wear NIOSH certified masks for dusts, mists, or fumes.
 - (9) Wear NIOSH certified respirator with appropriate cartridge for (specify type).
 - (10) Wear NIOSH certified supplied-air respirator.
 - (11) Use window exhaust fan to remove vapors and assure adequate ventilation (specify explosion proof if necessary).
 - (12) Use local exhaust hood (specify type).
 - (13) Do not heat above (specify degrees) without adequate ventilation.
 - (14) Do not use or mix with (specify material).
- (e) Has failed to affix on the label a statement on where to obtain more information, such as “call your local poison control center for more health information.”
- (f) Has failed to affix on the label the name and address of the manufacturer.
- (g) If all of the above information cannot fit on the package label, a package insert shall be required to convey all the necessary information to the consumer. In this event, the label shall contain a statement to refer to the package insert, such as “CAUTION: see package insert before use.” For purposes of this section, “package insert” means a display of written, printed, or graphic matter upon a leaflet or suitable material accompanying the art supply. The language on this insert shall be nontechnical and nonpromotional in tone and content.

Art or craft material offered for sale in containers that contain less than one fluid ounce (30 milliliters) or one ounce net (29 grams) shall be deemed to comply with this section if there is affixed on the container a precautionary label that includes the words “USE WITH CAUTION: Contains Hazardous Substances.” The requirements set forth in subdivisions (a) to (g), inclusive, shall not be considered to be complied with unless the required words, statements, or other information appear on the outside container or wrapper, or on a package insert that is easily legible through the outside container or wrapper and is painted in a color in contrast with the product or the package containing the product.

- (h) Pursuant to Section 108355, the department may exempt a material from full compliance with this article. In considering this exemption, the department shall take into consideration the potential for reasonably foreseeable misuse of a material by a child.
- (i) If an art or craft material complies with labeling standards D-4236 of the American Society for Testing and Materials (ASTM), the material complies with the provisions of this article, unless the department determines that the label on an art or craft material does not satisfy the purposes of this article.

108515.

- (a) The manufacturer of any art or craft material sold, distributed, offered for sale, or exposed for sale in this state shall supply to a national poison control network approved by the director the formulation information required by that network for dissemination to poison control centers. Failure to file formulation information with an approved poison control network is a violation of this chapter.
- (b) The requirements set forth in Section 108510 shall not be considered to be complied with unless all required words, statements, or other information accompany art or craft materials from manufacturer to consumer, not excluding any distributor, packager, repackager, or retailer.

HEALTH AND SAFETY CODE
SECTION 108550-108585
Toy Safety

108550. "Toy," as used in this article, means an article designed and made for the amusement of a child or for his or her use in play.

108555.

- (a) No person shall manufacture, sell, or exchange, have in his or her possession with intent to sell or exchange, or expose or offer for sale or exchange to any retailer, any toy that is contaminated with any toxic substance or that is any of the following:
 - (1) Is coated with paints and lacquers containing compounds of lead of which the lead content (calculated as Pb) is in excess of that permitted by federal regulations contained in Part 1303 of Title 16 of the Code of Federal Regulations adopted pursuant to the Consumer Product Safety Act (Title 15 (commencing with Section 2051) of the United States Code) and the lead limit as reduced by Congress in Section 101(f) of the Consumer Product Safety Improvement Act of 2008 (Public Law 110-314), or soluble compounds of antimony, arsenic, cadmium, chromium, mercury, selenium or barium, as identified in the ASTM International Standard F963-08 "Standard Consumer Safety Specification for Toy Safety" (ASTM F963).
 - (2) Consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance.
 - (3) Has been produced, prepared, packed, shipped, or held under unsanitary or other conditions whereby it may have become contaminated with filth or hazardous materials or otherwise rendered injurious to health.
 - (4) Is stuffed, padded, or lined with materials that are toxic or that would otherwise be hazardous if ingested, inhaled, or contacted.
 - (5) Is a stuffed, padded, or lined toy that is not securely wrapped or packaged.
- (b) The department and local health officers shall enforce this article.
- (c) Violation of this section is a misdemeanor punishable by a fine not exceeding one thousand dollars (\$1,000) for each violation or by imprisonment in the county jail for a period not exceeding one year, or both.

108560.

- (a) All toys offered for sale or exchange, shall contain a label with the name and place of business of the manufacturer, distributor, or importer in the United States.
- (b) It is unlawful to fail to provide any information required by this section upon the request of the department.

108565.

- (a) Whenever a duly authorized representative of the department or a local health officer finds, or has probable cause to believe, that any toy is or would be in violation of this article, he or she shall affix to the toy or a component thereof a tag or other appropriate marking, and shall give notice that the toy is suspected of being in violation of this article, that the toy has been embargoed, and that no person shall remove the toy until permission for removal or disposal is given by an authorized agent of the department, the local health officer, or the court.
- (b) A local health officer shall notify the department within 48 hours of any action taken by the local health officer pursuant to subdivision (a).

108570. No person shall knowingly remove, sell, or dispose of a detained or embargoed toy without permission of an authorized agent of the department, the local health officer, or the court. Violation of this section is a misdemeanor punishable by a fine not exceeding one thousand dollars (\$1,000) for each violation or by imprisonment in the county jail for a period not exceeding one year, or both.

108575. When an authorized agent of the department or the local health officer finds, or has reasonable cause to believe, that an embargo will be violated, he or she may remove the embargoed toy to a place of safekeeping.

108580. When a toy is alleged to be in violation of this article, the department or the local health officer shall commence proceedings in the superior court in whose county the toy is located, for condemnation of the article.

108585.

- (a) No person shall knowingly manufacture, sell, or offer for sale any toy that is designed to depict torture or resemble an instrument specifically designed for torture, or that specifically resembles a bomb or grenade.
- (b) This section shall not apply to any model of an aircraft, ship, motor vehicle, railroad engine, car, or rocketship or other spacecraft, or to any part of the model.
- (c) Violation of this section is a misdemeanor punishable by a fine of not more than six hundred dollars (\$600).

HEALTH AND SAFETY CODE
SECTION 108675-108680
Poison Prevention Act

108675. This chapter shall be known and may be cited as the “California Poison Prevention Packaging Act.”

108680. Unless the provisions or the context otherwise requires, these definitions, rules of construction, and general provisions shall govern the construction of this chapter. As used in this chapter:

- (a) “Department” means the State Department of Health.
- (b) “Household substance” means any substance that is customarily produced or distributed for sale for consumption or use, or customarily stored by individuals in or about the household and is one of the following:
 - (1) A hazardous substance as that term is defined in Section 108125.
 - (2) A food, drug, or cosmetic, as those terms are defined in Sections 109900, 109925, and 109935, that (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means; if it may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.
 - (3) A substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a residential dwelling.
- (c) “Package” means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household, and, for purposes of household substances, also means any outer container or wrapping used in the retail display of any such substance to consumers. “Package” does not include the following:
 - (1) Any shipping container or wrapping used solely for the transportation of any household substance in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof.
 - (2) Any shipping container or outer wrapping used by retailers to ship or deliver any household substance to consumers unless it is the only container or wrapping.
- (d) “Special packaging” means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging that all such children cannot open or obtain a toxic or harmful amount of within a reasonable time.
- (e) “Labeling” means all labels and other written, printed, or graphic matter upon any household substance or its package, or accompanying the substance.
- (f) “Federal act” means the “Poison Prevention Packaging Act of 1970” (15 U.S.C. Sec. 1471 et seq.).

108685. The department shall, pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, adopt regulations establishing standards for the special packaging of any household substance in accordance with this chapter if the regulations do not differ in substance or proscribe or require conduct that differs from the federal act or regulations issued pursuant to the federal act and if the department finds as follows:

- (a) The degree or nature of the hazard to children in the availability of the substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting the substance.
- (b) The special packaging to be required by the standard is technically feasible, practicable, and appropriate for the substance.

108690. In establishing a standard under Section 108685, the department shall consider all of the following:

- (a) The reasonableness of the standard.
- (b) Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances.

- (c) The manufacturing practices of industries affected by the standard.
- (d) The nature and use of the household substance.

108695. To the extent that the requirements of this chapter are identical with the federal act, all regulations and any amendments to the regulations adopted pursuant to the federal act, that are in effect on January 1, 1978, or that are adopted on or after that date, shall be the poison prevention packaging regulations of this state.

108700. Any federal regulation adopted by the department pursuant to this chapter shall take effect in this state 30 days after it becomes effective as a federal regulation. Any person who would 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 state 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, shall stay the adoption of the regulation in this state as a state regulation.

108705. 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 shall be heard at the hearing. The department shall act upon objections by order and shall mail the order to objectors by certified mail within a reasonable period of time after the hearing. The order shall be based on evidence contained in the record of the hearing. If the order concerns a proposed regulation of the department, 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.

108710. Nothing in this chapter shall authorize the department to prescribe specific packaging designs, product content, or package quantity, except as provided in subdivision (b) of Section 108715. In the case of a household substance for which special packaging is required pursuant to a regulation under this chapter, the department may prohibit the packaging of the substance in packages that it determines are unnecessarily attractive to children.

108715. For the purposes of making any household substance that is subject to a standard established under Section 108685 readily available to elderly or handicapped persons unable to use the substance when packaged in compliance with the standard, the manufacturer or packer, may package any household substance, subject to the standard in packaging of a single size that does not comply with that standard if both of the following are present:

- (a) The manufacturer or packer also supplies the substance in packages that comply with the standards.
- (b) The packages of the substance, that do not meet the standard, shall bear conspicuous labeling stating: "This package for household without young children." The department regulation may prescribe a substitute statement to the same effect for packaging too small to accommodate the labeling.

108720. If a household substance subject to such a standard is dispensed pursuant to an order of a physician, dentist, or other licensed medical practitioner authorized to prescribe the substance, then it may be dispensed in noncomplying packages only when directed in the order or when requested by the purchaser.

108725. If a household substance subject to such a standard is packaged pursuant to subdivision (b) of Section 108715 in a noncomplying package, and the department determines that the substance is not also being supplied by a manufacturer or packer in popular size packages that comply with the standard, the department may, after giving the manufacturer or packer an opportunity to comply with the purposes of this chapter, require by order that the substance be packaged by the manufacturer or packer exclusively in special packaging complying with the standard if it finds, after opportunity for hearing, that the exclusive use of a special packaging is necessary to accomplish the purposes of this chapter.

HEALTH AND SAFETY CODE
SECTION 108750-108785
Children's Poison Protection Act

108750. This chapter shall be known and may be cited as the Children's Poison Protection Act of 1990.

108755. As used in this chapter:

- (a) "Household" means any product used under any of the following circumstances:
 - (1) Directly on humans or pets.
 - (2) In, on, or around any structure, vehicle, article, surface, or area associated with the household, including, but not limited to, nonagricultural outbuildings, noncommercial greenhouses, pleasure boats, and recreational vehicles.
 - (3) In or around any preschool or day care facility.
- (b) "Liquid" means a liquid preparation that flows readily in its natural state at room temperature containing one or more soluble chemical substances usually dissolved in water or other solvents. "Solvent" includes, but is not limited to, aqueous acids (acetic, hydrochloric, and nitric acids) and nonaqueous solutions (spirits, liniments).
- (c) "Toxic household product" means any substance or mixture of substances that are customarily produced or distributed for sale for use in or about the household, or are customarily stored by individuals in or about the household, and the substance or mixture of substances have the capacity to produce significant personal injury or illness to humans when orally ingested in moderate amounts.

"Toxic household product" shall not include any of the following:

- (1) Products that contain hydrocarbons in which the only known toxicity is through lung aspiration of minute amounts and not absorption through the stomach.
- (2) Products that are intended for use in or around the mouth or are reasonably expected to be used orally or ingested.
- (3) Economic poisons packaged in containers of more than one gallon liquid or more than 10 pounds dry weight.
- (4) With the exception of products containing 2.5 percent or more by weight camphor in liquid formulations, any drug, as defined in the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) and the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875)).
- (5) Products that, immediately upon ingestion, cause severe damage or irritation to the mouth or tongue, or are fatal upon a single taste.
- (6) Products packaged in pressurized aerosol containers.
- (7) Products containing ethylene glycol that are described in paragraphs (7), (9), and (38) of subdivision (a) of Section 1500.83 of Part 1500 of Title 16 of the Code of Federal Regulations.

108760.

- (a) Except as provided in subdivision (b), any toxic household product that contains any substance listed in subdivision (a) of Section 108765, and manufactured on and after January 1, 1992, and sold in California, shall include within the product a bittering agent that is nontoxic, in a concentration so as to render the product aversively bitter, unless the product is packaged with child-resistant safety closures in accordance with the federal Poison Prevention Packaging Act of 1970 (15 U.S.C. Sec. 1471 et seq.) and regulations adopted thereunder (16 C.F.R. 1700.1 et seq.).
- (b) Any toxic household product that (1) is required to be registered with the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 135 et seq.), (2) is formulated for outdoor or food use economic poisons purposes, and (3) will be reformulated to include a bittering agent, shall comply with subdivision (a) no later than two years from the date when the Environmental Protection Agency has approved a bittering agent for use in outdoor or food use economic poisons.

108765.

- (a) Manufacturers of toxic household products that contain any of the following substances shall comply with Section 108760, unless the manufacturer documents that there are no signs of toxicity at an oral dose of five grams of product per kilogram of body weight, or the product's container, when full, contains a dose less than that which has previously been documented by the manufacturer to be nontoxic:
- (1) Acetonitrile.
 - (2) Sodium bromate (600 mg or more).
 - (3) Potassium bromate (50 mg or more).
 - (4) Carbamates (used in insecticide formulations).
 - (5) Chlorinated hydrocarbon insecticides and solvents (5 percent or more by weight).
 - (6) Cyanide.
 - (7) Diquat.
 - (8) Ethylene glycol (10 percent or more by weight).
 - (9) Organophosphate insecticides.
 - (10) Metaldehyde.
 - (11) Methanol (methyl alcohol)(4 percent or more by weight).
 - (12) Phenol (10 percent or more by weight).
 - (13) Pine oil, in concentrations of 20 percent or more.
 - (14) Strychnine formulations.
- (b) Due to the lack of long-term testing results for dermal exposure of available bittering agents, manufacturers of toxic household products that contain any of the following substances in liquid formulations shall, in lieu of complying with Section 108760, package their products with child-resistant safety closures in accordance with the federal Poison Prevention Packaging Act of 1970 (15 U.S.C. Sec. 1471 et seq.) and regulations adopted thereunder (16 C.F.R. 1700.1 et seq.):
- (1) Camphor (2.5 percent or more by weight).
 - (2) Diethyltoluamide (5 percent or more by weight).
 - (3) Ethylhexanediol (5 percent or more by weight).

108770.

- (a) It is unlawful for any person to distribute or sell a toxic household product or cause a toxic household product to be distributed or sold in this state if it does not meet the requirements of this chapter.
- (b) The prohibition contained in subdivision (a) shall not apply to a person engaged in the business of wholesale or retail distribution of a toxic household product, unless the person is engaged in the manufacture of the product, or has knowledge that a toxic household product that he or she is distributing or selling is in violation of this chapter.
- (c) Nothing in this section shall be construed to exempt a distributor of a house brand from any provision of this chapter.

108775.

- (a) Any person may bring a civil action in a court of competent jurisdiction to enforce the requirements of this chapter. The court may grant injunctive relief in any action brought pursuant to this section.
- (b) Exemplary damages, as provided for in Section 3294 of the Civil Code, may also be awarded in any action brought pursuant to this section.
- (c) Whenever the person bringing the action pursuant to this section is the prevailing party, he or she shall be awarded attorney's fees and costs by the court.

108780. Any person who violates any provision of this chapter shall be liable for a civil penalty not to exceed five thousand dollars (\$5,000) for each day of violation, that shall be assessed and recovered in a civil action brought in the name of the people of the State of California by the Attorney General in any court of competent jurisdiction.

108785. All civil penalties collected pursuant to Section 108780 shall be deposited in the Children's Poison Protection Act of 1990 Fund, that is hereby created in the State Treasury. Money in the fund shall be allocated by the Emergency Medical Services Authority, when appropriated thereto by the Legislature, to the California Regional Poison Control Centers for the purpose of their poisoning prevention education programs.

HEALTH AND SAFETY CODE
SECTION 108850-108855
Lead in Tableware

108850. The Legislature finds and declares all of the following:

- (a) The program maintained by the United States Food and Drug Administration to regulate the amount of lead and cadmium released from ceramic, metal, and other dishware and tableware is inadequate to protect Californians from the importation and sale of unsafe tableware in this state.
- (b) Recent inspection and sampling conducted by local and state health departments in California has demonstrated that significant amounts of unsafe tableware are in fact being imported and sold in California.
- (c) The standards established by the federal government for acceptable lead and cadmium release are likely inadequate to fully protect public health and may be inconsistent with requirements that already exist in California law governing exposure to lead and cadmium.
- (d) It is the intent of the Legislature that the department, first, establish its own program to protect the public from unsafe tableware and, second, develop standards for lead and cadmium release from tableware that are consistent with existing state law.

108855. For purposes of this chapter the following definitions shall apply:

- (a) "Director" means the Director of Health Services.
- (b) "Department" means the State Department of Health Services.
- (c) "Distributor" means any person who brings tableware into California from another state for sale.
- (d) "Importer" means any person who brings tableware into California from another country for sale.
- (e) "Manufacturer" means any person who makes tableware sold in California.
- (f) "Small business" means any manufacturer, importer, or distributor whose gross annual revenue for the sale of tableware is thirty thousand dollars (\$30,000) or less.
- (g) "Tableware" means any glazed ceramic, enamel metalware, or pewter article, container, or utensil that may be used in the preparation, serving, or storage of food or drink.

108860. It is unlawful to manufacture, process, import, sell, deliver, hold for sale, supply, or offer for sale in this state any tableware that releases a level of lead or cadmium in violation of the standards contained in the Compliance Policy Guides 7117.06 and 7117.07 as described in 54 Federal Register 23485 or any subsequent, more stringent standards adopted by the United States Food and Drug Administration, as determined by the director.

108870.

- (a) Except as provided in subdivisions (c) and (d), each piece of tableware sold, or offered for sale, in this state shall be permanently and indelibly marked with the name of the manufacturer or importer responsible for the sale of the tableware in California.
- (b) For the purposes of this section, permanently and indelibly marked means fired or manufactured into the glazed tableware.
- (c) This section shall not apply to any tableware that is manufactured without lead or cadmium as an intentionally added ingredient or as an unintentional contaminant.
- (d) This section shall not apply to any tableware product that is of a peculiar structure or too small to accommodate the name of the manufacturer or importer in accordance with subdivision (a), provided that the product either
 - (1) is permanently and indelibly marked with a registered trademark that is on file with the department, or is described and depicted in a certificate of registration that is on file with the department, or
 - (2) is part of a tableware set or pattern, one or more pieces that are marked in accordance with subdivision (a).

108875. The department is responsible for the administration and enforcement of this chapter. The department, upon request, shall report to the Legislature concerning the number and findings of inspections performed and samples taken to determine compliance with this chapter.

108880.

- (a) For fiscal years 1991-92 and 1992-93, the department shall levy a fee of five hundred dollars (\$500) for each manufacturer, importer, and distributor of tableware sold in this state to be used for the implementation of this chapter, except that the department shall levy a fee of one hundred fifty dollars (\$150) for small businesses. A penalty of 10 percent per month shall be added to any fee that is not paid when due. The fee shall not exceed the costs of administering and enforcing this chapter for the 1991-92 and 1992-93 fiscal years.

No later than July 1993, the department shall establish and implement a fee schedule that assesses an annual fee upon manufacturers, importers, and distributors of tableware sold in California. The fees shall be based on the reasonable anticipated costs that will be incurred by the department, and by local health officers if an agreement is executed pursuant to Section 108885, to implement and enforce this chapter. In calculating the necessary fees, the department shall include any civil penalties generated pursuant to Section 100425. Commencing in fiscal year 1993-94, the fee established pursuant to this subdivision shall be adjusted pursuant to Section 100425 and shall further be adjusted annually by reducing the fee by an amount equal to the total amount of civil penalties collected pursuant to Section 108900 during the previous calendar year, divided by the total number of manufacturers, importers, and distributors having paid fees during the previous calendar year. The fee collected pursuant to subdivision (a) shall terminate upon implementation of the fee schedule developed pursuant to this subdivision. The fee schedule shall provide for the recovery of all costs of implementing this chapter, including the cost of establishing the fee schedule as prescribed in this section. In the event that the department's reasonable costs in any one fiscal year exceed the available fees for that year, the department shall, as necessary, delay any activities in administering this chapter that will incur costs exceeding available fees until the following year. All moneys collected as fees pursuant to this section shall be expended in carrying out this chapter.

108885. The department and a health officer, as defined in Section 111015, may enter into an agreement designating the local health department of a city, county, city and county, or local health district as the department's authorized agent for the purposes of enforcing this chapter. If an agreement is executed pursuant to this section, the department shall make fee revenues available to the health officer for performing duties relating to enforcing this chapter.

108890.

- (a) For the purposes of enforcing this chapter, any authorized agent of the department may, upon presenting credentials showing that he or she is an authorized agent of the department and at a reasonable time, do any of the following:
- (1) Enter any factory, warehouse, or establishment in which any tableware is manufactured, held, distributed, used, or sold.
 - (2) Enter any vehicle that is being used to transport or hold tableware.
 - (3) Enter any place where any tableware is suspected of being held or sold in violation of this chapter.
 - (4) Inspect any factory, warehouse, establishment, vehicle, or place in which any tableware is manufactured, held, transported, distributed, used, or sold, and all equipment, raw materials, finished and unfinished materials, containers, and tableware therein. The inspection shall include any record, file, paper, process, control, and facility that has a bearing on whether the tableware complies with this chapter.
 - (5) Secure any sample or specimen of any tableware or of any release of lead or cadmium from tableware. If the agent obtains any samples prior to leaving the premises, he or she shall leave a receipt describing any sample obtained. The department shall secure only the quantity of tableware that is reasonably necessary to conduct the tests to determine the release of lead or cadmium as determined appropriate by the department.
 - (6) Have access to all records of carriers in commerce relating to the movement in commerce of any tableware, or the holding for sale of the tableware, and the quantity, shipper, and consignee.

- (b) It is unlawful for any person to refuse to permit entry or inspection, the taking of samples or other evidence, including photographs, or access to copying of any record as authorized by this chapter, or to conceal the samples or evidence, or withhold evidence concerning them.

108895. The department may publish or publicly distribute any information regarding tableware, including results of tests and investigations, after assuring the accuracy of those tests and investigations, as the department considers necessary for the protection of public health and safety of the consumer or for the protection of the consumer from fraud.

108900.

- (a) The department may impose a civil penalty payable to the department upon any person who violates this chapter or any regulation adopted pursuant to this chapter in the amount of not more than five thousand dollars (\$5,000) per day. Each day a violation continues shall be considered a separate violation.
- (b) If, after examination of a possible violation and the facts surrounding that possible violation, the department concludes that a violation has occurred, the department may issue a complaint to the person charged with the violation. The complaint shall allege the acts or failures to act that constitute the basis for the violation and the amount of the penalty. The complaint shall be served by personal service or by certified mail and shall inform the person so served of the right to a hearing.
- (c) Any person served with a complaint pursuant to subdivision (c) may, within 20 days after service of the complaint, request a hearing by filing with the department a notice of defense. A notice of defense is deemed to have been filed within the 20-day period if it is postmarked within the 20-day period. If a hearing is requested by the person, it shall be conducted within 90 days after the receipt by the department of the notice of defense. If no notice of defense is filed within 20 days after service of the complaint, the department shall issue an order setting the penalty as proposed in the complaint unless the department and the person have entered into a settlement agreement, in that case the department shall issue an order setting the penalty in the amount specified in the settlement agreement. When the person has not filed a notice of defense or where the department and the person have entered into a settlement agreement, the order shall not be subject to review by any court or agency.
- (d) Any hearing required under this section shall be conducted pursuant to Section 100171, except to the extent that the procedures specified in Section 100171 are inconsistent with this section.
- (e) Orders setting civil penalties under this section shall become effective and final upon issuance thereof, and payment shall be made within 30 days of issuance. A copy of the order shall be served by personal service or by certified mail upon the person served with the complaint.
- (f) Within 30 days after service of a copy of a decision issued by the director after a hearing, any person so served may file with the superior court a petition for writ of mandate for review of the decision. Any person who fails to file the petition within this 30-day period may not challenge the reasonableness or validity of the decision or order of the director in any judicial proceeding brought to enforce the decision or order or for other remedies. Section 1094.5 of the Code of Civil Procedure shall govern any proceedings conducted pursuant to this subdivision. In all proceedings pursuant to this subdivision, the court shall uphold the decision of the director if the decision is based upon substantial evidence in the whole record. The filing of a petition for writ of mandate shall not stay any corrective action required pursuant to this chapter or the accrual of any penalties assessed pursuant to this section. This subdivision does not prohibit the court from granting any appropriate relief within its jurisdiction.
- (g) The remedies under this section are in addition to, and do not supersede or limit, any and all other remedies, civil or criminal.
- (h) If the violation is committed after a previous imposition of a penalty under this section that has become final, if the violation is committed with intent to mislead or defraud, or if the violation concerns tableware primarily used by children or marketed for children, the person shall be subject to imprisonment for not more than one year in the county jail or imprisonment in state prison, by a fine of not more than ten thousand dollars (\$10,000), or by both the imprisonment and fine.

108905.

- (a) Whenever an authorized agent of the department finds, or has probable cause to believe, that any tableware has the potential to release amounts of lead or cadmium in violation of this chapter, he or

she shall affix to the tableware a detention tag, embargo tag, or other similar marking, as determined appropriate by the authorized agent. The tag or other marking shall give notice that the tableware is suspected of releasing amounts of lead or cadmium in violation of this chapter and that no person shall remove or dispose of the tableware by sale or otherwise until permission for removal or disposal is given by an authorized agent of the department or the court.

- (b) For the purposes of this section, an authorized agent has probable cause to believe that tableware has the potential to release amounts of lead or cadmium in violation of this chapter when, but not limited to instances when, the tableware tests positive for lead or cadmium release using the field test described in the document published by the United States Food and Drug Administration entitled Analytical Letters Vol. 21, 1988, pages 2145 to 2154, inclusive, or any other test for lead release subsequently approved for field use by the United States Food and Drug Administration and determined by the department to be at least as effective a test for lead or cadmium release as the test described in this subdivision.
- (c) If a field test conducted pursuant to subdivision (b) tests positive for lead release, the department shall use the Association of Official Analytical Chemists/American Society for Testing and Material 24-hour test method, or any other test subsequently approved by the federal Food and Drug Administration determined by the department to be at least as effective a test for lead or cadmium release as the test described in this subdivision. The department shall conduct or obtain those tests within a reasonable time after embargoing affected tableware, and shall release any tableware found not to violate the standards of this chapter within a reasonable time after the laboratory test has been completed. For any food establishment, as defined in Section 113780, the department shall conduct or obtain those tests within a reasonable time, not to exceed 10 days, after embargoing affected tableware, and shall release any tableware found not to violate the standards of this chapter within 96 hours after the laboratory test has been conducted.
- (d) If an item of tableware is found to violate this chapter, the manufacturer, importer, retailer, and distributor shall, at the option of the holder of the tableware, either provide the holder of the tableware with comparable replacement tableware acceptable to the holder or be liable to the holder of the tableware for the cost of purchasing comparable replacement tableware.
- (e) No person shall remove, sell, or dispose of detained or embargoed tableware without permission of an authorized agent of the department or a court.

108910. Any tableware that violates this chapter shall also be governed by the procedures set forth in Sections 111875, 111880, 111885, 111895, 111900, 111910, and 111915. Except for use of the procedures set forth in those sections, nothing in this section shall be interpreted as making this chapter part of Part 5 (commencing with Section 109875).

108915. This chapter shall become operative on July 1, 1991.

HEALTH AND SAFETY CODE
SECTION 108940-108941
Toxin-Free Infants and Toddlers Act

CHAPTER 12. BISPHENOL A

108940.

(a) On and after July 1, 2013, no person shall manufacture, sell, or distribute in commerce any bottle or cup that contains bisphenol A, at a detectable level above 0.1 parts per billion (ppb), if the bottle or cup is designed or intended to be filled with any liquid, food, or beverage intended primarily for consumption from that bottle or cup by children three years of age or younger.

(b) Subdivision (a) shall not apply to medical devices, as defined in Section 109920, or to food and beverage containers designed or intended primarily to contain liquid, food, or beverages for consumption by the general population.

(c) Notwithstanding subdivision (a), if the Department of Toxic Substances Control adopts a regulatory response described in Section 25253 regarding the use of bisphenol A in a product that is prohibited by this section, the prohibition of this section shall not apply to that product upon the date that the department posts a notice on its Internet Web site that it has adopted the response.

(d) Notwithstanding subdivisions (b) and (c) of Section 25257.1, this section shall not be construed to prohibit or restrict the authority of the Department of Toxic Substances Control to prioritize or take action on any products containing bisphenol A in order to limit exposure to or reduce the level of hazard posed by bisphenol A.

108941.

(a) Manufacturers shall use the least toxic alternative when replacing bisphenol A in containers in accordance with this chapter.

(b) Manufacturers shall not replace bisphenol A, pursuant to this chapter, with chemicals classified by the United States Environmental Protection Agency as carcinogenic to humans, likely to be carcinogenic to humans, or for which there is suggestive evidence of carcinogenic potential, or identified by the state to cause cancer as listed in the Safe Drinking Water and Toxic Enforcement Act of 1986 (Chapter 6.6 (commencing with Section 25249.5) of Division 20) list of chemicals known to cause cancer or reproductive toxicity.

(c) Manufacturers shall not replace bisphenol A, pursuant to this chapter, with reproductive toxicants that cause birth defects, reproductive harm, or developmental harm as identified by the United States Environmental Protection Agency or listed in the Safe Drinking Water and Toxic Enforcement Act of 1986 (Chapter 6.6 (commencing with Section 25249.5) of Division 20) list of chemicals known to cause cancer or reproductive toxicity.

HEALTH AND SAFETY CODE
SECTION 109250-109295
Cancer Law

109250. The effective diagnosis, care, treatment or cure of persons suffering from cancer is of paramount public importance. Vital statistics indicate that approximately 16 percent of the total deaths in the United States annually result from one or another of the forms of cancer. It is established that accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment that are scientifically proven, either materially reduces the likelihood of death from cancer or may materially prolong the useful life of individuals suffering therefrom.

Despite intensive campaigns of public education, there is a lack of adequate and accurate information among the public with respect to presently proven methods for the diagnosis, treatment, and cure of cancer. Various persons in this state have represented and continue to represent themselves as possessing medicines, methods, techniques, skills, or devices for the effective diagnosis, treatment, or cure of cancer, whose representations are misleading to the public, with the result that large numbers of the public, relying on the representations, needlessly die of cancer, and substantial amounts of the savings of individuals and families relying on the representations are needlessly wasted.

It is, therefore, in the public interest that the public be afforded full and accurate knowledge as to the facilities and methods for the diagnosis, treatment, and cure of cancer available in this state and that to that end there be provided means for testing and investigating the value or lack thereof of alleged cancer remedies, devices, drugs, or compounds, and informing the public of the facts found, and protecting the public from misrepresentation in these matters.

The importance of continuing scientific research to determine the cause or cure of cancer is recognized, and the department shall administer this article and Article 2 (commencing with Section 109300) with due regard for the importance of bona fide scientific research and the clinical testing in hospitals, clinics, or similar institutions of new drugs or compounds.

109255. There is in the department a Cancer Advisory Council composed of nine physicians and surgeons licensed to practice medicine in, and residing in, this state, three persons who are not physicians and surgeons, two persons representing nonprofit cancer research institutes recognized by the National Cancer Institute, and the director of the department, who shall be an ex officio member. The members of the council shall be appointed by the Governor to serve for terms of four years. The Governor, in appointing the first members, shall appoint at least one member from the faculty of each of the schools teaching medicine and surgery and located in this state that are approved by the Medical Board of California. The Governor shall endeavor to maintain one member from the faculty of each school in making subsequent appointments.

109260. The members of the council, other than the director of the department, shall receive no compensation for their services, but shall be allowed their actual necessary traveling expenses incurred in the discharge of their duties.

Except as provided in Section 109390 the council is not required to conduct meetings open to the public in accordance with Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

109265. The council shall annually elect one of its members to serve as chairman. The council shall meet at least twice each year, and as often in addition as necessary, for the purpose of carrying out its duties.

109270. The department shall:

- (a) Prescribe reasonable regulations with respect to the administration of this article and Article 2 (commencing with Section 109300).
- (b) Investigate violations of this article and Article 2 (commencing with Section 109300), and report the violations to the appropriate enforcement authority.

- (c) Secure the investigation and testing of the content, method of preparation, efficacy, or use of drugs, medicines, compounds, or devices proposed to be used, or used, by any individual, person, firm, association, or other entity in the state for the diagnosis, treatment, or cure of cancer, prescribe reasonable regulations with respect to the investigation and testing, and make findings of fact and recommendations upon completion of any such investigation and testing.
- (d) Adopt a regulation prohibiting the prescription, administration, sale or other distribution of any drug, substance, or device found to be harmful or of no value in the diagnosis, prevention or treatment of cancer.
- (e) Hold hearings in respect of those matters involving compliance with this article and Article 2 (commencing with Section 109300) and subpoena witnesses and documents. Any or all hearings may be held before the Cancer Advisory Council. Any administrative action to be taken by the department as a result of the hearings shall be taken only after receipt of the recommendations of the council. Prior to issuance of a cease and desist order under Section 109345, a hearing shall be held. The person furnishing a sample under Section 109295 shall be given due notice of the hearing and an opportunity to be heard.
- (f) Contract with independent scientific consultants for specialized services and advice.

In the exercise of the powers granted by this section, the department shall consult with the Cancer Advisory Council.

109275.

- (a) Upon a diagnosis of breast cancer, the physician and surgeon, meaning the primary provider who initially referred the patient for the screening or biopsy or, if different, the provider who has made the diagnosis of breast cancer and initially consulted with the patient about treatment, shall give the patient the written summary described in subdivision (c) and required by this section and shall note on the patient's chart that he or she has given the patient the written summary. The physician and surgeon may choose to provide the summary prior to the performance of a screening or biopsy for breast cancer upon a patient's request or at the discretion of the physician and surgeon in appropriate cases, including, but not limited to, instances when a patient has demonstrated risk factors, has a family history of breast cancer, or is otherwise susceptible.
- (b) The failure of a physician and surgeon to inform a patient, by means of a standardized written summary developed by the department on the recommendation of the Cancer Advisory Council in accordance with subdivision (c), in layperson's language and in a language understood by the patient, of alternative efficacious methods of treatment that may be medically viable, including surgical, radiological, or chemotherapeutic treatments or combinations thereof, when the patient is being treated for any form of breast cancer, constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.
- (c)
 - (1) A standardized written summary in layperson's language and in a language understood by the patient shall be developed by the department with the recommendations of the Cancer Advisory Council, and shall be printed and made available by the Medical Board of California to physicians and surgeons, for the purposes of informing the patient of the advantages, disadvantages, risks, and descriptions of the procedures with regard to medically viable and efficacious alternative methods of treatment for breast cancer as required by subdivision (a).
 - (2) Commencing no later than January 1, 1995, and every three years thereafter, the department shall review the written summary and shall revise the written summary if the department determines that new or revised information should be included in the written summary, and shall provide a copy of the revised summary to the Medical Board of California.
 - (3) At the next revision of the standardized written summary required by this section, the department shall incorporate all of the following additional information:
 - (A) Information regarding methods of treatment for breast cancer that are in the investigational or clinical trial stage and are recognized for treatment by the Physician's Data Query of the National Cancer Institute.
 - (B) Available reference numbers, including, but not limited to, the "800" telephone numbers for the National Cancer Institute and the American Cancer Society, in order for breast cancer patients to obtain the most recent information.

- (C) A discussion of breast reconstruction surgery, including, but not limited to, problems, benefits, and alternatives.
- (D) Statistics on the incidence of breast cancer.
- (d) The Medical Board of California shall establish a distribution system for the breast cancer treatment alternatives written summary, and shall provide a link to its Internet Web site that may be accessed by consumers interested in viewing and obtaining a copy of the summary.
- (e) The department and the Medical Board of California shall each post the summary on its Internet Web site.

109277.

- (a) Every person or entity who owns or operates a health facility or a clinic, or who is licensed as a physician and surgeon and rents or owns the premises where his or her practice is located, shall cause a sign or notice to be posted where a physician and surgeon performs breast cancer screening or biopsy as an outpatient service, or in a reasonably proximate area to where breast cancer screening or biopsy is performed. A sign or notice posted at the patient registration area of the health facility, clinic, or physician and surgeon's office shall constitute compliance with this section.
- (b) The sign or notice shall read as follows:

"BE INFORMED"

"Upon a diagnosis of breast cancer, your physician and surgeon is required to provide you a written summary of alternative efficacious methods of treatment, pursuant to Section 109275 of the California Health and Safety Code. Your physician and surgeon may choose to provide the summary prior to the performance of a screening or biopsy for breast cancer at your request or at the physician and surgeon's discretion, when appropriate."

"The information about methods of treatment was developed by the State Department of Health Services to inform patients of the advantages, disadvantages, risks, and descriptions of procedures."

- (c) The sign shall be not less than eight and one-half inches by 11 inches and shall be conspicuously displayed so as to be readable. The words "BE INFORMED" shall not be less than one-half inch in height and shall be centered on a single line with no other text. The message on the sign shall appear in English, Spanish, and Chinese.

109278.

- (a) The medical care provider primarily responsible for providing to a patient an annual gynecological examination shall provide to that patient during the annual examination a standardized summary in layperson's language and in a language understood by the patient containing a description of the symptoms and appropriate methods of diagnoses for gynecological cancers. Use of existing publications developed by nationally recognized cancer organizations is not precluded by this section.
- (b) For the purposes of this section, "medical care provider" means a health care professional licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code or pursuant to an initiative act referred to in that division providing medical care within his or her lawful scope of practice.

109280.

- (a) A standardized written summary in layperson's language and in a language understood by patients shall be approved by the department. The department may approve the use of an existing publication from a recognized cancer authority as the written summary. Commencing on January 1, 2003, and every three years thereafter, the department shall review its approval of the use of an existing publication from a recognized cancer authority as the written summary to ensure that the approved written summary comprises timely, new, and revised information regarding prostate cancer treatment options as the department determines is necessary. The written summary shall be printed or made available by the Medical Board of California to physicians and surgeons, concerning the advantages, disadvantages, risks, and descriptions, of procedures with regard to medically viable and efficacious

alternative methods of treatment of prostate cancer. Physicians and surgeons are urged to make the summary available to patients when appropriate.

- (b) The department and the Medical Board of California shall each post this summary on its Internet Web site for public use.
- (c) If the department updates this summary, it shall send the updated summary to the Medical Board of California and both the department and the Medical Board of California shall each post this updated summary on its Internet Web site.

109282.

- (a) Every person or entity who owns or operates a health facility or a clinic, or who is licensed as a physician and surgeon and rents or owns the premises where his or her practice is located, shall cause a sign or notice to be posted where prostate cancer screening or treatment is performed by any physician and surgeon, or in a reasonably proximate area to where prostate cancer screening or treatment is performed. A sign or notice posted at the patient registration area of the health facility, clinic, or physician and surgeon's office shall constitute compliance with this section.
- (b) The sign or notice shall read as follows:

"BE INFORMED"

"If you are a patient being treated for any form of prostate cancer, or prior to performance of a biopsy for prostate cancer, your physician and surgeon is urged to provide you a written summary of alternative efficacious methods of treatment, pursuant to Section 109280 of the California Health and Safety Code." "The information about methods of treatment was developed by the State Department of Public Health to inform patients of the advantages, disadvantages, risks, and descriptions of procedures."

- (c) The sign shall be not less than eight and one-half inches by 11 inches and shall be conspicuously displayed so as to be readable. The words "BE INFORMED" shall not be less than one-half inch in height and shall be centered on a single line with no other text. The message on the sign shall appear in English, Spanish, and Chinese.
- (d) Subject to future, regular production and replacement schedules from the implementation of the act adding this subdivision, these signs and notices shall include the Internet Web site address of the State Department of Public Health and the Medical Board of California, and a notice regarding the availability of updated prostate cancer summaries on these Web sites.

109285. For the purposes of this article and Article 2 (commencing with Section 109300) "cancer" means all malignant neoplasms regardless of the tissue of origin, including malignant lymphoma, Hodgkins disease, and leukemia.

109290. No person may undertake to treat or alleviate cancer by use of drugs, surgery, or radiation unless the person holds a license issued under a law of this state expressly authorizing the diagnosis and treatment of disease by use of drugs, surgery, or radiation.

109295. On written request by the department, delivered personally or by mail, any individual, person, firm, association, or other entity engaged, or representing himself, or itself, as engaged, in the diagnosis, treatment, alleviation, or cure of cancer shall furnish the department with the sample as the department may deem necessary for adequate testing of any drug, medicine, compound, or device used or prescribed by the individual, person, firm, association, or other entity in the diagnosis, treatment, alleviation, or cure of cancer, and shall specify the formula of any drug or compound and name all ingredients by their common or usual names, and shall, upon like request by the department, furnish further necessary information as it may request as to the composition and method of preparation of and the use that any drug, compound, or device is being put by the individual, person, firm, association, or other entity. This section shall apply to any individual, person, firm, association, or other entity that renders health care or services to individuals who have or believe they have cancer. This section also applies to any individual, person, firm, association, or other entity that by implication causes individuals to believe they have cancer.

The failure to either provide the sample, disclose the formula, or name the ingredients as required by this section shall be conclusively presumed that the drug, medicine, compound or device that is the subject of the department's request has no value in the diagnosis, treatment, alleviation, or cure of cancer.

109300. The sale, offering for sale, holding for sale, delivering, giving away, prescribing or administering of any drug, medicine, compound, or device to be used in the diagnosis, treatment, alleviation, or cure of cancer is unlawful and prohibited unless

- (1) an application with respect thereto has been approved under Section 505 of the federal Food, Drug and Cosmetic Act, or
- (2) there has been approved an application filed with the board setting forth:
 - (a) Full reports of investigations that have been made to show whether or not the drug, medicine, compound, or device is safe for the use, and whether the drug, medicine, compound, or device is effective in the use;
 - (b) A full list of the articles used as components of the drug, medicine, compound, or device;
 - (c) A full statement of the composition of the drug, medicine, compound, or device;
 - (d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug, medicine, or compound or in the case of a device, a full statement of its composition, properties, and construction and the principle or principles of its operation;
 - (e) Such samples of the drug, medicine, compound, or device and of the articles used as components of the drug, medicine, compound, or device as the board may require; and
 - (f) Specimens of the labeling and advertising proposed to be used for the drug, medicine, compound, or device.

109305. Within 180 days after the filing of an application provided for in subdivision (2) of Section 109300 or an additional period as may be agreed upon by the board and the applicant, the board shall either:

- (a) Approve the application if it finds that none of the grounds for denying approval specified in Section 109315 applies.
- (b) Give the applicant notice for an opportunity for a hearing before the board on the question whether the application is approvable. If the applicant elects to accept the opportunity for hearing by written request within 30 days after the notice, the hearing shall commence not more than 90 days after the expiration of the 30 days unless the board and the applicant otherwise agree. Any hearing shall thereafter be conducted on an expedited basis and the board order thereon shall be issued within 90 days after the date fixed by the board for filing final briefs.

Prior to approving the application or giving the applicant notice for an opportunity for a hearing, the board shall have received a written report from the Cancer Advisory Council setting forth its recommendations on the action the board should take. The report shall be signed by a majority of the members of the council.

109310. In the case of any drug, medicine, compound or device for that an approval of an application filed pursuant to this article and Article 1 (commencing with Section 109250) is in effect, the applicant shall establish and maintain the records, and make the reports to the board, of data relating to clinical experience and other data or information, received or otherwise obtained by the applicant with respect to the drug, medicine, compound, or device, as the board may prescribe on the basis of a finding that the records and reports are necessary in order to enable the board to determine, or facilitate a determination, whether there is or may be ground for suspension of the application.

Every person required under this section to maintain records, and every person in charge of custody thereof, shall, upon request of an agent of the board, permit the agent at all reasonable times to have access to and copy and verify the records. 109315. The board shall issue an order refusing to permit the application to become effective, if, after due notice to the applicant and opportunity for a hearing, the board finds any of the following:

- (a) The investigations, reports that are required to be submitted to the board pursuant to subdivision (2) of Section 109300 do not include adequate tests by all methods reasonably applicable to show whether or not a drug, medicine, compound, or device is safe for use in the diagnosis, treatment, alleviation, or cure of cancer.

- (b) The results of tests specified in subdivision (a) show that a drug, medicine, compound or device is unsafe for use under the conditions specified in subdivision (a) or do not show that the drug, medicine, compound, or device is safe for use under the conditions.
- (c) The methods used in, and the facilities and controls used for, the manufacture, processing, and packing of a drug, medicine, compound, or device are inadequate to preserve its identity, strength, quality, and purity and with respect to a device are inadequate to preserve its safety or effectiveness.
- (d) Upon the basis of the information submitted to it as part of the application, or upon the basis of any other information before it with respect to a drug, medicine, compound, or device, it has insufficient evidence to determine whether the drug, medicine, compound, or device is safe for use under the conditions specified in subdivision (a).
- (e) Evaluated on the basis of the information submitted to it as part of the application and any other information before it with respect to the drug, medicine, compound, or device, there is a reasonable doubt that the drug, medicine, compound, or device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling or advertising thereof.
- (f) The application contains any untrue statement of a material fact.

109320.

- (a) The board shall issue an order withdrawing approval of an application concerning any drug, medicine, compound, or device if, after due notice to the applicant and opportunity for a hearing, the board finds any of the following:
 - (1) That clinical or other experience, tests, or other scientific data show that the drug, medicine, compound, or device is unsafe for use under the conditions of use upon the basis that the application was approved;
 - (2) That new evidence of clinical experience, not contained in the application or not available to the board until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available to the board when the application was approved, shows that the drug, medicine, compound, or device is not shown to be safe for use under conditions of use upon the basis that the application was approved; or
 - (3) On the basis of new information with respect to the drug, medicine, compound, or device, evaluated together with the evidence available to the board when the application was approved, that there is a lack of substantial evidence that the drug, medicine, compound, or device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or advertising thereof; or
 - (4) That the application contains any untrue statement of a material fact.
- (b) If the board finds that there is an imminent hazard to the public health, it may suspend the approval of the application immediately.
- (c) The board may also, after due notice and opportunity for hearing, withdraw the approval of an application with respect to any drug, medicine, compound, or device under this section if the board finds any of the following:
 - (1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain the records or to make required reports, or the applicant has refused to permit access to, or copying or verification of, the records.
 - (2) That on the basis of new information before the board, evaluated together with the evidence before it when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, maintenance, processing, and packing of the drug, medicine, compound, or device are inadequate to assure and preserve its identity, strength, quality, and purity and with respect to a device are inadequate to preserve its safety or effectiveness and were not made adequate within a reasonable time after receipt of written notice from the board specifying the matter complained of.
 - (3) That on the basis of new information before it, evaluated together with the evidence before it when the application was approved, the labeling of the drug, medicine, compound, or device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the board specifying the matter complained of.

(d) Any order under this section shall state the findings upon which it is based.

109325. This article and Article 1 (commencing with Section 109250) shall not apply to the use of any drug, medicine, compound, or device intended solely for legitimate and bona fide investigational purposes by experts qualified by scientific training and experience to investigate the safety and therapeutic value thereof unless the department shall find that the drug, medicine, compound, or device is being used in diagnosis or treatment for compensation and profit. In order to qualify for an exemption under this section there shall be on file with the federal Department of Health, Education, and Welfare a current and unrevoked investigational new drug application issued pursuant to subdivision (i) of Section 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)), or the following conditions shall be complied with:

- (a) The label of the drug, medicine, compound, or device shall bear the statement "Caution: New drug (or medicine or compound or device). Use in the diagnosis, treatment, alleviation, or cure of cancer limited by law to investigational use."
- (b) The drug, medicine, compound, or device has had adequate testing on appropriate experimental animals to demonstrate a lack of toxicity and hazard sufficient to permit its use in or on human beings and to establish with clarity the margins of safety ordinarily recognized by experts qualified by scientific training and experience to investigate the safety and effectiveness of the drugs, substances, or devices.
- (c) The drug, medicine, compound, or device is to be used solely for investigational use by, or under the direction of, an expert qualified by scientific training and experience to investigate the safety and effectiveness of the drug, medicine, compound, or device.
- (d) A written statement signed by the expert has been filed with the board. The statement shall show what facilities the expert will use for the investigation to be conducted by him or her, and that the drug, medicine, compound, or device will be used solely by him or her or under his or her direction for the investigation. The statement shall contain information identifying any assistant or agent of the expert who uses the drug, medicine, compound, or device under the direction of the expert.
- (e) Complete records of the investigation shall be kept by the expert and all records shall be made available by the expert for inspection upon the request of any agent of the board at any reasonable hour as long as the expert desires exemption.
- (f) The expert shall inform any persons who participate in the investigation as patients, that the drug, medicine, compound, or device is being used for investigational purposes and shall obtain the consent of the persons or their representatives.

109330. Section 109300 does not apply to any device used within the scope of his or her license privileges by a physician and surgeon or dentist licensed as such in this state.

109335. The failure of any individual, person, firm, association, or other entity representing himself, or itself, as engaged in the diagnosis, treatment, alleviation, or cure of cancer to comply with any of the regulations adopted under this article and Article 1 (commencing with Section 109250) is a misdemeanor. A third, and subsequent violations, of this section is a felony. This article and Article 1 (commencing with Section 109250) shall not apply to any person who depends exclusively upon prayer for healing in accordance with the teachings of a bona fide religious sect, denomination, or organization, nor practitioner thereof.

109340. The investigation or testing of any product shall not be deemed to imply or indicate any endorsement of the qualifications or value of any product. No person shall make any representation that investigation or testing hereunder constitutes any approval or endorsement of his or her, or its, activities by the Cancer Advisory Council or the department. The investigation or testing of any product shall not be deemed to imply or indicate that the product is useless or harmful and during testing no person shall make any representation, except to the department or Cancer Advisory Council, that the product under test is discredited or that it has been found useless or harmful.

109345. Following an investigation or testing of the content or composition of any drug, medicine, compound, or device used by any individual, person, firm, association, or other entity in the diagnosis, treatment, alleviation, or cure of cancer, and after hearing as provided in Section 109270, the department,

upon recommendation of the Cancer Advisory Council, may direct that any individual, person, firm, association, or other entity shall cease and desist any further prescribing, recommending, or use of any drug, medicine, compound, or device, or any substantially similar drug, medicine, compound, or device, in the diagnosis or treatment of cancer. In the investigation or testing required by this article and Article 1 (commencing with Section 109250) to determine the value or lack thereof of any drug, medicine, compound or device in the diagnosis, treatment, or cure of cancer, the department shall, as it deems necessary or advisable, utilize the facilities and findings of its own laboratories or other appropriate laboratories, clinics, hospitals, and nonprofit cancer research institutes recognized by the National Cancer Institute, within this State or the facilities and findings of the Federal Government, including the National Cancer Institute. Upon a recommendation by the Cancer Advisory Council, the department shall arrange, by contract, for investigation by and submission to it of findings, conclusions, or opinions of trained scientists in the appropriate departments of universities, medical schools, clinics, hospitals, and nonprofit cancer research institutes recognized by the National Cancer Institute, and the submission to it of findings, conclusions, or opinions of other qualified scientists. Prior to the issuance of a cease and desist order under this section, the Cancer Advisory Council, by the affirmative vote of at least 11 of its members, at least one of whom shall not be a physician and surgeon, shall make a written finding of fact based on the investigation that the drug, medicine, compound, or device so investigated has been found to be either definitely harmful or of no value in the diagnosis, treatment, alleviation, or cure of cancer and the department must be satisfied beyond a reasonable doubt that the written findings of the fact are true.

109350. The department may direct that any individual, person, firm, association, or other entity shall cease and desist any further prescribing, recommending, or use of any drug, medicine, compound, or device for which no application has been approved under this article and Article 1 (commencing with Section 109250) unless its use is exempt under Section 109325 or 109330.

109355.

- (a) Any violation of this article and Article 1 (commencing with Section 109250), of the regulations adopted thereunder or of a cease and desist order issued by the department under Section 109345 or 109350 may be enjoined by the superior court in any county, on application of the department.
- (b) Proceedings under this section shall be governed by Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure.

109360. Any person against whom an injunction or cease and desist order has been issued, under this article and Article 1 (commencing with Section 109250), may not undertake to use in the diagnosis, treatment, alleviation, or cure of cancer any new, experimental, untested, or secret drug, medicine, compound, or device for which there is no approved application on file or that does not qualify for an exemption, without first submitting an application to the department.

109365. It is unlawful for any person, with the intent to defraud, to falsely represent and provide for compensation a device, substance, method or treatment as effective to diagnose, arrest, prevent, or cure cancer. Nothing in this section shall abridge the existent rights of the press.

109370. Except as provided in Section 109335, a violation of this article and Article 1 (commencing with Section 109250) is punishable by imprisonment in the county jail for a period not exceeding one year, or in the state prison, or by a fine not exceeding ten thousand dollars (\$10,000), or by both the imprisonment and fine.

109375. The director shall investigate possible violations of this article and Article 1 (commencing with Section 109250) and report violations to the appropriate enforcement authority.

109380. County health officers, district attorneys and the Attorney General shall cooperate with the director in the enforcement of this article and Article 1 (commencing with Section 109250).

109385. The department, upon recommendation of the Cancer Advisory Council, may from time to time publish reports based on its investigation or testing of any drug, medicine, compound, or device prescribed, recommended, or used by any individual, person, firm, association, or other entity, and when,

in the opinion of a majority of the members of the Cancer Advisory Council, the use of any drug, medicine, compound, or device in the diagnosis, treatment or cure of cancer constitutes an imminent danger to health or a gross deception of the public, the department may take appropriate steps to publicize the same.

109390. All hearings authorized by this article and Article 1 (commencing with Section 109250) shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1, Division 3, Title 2 of the Government Code.

109395. No provision of this article and Article 1 (commencing with Section 109250) shall preclude reconsideration of an application for use of any drug, medicine, compound or device for the diagnosis, treatment, alleviation or cure of cancer if new evidence or matter is presented to the department and the reconsideration is predicated upon compliance with the applicable sections of the law, and presentation of data developed subsequent to the applicable ruling of the board.

HEALTH AND SAFETY CODE
SECTION 111940-111945
Wholesale Foods

111940.

- (a) If any person violates any provision of Chapter 4 (commencing with Section 111950), Chapter 5 (commencing with Section 112150), Chapter 6 (commencing with Section 112350), Chapter 7 (commencing with Section 112500), Chapter 8 (commencing with Section 112650), Chapter 10 (commencing with Section 113025), or Article 3 (commencing with Section 113250) of Chapter 11 of this part, or Chapter 4 (commencing with Section 108100) of Part 3, or any regulation adopted pursuant to these provisions, the department may assess a civil penalty against that person as provided by this section.
- (b) The penalty may be in an amount not to exceed one thousand dollars (\$1,000) per day. Each day that a violation continues shall be considered a separate violation.
- (c) If, after examination of a possible violation and the facts surrounding that possible violation, the department concludes that a violation has occurred, the department may issue a complaint to the person charged with the violation. The complaint shall allege the acts or failures to act that constitute the basis for the violation and the amount of the penalty. The complaint shall be served by personal service or by certified mail and shall inform the person so served of the right to a hearing.
- (d) Any person served with a complaint pursuant to subdivision (c) of this section may, within 20 days after service of the complaint, request a hearing by filing with the department a notice of defense. A notice of defense is deemed to have been filed within the 20-day period if it is postmarked within the 20-day period. If a hearing is requested by the person, it shall be conducted within 90 days after the receipt by the department of the notice of defense. If no notice of defense is filed within 20 days after service of the complaint, the department shall issue an order setting the penalty as proposed in the complaint unless the department and the person have entered into a settlement agreement, in which case the department shall issue an order setting the penalty in the amount specified in the settlement agreement. When the person has not filed a notice of defense or where the department and the person have entered into a settlement agreement, the order shall not be subject to review by any court or agency.
- (e) Any hearing required under this section shall be conducted pursuant to the procedures specified in Section 100171, except to the extent they are inconsistent with the specific requirements of this section.
- (f) Orders setting civil penalties under this section shall become effective and final upon issuance thereof, and payment shall be made within 30 days of issuance. A copy of the order shall be served by personal service or by certified mail upon the person served with the complaint.
- (g) Within 30 days after service of a copy of a decision issued by the director after a hearing, any person so served may file with the superior court a petition for writ of mandate for review of the decision. Any person who fails to file the petition within this 30-day period may not challenge the reasonableness or validity of the decision or order of the director in any judicial proceeding brought to enforce the decision or order or for other remedies. Section 1094.5 of the Code of Civil Procedure shall govern any proceedings conducted pursuant to this subdivision. In all proceedings pursuant to this subdivision, the court shall uphold the decision of the director if the decision is based upon substantial evidence in the whole record. The filing of a petition for writ of mandate shall not stay any corrective action required pursuant to the Miscellaneous Food, Food Facility, and Hazardous Substances Act, as defined in subdivision (b) of Section 27, or the accrual of any penalties assessed pursuant to this section. This subdivision does not prohibit the court from granting any appropriate relief within its jurisdiction.
- (h) The remedies under this section are in addition to, and do not supersede, or limit, any and all other remedies, civil or criminal.

111945. In addition to injunctive relief, the court may impose as a civil penalty, damages up to a maximum amount of one thousand dollars (\$1,000) for each day the violation is continued. Damages shall be paid one-half to the State Treasury, and one-half to the county where the action is brought.

HEALTH AND SAFETY CODE
SECTION 111950-112130
California Food Sanitation Act

111950. "Food," as used in this chapter, includes all articles used for food, drink, confectionery, or condiment, whether simple or compound, and all substances and ingredients used in the preparation thereof.

111955. "Food processing establishment," as used in this chapter, shall mean any room, building, or place or portion thereof, maintained, used, or operated for the purpose of commercially storing, packaging, making, cooking, mixing, processing, bottling, canning, packing, slaughtering, or otherwise preparing or handling food except restaurants. "Food processing establishment" shall not include a cottage food operation that is registered or has a permit pursuant to Section 114365.

111960. Every food processing establishment shall be properly lighted, drained, plumbed, and ventilated; and shall be conducted with strict regard to the influence of lighting, drainage, plumbing, and ventilation upon the health of persons therein employed, and upon the purity and wholesomeness of the food therein produced, prepared for sale, manufactured, packed, stored, kept, handled, sold, or distributed.

111965. The floors, side walls, ceiling, furniture, receptacles, utensils, implements, and machinery of every food processing establishment shall at no time be kept in an unclean, unhealthful, or unsanitary condition. Any of the following is deemed to be "an unclean, unhealthful, or unsanitary condition":

- (a) If food in the process of manufacture, preparation, packing, storing, sale, or distribution is not securely protected from flies, dust, or dirt, and from all other foreign or injurious contamination.
- (b) If refuse, dirt, and waste products subject to decomposition and fermentation incident to the manufacture, preparation, packing, storing, selling, and distributing of food, are not removed daily.
- (c) If all trucks, trays, boxes, baskets, buckets, other receptacles, chutes, platforms, racks, tables, shelves, knives, saws, cleavers, and all other utensils, receptacles, and machinery used in moving, handling, cutting, chopping, mixing, canning, and all other processes employed in the preparation of food are not thoroughly cleaned daily.
- (d) If the clothing of employees is unclean or if they dress, undress, or leave or store their clothing in the place where the food is produced, prepared, manufactured, packed, sold or distributed.

111970. No live animal or fowl shall be kept or allowed in any establishment where food is prepared, manufactured, kept, stored, offered for sale or sold unless the establishment is exclusively devoted to the slaughter, processing and/or sale of the animal or fowl. This section does not apply to dogs used by uniformed employees of private patrol operators and operators of a private patrol service who are licensed pursuant to Chapter 11.5 (commencing with Section 7580) of Division 3 of the Business and Professions Code, while those employees are acting within the course and scope of their employment as private patrolmen.

The state department may adopt regulations as it determines are reasonably necessary under this section for the protection of the public health and safety.

111975. The side walls and ceilings of every bakery, confectionery, hotel, or restaurant kitchen shall be well plastered or ceiled with metal or lumber, or shall be oil painted or kept well lime washed, or otherwise kept in a good sanitary condition.

111980. All interior woodwork of every bakery, confectionery, hotel, or restaurant kitchen shall be kept well oiled or painted with oil paint, and shall be kept washed clean with soap and water, or otherwise kept in a good sanitary condition.

111985. Every building, room, basement, or cellar occupied or used for the preparation, manufacture, packing, storage, sale, or distribution of food shall have an impermeable floor, made of cement, or of tile laid in cement, brick, wood, or other suitable, nonabsorbent material that can be flushed and washed clean with water.

111990. Where practicable, the doors, windows, and other openings of every food producing or distributing establishment shall be fitted with stationary or self-closing screen doors and wire window screens, of not coarser than 14 mesh wire gauze.

111995. Every building, room, basement, or cellar occupied or used for the production, preparation, manufacture, packing, canning, sale, or distribution of food shall have convenient toilet or toilet-rooms, separate and apart from the room or rooms where the process of production, preparation, manufacture, packing, canning, selling, or distributing is conducted.

112000. The floors of toilet-rooms shall be made of cement, or of tile laid in cement, wood, brick, or other nonabsorbent material, and shall be washed and scoured daily.

112005. The toilets shall be furnished with separate ventilating pipes or flues discharging either into soil pipes or on the outside of the building in which they are situated.

112010. Lavatories and washrooms shall be adjacent to toilet-rooms and shall be supplied with soap, running water, and towels, and shall be maintained in a clean and sanitary condition.

112015. Employees and others who handle the material from which food is prepared or the finished product shall before beginning work and immediately after visiting a toilet or lavatory, wash their hands and arms thoroughly in clean water.

112020. No employee or other person shall sit or lie upon any table, bench, trough, shelf, or other equipment that is intended for use in connection with any food manufacturing process.

112025. No employee or other person shall expectorate or discharge any substance from his or her nose or mouth on the floor or interior side wall of any building, room, basement, or cellar where the production, preparation, manufacture, packing, storing, or sale of any food is conducted.

112030. No person shall, nor shall any person be allowed to, reside or sleep in any room of a bake-shop, public dining room, hotel or restaurant kitchen, confectionery, or other place where food is prepared, produced, manufactured, served, or sold.

112035. No employer shall require or permit any person to work, in a food processing establishment or vehicle used for the production, preparation, manufacture, sale, or transportation of food if the person is infected with any contagious, infectious, or communicable disease that can be transmitted by the food involved.

112040.

- (a) Prior to January 1, 2001, the department, its inspectors and agents, and all local health officers and inspectors may at all times enter any building, room, basement, cellar, or other place occupied or used, or suspected of being occupied or used, for the production, preparation, manufacture, storage, sale, or distribution of food, and inspect the premises and all utensils, implements, receptacles, fixtures, furniture, and machinery used.
- (b) Commencing January 1, 2001, only the department, its inspectors and agents, and the local health officers and inspectors of Los Angeles, San Bernardino, and Orange Counties and the City of Vernon may exercise the authority to enter and inspect granted in subdivision (a) except as provided in subdivision (c).
- (c) Commencing January 1, 2001, the local health officer or inspector of each city or county, or city and county may exercise the authority to enter and inspect granted in subdivision (a) for the sole purpose of inspecting a food processing establishment that only holds or warehouses processed food, provided that:
 - (1) The warehouse does not manufacture or pack processed food.
 - (2) The warehouse does not hold fresh seafood, frozen seafood held in bulk for further processing, or fresh or frozen raw shellfish.

- (3) The warehouse is not operated as an integral part of a food processing facility required to be registered pursuant to Section 110460.
 - (4) The warehouse facilities are located entirely within the area under the jurisdiction of the local health department.
 - (5) The warehouse does not salvage food as the primary business.
- (d) All inspections of food processing establishments conducted by local health departments shall be reported to the department within 60 days. The department shall consider this information when scheduling the department's inspection activities.

112045. If upon inspection any building, room, basement, cellar, or other place, or any vehicle, employer, employee, or other person is found to be in violation of or violating any of the provisions of this article, or if the production, preparation, manufacture, packing, storing, sale, or distribution of food is being conducted in a manner detrimental to the health of the employees or to the character or quality of the food being produced, prepared, manufactured, packed, stored, sold, distributed, or conveyed, the person making the inspection shall at once make a written report of the violation to the district attorney of the county, who shall prosecute the violator. He or she shall make a like report to the department. The department, from time to time, may publish the reports in its monthly bulletin.

112050. Every building, room, basement, cellar, or other place or thing kept, maintained, or operated in violation of this article, and all food produced, prepared, manufactured, packed, stored, kept, sold, distributed, or transported in violation of this article, is a public nuisance dangerous to health. Any such nuisance may be abated or enjoined in an action brought for that purpose by the local or state department or may be summarily abated in the manner provided by law for the summary abatement of public nuisances dangerous to health.

112055. The sections contained in this article are to be known as the California Food Sanitation Act.

112060. "Bottle," as employed in this article, includes any bottle or any glass or crockery food container, other than one not previously used, that is used or sold for use in the manufacture, production, preparation, compounding, blending, or packing for sale of any food, drug, or liquor.

112065. This article is not applicable to containers subject to Division 15 (commencing with Section 32501) of the Food and Agricultural Code.

112070. The provisions of this article in reference to sterilization procedures and methods in cleaning bottles, as in this article defined, shall apply to all persons cleaning previously used bottles who are engaged in the business of packaging food, drugs, or liquors and to all persons maintaining a place of business for the cleaning and resale of the bottles sold for and to be used for packing a food, drug or liquor.

The sale for use of any such bottle by any person not licensed by the board as herein provided, when the use intended by purchaser is to package for sale a food, drug or liquor produced or packaged by the purchaser is unlawful, except in the case of a sale to a purchaser for export out of this state or who is engaged in the business of packaging food, drugs, or liquors at a fixed place of business in this state and is equipped to cleanse and sterilize bottles as in this article provided.

112075. The department shall issue a license to an applicant therefor upon the receipt of the evidence as the department may require showing that the applicant is properly equipped for the cleansing and sterilization of bottles as provided in this article, or at its option upon the recommendation of a city, county or city and county health officer. This license is nontransferable. The license provisions of this article shall not apply to food, drug or liquor manufacturers or packers who buy bottles for their own use and purposes, but do apply to any other person, firm or corporation engaged in the business of cleaning, sterilizing and reselling bottles to manufacturers or packers except as hereinabove provided.

112080. An establishment is deemed properly equipped for the cleansing and sterilization of bottles if it maintains and employs the following standards:

- (a) Cleanses and sterilizes bottles by first soaking them in a hot caustic solution of not less than 120 degrees F. for a period of not less than five minutes which temperature shall be indicated by a thermometer. The solution shall contain not less than 2 1/2 percent of caustic soda expressed in terms of sodium hydrates.
- (b) Changes the cleansing solution frequently so as to prevent its becoming foul and insanitary.
- (c) Thoroughly rinses the bottles after the soaking.

112085. All bottles shall be cleansed and sterilized as specified in Section 112080, and shall be kept free from rust or contamination.

112090. A licensee shall issue a certificate of sterilization with each shipment of bottles to a purchaser, stating that the licensee has cleansed and sterilized the bottles in the manner required by this article.

112095. If any licensee fails to maintain his or her equipment and to cleanse or sterilize any bottle in the manner required by this article, and issues a certificate knowing its contents to be untrue the state department may revoke or suspend his or her license after a hearing. The proceedings for the revocation or suspension of a license shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the state department shall have all the powers granted therein.

112100. Any purchaser of a bottle who shows a certificate of sterilization signed by a licensed seller thereof complies sufficiently with this article.

112105. Nothing in this article prohibits the sale for use of any uncleaned or unsterilized bottle to a purchaser who is licensed under this article.

112110. Food containers manufactured from second-hand tin plate and intended for the packing of hermetically sealed canned food products intended to be used for human consumption shall not be so used unless the tin plate from which they are manufactured has, prior to their manufacture, been cleansed and sterilized by thorough immersion in boiling water, and then dried on hot rolls or by the use of heated air. The board may inspect any place where the containers are manufactured for the purpose of enforcing this section.

112115. This article, with the exception of any licensing provisions, may be enforced by any local enforcement division, which shall be construed to mean the local health department, headed by the duly appointed, qualified and acting health officer of any county, city or city and county. The territory may include one or more counties, cities, or cities and counties.

112120. A nonalcoholic soft drink, whether or not carbonated, shall be deemed to be misbranded if in a bottle or other closed container unless the name and address of the bottler or distributor thereof appears on the container by being molded, printed, or otherwise labeled thereon, or the name and address is shown on the crown or cap of the container if the container is a permanently and distinctively branded bottle. The beverage shall not be deemed to be misbranded under this section if in a bottle or other closed container on which is molded, printed or otherwise labeled the product name, trademark or brand of the distributor or bottler thereof and if a sworn affidavit has been filed with the department stating the name, trademark, or brand of the beverage, a full and complete description of each territory or area of the state in which the beverage is to be distributed, and the names and addresses of the persons as are responsible for the Miscellaneous Food, Food Facility, and Hazardous Substances Act (Section 27) in the bottling and distribution of the beverage in each territory or area of the state in which the beverage is distributed. Nothing in this section shall be deemed to exempt any bottler or distributor of a beverage or beverages from any provision of Part 5 (commencing with Section 109875).

112125. Except when sold in bulk for manufacturing purposes, it is unlawful to sell or otherwise dispose of at retail jams, jellies, preserves, marmalades, peanut butter, horse-radish, mayonnaise, or salad dressings other than in closed containers approved by the department, when the department determines that any

other method of sale or disposition of any such food or food product is conducive to its contamination by flies, insects, dust, dirt, or foreign material of any kind whatsoever.

112130. Any person, whether as principal or agent, employer or employee, who violates any of the provisions of this chapter is guilty of a misdemeanor punishable upon conviction by a fine of not more than one thousand dollars (\$1,000), or by imprisonment in the county jail for not more than six months, or by both the fine and imprisonment. Each day's violation is a separate and distinct offense.

CALIFORNIA HEALTH AND SAFETY CODE
SECTION 112150-112280
Sanitary Control of Shellfish

112150. The Legislature finds and declares that the public health interest requires that the people of this state be protected from adulterated shellfish grown and harvested in state waters for sale to the public and for introduction into interstate commerce. This protection is a matter of statewide concern and the purpose of this chapter is to establish uniform sanitation standards for the growing waters, harvesting, shucking, packing, repacking, and handling of shellfish and shellstock intended for human consumption.

112155. Unless the context otherwise requires, the definitions set forth in this article govern the construction of this chapter.

- (a) "Shellfish" means native or nonnative bivalve mollusks, which include oysters, rock scallops, clams, and mussels, either fresh or frozen, and either shucked or in the shell.
- (b) "Shellstock" means shellfish which remain in their shells.
- (c) "Growing area" means any offshore ocean, coastal estuarine, or freshwater area that may be classified by the department for natural shellfish growth or artificial shellfish propagation and includes open seawater systems.
- (d) "Approved area" means a shellfish-growing area not adversely affected by sewage or other wastes.
- (e) "Conditionally approved area" means a shellfish-growing area that may be occasionally affected by sewage or other wastes.
- (f) "Prohibited area" means a shellfish-growing area not certified because of its proximity to a waste discharge or because the area is influenced by other detrimental environmental factors.
- (g) "Restricted area" means a shellfish-growing area subjected to a limited degree of pollution which makes it unsafe to harvest shellfish for direct marketing but where harvesting for relaying or depuration may be permitted.
- (h) "Other wastes" means wastes, such as, but not limited to, animal, industrial, radiological, and agricultural wastes which would render shellfish unsafe or unfit for human consumption.
- (i) "Department" means the State Department of Health Services.
- (j) "Director" means the State Director of Health Services.
- (k) "Person" includes any individual, partnership, corporation, limited liability company, and association.
- (l) "Closed area" means an area that the shellfish taken therefrom have been declared to be unsafe or unfit for human consumption.

112160.

- (a) The director may declare any area within the jurisdiction of this state to be a closed area if it is determined that shellfish taken from the growing area may be unsafe or unfit for human consumption.
- (b) The director shall close to the taking of shellfish for a period deemed advisable any waters to which shellfish from a closed area may have been transferred.
- (c) The director shall establish by order the areas that he or she declares unsafe or unfit for shellfish harvesting and shall modify or revoke the order in accordance with the results of chemical, toxicologic, and bacteriological surveys conducted by the department.

The director shall file the order in the office of the department, and shall furnish copies of the orders describing closed areas to the Department of Fish and Game, the State Water Resources Control Board, and to any interested person without charge.

- (d) Prior to the director's declaration that shellfish-growing waters may be unsafe and shellfish grown in these waters may not be taken for human consumption, the department shall do all of the following:
 - (1) Give at least 20 days' notice of its intended action. The notice shall include a statement of either the terms or substance of the intended action or a description of the subject and issues involved, and the time when, the place where, and the manner in which, interested persons may present their views thereon.
 - (2) Afford all interested persons reasonable opportunity to submit data, views, or arguments orally or in writing. The department shall consider fully all written and oral submissions respecting the proposed action.

- (e) If the department finds that the shellfish harvested from an area is unsafe or unfit for human consumption and states in writing its reasons for that finding, it may proceed without prior notice or hearing to take emergency action. The action may be effective for a period of not longer than 30 days, during which time the department shall initiate the procedures contained in subdivision (d).

112165.

- (a) The department shall adopt regulations regarding all of the following:
 - (1) The classification and minimum requirements for growing and harvesting areas, for relaying and depuration procedures, and for aquaculture facilities that are used for the cultivation and production of shellfish.
 - (2) Specifications for plant facilities and for the harvesting, transporting, storing, handling, packing, and repacking of shellfish.
 - (3) Fees.
- (b) The department shall adopt regulations by January 1, 1999, to interpret and enforce the provisions of this chapter. 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.
- (c) The regulations shall conform, so far as possible, to the standards or procedures established in the guidelines adopted by the National Shellfish Sanitation Program that pertain to the evaluation of shellfish-growing areas and handling facilities, but shall provide for regulating other wastes or contaminants not covered by the guidelines adopted by the National Shellfish Sanitation Program that would render shellfish unsafe or unfit for human consumption. If the department adopts standards or procedures that exceed standards or procedures established in the guidelines adopted by the National Shellfish Sanitation Program, the department shall provide a written finding describing the public health need for those standards and procedures in the rulemaking process.

112170.

- (a) The director, or the director's duly authorized agent, shall conduct sanitary surveys of any shellfish growing water as deemed necessary to assure each of the following:
 - (1) Any shellfish grown in the water is safe as an article of food and meets bacteriological, chemical, and toxicologic standards as prescribed by regulation.
 - (2) Any shellfish grown in prohibited or restricted areas is either relayed to or depurated in approved water for a period of time as necessary to meet bacteriological, chemical, and toxicologic standards, as prescribed by regulation.
 - (3) For good cause shown, a shellfish grower or harvester may request the resurvey of restricted or unapproved growing water, and the director, or the director's duly authorized agent, shall conduct the sanitary resurvey.
- (b) If it is found that the shellfish and growing water are in compliance with the regulations promulgated under this chapter, the director shall issue a certificate attesting to the compliance to the lawful grower or harvester of the shellfish.

112175. It is unlawful for any person to engage in commercial shellfish cultivation or the harvesting for human consumption of shellfish from naturally occurring populations, except as provided for in Sections 5670, 7850, 8500, and 15101 of the Fish and Game Code and in regulations adopted by the department pursuant to this chapter, with regard to growing areas, relaying and depuration procedures, and aquaculture facilities.

112180. The director, or the director's duly authorized agent, may, at any reasonable hour of the day, do any of the following:

- (a) Enter and inspect any facility or area used for cultivation, production, depuration, processing, transporting, or sale of shellfish.
- (b) Obtain samples of water and shellfish. Upon request, split samples shall be given to the person from whose property the samples were obtained.
- (c) Inspect all shellfish plants and the practices followed in the handling and packaging of shellfish. If it is found that the operator is complying with the regulations promulgated under this chapter, the director shall issue a certificate attesting to the compliance.

- (d) Cause a reinspection to be made at any time and may revoke the certificate upon refusal of the operator to permit an inspection or free access at all reasonable hours, or upon a finding that the plant is not being operated in compliance with the regulations promulgated under this chapter.
- (e) No revocation, suspension, annulment, or withdrawal of any certificate is lawful unless, prior to the institution of department proceedings, the department gave notice by mail, to the certificate holder, of facts or conduct that warrants the intended action, and the certificate holder was given an opportunity to show compliance with all lawful requirements for the retention of the certificate, pursuant to Section 112265. This section does not preclude the department from taking immediate action in accordance with subdivision (e) of Section 112160.

112185. It is unlawful for any person to take, sell, offer, or hold for sale any shellfish from an area declared by the director to be unsuitable for harvesting for human consumption, without complying with all regulations adopted by the department to ensure that the shellfish have been purified.

The intent of this section is not to prohibit the transplanting of shellfish from restricted or prohibited growing areas, if permission for the transplanting is first obtained from the Department of Fish and Game pursuant to Section 237 of Title 14 of the California Code of Regulations.

112190. It is unlawful for any person to sell, offer, or hold for sale any shellstock or shucked shellfish that has not been harvested from a growing area which has been certified by the department or that has not been purified in accordance with Section 112170.

112195. It is unlawful for any person to sell, offer, or hold for sale any shellstock or shucked shellfish that has not been handled and packaged in accordance with specifications under this chapter, and regulations adopted pursuant to this chapter.

112200. It is unlawful for any person to sell, offer, or hold for sale any shellfish where the facilities for packaging and handling of the shellfish do not comply with regulations adopted by the department under this chapter.

112205. It is unlawful for any person to operate a shellfish plant engaged in the handling and packaging of shellfish, either shucked or in the shell, without a valid certificate issued by the department for each plant or place of business.

112210. It is unlawful for any person to sell, offer, or hold for sale any shellstock or shucked shellfish without a label that bears a valid certificate number and is in compliance with Chapter 4 (commencing with Section 110290) of Part 5.

112215. It is unlawful for any person to sell, offer, or hold for sale any shellfish not in a container bearing a valid certificate number from a state or a nation whose shellfish certification program conforms to the then current Manual of Recommended Practice for Sanitary Control of the Shellfish Industry, issued by the United States Public Health Service.

112220. The provisions of Sections 112210 and 112215, with respect to labeling requirements, shall not apply to any of the following:

- (a) Shellstock held in dry storage under refrigerated conditions not for shipment or sale.
- (b) Shellstock sold on premises when the sale is the ultimate point of sale.

112225. Any shellfish that are held or offered for sale at retail or for human consumption, and that have not been handled and packaged in accordance with the specifications fixed by the department under this chapter, or that are not in a certified container as provided in Sections 112210 and 112215, or that are otherwise found by the director to be unfit for human consumption, are subject to immediate condemnation, seizure, and confiscation by the director or the director's duly authorized agent. The shellfish shall be held, destroyed, or otherwise disposed of as directed by the director.

112230. The director may suspend or revoke any certificate issued pursuant to this chapter for any violation of this chapter or the regulations adopted pursuant thereto.

112235. The department shall charge and collect a fee for each certificate issued. The amount of the fee shall be established by regulation.

112240. Any person who willfully violates any provision of this chapter, or any regulation adopted pursuant to this chapter, is guilty of a misdemeanor and shall, if convicted, be subject to imprisonment for not more than six months in the county jail or a fine of not less than one hundred dollars (\$100) nor more than five hundred dollars (\$500), or both. If the violation is committed after a previous conviction under this section that has become final, or of the violation is committed with the intent to defraud or mislead, the person shall be subject to imprisonment for not more than one year in the county jail or a fine of not more than one thousand dollars (\$1,000), or both.

112245. One-half of all fines collected by any court or judge for any violation of any provision of this chapter shall be paid into the State Treasury to the credit of the General Fund.

112250.

- (a) The Attorney General, any district attorney, or any city attorney to whom the department reports any violation of this chapter shall begin appropriate proceedings in the proper court.
- (b) Before any alleged violation of this chapter 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

112255. The department is not required to institute proceedings under this chapter for minor violations of this chapter, if the department believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

112260. When the state asserts a violation of this chapter, the state need not negate any exemption or exception from the requirements of this chapter in any pleading, or in any trial, hearing, or other proceeding. The burden of proof with respect to any exemption or exception rests upon the person claiming its benefits.

112265.

- (a) Except to the extent otherwise provided in Section 112160 and subdivision (e) of Section 112180, or when a violation is asserted pursuant to Section 112240, when the department asserts a violation of this chapter, all affected persons shall be afforded an opportunity for an administrative hearing after 20 days notice.
- (b) The notice shall include all of the following:
 - (1) A statement of the time, place, and nature of the hearing.
 - (2) A statement of the legal authority and jurisdiction under which the hearing is to be held.
 - (3) A reference to the particular sections of the statutes, regulations, and rules involved.
 - (4) A short and plain statement of the matters asserted.
- (c) Opportunity shall be afforded all persons to respond and present evidence on the issues involved.
- (d) Hearings authorized or required by this chapter shall be conducted by the department or any agent as the department may designate for that purpose.
- (e) Oral proceedings or any part thereof shall be transcribed at the request of any person. The person requesting the transcription shall bear the cost of the transcript.
- (f) Final decisions or orders adverse to any person shall be in writing or stated in the record. A final decision shall include findings of fact and conclusions of law, that shall be separately stated. Persons shall be notified either personally or by mail of any decision or order.

112270. In lieu of administrative proceedings pursuant to Section 112265, the department may proceed under Section 119940.

112275. A person who has exhausted all administrative remedies available within the department and who is aggrieved by a final decision or order is entitled to judicial review pursuant to this chapter.

112280. All regulations applicable to this chapter, and currently in effect at the time this chapter takes effect, shall remain in effect until the department adopts regulations pursuant to Section 112165.

CALIFORNIA HEALTH AND SAFETY CODE
SECTION 112350-112495
Cold Storage

112350. Unless the context otherwise requires, the definitions set forth in this article govern the construction of this chapter.

112355. "Cold storage" means a place artificially refrigerated to a temperature above zero of 45 degrees Fahrenheit or below. It does not include any place where food that is privately owned and not held for resale is stored inside of lockers or compartments that are not more than 25 cubic feet in capacity, and which lockers or compartments are leased to private individuals for their exclusive use.

112360. "Cold stored" means the keeping of articles of food in cold storage for a period exceeding ten days.

112365. "Article of food" means any article of food used for human consumption. It includes fresh meat and fresh meat products (except in process of manufacture), fresh and dried fruit or vegetables, fish, shellfish, game, poultry, eggs, butter, and cheese, but not malt beverages.

112370. "Storer" means a person who offers articles of food for cold storage.

112375. This chapter does not apply to any cold storage or refrigerating plant or warehouse that is maintained or operated by a restaurant, hotel, exclusively wholesale or retail establishment, cannery, winery, brewery, or other food processing place that is used for the storage of food and which place is owned by or is for the exclusive use of the occupant owner or maintainer thereof, and said food is not stored for other persons.

112380. The term "locker plant" as used in this chapter shall mean any building or portion thereof that is artificially cooled to or below a temperature above zero of 45 degrees Fahrenheit and used exclusively for the storage of any article of food for the sole use of the storer, and that article or articles of food are not for resale.

If any article or articles of food stored in locker plants are for resale and/or to be used for manufacturing purposes, said locker plant is subject to the license provisions of this chapter and all sections thereof.

112385. Any person desiring to operate a cold storage or refrigerating warehouse for storing articles of food shall make application in writing to the board for a license for that purpose, stating the location of his or her plant or plants. For the purpose of securing the proper enforcement of this chapter, those buildings or structures that are served by a central refrigerating plant shall be considered as one cold storage or refrigerating warehouse or plant, and subject to one license.

112390. On receipt of the application the board shall examine into the sanitary condition of the plant.

112395. If it finds the plant to be in a sanitary condition and otherwise properly equipped for the business of cold storage, the state department, upon the payment of the license fee specified in this chapter, shall issue a license authorizing the applicant to operate a cold storage or refrigerating warehouse for a period of not more than one year.

112400. No person, firm, or corporation shall engage in the operation of a cold storage or refrigerating warehouse for storing articles of food without having obtained from the state department a license for each such place of business. This license is nontransferable.

112405. Each application for a license under this chapter shall be accompanied by a fee of fifty dollars (\$50). Each license issued under this chapter shall expire on December 31st of each calendar year. License fees of fifty dollars (\$50) are due on the first of January of each year. The fee for licenses initially issued after January 1st of each year shall not be prorated.

112410. The director shall keep a full and correct account of all fees received under this chapter. At least once each month he or she shall deposit all the fees with the Treasurer for credit to the General Fund.

112415. If any place or portion of a place for which a license is issued is deemed by the department to be in an unsanitary condition, the department shall give written notification to the licensee of the condition, stating in particular the matters found to be unsanitary.

112420. Upon failure of the licensee to correct the situation within a designated time the department shall prohibit the licensee from using the place or specified portion until such time as it is restored to a sanitary condition.

112425. Every licensee shall keep an accurate record of receipts and withdrawals of articles of food, and the department shall have free access to these records at any time.

112430. When requested by the department or an agent thereof, any licensee shall within a reasonable time submit a report setting forth in itemized particulars the quantity of food products held by him or her in cold storage.

112435. No storer shall place in cold storage any article of food whose keeping qualities have been impaired by disease, taint, or deterioration, or that has not been slaughtered, handled, and prepared for storage in accordance with food laws pertaining thereto and the regulations as may be prescribed by the state department for the sanitary preparation of food products for cold storage.

112440. Any article of food intended for use other than human consumption shall, before being cold stored, be marked by the owner in accordance with forms prescribed by the department in a way as to indicate plainly that the article is not to be sold for human food.

112445. Each separate lot of food, when deposited in cold storage, shall be marked plainly with the lot number covering that particular lot of articles of food indicated and recorded on the records maintained on the premises.

112450. The department shall inspect and supervise all cold storage or refrigerating warehouses, and make the inspection of the entry of articles of food therein as it deems necessary to secure the proper enforcement of this chapter.

112455. The department and its duly authorized employees shall be permitted access to cold storage or refrigerating warehouses at all reasonable times for purposes of inspection and enforcing this chapter.

112460. The department may also appoint at the salary as it may designate, any person it deems qualified to make any inspection required by this chapter.

112465. No person shall keep any article of food in cold storage for more than twelve calendar months, except with the consent of the board. Thirty days prior to the expiration of the 12-month period, the licensee shall send notice to the board advising them of this fact. Duplicate notice shall be sent to the owner of the food.

112470. The department shall, upon application, grant permission to extend the period of storage beyond 12 months for a particular consignment of goods, if the goods in question are found, upon examination, to be in proper condition for further storage at the end of 12 months. The length of time for which further storage is allowed shall be specified in the order granting the permission.

112475. For the purpose of determining whether or not food locker plants come under the provisions of this chapter, the operators or owners of all such frozen food locker plants shall make available, upon request to any agent of the department, the names and addresses of any and all persons, firms, or corporations renting, leasing, or occupying the lockers or compartments.

112480. Unless otherwise permitted by this article, it is unlawful to represent or advertise as fresh goods articles of food that have been placed in cold storage. This section shall not apply to vegetables, fruit or other foods sold as "fresh frozen" and so labeled, when stored at or below zero degrees Fahrenheit, or to eggs held in cold storage for 30 days or less.

112485. It is unlawful to return to cold storage any article of food that has once been released from such storage and placed on the market for sale to consumers. However, nothing in this section prevents the transfer of goods from one cold storage or refrigerating warehouse to another, if the transfer is not made for the purpose of evading any provision of this chapter.

112490. The department may make regulations to secure the proper enforcement of this chapter, including regulations with respect to the sanitary preparation of articles of food for cold storage, the use of marks, tags, or labels, and the display of signs

112495. Any person violating any of the provisions of this chapter, or any rule or regulation issued pursuant to this chapter, shall upon conviction be punished for the first offense by a fine not exceeding one thousand dollars (\$1,000) or by imprisonment for not more than 90 days, or by both. The punishment for a second offense is the same, except that the maximum fine is two thousand dollars (\$2,000).

CALIFORNIA HEALTH AND SAFETY CODE
SECTION 112500-112635
Frozen Foods

112500. When used in this chapter, unless the context otherwise requires:

- (a) "Food" means any article used by man for food, drink, confectionery or condiment, or which enters into the composition thereof, whether simple, blended, mixed or compounded.
- (b) "Locker" means the individual sections or compartments of a capacity of not to exceed 25 cubic feet in the locker room of a frozen food locker plant.
- (c) "Frozen food locker plant" means an establishment in which space in the individual lockers is rented, leased, or loaned to individuals, firms, or corporations, for the storage of food for their own use and which is artificially cooled for the purpose of preserving the food. The term includes service locker plant, storage locker plant, and branch locker plant.
- (d) "Service locker plant" means a frozen food locker plant in which patrons' foods are prepared or packaged by the operator of the plant before the foods are placed in the lockers for storage.
- (e) "Storage locker plant" means a frozen food locker plant, the operator of which does not prepare or package the foods of patrons.
- (f) "Branch locker plant" means a frozen food locker plant in any location or establishment artificially cooled in which space in individual lockers is rented, leased, or loaned to individuals, firms, or corporations for the storage of food for their own use after preparation for storage in a central or parent plant.
- (g) "Frozen" means food frozen in a room or compartment in which the temperature is plus 5 degrees Fahrenheit or lower.
- (h) "Temperature" means the average air temperature in refrigerated rooms.
- (i) "Department" means the State Department of Health Services.
- (j) "Operator" means any person, firm or corporation operating or maintaining a frozen food locker plant.
- (k) "Processor" means an establishment in which, for compensation directly or indirectly, meat or meat products are cut, wrapped, or frozen to be delivered for frozen storage by the ultimate consumer.

112505. No person hereafter shall engage within this State in the business of operating any frozen food locker plant without having applied for and obtained from the director of the department a license for each such place of business. Applications for the license shall be made in writing to the director of the department, on the forms and with the pertinent information as he or she may deem necessary. These licenses shall be granted promptly as a matter of right unless conditions exist that are grounds for denial of a license, as hereinafter set forth.

112510. The annual license fee for a frozen food locker plant shall be twenty-five dollars (\$25). Such fees shall be paid into the General Fund.

112515. Upon receipt of the application for a license accompanied by the required fee, the department shall promptly inspect the plant to be licensed and shall issue a license; provided, the plant, its equipment, facilities and its surrounding premises, and its operations comply with this chapter and regulations pertaining to this chapter. The department shall inspect all frozen food locker plants licensed under this chapter, whenever the department considers the inspection necessary. The department and its representatives shall have access to the plants at all reasonable times for the purpose of making inspections.

112520. The license issued hereunder shall be in a form as the department shall prescribe and shall be under the seal of the department and shall set forth the name of the licensee, the location for which the license is issued, the period of the license and other information as the department may determine. Licenses shall be for a term of one calendar year and shall be renewed annually. The license is nontransferable. The original license or a certified copy thereof shall be conspicuously displayed by the licensee in the locker plant for which the license is issued.

112525. The floors, walls and ceilings of frozen food locker plants shall be of a construction and finish that they can be conveniently maintained in a clean and sanitary condition. The lockers in any plant shall be so

constructed as to protect the contents from contamination, deterioration or injury. Lockers with perforated bottoms shall be provided with a suitable unperforated liner or tray.

112530. Any frozen food locker plant using a toxic gas refrigerant shall have at least one gas mask of a type approved by the department and shall keep the same where it will be readily accessible.

112535. All rooms of a frozen food locker plant shall at all times be maintained in a clean and sanitary condition. All equipment and utensils shall be cleaned when put into use and shall be thoroughly cleaned after each day's use and shall be so stored or protected as not to become contaminated. Lockers shall be thoroughly cleaned before they are leased or put into the possession of any patron. The premises and surroundings of the plants shall be maintained in a clean and sanitary condition. The food stored shall be protected from filth, flies, dust, dirt, insects, vermin and any other contamination and from any unclean or filthy practice in the handling thereof or caring therefor. No food shall be stored in a condition or in a manner as to cause injury to or deterioration of articles of food in adjacent lockers.

112540. Frozen food locker plants shall have an ample water supply readily available and the water that comes in contact with any food product or the equipment shall be uncontaminated. Such plants shall be provided with adequate toilet facilities so located as to be readily accessible to employees and equipped with adequate washing fixtures or have such fixtures or facilities convenient thereto and shall be supplied with running water, single soap and single towel service. The doors of all toilet rooms shall be full length and self-closing and no toilet room shall open directly into any room in which foods are prepared, processed, chilled, frozen or stored. Toilet facilities and rooms shall be kept in a clean and sanitary condition.

112545. The director shall publish and declare reasonable regulations as are consistent with the enforcement of the provisions of this chapter providing for adequate cleanliness and sanitation to protect public health.

112550. The refrigeration system for a frozen food locker plant shall be equipped with reliable controls for the maintenance of uniform temperatures as required in the various refrigerated rooms and shall be of adequate capacity to provide under extreme conditions of outside temperature and activity of the plant, the following temperatures in the several rooms, respectively:

- (a) In pre-cool, chill, or aging rooms, temperatures shall be commensurate with good commercial practice.
- (b) In locker rooms, temperature shall not exceed plus five (5) degrees Fahrenheit, with customary commercial variations. The foregoing temperatures shall not be construed as prohibiting variations therefrom as may occur during short periods of time incidental to operating conditions beyond the control of the operator.

112555. Any processor, prior to delivery to the consumer, shall quick-freeze all meat or meat products in a blast-type freezing room at zero degrees Fahrenheit with one side of the package exposed to circulated air, or in a still-air-type freezing room at a minimum of minus 10 degrees Fahrenheit with one surface side of each package in direct contact with coils of a freezing plate. This section shall not apply to the sale of retail cuts of meat sold over the counter.

112560. Thermometers in good order shall be provided in all rooms held under low temperature at locations therein that will reflect true storage temperatures of foods in the rooms.

112565. No frozen food locker plant shall be licensed under this chapter unless the following facilities are provided: Sufficient chill or aging room space, freezing facilities, locker room, and facilities for cutting, preparing, wrapping and packaging meats and meat products, except that storage locker plants and branch locker plants need install only locker room facilities as specified in Section 112550.

112570. A branch plant may be operated only in conjunction with a parent locker plant that shall have processing facilities sufficiently large for the locker plant and all branch plants.

112575. Storage of fish and game by patrons shall comply with federal and state fish and game laws. All pertinent abstracts of state and federal fish and game regulations shall be furnished by the department and shall be conspicuously displayed in the locker plant.

112580. Every operator of a frozen food locker plant, shall keep a record showing names and addresses of renters of lockers and the records shall be available for examination by the Director of Food and Agriculture or his or her representatives, or the department or its representatives, during business hours of the plants.

112585. Only food for human consumption, or clean, sanitary byproducts therefrom to be used for food, shall be stored in the frozen food locker plant. Each package of food wrapped and frozen for storage shall be labeled designating the product and identifying the processor.

112590. The person owning or operating a frozen food locker plant shall have a lien upon all property therein for all charges due from the owner of the property. The lien may be secured and enforced in the same manner as warehousemen's liens are secured and enforced.

112595. Operators of frozen food locker plants operating solely as such shall not be construed to be warehousemen or public utilities, nor shall receipts or other instruments issued by those persons in the ordinary conduct of their locker business be construed to be warehouse receipts or subject to the laws applicable thereto.

112600. Cold storage or refrigerating warehouses subject to Chapter 6 (commencing with Section 112350) shall be exempt from the licensing provisions of this chapter.

112605. The licensing provisions of this chapter shall not apply to retail premises in which individual frozen food lockers are not rented, leased, loaned, or otherwise furnished to individuals, firms or corporations, or processors.

112610. The department, after notice and hearing, may revoke the license issued for any frozen food locker plant for failure to comply with the provisions of this chapter. The proceedings under this section shall be conducted in accordance with Chapter 5 of Part 1 of Division 3 of Title 2 of the Government Code, and the department shall have all the powers granted therein.

112615. In the event the director suspends or revokes any license, the licensee may obtain judicial review of the order by filing a petition for a writ of mandate in accordance with the Code of Civil Procedure in the superior court of the county in which the licensed premises are located within thirty (30) days from the date notice in writing of the director's order revoking or suspending the license has been served upon said licensee.

112620. The liability of the owner or operator of lockers for loss of goods in lockers or in the owner's or operator's care shall be limited to negligence of the owner or operator or his or her employee.

112625. Upon the signed petition of at least 25 owners or operators of frozen food locker plants licensed under this chapter, the director shall within 10 days after receipt of said petition, cause to be held at places and at times as he or she may provide, a public hearing for the purpose of gathering facts and data for the revision, correction or amendment of any rule or regulation issued pertaining to this chapter.

112630. This chapter shall be known as the "Frozen Food Locker Plant Act of 1951."

112635. Any person who violates any of the provisions of this chapter is guilty of a misdemeanor, and upon conviction shall be punished by a fine of not less than fifty dollars (\$50) nor more than one thousand dollars (\$1,000), or by imprisonment in the county jail for a term not exceeding six months, or by both the fine and imprisonment.

CALIFORNIA HEALTH AND SAFETY CODE
SECTION 112650- 112855
Canneries

112650. "State board," or "State Board of Public Health," as used in this chapter, means the State Department of Health Services.

112655. "Meat or meat products" as used in this chapter, means any meat or meat product or poultry or poultry product that is not subject to the inspection of the Bureau of Meat Inspection or the Bureau of Poultry Inspection of the Department of Food and Agriculture, or of the Meat Inspection Division or Poultry Division of the United States Department of Agriculture, or of an approved municipal inspection department or establishment.

112660. "Food product," as used in this chapter, includes any fish or fish product, meat or meat product, or any other food product.

112665. The operation of noncommercial canning centers by community canning centers, schools, churches, other organizations, or housewives who pack hermetically sealed canned food products for their own consumption and do not sell the canned food, is exempt from the licensing provisions of this chapter.

112670. In lieu of a license, a permit to operate a canning center shall be issued without cost by the department upon the submission of evidence as the department requires to show that the persons operating the center are qualified and that the center is properly equipped and meets all other provisions of this chapter.

112675. Food products that do not require the use of a pressure cooker but necessitate acidulation and pH determinations come within this chapter.

112680. No act that is unlawful under Part 5 (commencing with Section 109875), relating to the adulterating, mislabeling, misbranding, false advertising, and sale of foods, is lawful by reason of this chapter.

112685. There is in the state government a Cannery Inspection Board consisting of the following six members:

- (a) The director of the state department, who shall act as chairperson.
- (b) One person appointed by the director who shall have had at the time of his or her appointment at least 10 years experience in or with canning technology and has a degree in chemistry, bacteriology, or medicine.
- (c) Four persons appointed by the director who are experienced, have substantial investments, and are actively engaged in the canning industry at the time of their appointment.

One of the four appointive members shall be engaged in the canning of animal food.

112690. Each appointed member holds office for a term of one year or until his or her successor is appointed.

112695. Members of the board serve without compensation. The board shall meet at least quarterly.

112700. The Cannery Inspection Board shall, subject to the approval of the department, estimate the cost of the separate inspection and laboratory control required to be made for each food product subject to this chapter.

112705. The estimate shall be made prior to the opening of the canning season for each product having a canning season of less than three consecutive months, and prior to each quarter for each product having a canning season of more than three consecutive months.

112710. For the purpose of prorating the estimated cost of inspection and laboratory control, the Cannery Inspection Board, subject to the approval of the department, shall estimate the number of cases to be packed, the number of tons to be packed, or the number of man-hours necessary to be employed, whichever in its discretion is most equitable as a basis of proration.

112715. Based on the estimates required by the last three sections, the Cannery Inspection Board, subject to the approval of the department, shall determine the probable cost of inspection and laboratory control per thousand cases, per ton, or per man-hour, whichever in its discretion is most equitable.

112720. The cost of laboratory control and research on products subject to this chapter shall be prorated by the Cannery Inspection Board in the same manner as the costs of inspection are prorated by it.

112725. If the delegation of discretion to determine whether the case, ton, or man-hour basis is most equitable as a basis of prorating the cost of inspection and laboratory control is held invalid as an unlawful delegation of legislative power, the invalidity shall not affect the validity of the remaining portions of this chapter. The Legislature hereby declares that if it had known that the delegation of the discretion would be declared invalid as an unlawful delegation of legislative power, it would have designated the man-hour basis of proration as the most equitable basis of proration. In the event of an invalidity, the cost of inspection and laboratory control shall be prorated on the man-hour basis.

112730. At the end of each quarter, or at the close of any canning season that does not exceed three consecutive months, the state department shall determine the actual cost of inspection and laboratory control of each separate food product for the preceding quarter or preceding canning season, and shall prorate the cost to each person licensed under this chapter on the basis of cases packed, tons packed, or number of man-hours necessary to be employed, whichever has been determined by the Cannery Inspection Board, with the approval of the state department, to be most equitable.

112735. In making any separate inspection and laboratory control for any food product, the state department shall not spend more than the amount estimated by the Cannery Inspection Board as the cost of the inspection without the approval of the Cannery Inspection Board.

112740. In making estimates, determinations, assessments, and prorations under this article and Article 2 (commencing with Section 112685), the Cannery Inspection Board and the state department may include as a part of the cost of inspection a reasonable charge for standby services of inspectors.

112745. In lieu of all other procedures in this article and Article 2 (commencing with Section 112685), each person licensed under this chapter may be assessed at an estimated annual hourly rate set by the Cannery Inspection Board with the approval of the department and of the State Director of Finance. The annual rate shall be set for each industry group based on the estimated cost.

112750. It is unlawful for any person to engage in the noncommercial canning of salmon, or in the commercial canning of any fish or fish product, meat or meat product, or any other food product for the use of man or animal, the sterilization of which in the opinion of the department requires the use of a pressure cooker or a retort, without first obtaining a license from the department.

112755. The department shall issue an annual license, that is nontransferable, to any person on the receipt of fifty dollars (\$50) per plant, and evidence as the board may require to show that (1) the applicant is properly equipped with a retort or pressure cooker that has recording thermometers, indicating thermometers, and pressure gauges to carry out regulations as the department may adopt for the sterilization of food products for the canning of which a license is sought and (2) the applicant is in compliance with the sanitary regulations of the department. The applicant shall be deemed to be in compliance with the sanitary regulations unless the applicant has been given written notice by the department not less than 60 days prior to the expiration of the existing license that the cannery does not comply with the sanitary regulations, and the applicant has subsequently failed to bring the cannery into compliance therewith.

112760. Any person who has been denied the annual license provided in this chapter may obtain a hearing by the department by mailing a written request therefor to the department. The department shall give the applicant at least 10 days notice of the hearing and shall hold such hearing within 30 days of the receipt of the request.

112765. In addition to the annual license fee, the department shall demand from each licensee a cash deposit for the payment of his or her pro rata share of the estimated cost of inspection and laboratory control as the department may deem necessary.

112770. If the deposit made by any licensee is insufficient to meet the actual cost of an inspection and laboratory control of any product determined by the department, the latter shall demand from the licensee, and the licensee shall immediately pay to the department, in addition to the license fee payable by the licensee, the difference between the deposit and his or her pro rata share of the actual cost of the inspection and laboratory control.

112775. If at the end of the calendar year, or at the end of any canning season of less than three consecutive months the deposit made by any licensee under this chapter is greater than the actual cost prorated to the licensee, the difference shall be refunded if requested by the licensee in accordance with law. If the difference is not so refunded, it shall be credited toward the required deposit for the next calendar year or canning season.

112780. No food product subject to the inspection required by this chapter shall be shipped by the licensee who packed it until the licensee has either paid his or her pro rata share of the estimated cost of inspection or has furnished the department a cash deposit for the payment of his or her pro rata share of the cost.

112785. The department may after notice and opportunity for hearing suspend or revoke a license issued under this chapter for any of the following causes:

- (a) Nonpayment of the pro rata share of the cost of inspection and laboratory control, or failure to comply with a demand for a cash deposit or other security by the holder of the license.
- (b) Noncompliance with any of the regulations of the department.
- (c) Operation of an insanitary cannery after due notice by registered mail has been received.
- (d) Inadequate ratproofing of a cannery throughout.
- (e) Willful packing of any canned food commodity that has been rejected by an agent of the department.
- (f) Packing of any canned food commodity subject to this chapter without notifying the department before packing.

112790. After conviction for a violation of Part 5 (commencing with Section 109875), the license of the person convicted may be suspended for a period of from 1 to 30 days.

112795. Proceedings for the suspension and revocation of licenses shall be conducted in accordance with Chapter 5 (commencing with Section 11500), Part 1, Division 3, Title 2 of the Government Code; and the department has all the powers granted therein.

112800. No person shall permit another to operate a steam-controlled retort used in the commercial canning industry for the sterilization of food products, unless the latter first obtains a permit from the department. The department may pass upon and determine the qualifications of the applicant with a view to the preservation of the public health.

Any permit granted is revocable by the department whenever in its judgment the public health requires such action.

112805. It is unlawful for any person to place upon the label of any bottle, can, jar, carton, case, box, barrel, or any other receptacle, vessel, or container of whatever material or nature that may be used by a packer, manufacturer, producer, jobber, or dealer for enclosing any canned food product, fish or fish product, or meat or meat product, any statement relative to the product having been inspected, unless the statement has been approved in writing by the department.

Approval of a statement is revocable at any time by the department upon written notice.

112810. Any food product packed in violation of this chapter may be quarantined by the department until a laboratory examination has established that the product meets the requirements of this chapter.

112815. Any person who packs any food product that has been quarantined by the department shall pay the department all reasonable costs of any laboratory examination, determined by the Cannery Inspection Board, subject to the approval of the department, to be necessary to ascertain that the seized product was packed in violation of this chapter.

112820. The Division of Cannery Inspections has supervision over the inspection and examination of raw fish and fish products preparatory to canning. The cost of the inspection and examination shall be determined and paid in the manner provided in Article 2 (commencing with Section 112685).

112825. The department may make regulations as it deems necessary for the proper enforcement of this chapter, and the regulations shall have the force and effect of law.

112830. No rule or regulation or amendment thereto shall be adopted unless submitted by the department to the Cannery Inspection Board at least five days prior to the date of adoption.

112835. The state board shall enforce its regulations and the provisions of Part 5 (commencing with Section 109875), relating to the canning of food products, through the Chief of the Bureau of Cannery Inspections and other employees as it deems necessary. The state board shall, so far as practicable, acquaint each licensee subject to this chapter with its regulations, and upon request therefor by any licensee shall furnish a copy of the regulations.

112840. The district attorney of the county in which any violation of this chapter occurs shall prosecute the person accused of the violation.

112845. The Cannery Inspection Fund is hereby established as a special fund in the State Treasury. All money received by the department under this chapter shall be deposited in the fund and expended by the department, upon appropriation by the Legislature, for the purpose of carrying out and implementing this chapter.

112850. Notwithstanding Section 112845, the department and the Department of Finance may authorize the deposit in the Special Deposit Fund of cash deposits received by the department under Section 112765; and in that event, upon the determination by the department that all or a part of any deposit is due the state for payment on account of the depositor's pro rata share of costs incurred by the state under this chapter, the amount so determined shall, on order of the Controller, be transferred from the Special Deposit Fund to the Cannery Inspection Fund.

All money deposited in the Special Deposit Fund under this section shall be subject to Article 2 (commencing with Section 16370) of Chapter 2 of Part 2 of Division 4 of Title 2 of the Government Code.

112855. Any person who does not obtain a license required of him or her by this chapter, or who engages in canning operations after his or her license has been suspended or revoked, or who otherwise violates this chapter, is guilty of a misdemeanor, and upon conviction is punishable by a fine of not less than fifty dollars (\$50) nor more than one thousand dollars (\$1,000), or by imprisonment in the county jail for not exceeding six months

CALIFORNIA HEALTH AND SAFETY CODE

SECTION 112875-112935

Olive Oil

112875. "Olive oil," as used in this chapter means the edible oil obtained solely from the fruit of the olive tree (*olea europea L.*) to the exclusion of oils obtained using solvents or reesterification processes and of any mixture with oils derived of other kinds except in the making of flavored olive oil, as defined in Section 112878.

112876. The hierarchy for virgin olive oil grades shall be, from highest to lowest, extra-virgin olive oil, virgin olive oil, and virgin olive oil not fit for human consumption, sometimes known as lampante virgin olive oil, which shall be the lowest level of quality among the virgin olive oils. In terms of hierarchy, olive oil and refined olive oil shall fall below the virgin olive oil category. Olive oil grades shall be in the following categories:

- (a) Virgin olive oils.
 - (1) Extra virgin olive oil.
 - (2) Virgin olive oil.
 - (3) Virgin olive oil not fit for human consumption without further processing, sometimes known as lampante virgin olive oil.
- (b) Olive oil.
- (c) Refined olive oil.

112876.5. The hierarchy for olive-pomace oil grades shall be, from highest to lowest, olive-pomace oil, refined olive-pomace oil, and crude olive-pomace oil, which is the lowest level of quality among the olive-pomace oils. Olive-pomace oil grades shall be in the following categories:

- (a) Olive-pomace oil.
- (b) Refined olive-pomace oil.
- (c) Crude olive-pomace oil.

112877. Olive oil grades are defined as follows:

(a) "Virgin olive oils" are the oils obtained from the fruit of the olive tree solely by mechanical or other physical means under conditions, including thermal conditions, that do not lead to alterations in the oil, and that have not undergone any treatment other than washing, decanting, centrifuging, and filtration. Virgin olive oils without further processing include:

(1) "Extra virgin olive oil" is virgin olive oil that has excellent flavor and odor expressed as a median of defects equal to zero and a median of fruitiness greater than zero, has a free fatty acid content, expressed as oleic acid, of not more than 0.8 grams per 100 grams oil, has a peroxide value of not more than 20 milliequivalent peroxide oxygen per kilogram oil and meets the additional requirements for "United States Extra Virgin Olive Oil" outlined in the United States Standards for Grades of Olive Oil and Olive-Pomace Oil published in the Federal Register that are in effect on October 25, 2010.

(2) "Virgin olive oil" is virgin olive oil that has reasonably good flavor and odor expressed as a median of defects between zero and 2.5 and a median of fruitiness greater than zero, has a free fatty acid content, expressed as oleic acid, of not more than 2 grams per 100 grams oil, has a peroxide value of not more than 20 milliequivalent peroxide oxygen per kilogram oil, and meets the additional requirements for "United States Virgin Olive Oil" outlined in the United States Standards for Grades of Olive Oil and Olive-Pomace Oil published in the Federal Register that are in effect on October 25, 2010.

(3) "Virgin olive oil not fit for human consumption without further processing," sometimes known as "lampante virgin olive oil," is virgin olive oil which has poor flavor and odor expressed as a median of defects between 2.5 and 6.0 or when the median of defects is less than or equal to 2.5 and the median of fruitiness is zero, has a free fatty acid content, expressed as oleic acid, of more than 2 grams per 100 grams, and meets the additional requirements of the "United States Virgin Olive Oil Not Fit For Human Consumption Without Further Processing" as outlined in the United States Standards for Grades of Olive Oil and Olive-Pomace Oil published in the Federal Register that are in effect on October 25, 2010. This grade of olive oil is intended for refining or for purposes other than food use.

(b) "Olive oil" is the oil consisting of a blend of refined olive oil and virgin olive oils fit for consumption without further processing. It has a free fatty acid content, expressed as oleic acid, of not more than 1 gram per 100 grams oil and meets the additional requirements for "United States Olive Oil" described in the United States Standards for Grades of Olive Oil and Olive-Pomace Oil published in the Federal Register that are in effect on October 25, 2010.

(c) "Refined olive oil" is the olive oil obtained from virgin olive oils by refining methods that do not lead to alterations in the initial glyceridic structure (basic glycerin-fatty acid content). It has a free fatty acid content, expressed as oleic acid, of not more than 0.3 grams per 100 grams oil, and meets the additional requirements for "United States Refined Olive Oil" described in the United States Standards for Grades of Olive Oil and Olive-Pomace Oil published in the Federal Register that are in effect on October 25, 2010.

(d) "Olive-pomace oil" is oil obtained by treating olive pomace, which is the product that remains after the mechanical extraction of olive oil, with solvents or other physical treatments, to the exclusion of oils obtained by synthetic processes and a mixture with oils of other kinds. Olive-pomace oils shall be labeled and marketed with the following designations and definitions:

(1) "Olive-pomace oil" is the oil comprising the blend of refined olive-pomace oil and virgin olive oils fit for consumption without further processing. It has a free fatty acid content, expressed as oleic acid, of not more than 1 gram per 100 grams oil, and meets the additional requirements for "United States Olive-Pomace Oil" outlined in the United States Standards for Grades of Olive Oil and Olive-Pomace Oil published in the Federal Register that are in effect on October 25, 2010.

(2) "Refined olive-pomace oil" is the oil obtained from crude olive-pomace oil by refining methods that do not lead to alterations in the initial glyceridic structure. It has a free fatty acid content, expressed as oleic acid, of not more than 0.3 grams per 100 grams oil, and meets the additional requirements for "United States Refined Olive-Pomace Oil" outlined in the United States Standards for Grades of Olive Oil and Olive-Pomace Oil Published in the Federal Register that are in effect on October 25, 2010.

(3) "Crude olive-pomace oil" is olive-pomace oil that is intended for refining for use for human consumption or that is intended for technical use and that meets the requirements for "United States Crude Olive-Pomace Oil" outlined in the United States Standards for Grades of Olive Oil and Olive-Pomace Oil published in the Federal Register that are in effect on October 25, 2010.

112878. "Flavored olive oil," as used in this chapter, means extra virgin olive oil, virgin olive oil, or olive oil, that is mixed with a flavoring, or olives that are processed into oil with any fruit, vegetable, herb, nut, seed, or spice and the product resulting from either process contains not less than 90 percent extra virgin olive oil, virgin olive oil, or olive oil, and is labeled for sale as an olive oil that has been flavored.

112879. "Imitation olive oil," as used in this chapter, means the mixture of any edible oil artificially colored or flavored to resemble olive oil.

112880. For purposes this chapter, the following definitions shall apply:

(a) "Median of defects" means a calculation of the median score from a panel of tasters that characterizes the negative flavor and odor attributes of virgin olive oil, such as, but not limited to, musty, fusty, winy-vinegary, muddy-sediment, and rancid.

(b) "Median of fruitiness" means a calculation of the median score from a panel of tasters that characterizes virgin olive oil produced from olives, such as, but not limited to, olive, apple, green, sweet, grass, nutty, and tomato.

(c) "Panel of tasters" means the method of analyzing organoleptic characteristics of virgin olive oil, as defined in the United States Standards for Grades of Olive Oil and Olive-Pomace Oil published in the Federal Register that are in effect on October 25, 2010.

112891. Any olive oil and olive-pomace oil labeled for sale shall be consistent with this chapter.

112893. Alpha-tocopherol may be added to refined olive oil, olive oil, refined olive-pomace oil, and olive-pomace oil to restore natural tocopherol lost in the refining process. The concentration of alpha-tocopherol in the final product shall not exceed 200 milligrams per kilogram.

112894. Virgin olive oil not fit for human consumption, sometimes known as lampante virgin olive oil, shall be refined before consumption.

112895.

- (a) It is unlawful to manufacture, sell, offer for sale, give away, or to possess imitation olive oil in California.
- (b) This section does not prohibit the blending of olive oil with other edible oils, if the blend is not labeled as olive oil or imitation olive oil, is clearly labeled as a blended vegetable oil, and if the contents and proportions of the blend are prominently displayed on the container's label, or if the oil is a flavored olive oil.
- (c) If any olive oil is produced, processed, sold, offered for sale, given away, or possessed in California, that indicates on its label "California Olive Oil," or uses words of similar import that indicate that California is the source of the oil, 100 percent of that oil shall be derived from olives grown in California.
- (d) Olive oil produced, processed, sold, offered for sale, given away, or possessed in California, that indicates on its label that it is from a specific region of California shall be made of oil at least 85 percent of which, by weight, is derived from olives grown in the specified region.
- (e) Olive oil produced, processed, sold, offered for sale, given away, or possessed in California, that indicates on its label that it is from a specific estate in California shall be made of oil at least 95 percent of which, by weight, is derived from olives grown on the specified estate.
- (f) Olive-pomace oil shall not be labeled as olive oil.

112905. It is unlawful to prepare, express, mix, or blend olive pomace or meats with any bland fixed oil other than olive oil.

112910. All records of those licensed under the provisions of this chapter that concern the amounts of olive oil produced, purchased, or produced and purchased, or the sale, distribution, or sale and distribution of any olive oil, shall be open to inspection upon demand of any agent of the department.

112915. It is unlawful to reuse any olive oil container, can, or drum for repacking any fixed oil intended to be used for food purposes, except on the premises of the processor.

112920. All olive oil for technical purposes shall be denatured with an odoriferous substance so as to render it unfit for food purposes.

112925. It is unlawful to sell or offer for sale olive oil containing more than 5 percent free fatty acid without first denaturing the oil and making it unfit for human consumption.

112930. The department shall enforce this chapter.

112935. Any person violating any of the provisions of this chapter is guilty of a misdemeanor, and upon conviction shall be punished by a fine of not less than five hundred dollars (\$500) nor more than one thousand dollars (\$1,000), or by imprisonment in the county jail for not exceeding one year, or by both fine and imprisonment.

HEALTH AND SAFETY CODE
SECTION 113025-113055
Pure Pet Food Act

113025. "Processed pet food" means a food for pets that has been prepared by heating, drying, semidrying, canning, or by a method of treatment prescribed by regulation of the department. The term includes, special diet, health foods, supplements, treats and candy for pets, but does not include fresh or frozen pet foods subject to the control of the Department of Food and Agriculture of this state.

113030. "Pet" means any household animal including but not limited to cats or dogs and other carnivores whether or not for exhibition.

113035. "Pet food ingredients" means each of the constituent materials making up a processed pet food. Pet food ingredients of animal or poultry origin shall be only from animals or poultry slaughtered or processed in an approved or licensed establishment. Such animal or poultry ingredients condemned for human food but passed for animal food in an establishment inspected by the United States Department of Agriculture or the Department of Food and Agriculture of this state may be used for pet food, provided it is properly denatured or handled in accordance with this chapter and regulations of the department and the regulations of the Department of Food and Agriculture of this state so as to render the ingredients safe for pet food. Animals or poultry classified as "deads" are prohibited.

113040. Incubator reject eggs may not be used in food for human consumption but may be used for animal food or animal-food products.

113045. The term "advertisement" means all representations disseminated in any manner or by any means for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of processed pet food. An advertisement shall be deemed false if it is false or misleading in any particular.

113050. If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only misrepresentations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of representations or material with respect to consequences that may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under conditions of use as are customary or usual.

113055. This chapter shall be known, and may be cited, as the Pure Pet Food Act of 1969.

113060. Every person who manufactures a processed pet food in California shall first obtain a license from, and every person who manufactures a processed pet food for import into California from another state shall first obtain a registration certificate from, the department. Each license or registration certificate is good for one calendar year from the date of issue and is nontransferable. An application for a license or registration certificate shall be made on an application form provided by the department.

113065. A separate license shall be required for each processing plant located in California. The annual license fee shall be one hundred dollars (\$100). The annual registration fee shall be one hundred dollars (\$100). The penalty for failure to apply for renewal of a license or registration certificate within 30 days after the expiration is thirty dollars (\$30) and shall be added to the renewal fee and be paid by the applicant before the renewal license or registration certificate may be issued. All fees collected shall be expended as appropriated by the Legislature in the carrying out of the provisions of this chapter and the regulations adopted thereto. The annual license fee for a pet food canner also licensed under Chapter 8 (commencing with Section 112650) is one hundred dollars (\$100). No additional fee is payable by such a person for a license issued to him or her under that chapter.

113070. An annual license or registration certificate shall be issued only when the following provisions have been met:

- (a) Inspection of the manufacturing facilities demonstrates that they are properly equipped and are operated in a sanitary manner.
- (b) In the case of an out-of-state manufacturer, the application for a registration certificate is accompanied by a certificate issued by a federal, state, or local health agency certifying that the processed pet foods manufactured conform to the requirements of this chapter or the regulations adopted hereunder.
- (c) The applicant submits to the department the label that would be attached to the container of each type of processed pet food and a complete list of the pet food ingredients thereof in their order of predominance by weight.

113075. The following acts and the causing thereof within the State of California are hereby prohibited:

- (a) The manufacture, sale, or delivery, holding or offering for sale of any pet food ingredient or processed pet food that is adulterated or misbranded.
- (b) The adulteration or misbranding of any pet food ingredient or processed pet food.
- (c) The dissemination of any false advertising.
- (d) The refusal to permit entry or inspection, or to permit the taking of a sample.
- (e) The removal, sale, or disposal of a detained or embargoed processed pet food without permission of an authorized agent or the court.
- (f) The giving of a guaranty or undertaking that is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the State of California from whom he or she received in good faith the pet food ingredient or the processed pet food.
- (g) The receipt in commerce of any pet food ingredient or processed pet food that is adulterated, misbranded or falsely advertised and the delivery or proffered delivery thereof for pay or otherwise.
- (h) Failure to obtain a license as required by this chapter.
- (i) Use of any pet food ingredient that fails to conform to the standard of identity for the pet food ingredient as adopted pursuant to Section 113115.

113080.

- (a) Any person who violates any of the provisions of this chapter or the regulations promulgated under this chapter is subject to imprisonment for not more than six months or a fine of not more than one thousand dollars (\$1,000), or both that imprisonment and fine; but if the violation is committed after a conviction of that person under this section has become final, or the violation is committed with intent to defraud or mislead, the person shall be subject to imprisonment for not more than one year, or a fine of not more than one thousand dollars (\$1,000), or both imprisonment and fine.
- (b) No person shall be subject to the penalties of subdivision (a) for having violated provisions of this chapter if he or she establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the State of California from whom he or she received in good faith the article, to the effect that the article conforms to all provisions of this chapter, designating this chapter. If the guaranty is to the effect that the article is not in violation within the meaning of the federal act, as provided in Section 303 (c) of the federal act, it shall be sufficient for all the purposes of this chapter and have the same force and effect as though it referred to this chapter, unless at any time the standard for the article concerned under this chapter is higher than the standard for a like article under the federal act.
- (c) No publisher, radio or television broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section for the dissemination of false advertisement, unless he or she has refused, on the request of the department, to furnish the department the name and post office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in the State of California who caused him or her to disseminate the advertisement.

113085. In addition to other remedies herein provided, the department may bring an action in the superior court, and the court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of this chapter. Any proceeding

under this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the department shall not be required to allege facts necessary to show or tending to show lack of adequate remedy at law or to show or tending to show irreparable damage or loss.

113090. A pet food ingredient or a processed pet food shall be deemed to be adulterated:

- (a) If it bears or contains any poisonous or deleterious substance that may render it injurious to health; but in case the substance is not an added substance, the pet food shall not be considered adulterated under this subdivision if the quantity of the substance in pet food does not ordinarily render it injurious to health.
- (b) If it bears or contains any added poisonous or deleterious substance, any food additive, any pesticide chemical, or any color additive that is unsafe within the meaning of the Federal Food, Drug and Cosmetic Act, or Part 5 (commencing with Section 109875), or Division 7 (commencing with Section 12501) of the Food and Agricultural Code.
- (c) If it contains a pet food ingredient for which a standard of identity has been established and the pet food ingredient fails to meet that standard.
- (d) If it has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome or injurious to health.
- (e) If its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.
- (f) If any valuable constituent has been in whole or in part omitted or abstracted therefrom.
- (g) If any substance has been substituted wholly or in part therefor.
- (h) If damage or inferiority has been concealed in any manner.
- (i) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight or reduce its quality or strength or make it appear better or of greater value than it is.

113095. A pet food ingredient or processed pet food shall be deemed to be misbranded:

- (a) If its labeling is false or misleading in any particular.
- (b) If its container is so made, formed or filled as to be misleading.
- (c) If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count.

Under clause (2) of subdivision (c), reasonable variation shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the department.

- (d) If any word, statement or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with conspicuousness (as compared with other words, statements, designs or emblems, in the labeling) and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

113100. A pet food shall be deemed to be misbranded if it is not subject to Section 113105, unless its label bears (a) the common or usual name of the food, if any there be, and (b) in case it is fabricated from two or more ingredients, the common or usual name of each ingredient listed in descending order of predominance in the product. Spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings, without naming each.

113105. A processed pet food shall be deemed to be misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by Section 113115 unless (a) it conforms to the definition and standard, and (b) its label bears the name of the processed pet food specified in the definition and standard, and, insofar as may be required by regulations, the common names of optional pet food ingredients present in processed pet food. Spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings, without naming each.

113110. A processed pet food shall be deemed to be misbranded:

- (a) If it purports to be or is represented for special dietary uses, unless its label bears information concerning its vitamin, mineral, and other dietary properties as the department determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for those uses.
- (b) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact. To the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the department.

113115. When in the judgment of the department the action will promote honesty and fair dealing in the interest of the ultimate purchaser, the department may promulgate regulations establishing for any processed pet food or pet food ingredient any of the following:

- (a) A reasonable definition and standard of identity.
- (b) A reasonable standard of quality or fill of container.
- (c) The method of treatment of products or ingredients to render them safe for pet feeding.
- (d) Labeling information necessary to fully inform the purchaser thereof.

113120. This chapter shall be administered by the department in accordance with Part 5 (commencing with Section 109875).

HEALTH AND SAFETY CODE
SECTION 119405
Electronic Cigarettes

119405.

- (a) To the extent not preempted by federal law, including, but not limited to, the regulation of electronic cigarettes by the United States Food and Drug Administration, it shall be unlawful for a person to sell or otherwise furnish an electronic cigarette, as defined in subdivision (b), to a person under 18 years of age.
- (b) "Electronic cigarette" means a device that can provide an inhalable dose of nicotine by delivering a vaporized solution.
- (c) A violation of this section shall be an infraction punishable by a fine not exceeding two hundred dollars (\$200) for the first violation, by a fine not exceeding five hundred dollars (\$500) for the second violation, or by a fine not exceeding one thousand dollars (\$1,000) for a third or subsequent violation.
- (d) Nothing in this section nor any other law shall be construed to invalidate an existing ordinance of, or prohibit the adoption of an ordinance by, a city or county that regulates the distribution of electronic cigarettes in a manner that is more restrictive than this section, to the extent that the ordinance is not otherwise prohibited by federal law.

**Health and Safety Code - Miscellaneous Sections
Regarding Food, Drug, Medical Device and Cosmetic Safety**

100325. The department shall cause special investigations of the sources of morbidity and mortality and the effects of localities, employments, conditions and circumstances on the public health and the department shall perform other duties as may be required in procuring information for state and federal agencies regarding the effects of these conditions on the public health.

106500.

- (a) The chief and those inspectors of the Food and Drug Section as he or she may designate, are peace officers for the purpose only of carrying out the duties of their employment. The authority of the peace officer shall extend to any place in the state as to any public offense committed, or which there is reasonable cause to believe has been committed, within this state that is a violation of any provision of Division 8.5 (commencing with Section 22950) of the Business and Professions Code, Part 5 (commencing with Section 109875), or the Miscellaneous Food, Food Facility, and Hazardous Substances Act (Section 27), or Chapter 4 (commencing with Section 41301) of Division 16 of the Food and Agricultural Code. This authority shall further extend to violations of any penal provision of this code, the Business and Professions Code, or the Penal Code, that are discovered in the course of and arise in connection with the employment of these officers.
- (b) Any inspector of the Food and Drug Section shall have the authority, as a public officer, to arrest, without a warrant, any person who, in his or her presence, has violated, or as to whom there is probable cause to believe has violated, any provision of Part 5 (commencing with Section 109875) or the Miscellaneous Food, Food Facility, and Hazardous Substances Act (Section 27), or Chapter 4 (commencing with Section 41301) of Division 16 of the Food and Agricultural Code.

In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

- (c) There shall be no civil liability on the part of and no cause of action shall arise against any person, acting pursuant to subdivision (b) and within the scope of his or her authority, for false arrest or false imprisonment arising out of any arrest that is lawful or that the arresting inspector, at the time of the arrest, had reasonable cause to believe was lawful. No inspector shall be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest or to prevent escape or to overcome resistance.
- (d) The chief and inspectors of the Food and Drug Section may serve all processes and notices throughout the state.

131075. The department may enjoin and abate public nuisances.

131080. The department may advise all local health authorities, and, when in its judgment the public health is menaced, it shall control and regulate their action.

131095. The department shall cause special investigation of the preparation and sale of drugs and food and their adulteration.

131100. The department shall perform duties as required by law for the detection and prevention of the adulteration of articles used for food and drink, and for the punishment of persons guilty of violation of any law providing against their adulteration.

131105. The department shall examine and may prevent the pollution of sources of public domestic water and ice supply.

131130.

- (a) Any person who willfully sells, keeps for sale, or offers for sale any food, drug, device, or cosmetic knowing, after a written notice from either (1) a manufacturer, wholesaler, distributor, or importer, or (2) the department or a local health officer that the product linked to an outbreak of illness, injury, or product tampering is being ordered removed from sale by the department pursuant to Section 131080, shall, upon conviction, be punished by a fine of not less than two thousand dollars (\$2,000) nor more than ten thousand dollars (\$10,000) for each day of violation, or by imprisonment in the county jail for not more than one year, or by both a fine and imprisonment.
- (b) If a second or subsequent violation is committed after a previous conviction under this section has become final, the person shall be punished by a fine of not less than five thousand dollars (\$5,000) nor more than twenty-five thousand dollars (\$25,000) for each day of violation, or by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by both a fine and imprisonment.
- (c) Notwithstanding any other provision of law, the court may suspend the minimum fines provided for in this section if it determines that there are circumstances in mitigation and the court states on the record its reasons for suspending the minimum fine.

131135. Whenever any person violates any provision of Section 131130, the court may, as a condition of probation, order the defendant to pay, in lieu of any fine, any expenses, both direct and indirect, incurred by a local health department or the department in monitoring compliance with the order pursuant to Section 131080, including, but not limited to, the costs of conducting inspections and imposing embargoes. The total costs payable to the department and local health departments collectively imposed pursuant to this section shall not exceed the maximum fine for the offense of which the defendant is convicted. Any amount collected under this section shall be paid to the local health department incurring the expenses or, if to reimburse costs of the department, into the General Fund.

STAKE Act
BUSINESS AND PROFESSIONS CODE
SECTION 22950-22963

22950. This Division shall be known and may be referred to as the Stop Tobacco Access to Kids Enforcement Act or the STAKE Act.

22950.5. For purposes of this division, the following terms have the following meanings:

- (a) "Department" means the State Department of Public Health.
- (b) "Enforcing agency" means the State Department of Public Health, another state agency, including, but not limited to, the office of the Attorney General, or a local law enforcement agency, including, but not limited to, a city attorney, district attorney, or county counsel.
- (c) "Smoking" means inhaling, exhaling, burning, or carrying any lighted or heated cigar, cigarette, or pipe, or any other lighted or heated tobacco or plant product intended for inhalation, whether natural or synthetic, in any manner or in any form. "Smoking" includes the use of an electronic smoking device that creates an aerosol or vapor, in any manner or in any form, or the use of any oral smoking device for the purpose of circumventing the prohibition of smoking.
- (d) (1) "Tobacco product" means any of the following:
 - (A) A product containing, made, or derived from tobacco or nicotine that is intended for human consumption, whether smoked, heated, chewed, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, including, but not limited to, cigarettes, cigars, little cigars, chewing tobacco, pipe tobacco, or snuff.
 - (B) An electronic device that delivers nicotine or other vaporized liquids to the person inhaling from the device, including, but not limited to, an electronic cigarette, cigar, pipe, or hookah.
 - (C) Any component, part, or accessory of a tobacco product, whether or not sold separately.
- (2) "Tobacco product" does not include a product that has been approved by the United States Food and Drug Administration for sale as a tobacco cessation product or for other therapeutic purposes where the product is marketed and sold solely for such an approved purpose.

22951. The Legislature finds and declares that reducing and eventually eliminating the illegal purchase and consumption of tobacco products by any person under 21 years of age is critical to ensuring the long-term health of our state's citizens. Accordingly, California must fully comply with federal regulations, particularly the "Synar Amendment," that restrict tobacco sales to minors and require states to vigorously enforce their laws prohibiting the sale and distribution of tobacco products to persons under 18 years of age. Full compliance and vigorous enforcement of the "Synar Amendment" requires the collaboration of multiple state and local agencies that license, inspect, or otherwise conduct business with retailers, distributors, or wholesalers that sell tobacco.

22952. The State Department of Public Health shall do all of the following:

- (a) Establish and develop a program to reduce the availability of tobacco products to persons under 21 years of age through the enforcement activities authorized by this division.
- (b) Establish requirements that retailers of tobacco products post conspicuously, at each point of purchase, a notice stating that selling tobacco products to anyone under 21 years of age is illegal and subject to penalties. The notice shall also state that the law requires that all persons selling tobacco products check the identification of a purchaser of tobacco products who reasonably appears to be under 21 years of age. The warning signs shall include a toll-free telephone number to the department for persons to report unlawful sales of tobacco products to any person under 21 years of age.
- (c) Provide that primary responsibility for enforcement of this division shall be with the department. In carrying out its enforcement responsibilities, the department shall conduct random, onsite sting inspections at retail sites and shall enlist the assistance of persons that are under 21 years of age in conducting these enforcement activities. The department may conduct onsite sting inspections in response to public complaints or at retail sites where violations have previously occurred, and investigate illegal sales of tobacco products to any person under 21 years of age by telephone, mail, or the Internet. A person under 21 years of age who participates in these enforcement

activities is immune from prosecution under any provision of law prohibiting the purchase of these products by a person under 21 years of age.

- (d) In accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department shall adopt and publish guidelines for the use of persons under 21 years of age in inspections conducted pursuant to subdivision (c) that shall include, but not be limited to, all of the following:
- (1) An enforcing agency may use persons under 21 years of age in random inspections to determine if sales of cigarettes or other tobacco products are being made to persons under 21 years of age.
 - (2) A photograph or video recording of the person under 21 years of age shall be taken prior to each inspection or shift of inspections and retained by the enforcing agency for purposes of verifying appearances.
 - (3) An enforcing agency may use video recording equipment when conducting the inspections to record and document illegal sales or attempted sales.
 - (4) The person under 21 years of age, if questioned about his or her age, need not state his or her actual age but shall present a true and correct identification if verbally asked to present it. Any failure on the part of the person under 21 years of age to provide true and correct identification, if verbally asked for it, shall be a defense to an action pursuant to this section.
 - (5) The person under 21 years of age shall be under the supervision of a regularly employed peace officer during the inspection.
 - (6) All persons under 21 years of age used in this manner by an enforcing agency shall display the appearance of a person under 21 years of age. It shall be a defense to an action under this division that the person's appearance was not that which could be generally expected of a person under 21 years of age, under the actual circumstances presented to the seller of the cigarettes or other tobacco products at the time of the alleged offense.
 - (7) Following the completion of the sale, the peace officer accompanying the person under 21 years of age shall reenter the retail establishment and shall inform the seller of the random inspection. Following an attempted sale, the enforcing agency shall notify the retail establishment of the inspection.
 - (8) Failure to comply with the procedures set forth in this subdivision shall be a defense to an action brought pursuant to this section.
- (e) Be responsible for ensuring and reporting the state's compliance with Section 1926 of Title XIX of the federal Public Health Service Act (42 U.S.C. Sec. 300x-26) and any implementing regulations adopted in relation thereto by the United States Department of Health and Human Services. A copy of this report shall be made available to the Governor and the Legislature.
- (f) Provide that any civil penalties imposed pursuant to Section 22958 shall be enforced against the owner or owners of the retail business and not the employees of the business.

22953. All moneys collected as civil penalties by the department and other state agencies pursuant to this division shall be deposited in the State Treasury to the credit of the Sale of Tobacco to Minors Control Account that is hereby established.

22954. Any cigarette or tobacco products distributor or wholesaler as defined in Sections 30011 and 30016 of the Revenue and Taxation Code, and licensed under Article 1 (commencing with Section 30140) of Chapter 3 of Part 13 of Division 2 of the Revenue and Taxation Code or Article 3 (commencing with Section 30155) of Chapter 3 of Part 13 of Division 2 of the Revenue and Taxation Code, and any cigarette vending machine operator granted a seller's permit under the Sales and Use Tax Law (Part 1 (commencing with Section 6001) of Division 2 of the Revenue and Taxation Code), shall annually provide to the State Department of Health Services, the names and addresses of those persons to whom they provide tobacco products, including, but not limited to, dealers as defined in Section 30012 of the Revenue and Taxation Code, for the purpose of identifying retailers of tobacco to ensure compliance with this division. Cigarette vending machine operators granted a seller's permit under the Sales and Use Tax Law (Part 1 (commencing with Section 6001) of Division 2 of the Revenue and Taxation Code), shall annually provide to the department their name and the address of each location where cigarette vending machines are placed, in order to ensure compliance with this division. The data provided, pursuant to this section, shall be deemed confidential official information by the department and shall be exempt from disclosure

under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

22955. Agents of the state department, while conducting enforcement activities pursuant to this division, are peace officers and are subject to all of the powers and immunities granted to Food and Drug Section inspectors pursuant to Section 106500 of the Health and Safety Code in the same manner as are any Food and Drug Section inspectors of the state department.

22956. All persons engaging in the retail sale of tobacco products shall check the identification of tobacco purchasers, to establish the age of the purchaser, if the purchaser reasonably appears to be under 21 years of age.

22957.

- (a) In addition to the primary enforcement responsibility assumed by the department, another enforcing agency may conduct inspections and assess penalties for violations of this division if the enforcing agency complies with this division and with all applicable laws and guidelines developed pursuant to this division.
- (b) State and local enforcement agencies are encouraged, in order to avoid duplication, to share the results of inspections and coordinate with the department when enforcing this division.

22958.

- (a) (1) An enforcing agency may assess civil penalties against any person, firm, or corporation that sells, gives, or in any way furnishes to another person who is under 21 years of age, any tobacco, cigarette, cigarette papers, any other instrument or paraphernalia that is designed for the smoking or ingestion of tobacco, tobacco products, or any controlled substance, according to the following schedule: (1) a civil penalty of from four hundred dollars (\$400) to six hundred dollars (\$600) for the first violation, (2) a civil penalty of from nine hundred dollars (\$900) to one thousand dollars (\$1,000) for the second violation within a five-year period, (3) a civil penalty of from one thousand two hundred dollars (\$1,200) to one thousand eight hundred dollars (\$1,800) for a third violation within a five-year period, (4) a civil penalty of from three thousand dollars (\$3,000) to four thousand dollars (\$4,000) for a fourth violation within a five-year period, or (5) a civil penalty of from five thousand dollars (\$5,000) to six thousand dollars (\$6,000) for a fifth violation within a five-year period.
(2) This subdivision does not apply to the sale, giving, or furnishing of any of the products specified in paragraph (1) to active duty military personnel who are 18 years of age or older. An identification card issued by the United States Armed Forces shall be used as proof of age for this purpose.
- (b) (1) In addition to the civil penalties described in subdivision (a), upon the assessment of a civil penalty for the third, fourth, or fifth violation, the department, within 60 days of the date of service of the final administrative adjudication on the parties or payment of the civil penalty for an uncontested violation, shall notify the State Board of Equalization of the violation. The State Board of Equalization shall then assess a civil penalty of two hundred fifty dollars (\$250) and suspend or revoke a license issued pursuant to Chapter 2 (commencing with Section 22972) of Division 8.6 in accordance with the following schedule:
 - (A) A 45-day suspension of the license for a third violation at the same location within a five-year period.
 - (B) A 90-day suspension of the license for a fourth violation at the same location within a five-year period.
 - (C) Revocation of the license for a fifth violation at the same location within a five-year period.(2) The provisions of Chapter 4 (commencing with Section 55121) of Part 30 of Division 2 of the Revenue and Taxation Code apply with respect to the collection of the penalty imposed by the State Board of Equalization pursuant to paragraph (1).
- (c) (1) For each suspension or revocation pursuant to subdivision (b), the civil penalty of two hundred fifty dollars (\$250) assessed pursuant to that subdivision, notwithstanding Section 22953, shall be deposited into the Cigarette and Tobacco Products Compliance Fund established pursuant to Section 22990. Moneys from that civil penalty deposited into this fund shall be made available to the State Board of Equalization, upon appropriation by the Legislature, for the purposes of meeting its duties under subdivision (b).

- (2) The department shall, upon request, provide to the State Board of Equalization information concerning any person, firm, or corporation that has been assessed a civil penalty for violation of the STAKE Act pursuant to this section when the department has notified the State Board of Equalization of the violation.
- (d) The enforcing agency shall assess penalties pursuant to the schedule set forth in subdivision (a) against a person, firm, or corporation that sells, offers for sale, or distributes tobacco products from a cigarette or tobacco products vending machine, or a person, firm, or corporation that leases, furnishes, or services these machines in violation of Section 22960.
- (e) An enforcing agency may assess civil penalties against a person, firm, or corporation that sells or deals in tobacco or any preparation thereof, and fails to post conspicuously and keep posted in the place of business at each point of purchase the notice required pursuant to subdivision (b) of Section 22952. The civil penalty shall be in the amount of two hundred dollars (\$200) for the first offense and five hundred dollars (\$500) for each additional violation.
- (f) An enforcing agency shall assess penalties in accordance with the schedule set forth in subdivision (a) against a person, firm, or corporation that advertises or causes to be advertised a tobacco product on an outdoor billboard in violation of Section 22961.
- (g) If a civil penalty has been assessed pursuant to this section against a person, firm, or corporation for a single, specific violation of this division, the person, firm, or corporation shall not be prosecuted under Section 308 of the Penal Code for a violation based on the same facts or specific incident for which the civil penalty was assessed. If a person, firm, or corporation has been prosecuted for a single, specific violation of Section 308 of the Penal Code, the person, firm, or corporation shall not be assessed a civil penalty under this section based on the same facts or specific incident upon which the prosecution under Section 308 of the Penal Code was based.
- (h) (1) In the case of a corporation or business with more than one retail location, to determine the number of accumulated violations for purposes of the penalty schedule set forth in subdivision (a), violations of this division by one retail location shall not be accumulated against other retail locations of that same corporation or business.
 (2) In the case of a retail location that operates pursuant to a franchise as defined in Section 20001, violations of this division accumulated and assessed against a prior owner of a single franchise location shall not be accumulated against a new owner of the same single franchise location for purposes of the penalty schedule set forth in subdivision (a).
- (i) Proceedings under this section shall be conducted pursuant to Section 131071 of the Health and Safety Code, except in cases where a civil penalty is assessed by an enforcing agency other than the department, in which case proceedings shall be conducted pursuant to the procedures of that agency that are consistent with Section 131071 of the Health and Safety Code.

22959.

- (a) The sum of two million dollars (\$2,000,000) shall be transferred annually from the portion of the federal Substance Abuse Prevention and Treatment block grant moneys allocated to the State Department of Alcohol and Drug Programs for administrative purposes related to substance abuse programs, to the Sale of Tobacco to Minors Control Account.
- (b) Upon appropriation by the Legislature, moneys in the Sale of Tobacco to Minors Control Account shall be expended by the state department to administer and enforce this division.

22960.

- (a) Except as provided in subdivision (b), no cigarette or tobacco product shall be sold, offered for sale, or distributed from a vending machine or appliance, or any other coin or token operated mechanical device designed or used for vending purposes, including, but not limited to, machines or devices that use remote control locking mechanisms.
- (b) (1) Commencing January 1, 1996, cigarette or tobacco product vending machines or appliances may be located at least 15 feet away from the entrance of a premise issued an on-sale public premises license as defined in Section 23039 by the Department of Alcoholic Beverage Control to sell alcoholic beverages.
 (2) As used in this subdivision "at least 15 feet away from the entrance" means within the premises of the licensed establishment and not outside those premises.
- (c) This section and subdivision (b) of Section 22958 set forth minimum state restrictions on the sale of

cigarettes or tobacco products from vending machines or devices and do not preempt or otherwise prohibit the adoption of a local standard that further restricts access to and reduces the availability of cigarette or tobacco products from vending machines or devices or that imposes a complete ban on the sale of cigarettes or tobacco products from vending machines or devices. A local standard that further restricts or imposes a complete ban on the sale of cigarettes or tobacco products from vending machines or devices shall control in the event of an inconsistency between this section and a local standard.

22961.

- (a) No person, firm, corporation, partnership, or other organization shall advertise or cause to be advertised any tobacco products on any outdoor billboard located within 1,000 feet of any public or private elementary school, junior high school, or high school, or public playground.
- (b) This section sets forth minimum state restrictions on the advertisement of any tobacco products on outdoor billboards near schools and public playgrounds and does not preempt or otherwise prohibit the adoption of a local standard that imposes a more restrictive or complete ban on billboard advertising or on tobacco-related billboard advertising. A local standard that imposes a more restrictive or complete ban on billboard advertising or on tobacco-related billboard advertising shall control in the event of any inconsistency between this section and a local standard.
- (c) This section shall not be construed to prohibit the display of a message or advertisement opposing the use of tobacco products. However, this subdivision shall not be construed to permit an advertisement promoting the use of tobacco products by including a message opposing the use of tobacco products within that advertisement.

22962.

- (a) For purposes of this section, the following terms have the following meanings:
 - (1) "Self-service display" means the open display of tobacco products or tobacco paraphernalia in a manner that is accessible to the general public without the assistance of the retailer or employee of the retailer.
 - (2) "Tobacco paraphernalia" means cigarette papers or wrappers, blunt wraps as defined in Section 308 of the Penal Code, pipes, holders of smoking materials of all types, cigarette rolling machines, or other instruments or things designed for the smoking or ingestion of tobacco products.
 - (3) "Tobacco product" means a product or device as defined in subdivision (d) of Section 22950.5 of the Business and Professions Code.
 - (4) "Tobacco store" means a retail business that meets all of the following requirements:
 - (A) Primarily sells tobacco products.
 - (B) Generates more than 60 percent of its gross revenues annually from the sale of tobacco products and tobacco paraphernalia.
 - (C) Does not permit any person under 18 years of age to be present or enter the premises at any time, unless accompanied by the person's parent or legal guardian, as defined in Section 6903 of the Family Code.
 - (D) Does not sell alcoholic beverages or food for consumption on the premises.
- (b) (1) (A) Except as permitted in subdivision (b) of Section 22960, it is unlawful for a person engaged in the retail sale of tobacco products to sell, offer for sale, or display for sale any tobacco product or tobacco paraphernalia by self-service display. A person who violates this section is subject to those civil penalties specified in the schedule in subdivision (a) of Section 22958.
 - (B) A person who violates this section is subject to those civil penalties specified in the schedule in subdivision (a) of Section 22958.
- (2) It is unlawful for a person engaged in the retail sale of blunt wraps to place or maintain, or to cause to be placed or maintained, any blunt wraps advertising display within two feet of candy, snack, or nonalcoholic beverage displayed inside any store or business.
- (3) It is unlawful for any person or business to place or maintain, or cause to be placed or maintained, any blunt wrap advertising display that is less than four feet above the floor.
- (c) Subdivision (b) shall not apply to the display in a tobacco store of cigars, pipe tobacco, snuff,

chewing tobacco, or dipping tobacco, provided that in the case of cigars they are generally not sold or offered for sale in a sealed package of the manufacturer or importer containing less than six cigars. In any enforcement action brought pursuant to this division, the retail business that displays any of the items described in this subdivision in a self-service display shall have the burden of proving that it qualifies for the exemption established in this subdivision.

- (d) The Attorney General, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this section.
- (e) This section does not preempt or otherwise prohibit the adoption of a local standard that imposes greater restrictions on the access to tobacco products than the restrictions imposed by this section. To the extent that there is an inconsistency between this section and a local standard that imposes greater restrictions on the access to tobacco products, the greater restriction on the access to tobacco products in the local standard shall prevail.

22963.

- (a) The sale, distribution, or nonsale distribution of tobacco products directly or indirectly to any person under 21 years of age through the United States Postal Service or through any other public or private postal or package delivery service at locations, including, but not limited to, public mailboxes and mailbox stores, is prohibited.
- (b) Any person selling or distributing, or engaging in the nonsale distribution of, tobacco products directly to a consumer in the state through the United States Postal Service or by any other public or private postal or package delivery service, including orders placed by mail, telephone, facsimile transmission, or the Internet, shall comply with the following provisions:
 - (1) (A) Before enrolling a person as a customer, or distributing or selling, or engaging in the nonsale distribution of, the tobacco product through any of these means, the distributor or seller shall verify that the purchaser or recipient of the product is 21 years of age or older. The distributor or seller shall attempt to match the name, address, and date of birth provided by the customer to information contained in records in a database of individuals whose age has been verified to be 21 years or older by reference to an appropriate database of government records kept by the distributor, a direct marketing firm, or any other entity. In the case of a sale, the distributor or seller shall also verify that the billing address on the check or credit card offered for payment by the purchaser matches the address listed in the database.
 - (B) If the seller, distributor, or nonsale distributor, is unable to verify that the purchaser or recipient is 21 years of age or older pursuant to subparagraph (A), he or she shall require the customer or recipient to submit an age-verification kit consisting of an attestation signed by the customer or recipient that he or she is 21 years of age or older and a copy of a valid form of government identification. For the purposes of this section, a valid form of government identification includes a driver's license, state identification card, passport, an official naturalization or immigration document, such as an alien registration receipt card (commonly known as a "green card") or an immigrant visa, or military identification. In the case of a sale, the distributor or seller shall also verify that the billing address on the check or credit card provided by the consumer matches the address listed in the form of government identification.
- (2) In the case of a sale, the distributor or seller shall impose a two-carton minimum on each order of cigarettes, and shall require payment for the purchase of any tobacco product to be made by personal check of the purchaser or the purchaser's credit card. No money order or cash payment shall be received or permitted. The distributor or seller shall submit to each credit card acquiring company with which it has credit card sales identification information in an appropriate form and format so that the words "tobacco product" may be printed in the purchaser's credit card statement when a purchase of a tobacco product is made by credit card payment.
- (3) In the case of a sale, the distributor or seller shall make a telephone call after 5 p.m. to the purchaser confirming the order prior to shipping the tobacco products. The telephone call may be a person-to-person call or a recorded message. The distributor or seller is not required to speak directly with a person and may leave a message on an answering machine or by voice mail.
- (4) The nonsale distributor shall deliver the tobacco product to the recipient's verified mailing

address, or in the case of a sale, the seller or distributor shall deliver the tobacco product to the purchaser's verified billing address on the check or credit card used for payment. No delivery described under this section shall be permitted to any post office box.

- (c) Notwithstanding subdivisions (a) and (b), if a seller, distributor, or nonsale distributor, complies with all of the requirements of this section and a person under 21 years of age obtains a tobacco product by any of the means described in subdivision (b), the seller, distributor, or nonsale distributor is not in violation of this section.
- (d) For the purposes of the enforcement of this section pursuant to Section 22958, the acts of the United States Postal Service or other common carrier when engaged in the business of transporting and delivering packages for others, and the acts of a person, whether compensated or not, who transports or delivers a package for another person without any reason to know of the package's contents, are not unlawful and are not subject to civil penalties.
- (e) (1) (A) For the purposes of this section, a "distributor" is any person or entity, within or outside the state, who agrees to distribute tobacco products to a customer or recipient within the state. The United States Postal Service or any other public or private postal or package delivery service are not distributors within the meaning of this section.
 - (B) A "nonsale distributor" is any person inside or outside of this state who, directly or indirectly, knowingly provides tobacco products to any person in this state as part of a nonsale transaction. "Nonsale distributor" includes the person or entity who provides the tobacco product for delivery and the person or entity who delivers the product to the recipient as part of a nonsale transaction.
 - (C) "Nonsale distribution" means to give smokeless tobacco or cigarettes to the general public at no cost, or at nominal cost, or to give coupons, coupon offers, gift certificates, gift cards, or other similar offers, or rebate offers for smokeless tobacco or cigarettes to the general public at no cost or at nominal cost. Distribution of tobacco products, coupons, coupon offers, gift certificates, gift cards, or other similar offers, or rebate offers in connection with the sale of another item, including tobacco products, cigarette lighters, magazines, or newspapers shall not constitute nonsale distribution.
- (2) For the purpose of this section, a "seller" is any person or entity, within or outside the state, who agrees to sell tobacco products to a customer within the state. The United States Postal Service or any other public or private postal or package delivery service are not sellers within the meaning of this section.
- (3) For the purpose of this section, a "carton" is a package or container that contains 200 cigarettes.
- (f) A district attorney, city attorney, or the Attorney General may assess civil penalties against any person, firm, corporation, or other entity that violates this section, according to the following schedule:
 - (1) A civil penalty of not less than one thousand dollars (\$1,000) and not more than two thousand dollars (\$2,000) for the first violation.
 - (2) A civil penalty of not less than two thousand five hundred dollars (\$2,500) and not more than three thousand five hundred dollars (\$3,500) for the second violation.
 - (3) A civil penalty of not less than four thousand dollars (\$4,000) and not more than five thousand dollars (\$5,000) for the third violation within a five-year period.
 - (4) A civil penalty of not less than five thousand five hundred dollars (\$5,500) and not more than six thousand five hundred dollars (\$6,500) for the fourth violation within a five-year period.
 - (5) A civil penalty of ten thousand dollars (\$10,000) for a fifth or subsequent violation within a five-year period.

22964. This division sets forth minimum state restrictions with respect to the legal age to purchase or possess tobacco products and does not preempt or otherwise prohibit the adoption of a local standard that imposes a more restrictive legal age to purchase or possess tobacco products. A local standard that imposes a more restrictive legal age to purchase or possess tobacco products shall control in the event of any inconsistency between this division and a local standard.

Cigarette and Tobacco Products Licensing Act
BUSINESS AND PROFESSIONS CODE
SECTION 22970-22974.83

22970. This division shall be known as and may be cited as the Cigarette and Tobacco Products Licensing Act of 2003.

22970.1. The Legislature finds and declares all of the following:

- (a) The State of California has enacted excise taxes on the distribution of cigarettes and tobacco products to provide funding for local and state programs, including health services, antismoking campaigns, cancer research, and education programs.
- (b) Tax revenues have declined by hundreds of millions of dollars per year due, in part, to unlawful distributions and untaxed sales of cigarettes and tobacco products conducted by organized crime syndicates, street gangs, and international terrorist groups.
- (c) The enforcement of California's cigarette and tobacco products tax laws is necessary to collect millions of dollars in lost tax revenues each year.
- (d) The licensing of manufacturers, importers, wholesalers, distributors, and retailers will help stem the tide of untaxed distributions and illegal sales of cigarettes and tobacco products.

22970.2. The board shall administer a statewide program to license manufacturers, importers, distributors, wholesalers, and retailers of cigarettes and tobacco products.

22970.3. The board may create a Tobacco Tax Compliance Task Force for the purpose of advising the board on cigarette and tobacco products tax compliance issues that may include, but not be limited to, representatives from the following:

- (a) The board.
- (b) The office of the Attorney General.
- (c) The Franchise Tax Board.
- (d) The Department of Alcoholic Beverage Control.
- (e) The State Department of Health Services.
- (f) Federal agencies necessary to coordinate programs to combat tobacco tax evasion, smuggling, and counterfeiting.
- (g) One person from each of the categories of persons required by this division to have a license.
- (h) Other states engaged in tobacco tax compliance efforts.
- (i) Local law enforcement agencies.

22971. For purposes of this division, the following terms shall have the following meanings:

- (a) "Board" means the State Board of Equalization.
- (b) "Brand family" has the same meaning as that term is defined in paragraph (2) of subdivision (a) of Section 30165.1 of the Revenue and Taxation Code.
- (c) "Cigarette" means a cigarette as defined in Section 30003 of the Revenue and Taxation Code.
- (d) (1) "Control" or "controlling" means possession, direct or indirect, of the power:
 - (A) To vote 25 percent or more of any class of the voting securities issued by a person.
 - (B) To direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, other than a commercial contract for goods or nonmanagement services, or as otherwise provided; however, no individual shall be deemed to control a person solely on account of being a director, officer, or employee of that person.
- (2) For purposes of subparagraph (B) of paragraph (1), a person who, directly or indirectly, owns, controls, holds, with the power to vote, or holds proxies representing 10 percent or more of the then outstanding voting securities issued by another person, is presumed to control that other person.
- (3) For purposes of this division, the board may determine whether a person in fact controls another person.
- (e) "Display for sale" means the placement of cigarettes or tobacco products in a vending machine or in retail stock for the purpose of selling or gifting the cigarettes or tobacco products. For purposes of this

definition, the clear and easily visible display of cigarettes or tobacco products shall create a rebuttable presumption that either were displayed for sale.

- (f) "Distributor" means a distributor as defined in Section 30011 of the Revenue and Taxation Code.
- (g) "Gifting" means any transfer of title or possession without consideration, exchange, or barter, in any manner or by any means, of cigarettes or tobacco products that have been purchased for resale under a license issued pursuant to this division if the transfer occurs while the license is suspended or after the effective date of its revocation.
- (h) "Importer" means an importer as defined in Section 30019 of the Revenue and Taxation Code.
- (i) "Law enforcement agency" means a sheriff, a police department, or a city, county, or city and county agency or department designated by the governing body of that agency to enforce this chapter or to enforce local smoking and tobacco ordinances and regulations.
- (j) "License" means a license issued by the board pursuant to this division.
- (k) "Licensee" means any person holding a license issued by the board pursuant to this division.
- (l) "Manufacturer" means a manufacturer of cigarettes or tobacco products sold in this state.
- (m) "Notice" or "notification" means, unless as otherwise provided, the written notice or notification provided to a licensee by the board by either actual delivery to the licensee or by first-class mail addressed to the licensee at the address on the license.
- (n) "Package of cigarettes" means a package as defined in Section 30015 of the Revenue and Taxation Code.
- (o) "Person" means a person as defined in Section 30010 of the Revenue and Taxation Code.
- (p) "Retailer" means a person who engages in this state in the sale of cigarettes or tobacco products directly to the public from a retail location. Retailer includes a person who operates vending machines from which cigarettes or tobacco products are sold in this state.
- (q) "Retail location" means both of the following:
 - (1) Any building from which cigarettes or tobacco products are sold at retail.
 - (2) A vending machine.
- (r) "Sale" or "sold" means a sale as defined in Section 30006 of the Revenue and Taxation Code.
- (s) "Tobacco products" means tobacco products as defined in subdivision (b) of Section 30121 and subdivision (b) of Section 30131.1 of the Revenue and Taxation Code.
- (t) "Unstamped package of cigarettes" means a package of cigarettes that does not bear a tax stamp as required under Part 13 (commencing with Section 30001) of Division 2 of the Revenue and Taxation Code, including a package of cigarettes that bears a tax stamp of another state or taxing jurisdiction, a package of cigarettes that bears a counterfeit tax stamp, or a stamped or unstamped package of cigarettes that is marked "Not for sale in the United States."
- (u) "Wholesaler" means a wholesaler as defined in Section 30016 of the Revenue and Taxation Code.

22971.1. Commencing January 1, 2006, the Bureau of State Audits shall conduct a performance audit of the licensing and enforcement provisions of this division, and shall report its findings to the board and the Legislature by July 1, 2006. The report shall include, but not be limited to:

- (a) The actual costs of the program.
- (b) The level of additional revenue generated by the program compared to the period before its implementation.
- (c) Tax compliance rates.
- (d) The costs of enforcement at the varying levels.
- (e) The appropriateness of penalties assessed in this division.
- (f) The overall effectiveness of enforcement programs.

22971.2. The board shall administer and enforce the provisions of this division and may prescribe, adopt, and enforce rules and regulations relating to the administration and enforcement of this division.

22971.3. Nothing in this division preempts or supersedes any local tobacco control law other than those related to the collection of state taxes. Local licensing laws may provide for the suspension or revocation of the local license for any violation of a state tobacco control law.

22971.4. No person is subject to the requirements of this division if that person is exempt from regulation under the United States Constitution, the laws of the United States, or the California Constitution.

22971.5. Any notice required by this division shall be served personally or by mail. If by mail, the notice shall be placed in a sealed envelope, with postage paid, addressed to the licensee at the address as it appears in the records of the board. The giving of notice shall be deemed complete at the time of deposit of the notice in the United States Post Office, or a mailbox, subpost office, substation, or mail chute, or other facility regularly maintained or provided by the United States Postal Service, without extension of time for any reason. In lieu of mailing, a notice may be served personally by delivering to the person to be served and service shall be deemed complete at the time of delivery. Personal service to a corporation may be made by delivery of a notice to any person designated in the Code of Civil Procedure to be served for the corporation with summons and complaints in a civil action.

22971.7. (a) For the purposes of this chapter, except as provided in subdivision (b), and notwithstanding subdivision (s) of Section 22971, a "tobacco product" includes a product or device as defined in subdivision (d) of Section 22950.5.

(b) This section does not apply to subdivision (b) of Section 22974.3.

(c) This section shall be operative on January 1, 2017.

22972.

(a) Commencing June 30, 2004, a retailer shall have in place and maintain a license to engage in the sale of cigarettes or tobacco products. A retailer that owns or controls more than one retail location shall obtain a separate license for each retail location, but may submit a single application for those licenses.

(b) The retailer shall conspicuously display the license at each retail location in a manner visible to the public.

(c) A license is not assignable or transferable. A person who obtains a license as a retailer who ceases to do business as specified in the license, or who never commenced business, or whose license is suspended or revoked, shall immediately surrender the license to the board.

(d) A license shall be valid for a 12-month period, and shall be renewed annually.

22972.1.

(a) Notwithstanding Section 22972 or Section 22973, the board may issue to a retailer a temporary license with a scheduled expiration date, as determined by the board, that occurs on or before September 30, 2004.

(b) A temporary license issued pursuant to this section shall be automatically terminated upon the board's issuance of a license pursuant to Section 22973.1.

(c) A temporary license issued pursuant to this section is subject to the same suspension, revocation, and forfeiture provisions that apply to licenses issued by the board pursuant to Section 22973.1.

22973.

(a) An application for a license shall be filed on or before April 15, 2004, on a form prescribed by the board and shall include the following:

(1) The name, address, and telephone number of the applicant.

(2) The business name, address, and telephone number of each retail location. For applicants who control more than one retail location, an address for receipt of correspondence or notices from the board, such as a headquarters or corporate office of the retailer, shall also be included on the application and listed on the license. Citations issued to licensees shall be forwarded to all addressees on the license.

(3) A statement by the applicant affirming that the applicant has not been convicted of a felony and has not violated and will not violate or cause or permit to be violated any of the provisions of this division or any rule of the board applicable to the applicant or pertaining to the manufacture, sale, or distribution of cigarettes or tobacco products. If the applicant is unable to affirm this statement, the application shall contain a statement by the applicant of the nature of any violation or the reasons that will prevent the applicant from complying with the requirements with respect to the statement.

(4) If any other licenses or permits have been issued by the board or the Department of Alcoholic

Beverage Control to the applicant, the license or permit number of those licenses or permits then in effect.

- (5) A statement by the applicant that the contents of the application are complete, true, and correct. Any person who signs a statement pursuant to this subdivision that asserts the truth of any material matter that he or she knows to be false is guilty of a misdemeanor punishable by imprisonment of up to one year in the county jail, or a fine of not more than one thousand dollars (\$1,000), or both the imprisonment and the fine.
 - (6) The signature of the applicant.
 - (7) Any other information the board may require.
- (b) The board may investigate to determine the truthfulness and completeness of the information provided in the application. The board may issue a license without further investigation to an applicant for a retail location if the applicant holds a valid license from the Department of Alcoholic Beverage Control for that same location.
- (c) The board shall provide electronic means for applicants to download and submit applications.
- (d) (1) A one-time license fee of one hundred dollars (\$100) shall be submitted with each application. An applicant that owns or controls more than one retail location shall obtain a separate license for each retail location, but may submit a single application for those licenses with a one-time license fee of one hundred dollars (\$100) per location.
- (2) The one-time fee required by this subdivision does not apply to an application for renewal of a license for a retail location for which the one-time license fee has already been paid. If a license is reinstated after its expiration, the retailer, as a condition precedent to its reinstatement, shall pay a reinstatement fee of one hundred dollars (\$100).

22973.1.

- (a) The board shall issue a license to a retailer upon receipt of a completed application and payment of the fees prescribed in Section 22973, unless any of the following apply:
- (1) The retailer, or if the retailer is not an individual, any person controlling the retailer, has previously been issued a license that is suspended or revoked by the board for violation of any of the provisions of this division.
 - (2) The application is for a license or renewal of a license for a retail location that is the same retail location as that of a retailer whose license was revoked or is subject to revocation proceedings for violation of any of the provisions of this division, unless:
 - (A) It has been more than five years since a previous license for the retail location was revoked.
 - (B) The person applying for the license provides the board with documentation demonstrating that the applicant has acquired or is acquiring the premises or business in an arm's length transaction. For purposes of this section, an "arm's length transaction" is defined as a sale 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. A sale between relatives, related companies or partners, or a sale for the primary purpose of avoiding the effect of the violations of this division that occurred at the retail location, is presumed not to be made at "arm's length."
 - (3) The retailer, or if the retailer is not an individual, any person controlling the retailer, has been convicted of a felony pursuant to Section 30473 or 30480 of the Revenue and Taxation Code.
 - (4) The retailer does not possess all required permits or licenses required under the Revenue and Taxation Code.
- (b) (1) Any retailer who is denied a license may petition for a redetermination of the board's denial of the license within 30 days after service upon that retailer of the notice of the denial of the license. If a petition for redetermination is not filed within the 30-day period, the determination of denial becomes final at the expiration of the 30-day period.
- (2) Every petition for redetermination shall be in writing and shall state the specific grounds upon which the petition is founded. The petition may be amended to state additional grounds at anytime prior to the date on which the board issues its order or decision upon the petition for redetermination.
- (3) If the petition for redetermination is filed within the 30-day period, the board shall reconsider the determination of the denial and, if the retailer has so requested in the petition, shall grant the

- retailer an oral hearing and shall give the retailer at least 10 days' notice of the time and place of the hearing. The board may continue the hearing from time to time as may be necessary.
- (4) The order or decision of the board upon a petition for redetermination becomes final 30 days after mailing of notice thereof.
 - (5) Any notice required by this subdivision shall be served personally or by mail. If by mail, the notice shall be placed in a sealed envelope, with postage paid, addressed to the retailer at the address as it appears in the records of the board. The giving of notice shall be deemed complete at the time of deposit of the notice in the United States Post Office, or a mailbox, subpost office, substation or mail chute or other facility regularly maintained or provided by the United States Postal Service, without extension of time for any reason. In lieu of mailing, a notice may be served personally by delivering to the person to be served and service shall be deemed complete at the time of such delivery. Personal service to a corporation may be made by delivery of a notice to any person designated in the Code of Civil Procedure to be served for the corporation with summons and complaint in a civil action.

22973.2. The board shall, upon request, provide to the State Department of Health Services, the office of the Attorney General, a law enforcement agency, and any agency authorized to enforce local tobacco control ordinances, access to the board's database of licenses issued to retailers within the jurisdiction of that agency or law enforcement agency. The agencies authorized by this section to access the board's database shall only access and use the board's database for purposes of enforcing tobacco control laws and shall adhere to all state laws, policies, and regulations pertaining to the protection of personal information and individual privacy.

22973.3. (a) Notwithstanding any other law, an application for a license for the sale of a tobacco product, as defined in subdivision (d) of Section 22950.5, that is not subject to a tax imposed by the Cigarette and Tobacco Products Tax Law pursuant to Part 13 (commencing with Section 30001) of Division 2 of the Revenue and Taxation Code shall be filed on a form prescribed by the board and shall include the following:

- (1) The name, address, and telephone number of the applicant.
 - (2) The business name, address, and telephone number of each retail location. For applicants who control more than one retail location, an address for receipt of correspondence or notices from the board, such as a headquarters or corporate office of the retailer, shall also be included on the application and listed on the license. Citations issued to licensees shall be forwarded to all addressees on the license.
 - (3) A statement by the applicant affirming that the applicant has not been convicted of a felony and has not violated and will not violate or cause or permit to be violated any of the provisions of this division or any rule of the board applicable to the applicant or pertaining to the manufacture, sale, or distribution of cigarettes or tobacco products. If the applicant is unable to affirm this statement, the application shall contain a statement by the applicant of the nature of any violation or the reasons that will prevent the applicant from complying with the requirements with respect to the statement.
 - (4) If any other licenses or permits have been issued by the board or the Department of Alcoholic Beverage Control to the applicant, the license or permit number of those licenses or permits then in effect.
 - (5) A statement by the applicant that the contents of the application are complete, true, and correct. Any person who signs a statement pursuant to this subdivision that asserts the truth of any material matter that he or she knows to be false is guilty of a misdemeanor punishable by imprisonment of up to one year in the county jail, or a fine of not more than one thousand dollars (\$1,000), or both the imprisonment and the fine.
 - (6) The signature of the applicant.
 - (7) Any other information the board may require.
- (b) The board may investigate to determine the truthfulness and completeness of the information provided in the application. The board may issue a license without further investigation to an applicant for a retail location if the applicant holds a valid license from the Department of Alcoholic Beverage Control for that same location.
- (c) The board shall provide electronic means for applicants to download and submit applications.

- (d) A fee of two hundred sixty-five dollars (\$265) shall be submitted with each application. An applicant that owns or controls more than one retail location shall obtain a separate license for each retail location, but may submit a single application for those licenses with an application license fee of two hundred sixty-five dollars (\$265) per location.
- (e) Every retailer shall file an application for renewal of its license, accompanied with a fee of two hundred sixty-five dollars (\$265) per retail location in the form and manner prescribed by the board.
- (f) (1) The board shall report back to the Legislature no later than January 1, 2019, regarding the adequacy of funding for the Cigarette and Tobacco Products Licensing Act of 2003 with regard to tobacco products for which a license is required by this section. The report shall include data and recommendations about whether the annual licensing fee funding levels are set at an appropriate level to maintain an effective enforcement program.
 (2) The report required by paragraph (1) shall be submitted in compliance with Section 9795 of the Government Code.
- (g) (1) This section shall apply to a retailer who sells a tobacco product, as defined in subdivision (d) of Section 22950.5, that is not subject to a tax imposed by the Cigarette and Tobacco Products Tax Law pursuant to Part 13 (commencing with Section 30001) of Division 2 of the Revenue and Taxation Code, and who does not already possess a valid license to sell cigarettes or tobacco products issued pursuant to Section 22972.
 (2) A retailer that possesses a valid license to sell cigarettes and tobacco products issued pursuant to Section 22972 may also sell under that license a tobacco product, as defined in subdivision (d) of Section 22950.5, that is not subject to a tax imposed by the Cigarette and Tobacco Products Tax Law pursuant to Part 13 (commencing with Section 30001) of Division 2 of the Revenue and Taxation Code.
- (h) This section shall become operative January 1, 2017.

22974. A retailer shall retain purchase invoices that meet the requirements set forth in Section 22978.4 for all cigarettes or tobacco products the retailer purchased for a period of four years. The records shall be kept at the retail location for at least one year after the purchase. Invoices shall be made available upon request during normal business hours for review inspection and copying by the board or by a law enforcement agency. Any retailer found in violation of these requirements or any person who fails, refuses, or neglects to retain or make available invoices for inspection and copying in accordance with this section shall be subject to penalties pursuant to Section 22981.

22974.3.

- (a) Notwithstanding any other provision of this division, upon discovery by the board or a law enforcement agency that a retailer or any other person possesses, stores, owns, or has made a retail sale of an unstamped package of cigarettes, the board or the law enforcement agency shall be authorized to seize unstamped packages of cigarettes at the retail, or any other person's location. Any cigarettes seized by a law enforcement agency shall be delivered to the board, or its designee, within seven days, unless the cigarettes will be destroyed by that law enforcement agency, or unless the cigarettes are otherwise required to be used as evidence in an administrative, criminal, or civil proceeding, or as part of an ongoing law enforcement operation. Any cigarettes seized by the board or delivered to the board by a law enforcement agency shall be deemed forfeited and the board shall comply with procedures set forth in Part 13 (commencing with Section 30436) of Division 2 of Chapter 7.5 of the Revenue and Taxation Code. In addition to the inventory of unstamped packages of cigarettes of a retailer or of any other person that is subject to forfeiture and seizure, the possession, storage, ownership, or retail sales of unstamped packages of cigarettes by a retailer or other person, as applicable, shall constitute a misdemeanor punishable by the following actions:
 - (1) A first violation involving seizure of a total quantity of less than 20 packages of unstamped cigarettes shall be a misdemeanor punishable by a fine of one thousand dollars (\$1,000) or imprisonment not to exceed one year in a county jail, or both the fine and imprisonment.
 - (2) A second violation within five years involving a seizure of a total quantity of less than 20 packages of unstamped cigarettes shall be a misdemeanor punishable by a fine of not less than two thousand dollars (\$2,000) but not to exceed five thousand dollars (\$5,000) or imprisonment not to exceed one year in a county jail, or both the fine and imprisonment, and shall also result in the revocation of the license.

- (3) A first violation involving seizure of a total quantity of 20 packages of unstamped cigarettes or more shall be a misdemeanor punishable by a fine of two thousand dollars (\$2,000) or imprisonment not to exceed one year in a county jail, or both the fine and imprisonment.
 - (4) A second violation within five years involving seizure of a quantity of 20 packages of unstamped cigarettes or more shall be a misdemeanor punishable by a fine of not less than five thousand dollars (\$5,000) but not to exceed fifty thousand dollars (\$50,000) or imprisonment not to exceed one year in a county jail, or both the fine and imprisonment, and shall also result in the revocation of the license.
- (b) Upon discovery by the board or a law enforcement agency that a retailer or any other person possesses, stores, owns, or has made a retail sale of tobacco products on which tax is due but has not been paid to the board, the board or law enforcement agency is authorized to seize such tobacco products at the retail, or any other person's location. Any tobacco products seized by a law enforcement agency shall be delivered to the board, or its designee, within seven days, unless otherwise required to be used as evidence in an administrative, criminal, or civil proceeding, or as part of an ongoing law enforcement operation. Any tobacco products seized by the board or delivered to the board by a law enforcement agency shall be deemed forfeited and the board shall comply with procedures set forth in Part 13 (commencing with Section 30436) of Division 2 of Chapter 7.5 of the Revenue and Taxation Code. It shall be presumed that tax has not been paid to the board on all tobacco products in the possession of a retailer or of any other person until the contrary is established by a proof of payment to the board or by a purchase invoice that shows that the retailer or other person, as applicable, paid the tax included purchase price to a licensed distributor, wholesaler, manufacturer, or importer as described in Section 22978.4. The burden of proof that tax has been paid on tobacco products shall be upon the retailer or the other person, as applicable, in possession thereof. Possession of untaxed tobacco products on which tax is due but has not been paid as required is a violation of this division and subjects the retailer or other person, as applicable, to the actions described in Section 22981.

22974.4. The board shall revoke the license, pursuant to the provisions applicable to the revocation of a license as set forth in Section 30148 of the Revenue and Taxation Code, of any retailer or any person controlling the retailer that has:

- (a) Been convicted of a felony pursuant to Section 30473 or 30480 of the Revenue and Taxation Code.
- (b) Had any permit or license revoked under any provision of the Revenue and Taxation Code.

22974.5. Any retailer who fails to display a license as required in Section 22972 shall, in addition to any other applicable penalty, be liable for a penalty of five hundred dollars (\$500).

22974.7. In addition to any other civil or criminal penalty provided by law, upon a finding that a retailer has violated any provision of this division, the board may take the following actions:

- (a) In the case of the first offense, the board may revoke or suspend the license or licenses of the retailer pursuant to the procedures applicable to the revocation of a license set forth in Section 30148 of the Revenue and Taxation Code.
- (b) In the case of a second or any subsequent offense, in addition to the action authorized under subdivision (a), the board may impose a civil penalty in an amount not to exceed the greater of either of the following:
 - (1) Five times the retail value of the seized cigarettes or tobacco products.
 - (2) Five thousand dollars (\$5,000).

22974.8.

- (a) Except as provided in subdivision (b), the board shall suspend or revoke the license of a retailer upon notification by the State Department of Public Health pursuant to subdivision (b) of Section 22958.
- (b) Notwithstanding any other provision regarding the suspension or revocation of a license pursuant to this part, the board shall provide a licensee with at least 10 days' written notice of a pending suspension or revocation pursuant to this section and an opportunity to appeal the suspension or revocation and the civil penalty assessed pursuant to subdivision (b) of Section 22958 only to correct a mistake or clerical error. The board shall not accept or consider an appeal of suspension or

revocation under this section if the appeal is founded upon the grounds of whether the retailer, or any employee or agent of the retailer, violated the STAKE Act (Division 8.5 (commencing with Section 22950)) for which violation civil penalties are imposed by the State Department of Public Health pursuant to subdivision (a) of Section 22958. This section shall not be construed to prevent the board from modifying its action on its own to correct a mistake or clerical error.

- 22980.2. (a) A person or entity that engages in the business of selling cigarettes or tobacco products in this state either without a valid license or after a license has been suspended or revoked, and each officer of any corporation that so engages in this business, is guilty of a misdemeanor punishable as provided in Section 22981.
- (b) Each day after notification by the board or by a law enforcement agency that a manufacturer, wholesaler, distributor, importer, retailer, or any other person required to be licensed under this division offers cigarette and tobacco products for sale or exchange without a valid license for the location from which they are offered for sale shall constitute a separate violation.
- (c) Continued sales or gifting of cigarettes and tobacco products either without a valid license or after a notification of suspension or revocation shall constitute a violation punishable as provided in Section 22981, and shall result in the seizure of all cigarettes and tobacco products in the possession of the person by the board or a law enforcement agency. Any cigarettes and tobacco products seized by the board or by a law enforcement agency shall be deemed forfeited.
- (d) For the purposes of this section, notwithstanding subdivision (s) of Section 22971, "tobacco products" includes a product or device as defined in subdivision (d) of Section 22950.5.
- (e) This section shall be operative on January 1, 2017.

**Penal Code Section 308
Tobacco Products**

308.

- (a) (1) (A) (i) Every person, firm, or corporation that knowingly or under circumstances in which it has knowledge, or should otherwise have grounds for knowledge, sells, gives, or in any way furnishes to another person who is under 21 years of age any tobacco, cigarette, or cigarette papers, or blunts wraps, or any other preparation of tobacco, or any other instrument or paraphernalia that is designed for the smoking or ingestion of tobacco, tobacco products, or any controlled substance, is subject to either a criminal action for a misdemeanor or to a civil action brought by a city attorney, a county counsel, or a district attorney, punishable by a fine of two hundred dollars (\$200) for the first offense, five hundred dollars (\$500) for the second offense, and one thousand dollars (\$1,000) for the third offense.
- (ii) This subparagraph does not apply to the sale, giving, or furnishing of any of the products specified in clause (i) to active duty military personnel who are 18 years of age or older. An identification card issued by the United States Armed Forces shall be used as proof of age for this purpose.
- (B) Notwithstanding Section 1464 or any other law, 25 percent of each civil and criminal penalty collected pursuant to this subdivision shall be paid to the office of the city attorney, county counsel, or district attorney, whoever is responsible for bringing the successful action.
- (C) Proof that a defendant, or his or her employee or agent, demanded, was shown, and reasonably relied upon evidence of majority shall be defense to any action brought pursuant to this subdivision. Evidence of majority of a person is a facsimile of or a reasonable likeness of a document issued by a federal, state, county, or municipal government, or subdivision or agency thereof, including, but not limited to, a motor vehicle operator's license, a registration certificate issued under the federal Selective Service Act, or an identification card issued to a member of the Armed Forces.
- (D) For purposes of this section, the person liable for selling or furnishing tobacco products to persons under 21 years of age by a tobacco vending machine shall be the person authorizing the installation or placement of the tobacco vending machine upon premises he or she manages or otherwise controls and under circumstances in which he or she has knowledge, or should otherwise have grounds for knowledge, that the tobacco vending machine will be utilized by persons under 21 years of age.
- (2) For purposes of this section, "blunt wraps" means cigar papers or cigar wrappers of all types that are designed for smoking or ingestion of tobacco products and contain less than 50 percent tobacco.
- (b) Every person, firm, or corporation that sells, or deals in tobacco or any preparation thereof, shall post conspicuously and keep so posted in his, her, or their place of business at each point of purchase the notice required pursuant to subdivision (b) of Section 22952 of the Business and Professions Code, and any person failing to do so shall, upon conviction, be punished by a fine of fifty dollars (\$50) for the first offense, one hundred dollars (\$100) for the second offense, two hundred fifty dollars (\$250) for the third offense, and five hundred dollars (\$500) for the fourth offense and each subsequent violation of this provision, or by imprisonment in a county jail not exceeding 30 days.
- (c) For purposes of determining the liability of persons, firms, or corporations controlling franchises or business operations in multiple locations for the second and subsequent violations of this section, each individual franchise or business location shall be deemed a separate entity.
- (d) It is the Legislature's intent to regulate the subject matter of this section. As a result, a city, county, or city and county shall not adopt any ordinance or regulation inconsistent with this section.
- (e) For purposes of this section, "smoking" has the same meaning as in subdivision (c) of Section 22950.5 of the Business and Professions Code.
- (f) For purposes of this section, "tobacco products" means a product or device as defined in subdivision (d) of Section 22950.5 of the Business and Professions Code.

308.1.

- (a) Notwithstanding any other provision of law, no person shall sell, offer for sale, distribute, or import any tobacco product commonly referred to as "bidis" or "beedies," unless that tobacco product is

sold, offered for sale, or intended to be sold in a business establishment that prohibits the presence of persons under 18 years of age on its premises.

- (b) For purposes of this section, "bidis" or "beedies" means a product containing tobacco that is wrapped in temburni leaf (*diospyros melanoxylon*) or tendu leaf (*diospyros exculpra*).
- (c) Any person who violates this section is guilty of a misdemeanor or subject to a civil action brought by the Attorney General, a city attorney, county counsel, or district attorney for an injunction and a civil penalty of up to two thousand dollars (\$2,000) per violation. This subdivision does not affect any other remedies available for a violation of this section.

308.2.

- (a) Every person who sells one or more cigarettes, other than in a sealed and properly labeled package, is guilty of an infraction.
- (b) "A sealed and properly labeled package," as used in this section, means the original packaging or sanitary wrapping of the manufacturer or importer which conforms to federal labeling requirements, including the federal warning label.

308.3.

- (a) A person, firm, corporation, or business may not manufacture for sale, distribute, sell, or offer to sell any cigarette, except in a package containing at least 20 cigarettes. A person, firm, corporation, or business may not manufacture for sale, distribute, sell, or offer to sell any roll-your-own tobacco, except in a package containing at least 0.60 ounces of tobacco.
- (b) As used in subdivision (a), "cigarette" means any product that contains nicotine, is intended to be burned or heated under ordinary conditions of use, and consists of, or contains any of, the following:
 - (1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco.
 - (2) Tobacco, in any form, that is functional in the product, that, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette.
 - (3) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in this subdivision.
- (c) Any person, firm, corporation, or business that violates this section is liable for an infraction, or in an action brought by the Attorney General, a district attorney, a county counsel, or a city attorney for a civil penalty of two hundred dollars (\$200) for the first violation, five hundred dollars (\$500) for the second violation, and one thousand dollars (\$1,000) for each subsequent act constituting a violation.

308.5.

- (a) No person or business shall sell, lease, rent, or provide, or offer to sell, lease, rent, or otherwise offer to the public or to public establishments in this state, any video game intended for either private use or for use in a public establishment and intended primarily for use by any person under the age of 18 years, which contains, in its design and in the on-screen presentation of the video game, any paid commercial advertisement of alcoholic beverage or tobacco product containers or other forms of consumer packaging, particular brand names, trademarks, or copyrighted slogans of alcoholic beverages or tobacco products.
- (b) As used in this section, "video game" means any electronic amusement device that utilizes a computer, microprocessor, or similar electronic circuitry and its own cathode ray tube, or is designed to be used with a television set or a monitor, that interacts with the user of the device.
- (c) A violation of this section is a misdemeanor.

308b.

- (a) Except as provided in subdivision (b), every person who knowingly delivers or causes to be delivered to any residence in this state any tobacco products unsolicited by any person residing therein is guilty of a misdemeanor.
- (b) It is a defense to a violation of this section that the recipient of the tobacco products is personally known to the defendant at the time of the delivery.
- (c) The distribution of unsolicited tobacco products to residences in violation of this section is a nuisance within the meaning of Section 3479 of the Civil Code.

- (d) Nothing in this section shall be construed to impose any liability on any employee of the United States Postal Service for actions performed in the scope of his employment by the United States Postal Service.

Penal Code 347

Crimes Against Public Decency And Good Morals: Other Injuries To Persons

- 347 (a) (1) Every person who willfully mingles any poison or harmful substance with any food, drink, medicine, or pharmaceutical product or who willfully places any poison or harmful substance in any spring, well, reservoir, or public water supply, where the person knows or should have known that the same would be taken by any human being to his or her injury, is guilty of a felony punishable by imprisonment in the state prison for two, four, or five years.
- (2) Any violation of paragraph (1) involving the use of a poison or harmful substance that may cause death if ingested or that causes the infliction of great bodily injury on any person shall be punished by an additional term of three years.
- (b) Any person who maliciously informs any other person that a poison or other harmful substance has been or will be placed in any food, drink, medicine, pharmaceutical product, or public water supply, knowing that such report is false, is guilty of a crime punishable by imprisonment in the state prison, or by imprisonment in the county jail not to exceed one year.
- (c) The court may impose the maximum fine for each item tampered with in violation of subdivision (a).

347b. It shall be unlawful for any person, firm or corporation to manufacture, sell, furnish, or give away, or offer to manufacture, sell, furnish, or give away any alcoholic solution of a potable nature containing any deleterious or poisonous substance, and the burden of proof shall be upon the person, firm, or corporation manufacturing, selling, furnishing, or giving away, or offering to manufacture, sell, furnish, or give away, any such alcoholic solution of a potable nature containing any deleterious or poisonous substance, to show that such alcoholic solution of a potable nature did not contain any deleterious or poisonous substance. Every person who violates any of the provisions of this section is guilty of a misdemeanor, and shall be punished by a fine not exceeding two thousand five hundred dollars (\$2,500), or by imprisonment in a county jail not exceeding one year, or by both such fine and imprisonment.

Penal Code Section 382 – 383
Crimes Against Public Health and Safety

382. Every person who adulterates or dilutes any article of food, drink, drug, medicine, spirituous or malt liquor, or wine, or any article useful in compounding them, with the fraudulent intent to offer the same, or cause or permit it to be offered for sale as unadulterated or undiluted; and every person who fraudulently sells, or keeps or offers for sale the same, as unadulterated or undiluted, or who, in response to an inquiry for any article of food, drink, drug, medicine, spirituous or malt liquor, or wine, sells or offers for sale, a different article, or an article of a different character or manufacture, without first informing such purchaser of such difference, is guilty of a misdemeanor; provided, that no retail dealer shall be convicted under the provisions of this section if he shall prove a written guaranty of purity obtained from the person from whom he purchased such adulterated or diluted goods.

382.6. Every person who sells, dispenses, administers or prescribes preparations containing diphenylamine, paraphenylenediamine, or paratoluylenediamine, or a derivative of any such chemicals, to be used as eyebrow and eyelash dye, shall be guilty of a felony, punishable by a fine not less than one thousand dollars (\$1,000) nor more than ten thousand dollars (\$10,000), or by imprisonment in the state prison, or by both such fine and imprisonment.

382.7. Every person who knowingly prescribes, dispenses, administers, or furnishes any liquid silicone substance for the purpose of injection into a human breast or mammary is guilty of a misdemeanor.

383. Every person who knowingly sells, or keeps or offers for sale, or otherwise disposes of any article of food, drink, drug, or medicine, knowing that the same is adulterated or has become tainted, decayed, spoiled, or otherwise unwholesome or unfit to be eaten or drunk, with intent to permit the same to be eaten or drunk, is guilty of a misdemeanor, and must be fined not exceeding one thousand dollars (\$1,000), or imprisoned in the county jail not exceeding six months, or both, and may, in the discretion of the court, be adjudged to pay, in addition, all the necessary expenses, not exceeding one thousand dollars (\$1,000), incurred in inspecting and analyzing such articles. The term "drug," as used herein, includes all medicines for internal or external use, antiseptics, disinfectants, and cosmetics. The term "food," as used herein, includes all articles used for food or drink by man, whether simple, mixed, or compound. Any article is deemed to be adulterated within the meaning of this section:

(a) In case of drugs:

- (1) if, when sold under or by a name recognized in the United States Pharmacopoeia, it differs materially from the standard of strength, quality, or purity laid down therein;
- (2) if, when sold under or by a name not recognized in the United States Pharmacopoeia, but which is found in some other pharmacopoeia or other standard work on materia medica, it differs materially from the standard of strength, quality, or purity laid down in such work;
- (3) if its strength, quality, or purity falls below the professed standard under which it is sold.

(b) In the case of food:

- (1) if any substance or substances have been mixed with it, so as to lower or depreciate, or injuriously affect its quality, strength, or purity;
- (2) if any inferior or cheaper substance or substances have been substituted wholly or in part for it;
- (3) if any valuable or necessary constituent or ingredient has been wholly or in part abstracted from it;
- (4) if it is an imitation of, or is sold under the name of, another article;
- (5) if it consists wholly, or in part, of a diseased, decomposed, putrid, infected, tainted, or rotten animal or vegetable substance or article, whether manufactured or not; or in the case of milk, if it is the produce of a diseased animal;
- (6) if it is colored, coated, polished, or powdered, whereby damage or inferiority is concealed, or if by any means it is made to appear better or of greater value than it really is; (7) if it contains any added substance or ingredient which is poisonous or injurious to health.

383a. Any person, firm, or corporation, who sells or offers for sale, or has in his or its possession for sale, any butter manufactured by boiling, melting, deodorizing, or renovating, which is the product of stale, rancid, or decomposed butter, or by any other process whereby stale, rancid, or decomposed butter is manufactured to resemble or appear like creamery or dairy butter, unless the same is plainly stenciled or branded upon each and every package, barrel, firkin, tub, pail, square, or roll, in letters not less than one half inch in length, "process butter," or "renovated butter," in such a manner as to advise the purchaser of the real character of such "process" or "renovated" butter, is guilty of a misdemeanor.

383b. Every person who with intent to defraud, sells or exposes for sale any meat or meat preparations, and falsely represents the same to be kosher, whether such meat or meat preparations be raw or prepared for human consumption, or as having been prepared under and from a product or products sanctioned by the orthodox Hebrew religious requirements; or falsely represents any food product, or the contents of any package or container, to be so constituted and prepared, by having or permitting to be inscribed thereon the words "kosher" in any language; or sells or exposes for sale in the same place of business both kosher and nonkosher meat or meat preparations, either raw or prepared for human consumption, who fails to indicate on his window signs in all display advertising in block letters at least four inches in height "kosher and nonkosher meats sold here"; or who exposes for sale in any show window or place of business as both kosher and nonkosher meat preparations, either raw or prepared for human consumption, who fails to display over each kind of meat or meat preparation so exposed a sign in block letters at least four inches in height, reading "kosher meat" or "nonkosher meat" as the case may be; or sells or exposes for sale in any restaurant or any other place where food products are sold for consumption on the premises, any article of food or food preparations and falsely represents the same to be kosher, or as having been prepared in accordance with the orthodox Hebrew religious requirements; or sells or exposes for sale in such restaurant, or such other place, both kosher and nonkosher food or food preparations for consumption on the premises, not prepared in accordance with the Jewish ritual, or not sanctioned by the Hebrew orthodox religious requirements, and who fails to display on his window signs in all display advertising, in block letters at least four inches in height "kosher and nonkosher food served here" is guilty of a misdemeanor and upon conviction thereof be punishable by a fine of not less than one hundred dollars (\$100), nor more than six hundred dollars (\$600), or imprisonment in the county jail of not less than 30 days, nor more than 90 days, or both such fine and imprisonment. The word "kosher" is here defined to mean a strict compliance with every Jewish law and custom pertaining and relating to the killing of the animal or fowl from which the meat is taken or extracted, the dressing, treatment and preparation thereof for human consumption, and the manufacture, production, treatment and preparation of such other food or foods in connection wherewith Jewish laws and customs obtain and to the use of tools, implements, vessels, utensils, dishes and containers that are used in connection with the killing of such animals and fowls and the dressing, preparation, production, manufacture and treatment of such meats and other products, foods and food stuffs.

383c. Every person who with intent to defraud, sells or exposes for sale any meat or meat preparations, and falsely represents the same to be halal, whether the meat or meat preparations is raw or prepared for human consumption, or as having been prepared under and from a product or products sanctioned by the Islamic religious requirements; or falsely represents any food product, or the contents of any package or container, to be so constituted and prepared, by having or permitting to be inscribed thereon the word "halal" in any language; or sells or exposes for sale in the same place of business both halal and nonhalal meat or meat preparations, either raw or prepared for human consumption, who fails to indicate on his or her window signs in all display advertising in block letters at least four inches in height "halal and nonhalal meats sold here"; or who exposes for sale in any show window or place of business as both halal and nonhalal meat preparations, either raw or prepared for human consumption, who fails to display over each kind of meat or meat preparation so exposed a sign in block letters at least four inches in height, reading "halal meat" or "nonhalal meat" as the case may be; or sells or exposes for sale in any restaurant or any other place where food products are sold for consumption on the premises, any article of food or food preparations and falsely represents the same to be halal, or as having been prepared in accordance with the Islamic religious requirements; or sells or exposes for sale in a restaurant, or other place, both halal and nonhalal food or food preparations for consumption on the premises, not prepared in accordance with the Islamic ritual, or not sanctioned by Islamic religious requirements, and who fails to display on his or her window signs in all display advertising, in block letters at least four inches in height "halal and nonhalal

food served here" is guilty of a misdemeanor and upon conviction thereof be punishable by a fine of not less than one hundred dollars (\$100), nor more than six hundred dollars (\$600), or imprisonment in a county jail of not less than 30 days, nor more than 90 days, or both that fine and imprisonment. The word "halal" is here defined to mean a strict compliance with every Islamic law and custom pertaining and relating to the killing of the animal or fowl from which the meat is taken or extracted, the dressing, treatment, and preparation thereof for human consumption, and the manufacture, production, treatment, and preparation of other food or foods in connection wherewith Islamic laws and customs obtain and to the use of tools, implements, vessels, utensils, dishes, and containers that are used in connection with the killing of animals and fowls and the dressing, preparation, production, manufacture, and treatment of meats and other products, foods, and food stuffs.