CDPH-24-003E
12/12/2025

California Code of Regulations
Title 17. Public Health
Division 1. State Department of Health Services
Chapter 5. Sanitation (Environmental)
Subchapter 2. Food and Drugs
Group 1. Rules and Regulations
Article 8. Cannery Inspection Regulations

Adopt Section 12350 to read as follows:
§ 12350 Applicability.

The regulations of this Article apply to any person engaged in the noncommercial manufacturing or packing of salmon, or in the commercial manufacturing or packing of shelf-stable acidified foods or low-acid foods packaged in hermetically sealed containers.

Note: Authority cited: Sections 100275, 110065, 112825, and 131200, Health and Safety Code.
Reference: Sections 112675 and 112750, Health and Safety Code.

Adopt Section 12355 to read as follows:
§ 12355 Definitions.
For the purposes of this Article, the following definitions shall apply:

"Acidified foods" means shelf-stable low-acid foods to which acid(s) or acid food(s) are added and packaged within hermetically sealed containers with a finished equilibrium pH of 4.6 or below and a water activity (a_w) greater than 0.85.

“Commercial sterility” of food means the condition achieved by the application of heat, the control of water activity (a_w), the control of pH, or other treatment which renders the food free of microorganisms capable of reproducing in the food under nonrefrigerated conditions of storage and distribution, and viable microorganisms (including spores) of public health significance.

“Critical factor” means any property, characteristic, condition, aspect, or other parameter, the variation of which may affect the scheduled process and the attainment of commercial sterility.

“Hermetically sealed container” means a container that is designed and intended to prevent the entry of microorganisms and thereby to maintain the commercial sterility of its contents after processing. “Low-Acid foods" means any shelf-stable foods, other than alcoholic beverages, packaged in hermetically sealed containers with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85 (historically referred to as “low-acid canned foods” or “LACF”). Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not low-acid foods.

"Official State Process Letters" means documents identifying critical factors and the scheduled process issued by the Department under the conditions of manufacture for a given food to achieve commercial sterility.

“Operational Documents” means documents identifying critical factors and the specifications issued by the Department under the conditions of manufacture for a given processing system to administer the scheduled process required of a given food to achieve commercial sterility.

“Process deviation” means the event in which any process or critical factor fails to satisfy the minimum requirements of the scheduled process identified in Official State Process Letters or Operational Documents for any acidified food, low-acid food, or processing system as disclosed from records by processor check or otherwise.

“Processing system” means retorts, aseptic processing and packaging systems, or any other equipment used to administer the scheduled process required of a given acidified food or low-acid food to achieve commercial sterility.

“Scheduled process” means the process selected by the processor under the conditions of manufacture for a given food to achieve commercial sterility. This process shall be at least equivalent to the process identified in Official State Process Letters and Operational Documents.

Note: Authority cited: Sections 100275, 110065, 112825, and 131200, Health and Safety Code.
Reference: Sections 12405 and 12455, California Code of Regulations. Title 21 Code of Federal Regulations Sections 113.3 and 114.3.

Repeal Section 12400:
~~**§ 12400. Applicability.**~~

~~Low acid (high pH) foods or acid foods containing low acid ingredients to an extent where a food poisoning hazard may exist when placed in hermetically sealed containers, and which are not processed by steam under pressure must be packed under the supervision of the Department of Public Health. This includes several types or classes of food products, among which are the following: vegetables in acidified brine or oil, vegetable juice cocktails, and various formulated products.~~

~~Cal. Admin. Code tit. 17, § 12400, 17 CA ADC § 12400~~

Adopt Section 12401 to read as follows:

§12401 Application for Official State Process Letters and Operational Documents

Official State Process Letters and Operational Documents must be obtained prior to manufacturing acidified foods or low-acid foods.

(a) Application for Official State Process Letters
  (1) Acidified Foods. Product and process information for acidified foods must be submitted to the Department on Form CDPH 8589 (Rev. 8/2023) Request For pH Control, hereby incorporated by reference.
  (2) Low-Acid Foods. Product and process information for low-acid foods must be submitted to the Department on Form CDPH 8562 (Rev. 10/2023) Request for Official Sterilization Process, hereby incorporated by reference.

(b) Application for Operational Documents
  (1) Processing system information must be submitted to the Department on Form CDPH 8562 (Rev. 10/2023) Request For Official Sterilization Process, hereby incorporated by reference.

(c) The completed applications provided for in paragraphs (a) and (b) must be submitted to the Department for review. These applications are available on the California Department of Public Health – Food & Drug Branch Cannery Inspection and Licensing Program's Web site at https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/CanneryInspectionProgram.aspx.
  (1) If an application is incomplete, the Department shall notify the applicant. The applicant must submit the missing information to the Department, or resubmit the application forms with the missing information, no later than thirty (30) calendar days from the date of notification from the Department. The application shall be deemed abandoned if the missing information is not submitted within the specified timeframe and the applicant must reapply.
  (2) The Department shall evaluate each complete application on a case-by-case basis, based on an analysis of each application's unique combination of factors including: pH, time and temperature values, product formulation, ingredients, preservative levels, the processing system, and the packaging

container materials, for each product in each container size. Upon completion of this evaluation, the Department shall issue Official State Process Letters and Operational Documents identifying requirements for processing system operations, scheduled processes, and critical factors requiring control under the conditions of manufacture for a given food to achieve commercial sterility.

(d) Any person that changes an evaluated product or processing system, for which the Department has issued Official State Process Letters or Operational Documents, must obtain new Official State Process Letters or Operational Documents from the Department. These changes include but are not limited to changes to processing systems, equipment employed, or equipment parts and components outside of routine maintenance, changes to product formulation, changes to container size or material, or any other condition related to the scheduled process. These changes shall render existing Official State Process Letters and Operational Documents invalid.

Note: Authority cited: Sections 100275, 110065, 112825, and 131200, Health and Safety Code.

Reference: Sections 12405 and 12455, California Code of Regulations. Title 21 Code of Federal Regulations Sections 108.25 and 108.35.

Repeal Section 12445:

~~**§ 12445. Releases.**~~

~~Batches of foods subject to pH control are not to be released by the state cannery inspector until authorization is received from the San Francisco Office.~~

~~Cal. Admin. Code tit. 17, § 12445, 17 CA ADC § 12445~~

Amend Section 12470 to read as follows:

§ 12470. Record of Cooks.

Each licensed retort operator shall keep a record of the cooks as required by the State Board of Public Health.

(a) The original and a duplicate of the production record must be kept by filling in accurately in complete detail the form approved by the Department of Public Health. Each entry in the record must be made by the operator at the time the specific retort operation is observed and not copied afterward. It must be in legible handwriting and be signed by the operator or operators.

(b) Chart of recording thermometer must show full time and temperature as required, otherwise the product will be restrained.

~~(c) Each production record and recording thermometer chart shall be stamped, initialed and numbered by a state cannery inspector before use and must be accounted for.~~

~~(d)~~ (c) The cook or batch number and size of cans involved must be recorded by the canner in each respective curve of all temperature charts.
~~(e) Production records and charts must be scrutinized and checked by a state cannery inspector before product is released for shipment.~~

~~Cal. Admin. Code tit. 17, § 12470, 17 CA ADC § 12470~~

Note: Authority cited: Sections 100275, 110065, 112825, and 131200, Health and Safety Code.
Reference: Title 21, Code of Federal Regulations, Section 113.40(a)(2), 113.100, 114.100, 117.305

Amend Section 12555 to read as follows:

§ 12555. Reporting Spoilage, Process Deviations, or Contamination with Microorganisms.

~~Spoilage in any canned products packed under inspection must be reported in writing to the nearest office of the Department of Public Health, or to any Cannery Inspector in person.~~

(a) Any person, per Section 12350, must report to the Department in writing, within one working day, any instance of spoilage, process deviation, or contamination with microorganisms in acidified foods or low-acid foods.

(b) Written reports to the Department must:

(1) Identify product affected, the manufacture date, the lot code, the number of affected containers, and the Official State Process Letter for the affected product;

(A) All cans containing swells to any degree, including buckling, springers, ~~and~~ or flippers, or any containers with broken seals, popped lids, found to be leaking or broken, or that present any other evidence that indicates spoilage of product ~~found in the warehouse~~ must be included in the report.

(2) Include copies of records of operations showing adherence to, or deviations from, scheduled processes identified in Official State Process Letters or Operational Documents, including but not limited to records of processing and production, temperature-recording device, container closure or seal integrity examination, pH measurement, or any other records of critical factors intended to ensure a safe product;

(3) Include copies of the file, or log identifying data, detailing the instance of spoilage, process deviation, or contamination with microorganisms and the corrective actions taken.

(c) This section does not apply to damaged or spoiled raw materials and ingredients.

~~Cal. Admin. Code tit. 17, § 12555, 17 CA ADC § 12555~~

Note: Authority cited: Section 100275, 110065, 112825, and 131200, Health and Safety Code.
Reference: Title 21, Federal Code of Regulations Section 113.89

Amend Section 12560 to read as follows:

§ 12560. Segregation.

(a) ~~When swells or other evidence~~ All foods subject to Section 12555 having any instance of spoilage, process deviation, or contamination with microorganisms ~~in excess of one-half of one percent, (5 cans per 1,000), are found in any warehouse lot, such spoilage~~ must be segregated ~~from the normal cans,~~ and the entire lot, ~~including flat cans,~~ batch, or other portion of production held pending ~~immediate notification of~~ evaluation as to any potential public health significance by the Department ~~of Public Health~~.

(b) No samples of such ~~material~~ foods identified under paragraph (a) of this section shall be drawn, removed, distributed, or disposed of for any purpose until authorization has been granted by the Department ~~of Public Health~~.

~~Cal. Admin. Code tit. 17, § 12560, 17 CA ADC § 12560~~

Note: Authority cited: Section 100275, 110065, 112825, and 131200, Health and Safety Code.
Reference: Section 111865, Health and Safety Code. Part 113, Title 21, Federal Code of Regulation 113.89 and 114.89.

Adopt Section 13250 to read as follows:

§ 13250. Severability.

In this article, if any section, subsection, clause, sentence, or phrase of these regulations is for any reason held to be invalid or unconstitutional, or if any application of this article to any person or circumstance is found to be invalid, the Department's intent is that the invalidity or unconstitutionality not affect any other section, subsection, clause, sentence, phrase, or application which can be given effect without the invalid provision or application in this article.

Note: Authority cited: Sections 100275, 110065, 112825, and 131200, Health and Safety Code. Reference: Section 110045, Health and Safety Code.