Finding of Emergency

Cannery Emergency Regulations
Batch Release Elimination
DPH-24-003E

The director of the California Department of Public Health (Department) finds that an emergency exists and that the proposed emergency regulations, as described below, are necessary to address a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, and general welfare of Californians.

Notice and Introduction

Notice is hereby given that the Department proposes to adopt the regulations described below.

Government Code section 11346.1(a)(2) requires that at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law, the adopting agency provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the Office of Administrative Law, the Office of Administrative Law shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6.

Additionally, the California Health and Safety Code section 112830 requires that, at least five days prior to the date of adoption of regulations or amendments thereto, the Department shall submit the proposed rule or regulation or amendment to the Cannery Inspection Board.

Deemed Emergency

The Department has statutory authority to adopt emergency regulations to implement the Cannery Inspection Program (CIP), and such emergency regulations are deemed to be an emergency and necessary for the immediate preservation of public health and safety. Section 110065, subdivision (b), paragraph (3) of the Health and Safety Code states that “the initial adoption of emergency regulations and the readoption of emergency regulations authorized by this section shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare.”

Authority and References

The Department is proposing to repeal, amend, and adopt the proposed rulemaking under the authority provided in sections 100275, 110065, 112825, and 131200 of the Health and Safety Code.

The Department is proposing to repeal sections 12400 and 12445, amend sections 12470, 12555, and 12560, and adopt sections 12350, 12355, 12401 and 13250 of Article 8 of Group 1 of Subchapter 2 of Chapter 5 of Division 1 of Title 17, California Code of Regulations in order to implement, interpret, or make specific sections 12405 and 12455 of California Code of Regulations; Sections 110045, 111865, 112675, and 112750 of the Health and Safety Code; and Part 108, Title 21 Code of Federal Regulations, Sections 108.25, 108.35, 113.100, 113.3, 113.40 (a)(2), 113.89, 114.89, 114.100,114.3, and 117.305.

Informative Digest/Police Statement Overview

Purpose

The proposed regulations will (1) remove the regulatory requirements for Batch Releases (Releases) and (2) update and clarify the notification requirement for spoilage and create new notification requirements for process deviations and contamination of microorganisms. Additionally, the proposed regulations will improve clarity by outlining the application process, modernizing language, and adding definitions. Lastly, the proposed regulations will protect public health and safety by more closely aligning with federal requirements and ensuring increased transparency by requiring notification to the Department for any instance of spoilage, process deviation, or contamination with microorganisms in acidified foods (AF) and low-acid foods (LAF).

Background

Existing state law

The CIP was established by law in 1925 by the California legislature through the Cannery Inspection Act. As part of the CIP, the Department regulates the commercial manufacturing and packing of AF and LAF products through the Health and Safety Code and California Code of Regulations. The CIP established the Cannery Inspection Fund for the collection of fees from each licensed California canner to pay for the carrying out and implementation of the CIP, including inspection, laboratory control and research, and licensing services.

Under current regulations, the Department is required to conduct Releases of AF and LAF products prior to distribution into commerce; an activity both separate and distinct from that of periodic inspections conducted by the Department to assess sanitary operations and overall compliance with state and federal laws and regulations.

Due to the Release requirement, all persons engaged in the commercial manufacture and packing of AF and LAF products cannot distribute products into commerce until the Department scrutinizes, reviews, stamps, and signs routine monitoring records of operations showing adherence to, or deviations from, the scheduled processes and

critical factors established by the Department (referred to as Official State Process Letters and Operational Documents).

The Department may investigate adulteration, good manufacturing practices and other issues to determine compliance with the CIP, state and federal laws. Enforcement may include:

- Administrative and civil penalties
- Suspension or revocation of license
- Quarantine of products for laboratory examination
- Seizure and embargo of products
- Voluntary Condemnation and Destruction (VC&D) of products.

Health and Safety Code sections 112810 and 112815 state that the Department "may quarantine any food product in violation of this chapter until laboratory examination has established that the product meets the requirements of this chapter," and that "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 to be necessary to ascertain that the seized product was packed in violation of this chapter."

Health and Safety Code section 112825 states that "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."

Federal law

Adopted by the Department in 1979, Title 21, Code of Federal Regulations (CFR), Part 113 and 114, further defines the requirements for AF and LAF products. Additionally, Congress passed the Food Safety Modernization Act (FSMA) in 2010, bolstering federal requirements for food processing businesses nationwide. The Department adopted the federal Good Manufacturing Practice found in FSMA, where such requirements have been, and remain in effect in California.

Current U.S. Food and Drug Administration (FDA) law, as set forth in Code of Federal Regulations, Title 21, Chapter 1, Subchapter B, Part 108, Sections 108.25(d) and 108.35(d), require commercial processors engaged in the processing of AF and LAF products to promptly report to the FDA any instance of spoilage, process deviation, or contamination with microorganisms, the nature of which has potential health-endangering significance, where any lot of such food has in whole or in part entered distribution in commerce.

Policy Statement Overview

The proposed regulations focus on protecting the public, by clarifying and expanding the requirements that must be followed for documentation and reporting, thus creating a more robust framework to regulate noncompliant canners. This proposed approach for AF and LAF products more closely aligns California with Federal standards.

The objectives of the proposed regulations are to more closely align with federal requirements and to ensure increased transparency by requiring notification to the Department for any instance of spoilage, process deviation, or contamination with microorganisms.

Removal of regulatory requirements for Releases

Currently, regulatory requirements for Releases mandate the Department to scrutinize, review, stamp, and sign routine monitoring records which ensures compliance with the scheduled processes for AF and LAF products before they are distributed into commerce. Since the CIP and Releases were implemented in 1925, there have been many improvements in AF and LAF products, science, processes, and subsequent reductions in food safety risks. The removal of Releases acknowledges the efficacy of these improvements in ensuring food safety and more closely aligns with federal requirements.

Notification requirement for spoilage, process deviations, and contamination of microorganisms

These proposed regulations ensure increased transparency by requiring notification to the Department for any instance of spoilage, process deviation, or contamination with microorganisms, as in part required by the FDA under the Code of Federal Regulations, Title 21, Chapter 1, Subchapter B, Part 108, Sections 108.25(d) and 108.35(d).

Effect of Regulatory Action

This proposed action will repeal Sections 12400 and 12445, amend Sections 12470, 12555, and 12560, and adopt Sections 12350, 12355, 12401, and 13250 of Article 8 of Group 1 of Subchapter 2 of Chapter 5 of Division 1 of Title 17, California Code of Regulations, as follows:

Add § 12350. Applicability.

This section provides that 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. This provision is necessary to clarify the scope of the regulations.

Add §12355. Definitions.

This section establishes definitions for Article 8 as follows:

“Acidified foods” is defined as 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. This definition is needed to further clarify provisions in the proposed regulations.

“Commercial sterility” of food is defined as the condition achieved by the application of heat, the control of water activity (aw), 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. This definition is needed to further clarify provisions in the proposed regulations and uses terminology that is consistent with Title 21 CFR 113.3.

“Critical factor” is defined as any property, characteristic, condition, aspect, or other parameter, the variation of which may affect the scheduled process and the attainment of commercial sterility. This definition is needed to further clarify provisions in the proposed regulations.

“Hermetically sealed container” is defined as 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. This definition is needed to further clarify provisions in the proposed regulations

“Low-acid foods” is defined as 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. This definition is needed to further clarify provisions in the proposed regulations.

“Official State Process Letters” is defined as 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. This definition is needed to further clarify provisions in the proposed regulations pursuant to California Code of Regulations, Sections 12405(b) and 12455. As described below in Section 12401, these letters are created from the product and process data submitted to the Department.

“Operational Documents” is defined as 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. This definition is needed to further clarify provisions in the proposed regulations pursuant to California Code of Regulations, Sections 12405(b) and 12455. As described below in Section 12401, these documents are created from the processing system information submitted to the Department.

“Process deviation” is defined as 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. This definition is needed to further clarify provisions in the proposed regulations. While this definition utilizes terminology consistent with Title 21 CFR 113 and 114, it also distinguishes that the identification of process deviations is based on minimum requirements set by the Department, as opposed to qualified persons pursuant to Title 21 CFR 113 and 114.

“Processing system” is defined as 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. This definition is needed to further clarify provisions in the proposed regulations.

“Scheduled process” is defined as 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. This definition is needed to further clarify provisions in the

proposed regulations. While this definition utilizes terminology consistent with Title 21 CFR 113 and 114, it also distinguishes that the establishment of the scheduled process is based on minimum requirements set by the Department, as opposed to qualified persons pursuant to Title 21 CFR 113 and 114.

Repeal § 12400. Applicability.

Repeal Section 12400, due to the definition of acidified foods being clarified in Section 12355. The applicability is now clarified in Section 12350. Therefore, this section is unnecessary, outdated, and potentially confusing.

Add § 12401. Application for Official State Process Letters and Operational Documents.

This section provides that Official State Process Letters and Operational Documents must be obtained prior to manufacturing acidified foods and low-acid foods. This provision is necessary to clarify that the scheduled process must be established by the Department, provided for in Official State Process Letters and Operational Documents, and pursuant to California Code of Regulations, Sections 12405(b) and 12455.

Adopt Subsection (a): to itemize required forms to be submitted to the Department for issuance of Official State Process Letters. This subsection is necessary to clarify requirements of what must be submitted to the Department for issuance of Official State Process Letters for acidified foods and low-acid foods and uses terminology that is consistent with Title 21 CFR 108.

- Paragraph (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, as incorporated by reference.
- Paragraph (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, as incorporated by reference.

Adopt Subsection (b): to identify the required form to be submitted to the Department for issuance of Operational Documents. This subsection is necessary to clarify requirements of what must be submitted to the Department for issuance of Operational Documents for processing systems and uses terminology that is consistent with Title 21 CFR 108.

- Paragraph (1): requires that processing system information must be submitted to the Department on Form CDPH 8562 (Rev. 10/2023) Request For Official Sterilization Process, as incorporated by reference.

Adopt Subsection (c): provides that 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. This subsection is necessary to clarify where required forms, as identified within paragraphs (a) and (b), can be

obtained by an applicant to be completed and submitted to the Department for evaluation.

- Paragraph (1): requires that 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. This paragraph is necessary to clarify the measures that must be taken should incomplete applications be submitted to the Department for evaluation.
- Paragraph (2): requires that the Department, upon evaluation of the information from the applications, shall issue Official State Process Letters and Operational Documents identifying requirements for processing system operation, scheduled processes, and critical factors requiring control under the conditions of manufacture for a given food to achieve commercial sterility. This paragraph is necessary to clarify and expand upon California Code of Regulations, Sections 12405(b) and 12455, which requires that the Department be consulted or contacted for these requirements. Specifically, this paragraph clarifies the information that the Department evaluates and that the requirements for a given food to achieve commercial sterility are outlined in the Official State Process Letters and Operational Documents issued by the Department.

Adopt Subsection (d): provides that 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. This subsection is necessary to ensure that when changes are made in relation to the scheduled process the Department maintains oversight.

Repeal § 12445. Releases.

Repeal Section 12445, due to being unnecessary, outdated, and to remove regulatory requirement of the Department to conduct Releases.

Amend § 12470. Record of Cooks.

Amend Section 12470, due to being unnecessary and to remove regulatory requirement of the Department to conduct Releases.

Subsection (c): Repeal this subsection due to being unnecessary and to remove the regulatory requirements of the Department to conduct Releases.

Subsection (e): Repeal this subsection due to being unnecessary and to remove the regulatory requirements of the Department to conduct Releases.

Amend § 12555. Reporting Spoilage.

Amend Section 12555 to expand the section title to Reporting Spoilage, Process Deviations, or Contamination with Microorganisms. Additionally, amend Section 12555 to clarify and expand upon requirements of when the Department must be notified and what must be included within reports. The proposed amendments to this section are necessary to ensure increased transparency by requiring notification to the Department, as in part required under the FDA under the Code of Federal Regulations, Title 21, Chapter 1, Subchapter B, Part 108, sections 108.25(d) and 108.35(d).

Adopt Subsection (a): requires that 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. This is needed to clarify and expand upon requirements of when and how the Department must be notified.

Adopt Subsection (b): to itemize required information or items to be included in written reports to the Department. This is needed to clarify and expand upon requirements of what must be included within written reports to allow evaluation of any potential public health significance by the Department and uses terminology that is consistent with Title 21 CFR 113, 114, and 108.

- Paragraph (1): requires that written reports to the Department must identify product affected, the manufacture date, the lot code, the number of affected containers, and the Official State Process Letter for the affected product.
- Subsection (A): All cans containing swells to any degree, including buckling, springers, 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 must be included in the report. The identification of information provided by this paragraph is the minimum necessary to allow traceability of product, correlate product with records of scheduled processes applied or lack thereof, and to allow the Department issuance of Quarantine/Restraining Order **(**QRO) or laboratory evaluation as to any potential public health significance. These requirements are necessary to clarify that certain standards shall be maintained upon removal of Releases. Additionally, this section expands upon examples of observations that must be included in reports; not being limited to characteristics or properties found in tin cans.
- Paragraph (2) requires that written reports to the Department must 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. This paragraph is needed to clarify and expand upon examples of documentation that must be included within the reports to allow the Department laboratory evaluation as to any potential public health significance.

- Paragraph (3) requires that written reports to the Department must include copies of the file, or log identifying the data, detailing the instance of spoilage, process deviation, or contamination with microorganisms and the corrective actions taken. This paragraph is needed to clarify and expand upon documentation that must be included within the reports to allow the Department laboratory evaluation as to any potential public health significance. These requirements are necessary to clarify that certain standards shall be maintained upon removal of Releases; with influence by Federal record requirements in events of departures from scheduled processes under 21 Code of Federal Regulations 114.100(c).

Adopt Subsection (c): provides that this section does not apply to damaged or spoiled raw materials and ingredients. This subsection is needed to clarify that written reports apply to finished food products intended for distribution, as State and Federal laws and regulations provide requirements for raw materials and ingredients.

Amend § 12560. Segregation.

Amend Section 12560 to clarify and expand upon requirements of segregating and holding foods due to spoilage, process deviations, or contamination with microorganisms.

Subsection (a) provides that all foods subject to Section 12555 having any instance of spoilage, process deviation, or contamination with microorganisms must be segregated and the entire lot, batch, or other portion of production held pending evaluation as to any potential public health significance by the Department. This subsection is needed to clarify and expand upon the requirement that affected foods, as identified within Section 12555, must be held for evaluation by the Department.

Subsection (b) provides that no samples of such 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. This subsection is needed to expand upon and clarify that all foods identified under Subsection (a) must not be removed or disposed of for any reason unless authorization is received by the Department; with influence of standards and requirements of processors under Health and Safety Code Section 111865 (seizure and embargo).

Add § 13250. Severability.

This section provides that should a part of the regulation be challenged, the remaining parts will remain in effect. This provision is needed to preserve the remaining, valid parts of the regulations to ensure the protection of public health and safety.

Statements of Determinations and Economic Impact Assessment

The Department has determined that the proposed regulatory action would not have a significant economic impact on California business enterprises and individuals.

Evaluation as to Whether the Regulations are Inconsistent or Incompatible with Existing Regulations
The Department has made a determination that these regulations are not inconsistent or incompatible with existing state regulations as there are no other state regulations that address the same topics.

Mandated by Federal Law or Regulations
The Department has made a determination that this proposal is not mandated by federal law or regulations.

Local Mandate
The Department has determined that this regulatory action would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

Fiscal Impact Assessment
A. **Cost to Any Local Agency or School District:** None.
B. **Cost or Savings to Any State Agency:** None.
C. **Other Nondiscretionary Cost or Savings Imposed on Local Agencies:** None.
D. **Cost or Savings in Federal Funding to the State:** None.

Documents Relied Upon

1. Emergency Permit Control, 21 Code of Federal Regulations, Part 108:
2. Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, 21 Code of Federal Regulations, Part 113
3. Acidified Foods, 21 Code of Federal Regulations, Part 114
4. Penalties and Remedies, Health and Safety Code, Division 104, Part 5, Chapter 8
5. Canneries, Health and Safety Code, Division 104, Part 6, Chapter 8
6. Request For pH Control Form CDPH 8589 (Rev. 8/2023)
7. Request For Official Sterilization Process Form CDPH 8562 (Rev. 10/2023)

Contact Person
Inquiries regarding the proposed regulatory action can be directed to Michael Boutros, with the Office of Regulations at (279) 217-0866, or the designated backup contact, Dawn Basciano at (916) 440-7367.