

**NOTICE OF PROPOSED RULEMAKING**  
**Shellfish Sanitation Standards (DPH-18-020)**  
**Notice Published February 14, 2025**

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent after considering all comments, objections, and recommendations regarding the regulation.

**PUBLIC PROCEEDINGS**

The Department is conducting a 45-day written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

To request copies of the regulatory proposal in an alternate format, please write or call: David Martin, Office of Regulations, 1415 L Street Suite 500, Sacramento, CA 95814, at (279) 217-0888, email to [David.Martin@cdph.ca.gov](mailto:David.Martin@cdph.ca.gov) or use the California Relay Service by dialing 711.

**PUBLIC HEARING**

A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a public hearing if a written request for a public hearing is received from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period, pursuant to Government Code Section 11346.8.

**ASSISTIVE SERVICES**

For individuals with disabilities, the Department will provide assistive services such as conversion of written materials into Braille, large print, audio format, and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takers, reading, or writing assistance. To request these assistive services, please call David Martin at (279) 217-0888 or (California Relay at 711 or 1-800-735-2929), or email [Regulations@cdph.ca.gov](mailto:Regulations@cdph.ca.gov) or write to the Office of Regulations

at the address noted above. Note: The range of assistive services available may be limited if requests are received less than 10 business days prior to public hearing.

### **WRITTEN COMMENT PERIOD**

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations on April 10, 2025, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written Comments must be submitted as follows:

1. By email to: [Regulations@cdph.ca.gov](mailto:Regulations@cdph.ca.gov). It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier “DPH-18-020 Shellfish Sanitation Standards” in the subject line to facilitate timely identification and review of the comment.
2. By fax transmission to: (916) 636-6220.
3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments, including email or fax transmissions, should include the regulation package identifier, DPH-18-020 Shellfish Sanitation Standards, along with your name and your mailing address or email address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

### **AUTHORITY AND REFERENCE**

The Department is proposing to adopt, amend, or repeal Title 17, CCR, sections 7700 to 7762 under the authority provided in sections 100275, 110065, 110105, 112165, 112235 and 131200 of the HSC. This proposal implements, interprets, and makes specific sections 112155, 112160, 112165, 112170, 112175, 112180, 112185, 112190, 112195, 112200, 112205, 112210, 112215, 112220, 112225, and 112230 of the HSC.

### **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

#### **Summary of Proposal**

The proposed regulations will update the existing shellfish regulations and adopt the National Shellfish Sanitation Program (NSSP Guide) national standards for shellfish sanitation. The proposed regulations ensure consistency with the NSSP Guide, including provisions for shellfish sanitation standards, safety of shellfish, health of employees, recordkeeping requirements, standards for shellfish growing areas, plants, and operations. Shellfish is regulated in California pursuant to Part 6, chapter 5, sections 112150 through 112280 of the Health and Safety Code (HSC), and the Sherman, Food, Drug and Cosmetic Law in Part 5.

## Background

California allows shellfish dealers to transport shellfish into interstate commerce. As such, the California Department of Public Health (Department), which is the State Shellfish Control Authority (Authority) for the State of California, is required by the U.S. Food and Drug Administration (FDA) to enforce standards in the NSSP Guide for the Control of Molluscan Shellfish: 2023 Revision (NSSP Guide). The NSSP Guide applies to bivalve molluscan shellfish (oysters, clams, mussels, and scallops) that are raw or that are subjected to post-harvest processing. The NSSP Guide does not apply to crab, lobster, or shrimp. For simplicity, the NSSP Guide refers to bivalve molluscan shellfish as “shellfish,” and the Department similarly uses the same convention.

The NSSP Guide is the standard for shellfish harvesting and handling industry practices. As the authority for the State of California, the Department is responsible for all NSSP Guide program elements: plant sanitation, growing area classification, patrol enforcement, vibrio control, and laboratory services. These program elements set standards for sanitary quality of growing waters, issuing certificates, harvesting, shellfish handling activities that include wet storage, depuration, tagging, labeling, and assuring compliance with the NSSP Guide for dealers on the Interstate Certified Shellfish Shippers List. For companies that want to participate in interstate commerce, the Department ensures these companies comply with requirements in the NSSP Guide.

This regulatory action will clarify that the Department adopts the 2023 NSSP Guide, which is the most recent revision. Additionally, this regulatory action will add definitions for clarity and will modernize related sections to reflect current industry practice. Updating the regulations will allow the Department to conform to the most up-to-date national standards and to continue fulfilling its responsibility to regulate commercial shellfish to protect public health.

*Existing Laws and Regulations:* Currently, the Department regulates commercial shellfish through sections 112150 through 112280 of the HSC and through section 7706 through 7762 of Title 17 of the California Code of Regulations (CCR).

## Problem Statement

The Department requires regulations to clarify its processes related to shellfish sanitation. Existing law does not include the most updated national standards protective of public health, which creates uncertainty in the industry as to what is required in California. In 2023, the National Shellfish Sanitation Program (NSSP) updated its NSSP Guide, which the Department wishes to incorporate by reference into regulations. The Department also proposes to add definitions for clarity and to modernize some sections to reflect current industry practices.

## Objectives (Goals) of the Regulation

- Effectuate the Department’s mandate to promote the sanitation of shellfish moving in interstate commerce.
- Protect the health and safety of the public.
- Codify the current nationally recognized public health standards as set forth in the NSSP Guide.
- Improve clarity regarding specific definitions.

- Maximize efficiency in processing applications.

### Anticipated Benefits

Anticipated benefits from this proposed regulatory action are:

- Consistency with national standards for shellfish grown, harvested, and handled in California.
- Improved clarity and reduced confusion for the shellfish industry regarding required standards.
- More efficient processes for the Department's reviewing of applications.
- Shellfish continue to be safe for consumption.

### Evaluation as to Whether the Proposed Regulations Are Inconsistent or Incompatible with Existing State and Federal Regulations

The Department evaluated whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's laws, general regulations, and regulations that are specific to the implementation of California shellfish law.

No known statute or regulation conflicts with this proposed regulatory update. The Department determined that the proposed regulations are not inconsistent or incompatible with other state regulations. Therefore, the proposed regulations, if adopted, would not be inconsistent or incompatible with existing state regulations.

### Substantial Difference from Federal Regulation or Statute

The Department has determined these regulations are not substantially different from either a federal regulation or statute.

### **INCORPORATION BY REFERENCE**

The Department is proposing to incorporate by reference the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2023 Revision.

### **MANDATED BY FEDERAL LAW OR REGULATIONS**

The Department determined these regulations are not identical to previously adopted or amended federal regulations.

### **OTHER STATUTORY REQUIREMENTS**

The Department has determined there are no other statutory requirements.

### **LOCAL MANDATE**

The Department has determined 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 ESTIMATES**

### **Cost to any local agencies or school districts that must be reimbursed pursuant to Section 17561 of Government Code:**

The Department has determined that these regulations would not impose a mandate on any local agencies or school districts.

### **The cost or savings to any state agency**

The Department does not anticipate an increase in enforcement costs, staff, or budget as a result of the proposed regulations.

### **Other Nondiscretionary Cost or Savings Imposed on Local Agencies:**

The Department does not anticipate any other nondiscretionary cost or savings imposed on local agencies.

### **Cost or Savings in Federal Funding to the State:**

The Department has determined that the regulations will not affect federal funding.

## **HOUSING COSTS**

The Department has determined that the regulations will not affect housing costs.

## **SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE**

The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

## **STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT (EIA)**

The Department has determined that the regulations affect the following as described:

### **A. The creation or elimination of jobs within the State of California.**

The proposal will not impact the creation or elimination of jobs to the commercial shellfish industry because a large portion of the industry already complies with the requirements of the NSSP Guide.

### **B. The creation of new businesses or the elimination of existing businesses within the State of California.**

The proposal will not impact the creation or elimination of jobs because this is a national shellfish standard that is enforced for all interstate commerce of shellfish.

### **C. The expansion of businesses currently doing business within the State of California.**

The proposal will not impact the expansion of businesses because this is a national shellfish standard that already is applicable for all interstate commerce of shellfish for human consumption. Additionally, the majority of intrastate dealers already do adhere to the national standard for interstate dealers.

**D. The benefits of the regulation to the health and welfare of California residents, worker safety, and the state’s environment.**

The proposed regulations increase and strengthen the public health of California residents by conforming California to the most national guidelines for shellfish standards.

**COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS**

The proposed regulations will establish annual certification fees. This will be a new cost to certificate holders and will provide the Department the resources to implement the amended regulations and recuperate a portion of their program costs. This regulation will impose a new fee for:

- New and renewal Shellfish Handling and Marketing Certificate applications.
- The additional time and resources to ensure the compliance of a new wet storage system, including but not limited to, the installation of new equipment, review, and approval of written operation manuals, oversee validation study, and ongoing testing requirements set forth in the NSSP Guide.

**BUSINESS REPORTING REQUIREMENTS**

The proposed regulation does not change existing reporting requirements. Certificate holders are already familiar with Seafood HACCP record requirements. Each harvester/dealer also reports their harvest quantities by species to the Authority. It is necessary for the health, safety, or welfare of the people of the state that the regulation which requires a report apply to businesses.

**EFFECT ON SMALL BUSINESS**

The Department does not anticipate any negative effect on small businesses. Shellfish businesses are already familiar and compliant with the majority of the national standards. The proposed regulatory changes unify California’s existing shellfish regulations with the national shellfish standards established in the NSSP Guide.

**CONSIDERATION OF ALTERNATIVES**

The Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulatory action or would be more cost-effective to affected private persons. The Department invites interested persons to submit alternatives with respect to the proposed regulation during the comment period.

**TECHNICAL, THERETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS RELIED UPON**

The following were used by the Department in development of these regulations:

- National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 2023 Revision
- Fish and Fishery Products Hazards and Control Guidance, Fourth Edition – June 2022

- Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive Controls for Human Food, 21 Code of Federal Regulations (CFR) Part 117, Subparts A and B
- Fish and Fishery Products, 21 CFR Part 123

### **CONTACT PERSON**

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Christina Grant, Shellfish Program Specialist, at [FDBComments@cdph.ca.gov](mailto:FDBComments@cdph.ca.gov).

All other inquiries concerning the action described in this notice may be directed to David Martin, Office of Regulations, at (279) 217-0888.

**In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-18-020 Shellfish Sanitation Standards.**

### **AVAILABILITY STATEMENTS**

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, will be the custodian of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call David Martin 279-217-0867, (or the California Relay Service at 711), send an email to [regulations@cdph.ca.gov](mailto:regulations@cdph.ca.gov), or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audio format, or computer disk.

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

### **Final Statement of Reasons**

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

### **INTERNET ACCESS**

Materials regarding the action described in this notice (including this public notice, the text of the proposed regulations, and the initial statement of reasons) that are available via the Internet may be accessed at [www.cdph.ca.gov](http://www.cdph.ca.gov) by clicking on these links, in the following order: I am Looking For: Administrative, Proposed Regulations, Current Regulatory Proposals.

