

Initial Statement of Reasons

Summary of the Proposal

The proposed regulations for shellfish in California are critical to ensure the safety and quality of shellfish products sold and distributed in the state. Shellfish is regulated in California pursuant to Part 6, chapter 5, sections 112150-112280, and the Sherman Law in Part 5. The proposed regulations ensure consistency with the National Shellfish Sanitation Program and specifically with the [National Shellfish Sanitation Program](#) Guide for the Control of Molluscan Shellfish: 2023 Revision (NSSP Guide), including provisions for shellfish sanitation standards, safety of shellfish, health of employees, recordkeeping requirements, standards for shellfish growing areas, plants, and operations.

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 crabs, lobster, or shrimp. For simplicity, the NSSP Guide refers to bivalve molluscan shellfish as “shellfish,” and the Department similarly uses the same convention in this Initial Statement of Reasons.

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

Authority and Reference

The Department is proposing to adopt, amend, or repeal Title 17, CCR, sections 7700 to

7762 under the authority provided in HSC sections 100275, 110065, 110105, 112165, 112235 and 131200. This proposal implements, interprets, and makes specific HSC sections 112155, 112165, 112170, 112180, and 112185 through 112230.

Policy Statement Overview

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 into regulations. The Department also proposes to add definitions for clarity and to modernize some sections to reflect current industry practices.

Objectives: The broad objectives of this proposed regulatory action are the following:

- 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.

Benefits:

- 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 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.

Background/Authority

California shellfish law, codified in HSC sections 112150 through 112280, was enacted to protect the public from adulterated shellfish grown and harvested in state waters for sale to the public and to provide uniform sanitation standards for the handling of shellfish

and shellstock that is introduced into commerce. The regulations that implement, interpret, and make specific the provisions of shellfish statutes are in Title 17, CCR, sections 7706 through 7762. Pursuant to these statutes and regulations, the Department certifies and inspects shellfish growers and dealers (companies that own and sell shellfish).

In addition to the Department's general authority to adopt regulations (HSC section 131200), the Department also has specific authority to adopt regulations related to shellfish. HSC section 112165 authorizes the Department to adopt regulations regarding (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 that harvest, transport, store, handle, pack, and repack shellfish, and (3) fees.

California regulates two types of shellfish dealers: (1) those that sell only within the state California Only Shellfish Dealer, and (2) those who also sell outside of California into interstate commerce (listed on the Interstate Certified Shellfish Shippers List). Currently, as of this date (10/16/2023), there are approximately 179 California Only Shellfish Dealers and approximately 198 dealers in California on the Interstate Certified Shellfish Shippers List (or pending applications).

The NSSP Guide is the federal and state cooperative program, recognized by both the Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference, for the sanitary control of shellfish produced and sold for human consumption. The purpose of the NSSP Guide is to promote and improve the sanitation of shellfish (oysters, clams, mussels, and scallops) moving in interstate commerce through federal and state cooperation and uniformity of state shellfish programs. Participants in the NSSP Guide include agencies from shellfish-producing and non-producing states, FDA, US Environmental Protection Agency, National Oceanic and Atmospheric Administration, Tribes, academia, and the shellfish industry. Under international agreements with the United States Food and Drug Administration, foreign governments also participate in the NSSP Guide. Other components of the NSSP Guide include program guidelines, state growing area classification and dealer certification programs, and FDA evaluation of state program elements.

"Authority" is defined in the NSSP Guide as "the State shellfish control authority, which is responsible for the enforcement of this Code." NSSP Guide Section II Chapter I is the chapter dedicated to explaining the "Shellfish Sanitation Program Requirements for the Authority." The Department is the State Shellfish Control Authority in the state of California and is responsible for certifying and monitoring commercial shellfish growing areas and regulating the commercial shellfish industry to ensure conformance with requirements of the NSSP Guide.

The Department's compliance with the NSSP Guide allows shellfish dealers in California to be included on the Interstate Certified Shellfish Shippers List, which allows their product to be sold into interstate commerce. The Department's Environmental Management Branch (EMB) is responsible for implementing and enforcing pre-harvest requirements,

which include evaluation, classification and certification of commercial shellfish growing areas, routine monitoring for marine biotoxins, and coordination of patrol and prevention of illegal harvesting. The Department's Food and Drug Branch (FDB) is responsible for post-harvest requirements, including shellfish handling, processing, storage and distribution, labeling, and identification of shellfish moving in commerce. FDB also performs patrol and prevention of illegal shellfish harvesting, as well as conducts illness investigations.

Shellfish dealers are companies that maintain ownership of shellfish and are certified to store, distribute, and process shellfish. A shellfish dealer sells shellfish to other wholesale dealers, manufacturers, and retail establishments. Shellfish are potentially hazardous foods that are often consumed raw. Shellfish have known hazards, which can be controlled by strictly ensuring the source of the shellfish come from approved growing waters and sent through the distribution chain by certified dealers. The NSSP Guide is structured on the food safety premise that shellfish hazards are controlled by time, temperature, and traceability requirements. The benefit of the Department's enforcement of the standards set forth in the NSSP Guide allows the shellfish dealers in California to be included on the Interstate Certified Shellfish Shippers List, which allows the dealers to sell shellfish across state lines and expand their customer base. The dealers in other states that are listed, have been certified by various regulatory food agencies ("Authorities" as defined in the NSSP Guide) in the United States, Canada, Korea, New Zealand, and Mexico under the uniform sanitation requirements of the NSSP Guide. Control measures of the states are evaluated by the FDA. Canadian, Korean, New Zealand, and Mexican shellfish dealers are included under the terms of the shellfish sanitation agreements with the governments of these countries.

DETAILED DISCUSSION OF EACH REGULATION

The Department proposes to adopt, amend, or repeal the following sections as follows:

Amend Article 1 title, to change from "Shellfish Certificates" to "Shellfish Sanitation Standards and Certificates". This title more accurately reflects the Department's authority over shellfish sanitation, not just issuing certificates. Shellfish sanitation is paramount to safety of shellfish. Sanitation encompasses all areas from shellfish growing in the marine environment to ultimately selling to the retail establishment.

Adopt Section 7700, regarding incorporation of the National Shellfish Sanitation Program.

Subsection (a), adopt language to establish adoption of the 2023 NSSP Guide by reference. The Department proposes to use the shellfish sanitation standards set forth in the NSSP Guide as the standards in California along with additional specifications in these proposed regulations. The NSSP Guide is the federal and state cooperative program recognized and evaluated by the FDA for the sanitary control of shellfish produced and sold for human consumption entering interstate commerce. Dealers listed on the Interstate Certified Shellfish Shippers List are inspected and held to the requirements established in the NSSP Guide. If a dealer is not on the Interstate Certified Shellfish Shippers List, the dealer cannot sell or distribute shellfish products

out of the state, and other states can take enforcement actions to remove the products from commerce.

The 2023 Revision of the NSSP Guide is the most recent version. The NSSP Guide is revised approximately every two years following the Interstate Shellfish Sanitation Conference's biennial meeting and FDA review and concurrence. The Interstate Shellfish Sanitation Conference did not meet in 2021 due to the COVID-19 pandemic, so there was not a 2021 Revision of the NSSP Guide.

Subsection (b), adopt language to establish that all dealers, meaning intrastate only (California Only Shellfish Dealers) and interstate dealers, are subject to the 2023 NSSP Guide standards, with one exception noted in subsection (c) for California Only Shellfish Dealers' frequency of inspection. The NSSP Guide pertains to dealers who wish to sell into interstate commerce. However, the Department proposes that the NSSP Guide standards also apply to intrastate-only dealers (California Only Shellfish Dealers). Current industry practice is that California Only Shellfish Dealers follow the NSSP Guide because the standards are recognized as being protective of public health. Thus, the Department would be codifying into regulation the standards already being implemented by California Only Shellfish Dealers. A dealer is responsible for the temperature handling, sanitary practices, and traceability of purchased and distributed shellfish. Whether a California Only Shellfish Dealer or an interstate dealer on the Interstate Certified Shellfish Shippers List, both types of dealers handle a potentially hazardous food that is often consumed raw. The NSSP Guide is the national standard for the health and safety of this commodity. California residents, as well as visitors to California, must be protected as well.

Subsection (c), adopt language to describe dealer inspection frequency for California Only Shellfish Dealers. Though California Only Shellfish Dealers are still subject to inspection, this provision makes clear that the inspection frequency is not the same as for dealers on the Interstate Certified Shellfish Shippers List who must conform to the frequency identified in the NSSP Guide.

The Department is proposing a distinction in the inspection frequency between California Only Shellfish Dealers and interstate dealers who are on the Interstate Certified Shellfish Shippers List. Dealers on the Interstate Certified Shellfish Shippers List are physically inspected multiple times a year, as mandated by the NSSP Guide and based on the dealer's certified activities. For instance, depurators are inspected monthly, shucker packers and repackers are inspected quarterly, and other dealers are inspected twice per year.

Shellfish is a high-risk commodity, like other high-risk commodities that FDB licenses and inspects, such as juice processors, seafood processors (i.e., tuna, salmon, and crab), ready-to-eat sandwiches and salads, and cannery products. Companies that manufacture or handle high-risk foods are generally inspected once every two to four years, in line with FDB's workplan.

However, the Department conducts additional inspections as warranted by recalls,

illness outbreaks, or product complaints.

California Only shellfish are also considered high-risk commodities. By exempting California Only Shellfish Dealers from the inspection frequency in the NSSP Guide, the California Only Shellfish Dealers would then be subject to the Department's existing protocol for inspecting high-risk commodities, meaning that California Only Shellfish Dealers would be inspected at the same rate as other high-risk commodities under the Department's jurisdiction. Each year, the frequency of such inspections is based on the workplan. Currently, FDB inspects California Only Shellfish Dealers based on the workplan, which is a lower frequency than what is required in the NSSP Guide for interstate dealers who are on the Interstate Certified Shellfish Shippers List. California Only Shellfish Dealers only aim to sell their shellfish products within the state and do not require inclusion on the Interstate Certified Shellfish Shippers List.

Alternatives considered: The Department considered requiring all shellfish dealers, including California Only Shellfish Dealers, to be on the Interstate Certified Shellfish Shippers List and thus meet all requirements in the NSSP Guide including inspection frequency even if they only sell intrastate. The Department decided against this alternative because California Only Shellfish Dealers made the business decision to sell only within the state, and thus they do not need to be on the Interstate Certified Shellfish Shippers List. Having California Only Shellfish Dealers and Interstate Certified Shellfish Shippers List dealers on the same inspection frequency would place an additional inspection burden on California Only Shellfish Dealers above what is needed to protect public health.

Adopt Section 7702, to define new terminology and update existing terminology to align with the NSSP Guide and industry practice. This section provides operational definitions of terms used in the body of sections 7700 through 7752, thereby providing uniform interpretation of the terms associated with shellfish sanitation.

Adopt the term "Business Operator" to mean a person who works at the shellfish facility and operates, controls, or supervises the shellfish facility. The business operator term is used in the application in section 7706 for the Shellfish Growing Area Certificate and the application in section 7707 for the Shellfish Handling and Marketing Certificate. This person is someone who has knowledge of the shellfish facility and whom the Department will contact regarding the certificates, compliance with regulations, operational questions, recall effectiveness checks, inspectional scheduling, and notifications.

Adopt the term "California Only Shellfish Dealer" to mean a dealer not listed on the Interstate Certified Shellfish Shippers List and does not distribute shellfish outside of California. This definition is needed because it is a separate type of dealer not contemplated by the NSSP Guide.

Adopt the term "Dealer" to mean any person, who maintains ownership of, shucks, packs, processes, labels, stores, transports, sells, or distributes shellfish, which is consistent with the 2023 NSSP Guide. Additionally, the definition also states what is

included, and what is excluded, from the definition. This inclusion and exclusion are needed because California has California Only Shellfish Dealers and a retail component not contemplated by the NSSP Guide.

Adopt the term “Designee” to mean an authorized representative approved by the owner, including but not limited to a correspondent. The purpose behind incorporating this term is to enable owners to designate an individual as a point of contact to help facilitate communication between them and the Department. This will simplify and streamline the application process.

Adopt the term “Interstate Certified Shellfish Shippers List” to align with the NSSP Guide, assist with Department compliance tracking on the certificate application, and identify out of state shellfish. This definition is consistent with the NSSP Guide with the addition of language referencing the most current version of the NSSP Guide. This definition clarifies the term for sections 7702, 7713 and 7714.

Adopt the term “National Shellfish Sanitation Program” to mean the federal and state cooperative program recognized by the FDA and the Interstate Shellfish Sanitation Conference for the sanitary control of shellfish produced and sold for human consumption moving in interstate commerce. This is defined to describe the industry requirements that are enforced for domestic and foreign harvesters and dealers. The NSSP is the nationally recognized standard for shellfish sanitation for interstate commerce. This term adds clarity to sections 7700(a).

Adopt the term “The NSSP Guide for the Control of Molluscan Shellfish” (NSSP Guide) to mean the document that establishes the minimum requirements necessary for the sanitary control of shellfish. This document is updated approximately every two years following the Interstate Shellfish Sanitation Conference biennial meeting and after FDA concurrence. The current version is the 2023 NSSP Guide.

Adopt the term “Seed” to mean shellfish that are less than market size for human consumption and have a maximum shell length of:

- (A) Thirteen millimeters (1/2 inch) for mussels;
- (B) Twenty-five millimeters (1 inch) for scallops;
- (C) Thirty-eight millimeters (1 and 1/2 inch) for Pacific oysters;
- (D) Nineteen millimeters (3/4 inch) for Olympia oysters;
- (E) Twenty-five millimeters (1 inch) for Kumamoto oysters;
- (F) Thirty-eight millimeters (1 and 1/2 inch) for other oyster species;
- (F) Thirty-eight millimeters (1 and 1/2 inch) for geoducks; and
- (G) Thirteen millimeters (1/2 inch) for other clam species.

This definition specifies what the Department considers shellfish seed by setting a maximum size per species.

In the NSSP Guide, the maximum seed sizes must be established by the state shellfish authority, in this case the Department. The 2023 NSSP Guide states that “The Authority shall establish the maximum seed size for each species of shellfish that can be

produced in prohibited waters. In determining the maximum seed size, authorities shall establish sizes that require a minimum of 120 days of growing to reach market size.” No other California state agency defines shellfish seed size in regulation.

Shellfish cultivated using aquaculture techniques that are below the seed size are allowed to be located in the prohibited classification or unclassified waters, where shellfish over the seed size are not allowed. Shellfish seed cultivated for human consumption must be moved to a certified growing area before they exceed the seed size limits. This is a way for the Department to assure that the proper time requirement for growth has elapsed and that all shellfish harvested for human consumption are harvested from certified growing areas are clean and free from any possible contaminants in the prohibited or uncertified areas where the seed was sourced. The 2023 NSSP Guide specifies a minimum 120-day timeframe for shellfish to be grown in a certified growing area before it can be harvested for human consumption to allow for natural depuration of contaminants. Seed size is also important for harvesting enforcement, as the seed size needs to be sufficiently separate and discernable from the smallest size of shellfish sold for human consumption, also referred to here as minimum market size. Seed size allows the Department and enforcement officials to discern if shellfish being cultivated in prohibited or unclassified waters meets the size standards for seed.

The Department completed a survey and solicited feedback of the current certified harvesters and some shellfish distributors in 2023 to determine approximate minimum market size and growth rates of shellfish. From the survey results, the Department determined that the seed lengths used by the states of Washington and Oregon were acceptable for use in California for the following groups: scallops, mussels, geoducks, Olympia oysters, and other clam species. The Department determined seed sizes in length for the groups: Pacific oysters, Kumamoto oysters, and other oyster species.

The Department conducted a survey in 2023 of industry stakeholders, including harvesters and distributors, with 17 respondents. The survey results indicated that the 2-inch maximum seed size for Pacific oysters used by Washington and Oregon was too close to the minimum market size. The smallest Pacific oysters that are sold for human consumption are approximately 2 inches in shell length. This would not sufficiently allow for the 120 days of natural cleansing and growth time between transfer to a certified area and harvest for human consumption. Additionally, growth rates for shellfish species tend to be faster in California compared to Oregon and Washington which reduces the time seed takes to get to market size. Using estimates of growth rates, the Department determined that the maximum seed size for Pacific oysters and the category of “other oyster species” should be 1 and 1/2 inches (38 millimeters). This assures a discernable size difference between seed and market-sized oysters, ensuring harvesters will be cultivating them in the certified growing area for at least 120 days.

The Department determined a different seed size for Kumamoto oysters compared to the Washington and Oregon standard size upon a request from the shellfish industry and after a review of growth rates and market size. Washington and Oregon use a 3/4-

inch (19 millimeters) seed size for Kumamoto oysters. A representative from the California shellfish industry told the Department that the 3/4-inch maximum shell length of Kumamoto seed is too restrictive in practice for their operation and requested an evaluation to see if the size could be larger. The Department reviewed the 2023 survey information and conducted an additional survey in 2021 of Kumamoto oyster growers in California to understand growth rates and market size for the species. The growers reported that the Kumamoto oysters grow at much slower rate than Pacific oysters, and that they typically spend 1 to 2.5 years in the classified growing area after reaching the current maximum seed size of 3/4 inch. In the survey, Kumamoto oysters were considered marketable for human consumption starting at 1 and 1/2 inches (38 millimeters) but usually are desired to be larger. The Department determined that the maximum shell length for Kumamoto oyster seed should be 1 inch (25 millimeters). The 1-inch seed size would allow the oysters to meet the minimum requirement of 120 days of growth in the certified growing area prior to harvest for human consumption.

Adopt Section 7703, to include a severability clause. If any section, subsection, clause, sentence, or phrase of these Sanitary Control of Shellfish regulations is for any reason held to be invalid or unconstitutional, or if any application of these regulations 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 these regulations. This ensures that if a part of the regulations is not enforceable, then the remaining parts would be in effect to protect public health and safety. Severability in regulatory language is necessary to ensure that any portion of the regulations affected by a successful and final legal challenge does not affect the validity of the remaining regulations. The benefit of severability language is to avoid this type of problem in advance. These regulations have already been subject to legal challenges making severability language important and relevant.

Therefore, this provision is necessary to make clear that if one or more provisions of these regulations are invalidated the remaining provisions shall continue in full force and effect. Courts generally presume that statutes and regulations are severable and the severability statement here is intended to resolve any doubt as to the drafters' intent in this regard.

The doctrine of severability holds that upon finding a component of a regulation, statute, or provision to be unenforceable, inapplicable, or unconstitutional, a court may, in appropriate circumstances, excise the unenforceable, inapplicable, or unconstitutional part rather than declare the entire regulation, statute, or provisional framework invalid. One rationale for severance is that it can minimize judicial interference with administrative regulation making and thus honoring the administrative intent.

The doctrine is relevant given the current legal challenge to these regulations that began when they were filed as emergency regulations. Any potential ruling that these regulations are partially invalid will give rise to questions concerning what to do with the valid remainder making the severability clause highly relevant.

Amend Section 7706, to update terminology related to the certificate for cultivating and harvesting shellfish. For the section title, the term “bed” was changed to “growing area” as this is consistent with the NSSP Guide terminology. The term “bed” is too narrow for certificate applicability. The term “growing area” is defined in the NSSP Guide as “any site which supports or could support the propagation of shellstock by natural or artificial means.” The word “issuable” was removed because it does not add any meaning. The regulation text makes clear that the Department is the authority to issue certificates therefore it is redundant. The term “State Board of Public Health” was removed because the “State Board of Public Health” is an outdated name no longer in use.

For subsection (a), the term “firm, or corporation” was removed because “person” is already defined broadly in shellfish statute. HSC section 112155 (k) “Person” includes any individual, partnership, corporation, limited liability company, and association. “Oysters, clams, or mussels” was changed to “shellfish” for consistent terminology use in the regulations. The change to “shellfish” also is consistent with NSSP Guide terminology, which includes scallops as a bivalve molluscan subject to the NSSP Guide. This change to “shellfish” now makes clear that scallops are also included and is consistent with HSC section 112155(a) and the Department’s proposed definition of “shellfish” in section 7702.

Additional language is added to describe that this certification is required to use natural water to wet store or deplete shellfish. This additional language is needed because it is a requirement in the NSSP Guide that natural water from a growing area used for the purposes of wet storage or depuration must be certified and must meet specific classification standards as specified in the NSSP Guide. The Department does not issue a shellfish growing area certificate if the depuration or wet storage system only uses artificial water, that is potable freshwater in which salt has been added.

The word “shall” was replaced with “must” for consistency. The Department has opted to use the term “must” instead of switching back and forth between the two words.

The term “Shellfish Growing Area” was added to “certificate” to provide clarity about which certificate is required because the outdated term “Shellfish *Bed* Certificate” in the section 7706 title is proposed to be updated to the modern term “Shellfish *Growing Area* Certificate.” Additionally, the Department issues more than one kind of certificate, and even though the title of the certificate is in the section title, the Department wishes to also specify the title of the certificate in the regulation text, so that the regulation text is clear as to which certificate is required.

The term “State Board of Public Health” was removed because the “State Board of Public Health” is an outdated name no longer in use.

For subsection (b), the Shellfish Growing Area Certificates meet the requirements of harvester licenses in the NSSP Guide. The certificate is issued for a specific location as that specific location is evaluated and monitored for sanitary quality by the Department.

Adopt Section 7706.1, to ensure that shellfish relaying is performed in a safe and controlled manner. The Department requires that any person with a valid Shellfish Growing Area Certificate who performs shellfish relay must possess a Shellfish Relay Certificate from the Department. This certificate is valid only for the specific activities, conditions, and time period described in the Shellfish Relay Certificate. The purpose of this regulation is to ensure that shellfish relaying is performed in a manner that is safe for human consumption. The Shellfish Relay Certificate will help to ensure that the shellfish being relayed are free from harmful bacteria and other microbiological contaminants, and that they are being relayed in a manner that is consistent with the Department's regulations.

Relays are a specific procedure used to transfer shellfish for cleaning prior to harvest. The NSSP Guide definition of relay is "to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process." The relay procedures and timelines are described in Chapter V. of the NSSP Guide.

The NSSP Guide requires relays to be licensed. NSSP Guide Chapter V. @.03 states: "The Authority shall require that each harvester that relays or harvests shellstock for delivery to a low acid canned food processing facility from growing areas in the conditionally approved (in the closed status), restricted or conditionally restricted classification possesses a valid harvester or relay license." These Shellfish Relay Certificates meet the requirements of relay licenses in the NSSP Guide. The Department utilizes the relay certificate to specify the conditions of the relay and ensure the relay is performed pursuant to the NSSP Guide. The relay certificate is valid only for the specific activities, conditions, and time period described. Relay is a controlled procedure that the Authority oversees and tracks so the shellstock does not get harvested before meeting the NSSP Guide standards.

The applicant must possess a valid Shellfish Growing Area Certificate as the movement of product can only be between already certified growing areas and only Shellfish Growing Area Certificate holders can harvest shellstock from their certified growing areas. NSSP Guide Chapter V. .01 B. states: "No person shall relay shellstock or shall harvest shellstock for low acid canned food processing without a valid harvester license from the Authority." The Shellfish Growing Area Certificates meet the requirements of harvester licenses in the NSSP Guide.

These provisions are necessary to update the regulations to reflect current industry practices and compliance tracking.

Amend Section 7707, to update terminology and specify requirements to apply for shellfish handling and marketing certificates.

For the title, the term "Plant" was changed to "Handling and Marketing" because "plant"

is too narrow of a term. In addition, the certificate is required for all owners of shellfish, even if they do not have a physical facility or plant. The word “issuable” was removed because it does not add any meaning. The regulation text makes clear that the Department is the authority to issue certificates therefore it is redundant.

The term “State Board of Public Health” was removed because the “State Board of Public Health” is an outdated name no longer in use.

For subsection (a), “any person, firm, or corporation” was changed to “a dealer” because the term aligns with industry and NSSP Guide standards. “A plant engaged in culling, shucking, packing or repacking” was changed to “any facility or area used for the handling, production, depuration, wet storage, processing, storing, transporting or sale of” to be consistent with the NSSP Guide and encompass current industry practices. “Fresh oysters, clams, or mussels” was changed to “shellfish” for consistent terminology use in the regulations. The change to “shellfish” also is consistent with NSSP Guide terminology, which includes scallops as a bivalve molluscan subject to the NSSP Guide. This change to “shellfish” now makes clear that scallops are also included and is consistent with HSC section 112155(a) and the Department’s proposed definition of “shellfish” in section 7702. The word “shall” was replaced with “must” for consistency. The program has opted to use the term “must” instead of switching back and forth between the two words.

The term “Shellfish Handling and Marketing Certificate” replaces “certificate” to provide clarity about which certificate is required because the outdated term “Shellfish *Plant* Certificate” in the section 7707 title is proposed to be updated to the modern term “Shellfish Handling and Marketing Certificate.” Additionally, the Department issues more than one kind of certificate, and even though the title of the certificate is in the section title, the Department wishes to also specify the title of the certificate in the regulation text, so that the regulation text is clear as to which certificate is required.

The term “State Board of Public Health” was removed because the “State Board of Public Health” is an outdated name no longer in use.

For subsection (b), this item was added to ensure that there is knowledgeable and trained staff for the handling of highly potentially hazardous foods that are often consumed raw. There is a history of new companies hiring consultants to create Hazard Analysis Critical Control Point (HACCP) plans then leaving so that the monitoring and documentation of critical hazards is in the hands of untrained employees. This new language assures that at least one person is qualified pursuant to the requirements in Title 21 Code of Federal Regulations Part 123.10, Fish and Fishery Products. Thus, this provision addresses a practice that may leave some facilities with only untrained persons who cannot ensure safety for shellfish consumers.

Adopt Section 7707.1, to establish annual fees for Shellfish Handling and Marketing Certificate and Wet Storage Permit Certificate. The wet storage permit certificate fee will be required for new systems and any significant changes to an existing system that will require a new validation study.

The adoption of this section will provide the Department the resources to implement the amended regulations and recuperate a portion of their program costs. This section 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.

For subsection (a), the Department requires the applicant to complete an annual certificate application, accompanied by a non-refundable fee of \$1,599. The application fee is not refundable as it will offset Department staff time spent processing, reviewing the application, and conducting the inspection. For subsection (a) the HSC statute section 112205 requires a valid certificate. This is necessary because the Department needs to obtain the responsible party information and to identify the applicant.

For subsection (b), this item was added to describe the fee for new and renewal certificates. A dealer must pay the fee of \$1,599 for all dealer certificate types, as defined in the NSSP, (reshipper, shellstock shipper, repacker, shucker packer, and depuration processor) to the Department has been established following a thorough program cost analysis. See table below.

Considering the impact to the shellfish industry and to offset the costs of the program, Food and Drug proposes a flat annual fee for all dealers at the cost of \$1,599 per year.

Table. Average Inspection Time per Inspection per Dealer Type per Year and Rounded Average Cost.

Average Inspection Time per Inspection per Year by Dealer Type (hours)

Dealer Type	2018	2019	2020	2021	2022	2023	Average hours
Reshipper	8.13	8.84	8.93	8.43	8.05	7.12	\$1,288
Shellstock Shipper	9.55	11.43	10.99	12.27	10.26	8.88	\$1,649
Shucker Packer	8.90	9.84	9.43	16.59	10.84	12.42	\$1,769
Repacker	11.30	13.20	10.75	13.31	8.28	12.75	\$1,810
Depuration Processor	8.56	9.04	10.93	9.58	10.00	8.66	\$1,477
Average of all dealer types							\$1,599

For subsection (c), this item mandates the payment of a fee for the initial permit for wet store shellstock in artificial bodies of water in a land-based facility. The fee of \$1,249 to wet storage or depurate shellstock is for the initial system permitting fee, which encompasses wet storage or depuration operation manual approval, validation study oversight, and continuous water test monitoring, and the need for revalidation when updating existing systems.

The wet storage evaluation fee is calculated based on the average time of eight hours. During this period, the Department assesses wet storage operation manuals and validation study test results for the wet storage system. The hourly rate of \$156.08 ensures thorough compliance and quality assurance and this rate times eight hours is rounded up to \$1,249. By allocating this fee, the Department prioritizes safety, accuracy, and adherence to regulations, safeguarding the public.

Wet storage is an operation when a dealer wants to store live oysters, clams, mussels, or scallops in an artificial body of water. Depuration is wet storage plus the requirement to test the shellstock tissue for acceptable levels of fecal coliforms. To permit this activity, the NSSP Guide mandates specific operating parameters, written procedures, and a validation study to demonstrate that the disinfection system can consistently produce water that tests negative for the coliform group under normal operating conditions. The Department must approve this process. To offset the cost of this additional processing activity, FDB proposes to establish an evaluation fee of \$1,249, in addition to the standard application fee (\$1,599) for the initial system permitting. This fee would also be collected if the dealer modified the system where another validation study was required.

For subsection (d), this item was added to describe how the Shellfish Handling and Marketing certificate and wet storage permit certificate fee amounts will be adjusted, which will be annually pursuant to the process in HSC section 100425. This is consistent with other programs within FDB, such as Bottled, Vended, Hauled, and Processed Water program (HSC section 111130) and Processed Pet Foods program (HSC section 113065) whose fee adjustments are governed by the process in HSC section 100425. Adjusting the fee incrementally as described in HSC section 100425 will ensure that FDB will be able to sustain and cover the costs of administering the shellfish program, so that public health will continue to be protected. Additionally, adjusting the fee incrementally should not be burdensome on industry.

For subsection (e), to state that all moneys received from the certificate and wet storage permit fees shall be deposited into the Food Safety Fund as specified by Section 110050.

Adopt Section 7707.2, to state the amount of the re-inspection fee. HSC section 112180(d) authorizes the Department to re-inspect if the firm is not in compliance. Re-inspections can happen when conditions and practices observed in the facility result in

the production of a product that was unwholesome or that presented a threat to consumer health or safety. A re-inspection is a specific activity to ensure egregious sanitation violations were corrected from the initial inspection.

The fee of \$156 per hour is similar to HSC section 110466(c), which imposes a re-inspection fee of \$100 per hour for the Processed Food Registration (PFR) program. The PFR reinspection statute used \$100 per hour, but that statute was last amended in 2005. Due to rising cost of resources, the shellfish reinspection fee reflects the currently hourly rate of shellfish trained staff. The Department selected 12 months as the most appropriate time period because a certificate is valid for one year.

An average of two shellfish dealers have required a re-inspection within a 12-month period to ensure that operations were conducted in a sanitary manner. The average re-inspection time was approximately six hours, which included an on-site inspection, report, and travel time. Two to three re-inspections could be needed to ensure compliance with new shellfish regulations for firms that are out of compliance.

Amend Section 7708, to update the Department's name. This change is necessary for consistency.

In subsection (a), the phrase "so issued shall be" was removed and replaced with "is" as this is a better wording for simplicity. The language "the Department" replaced "State Board of Public Health" because "State Board" is an outdated name no longer in use.

Amend Section 7709, to change the words "shall be" to "is" referring to the one-year term the certificates are valid, as this is a better wording for simplicity. "Shall" also does not make sense in this context as the Department is defining the length of time the certificate is valid and not something for the regulated community to do. Add the phrase "unless suspended, revoked, or expired" because these conditions would result in an invalid certificate. It was also added to ensure that the certification remains up-to-date and reflective of current safety standards. In the next sentence, the word "shall" was replaced with "must" for consistency. The program has opted to use the term "must" instead of switching back and forth between the two words. The phrase "expiration dates are as follows:" was added to introduce and clarify the different Department shellfish certificate expiration dates. This change is needed because each type of certificate is administered independently. The annual timeline for issuance of certificates will not change.

For subsection (a), the February 15 expiration date has not changed.

For subsection (b), the Shellfish Relay Certificate expires on February 15. The February 15 date is the same, however, we are making it clear that the date applies specifically to the Shellfish Relay Certificate.

For subsection (c), the Shellfish Handling and Marketing Certificate expires at the end of each certification period, March 31 of each year. This change is necessary because it

would ensure that the certification remains up-to-date and reflective of current safety standards.

Repeal Section 7710, due to being duplicative, unnecessary, and potentially confusing. “Shellfish” already is defined in statute at HSC Section 112115(a), which states: “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. Section 7710, which is proposed to be repealed, appears to have been an attempt to clarify that *all varieties* of oysters, clams, and mussels are included. However, even though the statute does not include the term *all varieties*, the term is unnecessary. Thus, Section 7710 does not clarify the definition in statute and may cause confusion.

Repeal Section 7711, due to the types of certificates are now clarified in sections 7706 through 7707. This section is not necessary. Repealed section “A” is about a harvesting certificate that can be found in Section 7706 is for the Shellfish Growing Area Certificate. Repealed section “B” about shellfish handling “culling, shucking, packing, and repacking” can be found in Section 7707 is for the Shellfish Handling and Marketing Certificate. Repealed section “C” is about a limited certificate related to Section 7744 which is being repealed. See Section 7744 for additional information.

Amend Section 7712, to specify what is required for an application for a Shellfish Growing Area Certificate. The Shellfish Growing Area Certificate is introduced in Section 7706. A separate section 7712.5 was added for the Shellfish Handling and Marketing Certificate application, introduced in section 7707. There are some differences in information to be included in each certificate application, so they were put into their own sections.

For subsection (a), it describes that the Shellfish Growing Area Certificate is issued for each individual growing area, water bottom-location, or intake point. This is needed because the certificate is issued for a specific location that is classified, evaluated, and monitored for sanitary quality by the Department.

For subsection (b), this provision makes clear that all requested information must be received for the Department to be able to assess whether the application should be approved. This is necessary because receiving incomplete information makes it impossible for the Department to make a determination.

For subsection (c), the information required in the application is pertinent for the Department to evaluate the application. The applicant needs to provide the following information to the Department in writing or electronically (online application) because verbal conveyance of information can lead to misunderstandings. Firms and the Department are better protected when critical information is submitted in writing or electronically (online application).

For subsection (c) (1), the type of application (new, renewal, or ownership change) is needed so the Department can distinguish how to handle the application. New

applications may need a sanitary survey, a shoreline survey, and sampling of the growing area completed before a classification can be determined and certificate could potentially be issued. The classification process including sanitary survey requirements and water quality standards are described in the NSSP Guide Chapter IV. Shellstock Growing Areas. The sanitary survey report is a full evaluation of all potential and actual pollution sources for a specific growing area. The sanitary survey report is completed by the Department and the results determine what classification is appropriate. There are five possible classifications that are described in the definitions section: Approved, Conditionally Approved, Restricted, Conditionally Restricted, and Prohibited. Renewal applications for already certified areas need to be reviewed for updates to the current contact and growing area information already on file. Renewal applications are needed, as the certificate term described in section 7709 has a one-year term and requires an application to renew.

Ownership change applications are for areas where a certificate has already been issued. The certificates are non-transferrable, so the Department will use the ownership change application to issue a new certificate to the person responsible and invalidate the old certificate.

Subsection (c) (2) (A-C), specifies the business information an applicant must provide, including legal name; Employer Identification or Taxpayer Identification Number; primary office physical address, mailing address, telephone number, alternate telephone number, 24-hour emergency telephone number, web address, and the email address of the owner, business operator, or designee acting on behalf of the owner. (See section 7702 for the definition of business operator.) The Department needs the contact information for the business operator because this person serves as the point of contact for the Department concerning matters such as certificates, compliance with regulations, operational questions, recall effectiveness checks, inspectional scheduling, and notifications related to the growing area. The required business information is comparable to OCAL 17 CCR Section 10402, Subdivision (a) (1-8). The Department strives to use the same language within the programs to keep a consistent approach within the branch.

For subsection (3), the growing area, lease, or intake point description including name, location, coordinates, and map showing location and legal boundaries are all needed for the Department to know what area to evaluate and what area to issue the certificate for.

For subsection (4), the proof of legal authorization to access growing area, including proof of ownership, lease, or other written authorization to conduct commercial shellfish operations in the growing area as well as copies of all permits including authorizing agency, permit or lease number, issue date, and expiration date are all needed so that the applicant can establish proof of legal authorization to access the growing area and to operate commercially. The Department needs this information to physically enter the premises safely and legally for sampling and inspections.

For subsection (5), the species of shellfish to be harvested and culture method(s) is

needed so the Department can evaluate risk. The species of shellfish harvested is needed as each species has separate biotoxin risks, and the Department needs to evaluate which species needs to be sampled and when. Culture methods are needed so the Department can assess the cultivation methods for risks to public health including potential wildlife impacts.

For subsection (6), the sources of shellfish seed including source location and company name is needed because the NSSP Guide requires the Authority to sanction the source of seed. Including the source of seed in the application allows the Department (as the Authority) to keep track of sources of seed to comply with the NSSP Guide requirements. Knowing where the seed comes from helps the Department be aware of potential sources of contamination if there is an outbreak in the certified growing area. Seed is already defined in the definitions section.

For subsection (7), the vessel registration number and make/model description for any vessels used for shellfish harvest is needed for investigations or patrolling. The harvesting equipment and vessel registration numbers are needed when law enforcement partners or the Department is investigating or patrolling when a growing area is closed to ensure that no illegal harvesting is occurring. The investigators will be able to identify if a firm's vessels are used for illegal harvesting.

For subsection (8), the signature, printed name, title of owner and date signed, under penalty of perjury is needed so the Department knows who the responsible party is, and that the information submitted is true and correct. The owner of a business is the ultimate responsible party for compliance with the certificate conditions, and so the Department needs to know that the owner has approved the submission of the application and its contents.

For subsection (9), the Department is proposing the addition of a fee to the application process. The Department is proposing any applicable application fee(s) to be submitted with a certificate application to cover the Department's costs for reviewing and processing the application and an annual certificate fee to cover the costs of program administration. The Department is authorized to assess a fee pursuant HCS 112165.

Subsection (d) (1-2) was added to specify a new 90-day timeframe for an applicant to submit missing information once notified by the Department. The current process is that the application remains open until (1) the certificate is issued, (2) the applicant withdraws the application, or (3) the time period for the certificate expires. However, it is to an applicant's benefit to quickly submit missing information once notified by the Department. Ninety days is a reasonable amount of time for an applicant to rectify missing information on an application so that the Department may efficiently process the application. If an applicant does not submit missing information within the 90-day timeframe, their application will be deemed abandoned. This concept of deeming an application as abandoned is new and would allow the Department to close an application file for an applicant who cannot provide all required information. Currently, the Department spends time and resources reaching out to the applicant, far beyond 90

days, which is an inefficient use of Department time and resources in a busy Shellfish Sanitation program. The Department requires the information above to evaluate applications, allocate resources effectively, and update regulations to reflect current industry practices. This is comparable to OCAL 17 CCR Section 22110, Subsection (b).

Adopt Section 7712.1, to itemize the application requirements for Shellfish Relay Certificate.

For subsection (a), this provision makes clear that all requested information must be received for the Department to be able to assess whether the application should be approved. This is necessary because receiving incomplete information makes it impossible for the Department to make a determination.

For subsection (b), the information required in the application is pertinent for the Department to evaluate the application. The applicant needs to provide the following information to the Department in writing or electronically (online application) because verbal conveyance of information can lead to misunderstandings. Firms and the Department are better protected when critical information is submitted in writing or electronically (online application). The information provided will be specified as conditions in the relay authorization. These conditions are stated in NSSP Guide Chapter V. @.03.

For subsection (b) (1-2), the relay source location and destination location including certificate numbers. This information is needed so the Department can know what area the shellfish are coming from and assure the area is certified. The destination location including certificate number is needed so the Department knows where the product is going to be placed and tracked. This information also is needed if the Department visits the site for verification inspections. The NSSP Guide Chapter V. @.03 D. about relay licenses states "The license conditions shall include: (1) The source, destination, and species to be relayed or harvested for low acid canned food processing".

For subsection (b) (3), the proposed date(s) of relay(s). This information is needed so the Department knows when the activity is to take place. The Department will issue the relay certificate for the specific dates and will need to track time spent at the destination location from the start date that the product is moved to the destination location. The NSSP Guide Chapter V. @.03 C. related to relay licenses states "A license shall be valid only when issued for: (1) A specific relay or harvest activity".

For subsection (b) (4), the shellfish species to be relayed and the container type. This information is needed because effective natural microbiological cleansing times may vary between species and container type. The NSSP Guide Chapter V. @.03 D. about relay licenses states "The license conditions shall include: (1) The source, destination, and species to be relayed or harvested for low acid canned food processing". The NSSP Guide Chapter V. @.01 D. about relays states "If shellstock are relayed in containers: (1) The containers are: (a) Designed and constructed so that they allow free flow of water to the shellstock".

For subsection (b) (5), the approximate quantity of shellstock to be relayed. This information is needed to determine adequacy of tracking and marking measures of the relayed shellfish. The relayed shellfish may need special labeling or demarking in the destination growing area so it can be differentiated from the other shellfish being cultivated at the destination location. The quantity of shellstock is also needed to assess sampling needs if a contaminant reduction study is requested by the applicant to allow for a shorter cleansing time at the destination location than the minimum 60 days as required in the NSSP Guide.

For subsection (b) (6), the proposed method for maintaining separation between different lots of shellfish. This information is needed to assure that the relayed shellfish lots will be separated. The relayed lots are being transferred from a source location with limited bacteriological or viral contamination to the cleaner destination location to naturally cleanse. The destination location may already have shellfish being cultivated there and the relayed lots need to be adequately separated so they are not confused with the clean shellfish and harvested before the allowed cleansing time. The information is also needed for inspections so the Department staff can confirm and identify the lots of relayed shellstock. The NSSP Guide Chapter V. @.03 D. about relay licenses states “The license conditions shall include: ... (3) The method used to maintain adequate separation between different lots of shellfish”.

For subsection (b) (7), requires an applicant to pay any applicable fees. Fees are required by the Department to help cover administrative expenses related to thoroughly reviewing and processing applications. The Department is authorized to assess a fee pursuant HCS section 112165.

Subsection (c) (1-2) was added to specify a new 90-day timeframe for an applicant to submit missing information once notified by the Department. The current process is that the application remains open until (1) the certificate is issued, (2) the applicant withdraws the application, or (3) the time period for the certificate expires. However, it is to an applicant’s benefit to quickly submit missing information once notified by the Department. Ninety days is a reasonable amount of time for an applicant to rectify missing information on an application so that the Department may efficiently process the application. The Department considered thirty and sixty days but decided against them because the Department acknowledges that firms may have internal business processes that may cause the business to take more than thirty or sixty days to rectify missing information. If an applicant does not submit missing information within the 90-day timeframe, their application will be deemed abandoned. This concept of deeming an application as abandoned is new and would allow the Department to close an application file for an applicant who cannot provide all required information that certified applicants are able to provide. Currently, the Department spends time and resources reaching out to the applicant, far beyond 90 days, which is an inefficient use of Department time and resources in a busy Shellfish Sanitation program. The Department requires the information above to evaluate applications, allocate resources effectively, and update regulations to reflect current industry practices. The is comparable to OCAL

17 CCR Section 22110, Subsection (b).

Adopt Section 7712.5, to itemize the application requirements for Shellfish Handling and Marketing Certificates. The certificates are issued for each dealer for each facility location. The information is pertinent for the Department to evaluate the applications.

For subsection (a), it describes that the Shellfish Handling and Marketing Certificate is required for all dealers. This is needed because the HSC section 112205 requires a valid certificate for handling and packaging shellfish.

For subsection (b), this provision makes clear that all requested information must be received for the Department to be able to assess whether the application should be approved. This is necessary because receiving incomplete information makes it impossible for the Department to make a determination. The Department mandates that the applicant complete an annual certificate application. Shellfish dealers handle raw oysters, clams, mussels, and scallops that have already been harvested. These dealers are responsible for maintaining adequate temperatures throughout their chain of custody or contacted transportation to their customers. Post-harvest handling can lead to temperature abuse, shellstock contamination through inadequate storage practices, and misbranding. Shellfish lot identity and traceability are essential requirements to effectively remove shellfish from the commerce during an illness outbreak. The responsible party identified on the application is someone who has knowledge of the shellfish facility and whom the Department will contact regarding the certificates, compliance with regulations, operational questions, recall effectiveness checks, inspectional scheduling, and notifications.

For subsection (c), the information required in the application is pertinent for the Department to evaluate the application. The applicant needs to provide the following information to the Department in writing or electronically (online application) because verbal conveyance of information can lead to misunderstandings. Firms and the Department are better protected when critical information is submitted in writing or electronically (online application).

For subsection (c) (1), the type of application (new, renewal, ownership change, or relocation) is needed so the Department can route the application appropriately, track, and monitor business operations. New applicants, ownership changes, and relocations are contacted to schedule a physical onsite inspection, establish if the facility is ready for inspection, and if the applicant meets training and HACCP plan requirements. Renewal applications need to be reviewed for updates.

For subsection (c) (2) (A-D), specifies the business information an applicant must provide, including legal name; Employer Identification or Taxpayer Identification Number; primary office physical address, mailing address, telephone number, alternate telephone number, 24-hour emergency telephone number, web address, and the email address of the owner, business operator, or designee acting on behalf of the owner. (See section 7702 for the definition of business operator.) The Department needs the contact information for the

business operator because this person serves as the point of contact for the Department concerning urgent matters such as certificates, compliance with regulations, operational questions, recall effectiveness checks, inspectional scheduling, and notifications related to the growing area. The facility address is needed for any inspections of areas where shellfish will be handled and held. A certificate is required for separate facilities. The mailing address is needed for correspondence and issues the certificate documents. The physical address where the shellfish is stored is important because shellfish can be stored at third party logistics companies. Shellfish dealers are not required to physically maintained custody of the shellfish. The Department needs to know where the product is stored. Third party logistics companies are required to have a FDB Cold Storage Facility license. FDB also needs to know of dealers that own but only transport shellfish. The business structure (e.g., limited liability company, partnership, corporation, or operation as a sole proprietor, etc.). The Country information is needed to ensure knowledge and compliance with import requirements. The FDA Establishment information is needed to ensure knowledge and compliance with import requirements. The Dealer's website information is needed for additional contact and advertising information to determine if any advertisements or products are not in compliance. This number will assist with any inquiries and correspondence with FDA. Interstate receiving and shipping information is needed so the Department can distinguish how to handle the application. The ownership type is needed to know the legal business structure of the company. The State of Incorporation is needed to know the legal profile of the company. The owner's names and titles are needed to know who the responsible person for the company is and able to make any legal decisions. The required business information is comparable to OCAL 17 CCR Section 10402, Subdivision (a) (1-8). The Department strives to use the same language within the programs to keep a consistent approach within the branch.

For subsection (c) (3), the species of shellfish handled is needed to identify the certificate requirements and inform the Department.

For subsection (c) (4), the signature, printed name, title of owner and date signed, under penalty of perjury. The owner information is needed to know that the owner has approved of the submission of the application to the Department. The signature is needed as acknowledgement that the information is true and correct, and the owner is ultimately responsible for compliance with the certificate conditions.

For subsection (c) (5), requires an applicant to pay any applicable fees. Fees are required by the Department to help cover administrative expenses related to thoroughly reviewing and processing applications. The Department is authorized to assess a fee pursuant HCS 112165.

Subsection (d) (1-2) was added to specify that an application will be deemed abandoned if the applicant does not submit missing information within the 90-day timeframe. The applicant will need to reapply and pay any applicable application fees. The concept of the Department deeming an application as abandoned is new. As explained above, an application with missing information can continue to remain open for an entire year (until the time period of the certificate expires). Currently, the

Department would continue to spend time and resources reaching out to the applicant, far beyond 90 days, which is an inefficient use of Department time and resources in a busy Shellfish Sanitation program. Adding this provision would allow the Department to close an application file for an applicant who cannot provide all required information that certified applicants are able to provide the Department is authorized to assess a fee pursuant HSC section 112165.

Amend Section 7713, due to the language from this section being edited to update the terminology and to align with the NSSP Guide.

The title of the previous section 7713 was changed by removing the words “no” and “unless” and adding “must be”. This wording makes it easier to understand what must be certified. The new title is: Shellfish Grown in the State of California Must Be Certified to Be Sold or Distributed.

For subsection (a), to align with the wording in the title and for clarity, the words “No” and “except” were removed and the word “to” and the phrase “must only be” was added. The term “approved” was changed to “classified for harvest” because “approved” is only one of the four classifications (approved, conditionally approved, restricted, and conditionally restricted) that allow harvest under the NSSP Guide. The term “State Board of Public Health” was changed to “Department” for consistency with current terminology.

For subsection (b), to replace the word “shall” with “must”. This change is necessary for consistency. The phrase “into California” was added to describe that the shellfish discussed in section (b) are not from the state of California but are being brought into the state from other locations. The phrase “or countries” was included to extend the regulation to shellfish coming from growing areas in other countries, not just from other states within the U.S. This ensures that all shellfish, regardless of their origin, meet the same or equivalent health and safety standards before they are sold or distributed in California. By adding these phrases, the regulation becomes more precise and leaves less room for misinterpretation. This is important because it ultimately helps protect public health.

The phrase “obtained therefrom” was removed because it is unnecessary and does not provide clarity to the sentence. The phrase “that is valid on the Interstate Certified Shellfish Shippers List” was added for out of state shellfish lots because dealers can lose their certification when they do not meet requirements set forth in the NSSP Guide. This addition clarifies the current industry practice to discourage fraud, use of invalid numbers, and operating without current certifications. The certificate numbers are issued by the Shellfish Authorities in other states or countries. The words “certificate number” were moved before “that is valid on the Interstate Certified Shellfish Shippers List” because the Interstate Certified Shellfish Shippers List does not issue the certificate numbers, but rather lists the valid ones. The phrase beginning with “designating a certificate” was deleted as superfluous wording. The intent of subsection (b) is to reinforce and clarify that all dealers must be certified. Shellfish coming from out

of state therefore must be on the Interstate Certified Shellfish Shippers List. Enforcement actions can be taken if any shellfish was obtained from an uncertified dealer.

Amend Section 7714, due to the language from this section being edited to update the terminology to align with the NSSP Guide. The title of the previous section 7714 was changed by removing the words “no” and “unless” and adding “must be certified”. This wording makes it easier to understand what must be certified. The new title is: Shucked Shellfish Must be Certified to Be Sold or Distributed.

For subsection (a), to align with the wording in the title and for clarity, the words, and phrases “No,” “shall,” and “except where such shellfish have been handled,” “for which” and “has been” were removed and the words and phrases “to” and “must only be shucked,” “with a valid” were added. This change is necessary to enhance readability and to make the wording easier to understand on what is allowed with a valid certificate. The term “State Board of Public Health” was changed to “Department” for consistency with current terminology.

For subsection (b), to replace the word “shall” with “must”. This change is necessary for consistency. The phrase “into California” was added to describe that the shellfish discussed in this section (b) are not from the state of California but are being brought into the state from other locations. The phrase “or countries” was included to extend the regulation to shellfish coming from growing areas in other countries, not just from other states within the U.S. This ensures that all shellfish, regardless of their origin, meet the same or equivalent health and safety standards before they are sold or distributed in California. By adding these phrases, the regulation becomes more precise and leaves less room for misinterpretation. This is important because it ultimately helps protect public health. The phrase “that is valid on the Interstate Certified Shellfish Shippers List” was added for out of state shellfish lots because dealers can lose their certification when they do not meet requirements set forth in the NSSP Guide. This addition clarifies the current industry practice to discourage fraud, use of invalid numbers, and operating without current certifications. The certificate numbers are issued by the Shellfish Authorities in other states or countries. The words “certificate number” were moved before “that is valid on the Interstate Certified Shellfish Shippers List” because the Interstate Certified Shellfish Shippers List does not issue the certificate numbers, but rather lists the valid ones. The phrase beginning with “designating a certificate” was deleted as superfluous wording. “Obtained therefrom” was deleted because it was superfluous wording. The intent of subsection (b) is to reinforce and clarify that all dealers must be certified. Shellfish coming from out of state therefore must be on the Interstate Certified Shellfish Shippers List. Enforcement actions can be taken if any shellfish was obtained from an uncertified dealer.

Repeal Section 7720, due to the section being outdated and unnecessary because the NSSP Guide is being incorporated by reference in the proposed section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .02 A (7) and dealer chapters XI-XV .02 G. Provisions for employee disease control are currently

mandated in federal regulation, 21 CFR 117.10 (a), which has been previously adopted in HSC section 110105.

Why is this important: Persons infected with communicable disease can contaminate ready to eat foods, such as raw molluscan shellfish through handling. The control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces directly affects the safety of shellfish. Shellfish is often consumed raw or undercooked.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7720, addresses persons infected with communicable diseases. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7720. Persons Infected with Communicable Diseases.	NSSP Guide Citation and Summary
<p>Persons who are infected with or are carriers of organisms of typhoid fever, dysentery, septic sore throat, or certain other communicable diseases which might be transmitted through shellfish or who have infected wounds or open lesions on exposed portions of the body shall not be employed in the growing beds or shucking, packing, or repacking plant. If the owner or manager has reason to suspect that any employee has contracted such a communicable disease, he shall immediately exclude said employee from the growing beds or plant.</p>	<p>NSSP Guide Chapter X. .02 A (7) and dealer chapters XI-XV .02 G.</p> <p>Control of Employees with Adverse Health Conditions. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces. The dealer and the supervisor shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The pathogens causing diseases which are transmissible from food workers through food are those determined by the U.S. Centers for Disease Control and Prevention.</p> <p>The NSSP Guide mandates that shellfish processors monitor and document their employee health conditions. Shellfish dealers must take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces.</p> <p>Specific diseases and various symptoms are also outlined in the NSSP Guide. Directives are outlined in the dealer chapters XI-XV .02 G for when employees can return to work.</p>

Amend Section 7725, to eliminate outdated standards. The daily records sentence was deleted because provisions for this repealed section are outlined in the NSSP Guide Chapter X .08 B., which we are incorporating by reference in proposed section 7700. The phrase “All shellfish records required per the NSSP Guide, Code of Federal Regulations, California HSC, and CCR” was added to make clear what records are required. Provisions for recordkeeping are currently mandated in federal regulations, 21 CFR 123.9, which have been previously adopted into California regulations pursuant to 17 CCR 10862. The NSSP Guide is specific to shellfish, lot traceability, and transaction records and not in conflict with the generally broad 21 CFR 123.9 for seafood HACCP records. This section also updates the Department’s name for consistency with current terminology. This section is also being amended to replace the word “shall” with “must”. This change is necessary for consistency.

The 48-hour timeframe was added to facilitate the Department responding to illness investigations, product recalls, and compliance inspections in a timely manner. The majority of illness investigations begin with laboratory results indicating the presence of *Vibrio* bacteria in the shellfish consumer’s stool specimen. *Vibrio* bacteria naturally live in certain coastal waters and are present in higher concentrations between May and October when water temperatures are warmer. The most common species causing human illness in the United States are *Vibrio parahaemolyticus*, *Vibrio vulnificus*, and *Vibrio alginolyticus*. Most people become infected by eating raw or undercooked shellfish, particularly oysters. Determining where the consumer purchased the shellfish, and the source of the shellfish is vital to prevent further illnesses. Records must be maintained and made accessible within 48 hours to ensure quick access for staff. This process is critical for promptly identifying and confirming the source of any potential contaminants or adulterations during foodborne inspections carried out by the Department.

During onsite inspections and complaint investigations, HACCP plans and corresponding monitoring records are reviewed. If a dealer cannot provide the records at the time of inspection, the records can be sent to the Authority to complete the inspection. While other regulations require the records to be created and retained by the processor, they do not designate a time frame when the records must be provided for official review. 21 CFR 123.9 (c) states, “Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.” The NSSP Guide mirrors the identical language in the CFR. Establishing a time limit for the records to be provided will aid in timely review and help prevent the production of fraudulent documents.

Adopt Section 7727, to have a clear and concise regulation that addresses the growing issue of required HACCP and NSSP Guide records that are willfully incorrect. Records are an instrumental tool used to determine compliance and product safety. This section will assist in enforcement and accountability for the harvesters and dealers.

Subsection (a) makes clear what actions are unlawful as to the integrity of records. Dealers are required to monitor critical control points in their process and document the

date and time of monitoring, who performed the monitoring, and document the actual values obtained. Dealers are required to measure temperatures of shellfish at receiving, during processing, storage, and prior to shipment. Dealers are required to document harvest dates, locations, supplier information and sales data. This information allows the dealers and the Department to perform timely and effective recalls during illness outbreaks or product defects. When the information in the records is falsified or misleading, the Department cannot trace the product back to the source to reduce illnesses.

Subsection (b) describes examples of what actions could be defined as falsification or misrepresentation. These are concrete examples that make clear to the regulated public what the Department views as falsification or misrepresentation, which includes not only incorrect information, but also includes information entered after it was observed and missing information. The Department uses reported information to help determine that the firms are using safe practices. When false and misrepresented information is given to the Department, public health safety can be severely compromised.

Subsection (c) inserts language stating that it is unlawful for any person to forge, falsify, fail to retain, fail to obtain, or fail to disclose records. This language is consistent with Department practices in its OCAL program at 17 CCR section 22175. This provision is necessary because it makes clear to firms that certain actions are unlawful. With this language, the Department may cite firms and pursue administrative penalties to pursue clear consequences for violations. The Department identified a need for this provision because firms have done this in the past.

Subsection (d) inserts language stating that it is unlawful for any person to alter any registration certificate or registration document. This language is consistent with Department practices in its OCAL program at 17 CCR section 22190. This provision is necessary because it makes clear to firms that certain actions are unlawful. With this language, the Department may cite firms and pursue administrative penalties to impose clear consequences for violations. The Department identified a need for this provision because firms have done this in the past.

Amend Section 7730, to update the terminology. This change is needed to align with NSSP Guide language. The term “bed” was replaced with “growing areas”. Bed is an outdated term that does not apply to all types of areas where shellfish are harvested. The first sentence was re-worded to make sense by moving the term growing area to the beginning of the sentence and removing the duplicative use of growing area in the middle of the sentence. The revised wording does not change the meaning of the first sentence. This section is also being amended to replace the words “shall” with “must”. This change is necessary for consistency.

Amend Section 7731, regarding harvest vehicle or vessel sewage disposal to update the terminology and add specific requirements for vessel sewage handling.

In the title, “boat” was replaced with “vehicle or vessel” to be more consistent with NSSP

Guide language in Chapter VIII. .02 D. The title was also changed by adding “Harvest” to be more specific to the use of vehicle or vessel. “Sewage Disposal” was added at the end to replace “Sanitation” to be specific about what the section regulates.

In the text, the existing text is deleted because provisions for this section are outlined in the NSSP Guide Chapter VIII. .02 C and Chapter VIII. .02 D, which we have incorporated by reference in proposed section 7700.

For subsection (a), adopt language to replace the requirement “Persons in boats over the shellfish beds shall not discharge human wastes into waters” in section 7731. The language revises the wording to be consistent with NSSP Guide language in Chapter VIII. .02 D. The language added from the NSSP Guide is “Human sewage and vomitus shall not be discharged overboard from any vehicle or vessel used in the harvesting of shellstock.” The NSSP Guide language expands upon the older terminology of “boats” to include “vessels or vehicles.”

For subsection (b) adopt language to replace the requirement for “adequate facilities for disposal for human waste” in section 7731. The language revises previous wording in section 7731 to be specific as to the definition of “adequate” by defining the types of receptacles and requirements. The sewage disposal receptacle requirements are considered optional “as required by the Authority” within the NSSP Guide Chapter VIII. .02 D. The Department wants to make this section in the NSSP Guide a requirement in California. It provides a clear expectation to the harvester of what should be done to contain human waste on vessels and multiple options for compliance. The Department also further elaborates upon the NSSP Guide language to enhance clarity. The Department added “harvest” in front of “vessel” to indicate the vessels that this section applies to. The language “be accessible adjacent to the harvest site” was also added to expand and define the options for where the disposal receptacles can be located. This language was added after reviewing the sewage disposal options at the current growing areas and to allow for options like disposal receptacles located on barges in the growing area that are adjacent to harvest site.

Alternatives considered: Keeping the language as-it was considered. If the NSSP Guide language for disposal of human sewage was not adopted in this section, the language of “adequate facilities shall be provided for disposal of human wastes” would remain undefined and vague to both the harvester and the Department trying to enforce the regulations. This is not a preferred alternative.

Amend Section 7732, to update the terminology to align with the NSSP Guide. The terms “unclassified” and “prohibited” were added because this is consistent with NSSP Guide terminology. The terms “unclassified or prohibited” refers to all waters that are not in the classifications that allow shellfish harvest for human consumption. The term “bed” was changed to “growing area” as this is consistent with the NSSP Guide terminology. Language about special approval was deleted because that practice is not allowed in the NSSP Guide for shellfish over seed size. The exception language for shellfish seed was added because shellfish seed is allowed to be moved from an unclassified or

prohibited area into a growing area that has a valid certificate per the NSSP Guide.

Repeal Section 7733, due to the section being both outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .02 A (1) and all dealer chapters .02 A.

Why is this important: Water can be a source of contamination for the washing, storage, and sanitary practices for handling shellfish. Bivalve shellfish are filter feeders, which means they feed by straining the surrounding water in order to collect food particles; these particles (including bacteria) can then become concentrated in their guts.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7733, addresses water quality for shell stock. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7733. Water Quality.	NSSP Guide Citation and Summary
<p>Shell stock shall not be cleaned, stored, floated, or conditioned in water, the standard of which is not as rigid as that required at certified shellfish beds.</p>	<p>Chapter IV. Shellstock Growing Areas Established biotoxin and bacteria values that would close a growing area and prevent shellstock harvesting.</p> <p>Chapter VI. Shellfish Aquaculture Established the water quality in different systems must meet requirements in Ch VII.</p> <p>Chapter VII. Wet Storage Established source water quality and validation study protocols to hold shellstock in flow through and recirculating water storage systems.</p> <p>Chapter VIII. Control of Shellfish Harvesting Established the standards for the safety of water and ice. Requirements monitoring of conditions and documentation.</p> <p>Chapter X. General Requirements for all dealers Established the standards for the safety of water and ice. Requirements monitoring of conditions and documentation.</p> <p>Chapter XI - Chapter XV (dealer activity chapters) .02 in each chapter addresses the sanitation standards, including the water supply to the facility, ice production, and shellstock washing.</p> <p>Dealers are required to rinse shellstock with potable water or approved growing area water to remove excess mud and debris. The NSSP Guide also stipulates the type of water that can produce ice used to cool shellstock. Water quality is important to the health and safety of the shellstock and the NSSP Guide contains the most comprehensive and uniform standard.</p>

Amend Section 7738, to update the terminology to align with the NSSP Guide. For the title, the term “Plant” was changed to “Operations” because “plant” is too narrow of a term. Clarifying sentences were added to explain culling operations and the sanitary requirements. Culling operations can occur dockside or on a vessel.

The words “shall” were replaced with “must” throughout this section. This change is necessary for consistency. The word “insanitary” was changed to “unsanitary” because the word “unsanitary” is more commonly understood by the general public and in the NSSP. The term “potable or growing area” was added before “source” because the Department needs to define what type of water source is sanitary so that shellfish will be fit for human consumption and not contaminated when hosing down floors, benches, and cleaning the shellfish. Culling is not mentioned in the NSSP Guide, thus it’s important to keep this section in the state regulations and align with terminology used in the NSSP Guide for uniformity.

This section also updates the Department’s name for consistency with current terminology.

Amend Section 7739, to update the title with the words “Wet” and “or Depuration System Validation” to clarify requirements for wet storage and depuration system validation. The deleted text is unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Dry storage provisions for this section are outlined in the NSSP Guide Chapter X. .02 A (3) and all dealer chapters .02 C., which we have incorporated by reference in proposed section 7700. Provisions are currently mandated in federal regulation, 21 CFR 117.80(a), which has been previously adopted in HSC section 110105.

The new text in this section will establish the requirements to validate wet storage and depuration systems that are not addressed in the NSSP Guide with enough specificity. As defined in the NSSP Guide, wet storage means the storage, by a dealer, of shellstock in tanks containing natural or synthetic seawater at any permitted land-based activity or facility. Oysters, clams, and mussels are filter feeders therefore the sanitation of the water surrounding them are critical to the safety of the shellstock. Thus, the critical limit for a wet storage system is the recirculated water must test negative for total coliforms. A study shall be required to demonstrate that the disinfection system can consistently produce water that test negative for the coliform group under normal operating conditions. The NSSP Guide goes on to describe the duration of the study and the number of samples that must be collected for each day.

Process validation is defined as the collection and evaluation of data, from the process design stage throughout production, which establishes scientific evidence that a process is capable of consistently delivering quality products. The NSSP Guide required study is designed to be performed under preapproved and predetermined parameters. The construction and design of the system is set to function at a certain water capacity to accommodate a maximum amount of shellfish in the system. The installed ultraviolet light has a maximum capacity that will disinfect water at a certain flow rate in gallons per

minute. For example, when a dealer applies for a wet storage permit, they also submit a wet storage operation plan that identifies they will design a system with five tanks, that will hold a total of 5,000 gallons for 10,000 Pacific Oysters, *Crassostrea gigas*. They are required to keep accurate traceability of the source of the water and source of the oysters by harvest date and harvest location. Process and source water samples are collected each day and tested for total coliforms. No sample can be positive for coliforms. If there is a positive result, the study must restart and the oysters in the tanks must be evaluated for contamination.

Similar to other food, drug, and medical device process validations, the validation process is product and process specific. Therefore, once validated, that system was proven to disinfect no more than 10,000 Pacific Oysters in 5,000 gallons of water with the equipment, construction, and design used in the study. This is the set parameters and what the regulatory industry deems normal operating conditions.

For subsection (a)(1), a validation study upon initial system installation is important to establish the control factors of the system and the normal operating conditions that yields disinfected water which is negative for the coliform group. The parameters are control factors established at the time of the initial study, such as quantity of shellstock in the system, amount of water flowing through the system to adequately submerge the shellstock, and construction and design of the equipment.

For subsection (a)(2), a validation study upon modifications is important because the evidence collected, and study performed was specific to the equipment, construction, design, and capacity established. While the NSSP Guide requires a study to demonstrate that the disinfection system can consistently produce water that tests negative for the coliform group, the NSSP Guide does not address what actions must be taken when the dealer modifies the parameters established in the initial study.

For illustration purposes, a land-based system is validated to consistently produce water that is negative for total coliforms in a system that holds 20,000 oysters, held over four tanks, and recirculates 50 gallons of water per minute. If the dealer wants to add another tank to the existing system, which will add another 5,000 oysters and additional water to the system, the system parameters have changed. Critical questions include the following: Will the system still produce water that is negative for total coliforms? Can the existing ultraviolet light disinfection unit handle the extra biological load? Will the increase in system water exceed the flow rate capacity of the disinfection unit? Conducting another study must be performed to answer those critical questions.

Subsection (b)(1) states that the dealer shall validate the system at the dealer's maximum capacity for shellstock to establish normal operating conditions. This is needed because if the system can hold 20,000 oysters, but the study is performed with 15,000 then the system is proven to work, validated to hold 15,000 oysters. If the dealer has a large order or a high season and wants to put in more oysters, then they would be in violation. With the reverse, if the system can hold 20,000 oysters and study performed at 20,000, but the dealer chooses to operate with only 15,000, they have that

flexibility to increase or decrease their handling. Oysters, even washed and culled, have mud on them from the growing area and uneven shell surfaces. Bivalve shellfish are filter feeders and concentrates materials found in the surrounding waters. Wet storing shellstock is a high-risk activity that has significant hazards that are controlled through a HACCP plan. Critical limits, such as functioning UV light, flow rate, and process water testing is monitored on a daily basis.

Subsection (b)(2) states that the dealer shall not remove any shellstock from the system or alter from the initial loading of the system, excluding water sampling. This is needed to ensure the study can be performed in a controlled process with known factors. The traceability of the shellstock within the tank is maintained because different lots of shellstock are not being removed and newly harvested shellstock being replaced in the system during the validation period. Potential contamination sources are also reduced by eliminating personnel activity in the tanks. The NSSP Guide prescribes the number of water samples that must be collected each day during the five-day validation period. It is acceptable to use sanitary practices to remove the required water samples.

Repeal Section 7740, due to the section being duplicative with the NSSP Guide. The NSSP Guide is more thorough, and the section is unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .03 and all dealer chapters .03 F.

Why is this important. The cleanliness of shellstock is important because the product is consumed raw or undercooked. Reducing the amount of sediment and cleaning the shellstock prior to distribution is best practice to decrease the bacterial load. *Vibrio parahaemolyticus* is a bacterium that is present in marine environments and a significant hazard for molluscan shellfish.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7740, addresses the cleanliness of shellstock. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7740. Cleanliness of Shellstock.	NSSP Guide Citation and Summary
Only shellstock that is reasonably clean and reasonably free of mud shall be shipped or marketed. Oysters, clams, or mussels which are dead or do not have tight shells shall not be shipped or marketed.	Chapter XI., XIII, XIV, and XV .03 F Shellfish Storage and Handling. The guidelines for shellfish storage and handling require dealers to ensure that shellstock is reasonably free of sediment and culled. They must inspect incoming shipments, reject dead or inadequately protected shellstock.

Repeal Section 7741, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter IX. and Chapter X. .05 - .07.

Why is this important. The distribution of shellstock and shellstock tagging are critical control points in the handling of the raw shellfish. Shellstock is required to have a tag with specific information. NSSP Guide tagging standards have exceeded what section 7741 identifies. The tagging requirements are established in Chapter X .05-.08. Uniform standards lend to fair business practices, better understanding, and familiarity with harvest lot information. During illness investigations and recalls the shellstock tags are the only way to identify the shellstock. Local environmental health inspectors and FDB staff request traceback information, tags and invoices from retailers and wholesale dealers. The information on the tag provides type of shellstock, harvest dates, harvest site location, quantity, and certification numbers. This tells the story of who has handled the shellstock prior to consumption.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7741, addresses shipping. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7741. Shipping.	NSSP Guide Citation and Summary
Shellstock shall be handled and shipped under such temperature as will keep them alive.	<p>Chapter IX.04 Shellfish dealers shall ship shellfish adequately iced; or in a conveyance pre-chilled at or below 45 °F (7.2 °C) ambient air temperature.</p> <p>A. All shipments of shellstock shall be accompanied with documentation indicating the following: (1) Date and time of shipment; and (2) The temperature of the shellstock recorded by the shipping dealer at the time of shipment.</p> <p>B. For shipments of shellstock harvested under the requirements of Chapter VIII. at.02 A. (3) that has not been cooled to an internal temperature of 50°F (10°C) prior to shipping and where the shipping time is greater than four (4) hours, the documentation shall also indicate the presence of a time/temperature recording device.</p>

<p>Each lot of shellstock shall be shipped in clean containers such as bags, boxes, or barrels so as to prevent spoilage or contamination during shipping.</p>	<p>Chapter IX.03 Cargo Protection from Cross Contamination</p> <p>A. General. All containers used for storing shellfish shall be clean and fabricated from safe materials.</p> <p>B. Shellfish Cargo Only. (1) The entire cargo shall consist of shellfish products only. (2) Except for bulk shipments, shellstock shipments shall be shipped on pallets. (3) In-shell product shipments shall be shipped on pallets. (4) If the conveyance does not have a channeled floor, pallets shall be used for all shellfish.</p> <p>C. Mixed Cargoes. Shellfish shall be shipped as part of a mixed cargo of seafood or other food product only when: (1) Shellfish products are protected from contamination by the other cargo; (2) All cargo is placed on pallets; and (3) No other cargo is placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers.</p> <p>D. Ice. Any ice used to cool shellfish shall meet the requirements of Chapter XI. .02 A. (2).</p>
<p>Each lot shall be plainly marked with the name and address of the shipper, the certificate number of the bed from which the oysters, clams, or mussels were obtained, and the date of harvest.</p>	<p>Chapter X .05 Shellstock Identification</p> <p>Chapter X .06 Shucked Shellfish Labeling</p> <ul style="list-style-type: none"> • Chapter X .07 In-Shell Product or Post-Harvest Processed In-Shell Labeling Scallops, subject to NSSP Guide must be tagged. • NSSP Guide also requires wet storage lot numbers, depuration processing dates, 90-day tag retention statement, consumer advisory, and Perishable Keep Refrigerated statements. • NSSP Guide requires the tag to be waterproof, with indelible ink. <p>The NSSP Guide requires transportation temperature records, traceability provisions, and container specifications. The cleanliness and sanitary controls are also prescribed to prevent cross contamination from other foods during shipping activities. Handling practices from harvesting to the final sale to the direct consumer is important to the health and safety of the shellstock. The shipping requirements in the NSSP Guide contain the most comprehensive and uniform standard.</p>

Repeal Section 7742, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter XI.

Why this is important: Shucker packers are dealers who have been certified to remove one or both shells from live oysters, clams, mussels, or scallops. Shucker packers are handling raw shellfish directly from the harvester or part of the distribution chain. This

processing activity requires strict time to temperature cooling requirements and more stringent sanitary practices. Processors are handling the shellstock with knives, machines, and other processing equipment. Ice and water are in direct contact with the meat and employees are directly handling the shellfish. The shellfish is often consumed without a process to reduce pathogens. Handling practices from harvesting to the final sale to the direct consumer is important to the health and safety of the shellstock.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7742, addresses shucking, packing plants, and equipment. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7742. Shucking and Packing Plants and Equipment.	NSSP Guide Citation and Summary
<p>Shellfish shall be shucked and packed in such a manner that they are not subject to contamination.</p>	<p>Chapter XI Shucking and Packing. 02 Sanitation C. Prevention of Cross Contamination</p> <p>Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. Shellfish shall be protected from contamination. Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination.</p> <p>Chapter XI. Shucking and Packing outlines, over 11 pages, of requirements for the plant and equipment.</p>
<p>Shellstock shall be free of mud when they are shucked. Only live shellfish shall be shucked.</p>	<p>Chapter XI .03 F. Shellfish Storage and Handling (1)(a) and (3)</p> <p>The dealer shall assure that shellstock is reasonably free of sediment and culled. Inspect incoming shipments and shall reject dead or inadequately protected shellstock</p>

<p>Shucked shellfish shall not remain on the shucking table for more than one hour unless refrigerated at .50 degrees Fahrenheit or less.</p>	<p>.01 D. Processing Critical Control Point – Critical Limits</p> <p>The dealer shall ensure that:</p> <p>(1) For shellstock which has not been refrigerated prior to processing:</p> <p>(a) Shucked meats are chilled to an internal temperature of 45 °F (7.2 °C) or less within three (3) hours of shucking.</p> <p>(b) In-shell product is chilled to an internal temperature of 45 °F (7.2 °C) or less within three (3) hours of processing.</p> <p>(2) For shellstock refrigerated prior to processing:</p> <p>(a) Shucked meats are chilled to an internal temperature of 45 °F (7.2 °C) or less within four (4) hours of removal from refrigeration.</p> <p>The NSSP Guide, which contains the most comprehensive and uniform standard details the time and temperature requirements for the shucking and pack of molluscan shellfish.</p>
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Repeal Section 7743, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .02 A (1) and dealer chapters XI - XII.02 A. and B, and Chapters XI – XII .03 F.

Why this is important: Shucked shellfish handling is a high-risk activity because employees are in direct contact with the meat. Pathogens of public health significance are reduced when meat is cleaned with an approved water source and when surfaces that come in contact with the meat (such as knives, containers, and tables) are properly cleaned and sanitized.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7743, addresses washing. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7743. Washing.	NSSP Guide Citation and Summary
<p>All shucked shellfish shall be properly washed and shall be free of sand, mud, and other foreign material.</p>	<p>Chapter XII. .02 Sanitation. B.</p> <p>Shucked shellfish washing requirements in the NSSP Guide contain the most comprehensive and uniform standard. Removing one or both shells can introduce pathogens and other contaminants.</p>

<p>All shucked shellfish shall be properly washed and shall be free of sand, mud, and other foreign material.</p>	<p>Chapter XI. .03 Other Model Ordinance Requirements. F. Shellfish Storage and Handling.</p> <p>The dealer shall:</p> <ul style="list-style-type: none">(1) Assure that shellstock is:<ul style="list-style-type: none">(a) Reasonably free of sediment; and(b) Culled.(2) Assure shucking buckets are completely empty at the packing room so that no overage is returned to the shucker.(3) Inspect incoming shipments and shall reject dead or inadequately protected shellstock.(4) Not allow the use of dip buckets for hand or knife rinsing.(5) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source.(6) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161 Section 130.(7) Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room. <p>Chapter XII. .02 Sanitation. Safety of Water for Processing and Ice Production</p> <ul style="list-style-type: none">(a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock.(b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:<ul style="list-style-type: none">(i) Obtain approval for the construction or remodeling of the system from the Authority.(ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and(iii) Test bacteriological water quality daily.(c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed twenty (20) nephelometric turbidity units (NTUs) measured using the method in the American Public Health Association (APHA) Standard Methods for the Examination of Water and Wastewater.
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<p>Methods and equipment used for washing the shucked shellfish shall be adequate to accomplish this purpose and shall be approved by the State Health Department. All water used for washing the shellfish shall meet the requirements of Section T17-7753 of these regulations.</p>	<p>Chapter XI .02 Sanitation Shellstock Washing.</p> <p>(a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. (b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall: (i) Obtain approval for the construction or remodeling of the system from the Authority. (ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and (iii) Test bacteriological water quality daily.</p>
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Repeal Section 7744, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapters XI - XII.

Why this is important: Separate rooms and adequate space between live shellstock and the washing and packing of the shucked meat is important to reduce the risk of contamination. Live animals have two shells and can contain mud/sediment on the outer shells. Employees removing one or both shells have to touch the outer shell to open the animals. When the shells are removed, the meat is exposed and must be cleaned. Separating these shucking and washing processes is the best way to reduce cross contamination for the final shucked meat product.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7744, addresses plant arrangement. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7744. Plant Arrangement.	NSSP Guide Citation Summary
<p>Unless shellfish are shucked directly into packing containers with no further processing, the shucking and packing processes shall be done in separate rooms. There shall be installed in the partition between the two rooms a delivery window through which the shucked stock is passed to the packing room. Provision shall be made for storing the employees' outer garments, aprons, gloves, etc., in a separate room.</p> <p>* In special instances where shucking is done on a small scale for local retail sales, shucking and packing may be permitted in a single room if approved by the State Department of Public Health. This single room and all operations shall conform to all requirements of these regulations except that of separate shucking and packing rooms. "Limited" certificates shall be issued in these instances and all containers of shucked shellfish shall be clearly labeled or marked with the words "limited certificate" and the appropriate certificate number.</p> <p>* Not a building standard.</p>	<p>Chapters XI - XII.02 C. Prevention of Cross Contamination.</p> <p>Shucking operations can soil a shucker's clothing. A delivery window has proven to be an effective means of keeping shuckers out of the packing room. This measure helps avoid potential contamination.</p> <p>The NSSP Guide dedicates Chapter XI and Chapter XII, to establish the requirements for shucker packers and contains the most comprehensive and uniform standard. Removing one or both shells can introduce pathogens and other contaminants. Shuck shellfish processing and plant arrangements are detailed in the NSSP Guide. In the NSSP Guide Chapter XI .01, critical control points and critical limits are established.</p> <p>In Chapter XI and XII .02, sanitation requirements outline water supply, ice production, cleanliness of food contact surfaces, and prevention of cross contamination to name a few. Chapter X .06 details the labeling requirements of shucked shellfish to include a sell by or best if use by date, packers name and certification number, Keep Refrigerated statement and consumer health advisory. Chapter X .06 Shucked Shellfish Labeling</p> <p>The dealer must maintain lot integrity when using in-plant reusable containers. The dealer can use returnable containers to transport shucked shellfish between dealers, but they must include a transaction record with the original shucker-packer's name, certification number, shucking date, and quantity of shellfish. The dealer can use master shipping cartons, but they must ensure that the individual containers inside are properly labeled.</p>

Repeal Section 7745, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .03 and dealer chapters XI to XV .03 A. Provisions are currently mandated in federal regulation, 21 CFR 117.20, which has been previously adopted in HSC section 110105.

Why this is important: The sanitary conditions and general maintenance of any food

facility is important to limit sources of contamination. The condition of the floors in a shellfish facility can harbor bacteria that can serve as a vehicle for cross contamination. Shellfish facilities are wet and cold. Shellstock can be stored in mesh bags, stored on pallets that are six inches in height, and stored on ice or in a cooler. Ice melts can pool if the dealer does not properly monitor the condition of the facility. Foot traffic and splashing from wet floors can contaminate stored shellfish. Exposed aggregate on concrete floors and uneven surfaces can house pathogenic bacteria and contaminants.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7745, addresses floors. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7745. Floors.	NSSP Guide Citation and Summary
<p>The floors of all rooms in which shellfish are stored, shucked, washed, packed, or otherwise processed shall be constructed of concrete or other equally impervious material, graded to drain quickly, free from cracks or uneven surfaces that might interfere with proper cleaning or drainage, and maintained in a clean and satisfactory condition.</p>	<p>Chapters XI – XV .03 A Plants and Grounds.</p> <p>Properly graded, durable floors, smooth washable walls and ceilings, and the use of light-colored finishes enhances sanitation and aids in the detection of unclean surfaces. Keeping the plant grounds clean and implementing physical barriers helps protect against contaminants such as filth, chemicals, and microorganisms, while minimizing interference from miscellaneous equipment that can complicate cleanup.</p> <p>The NSSP Guide addresses the condition of the floors in each dealer chapter, Chapter XI-XV .03 A Plants and Grounds. Specifically, .03 A (5) Plant Interior (a-c) outlines the requirements for dry areas, wet areas, and general facility sanitation. .03 B Plumbing and Related Facilities addresses the requirements for adequate floor drainage.</p>

Repeal Section 7746, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .03 and dealer chapters XI - XV.03 A. Provisions are currently mandated in federal regulation, 21 CFR 117.20, which has been previously adopted in HSC section 110105.

Why this is important: The sanitary conditions and general maintenance of any food facility is important to limit sources of contamination. The condition of the walls and ceilings in a shellfish facility can harbor bacteria that can serve as a vehicle for cross contamination. Shellfish facilities are wet and cold. Shellstock can be stored in mesh bags, stored on pallets that are six inches in height, and stored on ice or in a cooler.

The difference in temperatures can create condensation. When the dealer does not properly monitor the condition of the facility, condensation builds up and drips down, carrying microorganisms with each droplet.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7746, addresses walls and ceilings. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7746. Walls and Ceilings.	NSSP Guide Citation and Summary
<p>Walls and ceilings shall be maintained in a smooth, clean, washable, light-colored condition. They shall be impervious to moisture and shall be kept in good repair. Walls contiguous to benches shall, to a height of two feet above the bench top, be of smooth concrete, metal, or equally nonabsorbent material.</p>	<p>Chapters XI – XV .03 A Plants and Grounds.</p> <p>Properly graded, durable floors, smooth washable walls and ceilings, and the use of light-colored finishes enhances sanitation and aids in the detection of unclean surfaces.</p> <p>The NSSP Guide addresses the condition of the walls and ceilings in each dealer chapter XI-XV .03 A Plants and Grounds. Specifically, .03 A (5) Plant Interior (d) outlines the requirements for walls and ceilings and general facility sanitation.</p>

Repeal Section 7747, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .03 and dealer chapters XI - XV.03 A. Provisions are currently mandated in federal regulation, 21 CFR 117.20, which has been previously adopted in HSC section 110105.

Why this is important: The sanitary conditions and general maintenance of any food facility is important to limit sources of contamination, such as access to insects and vermin. Tightly sealed doors, windows, screening windows and other measures are needed to prevent the entry of pests.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7747, addresses screening. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7747. Screening.	NSSP Guide Citation and Summary
<p>The plant shall have all openings effectively screened with not less than 16-mesh screening, unless other effective means are provided to prevent the entrance of flies and other insects.</p>	<p>Chapters XI – XV .03 A Plants and Grounds.</p> <p>The NSSP Guide addresses screening in the facility in each dealer chapter XI-XV .03 A Plants and Grounds. Specifically, .03 A (4) Plant Interior (b) outlines the requirements for screening not less than fifteen (15) mesh per inch. The guidelines for shellfish facility management include the use of screening with a mesh of not less than fifteen (15) mesh per inch as a measure to prevent the presence of insects and vermin in the facility. This mesh is used in conjunction with other measures like tight-fitting, self-closing doors to control access. These precautions aim to exclude contaminants and maintain sanitary conditions throughout the facility, ensuring the protection of shellfish from potential adulteration and contamination.</p>

Repeal Section 7748, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .03 and dealer chapters XI - XV.03 C. Provisions are currently mandated in federal regulation, 21 CFR 117.20, which has been previously adopted in HSC section 110105.

Why this is important: Adequate lighting is required to ensure proper sanitation monitoring to promote good manufacturing practices.

NSSP Guide compared to the repealed section:

The regulation being repealed, which is section 7748, addresses light. Measuring light intensity by 10-foot candles is an outdated term. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7748. Light.	NSSP Guide Citation and Summary
<p>Ample light to work by shall be provided in all working rooms. A light intensity of not less than 10 foot-candles shall be maintained on all working surfaces when workers are at their working positions.</p>	<p>Chapters XI – XV .03 C</p> <p>The NSSP Guide addresses lighting throughout the facility in each dealer chapter XI-XV .03 C. Utilities. The dealer is required to ensure that the facility has adequate lighting to promote good manufacturing practices.</p>

Repeal Section 7749, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .02 and dealer chapters XI - XV.02 E. (5). Provisions are currently mandated in federal regulation, 21 CFR 117.20, which has been previously adopted in HSC section 110105.

Why this is important: Ventilation, heating and cooling systems can create conditions that may cause shellfish products to become contaminated. Limiting airborne pathogens is a best practice for facility maintenance. The difference in temperatures in a cooler and in the facility will cause condensation to form on fans, fixtures, and other equipment in the facility. The water that forms on these surfaces can drip onto bags and boxes of shellstock. If the surfaces are not cleaned and sanitized with sufficient frequency, the water and any contaminants will fall onto the stored products below. Shellstock are often consumed raw or with inadequate heat treatment that do not kill pathogens of public health concern, such as *Vibrio* species and *Listeria* species to name a few.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7749, addresses ventilation. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7749. Ventilation.	NSSP Guide Citation and Summary
Adequate ventilation shall be provided to prevent condensation on ceilings or other surfaces.	Chapters XI – XV .02 E Protection from Adulterants. The NSSP Guide addresses ventilation throughout the facility in each dealer chapter XI-XV .03 C. Adequate ventilation is necessary to reduce condensation in areas where food is stored, processed, or packed. Air pump intakes should be placed in protected locations, and air filters are required on blower air pump intakes, with oil bath type filters prohibited.

Repeal Section 7750, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .02(4) and dealer chapters XI - XV .02 D. Provisions are currently mandated in federal regulation, 21 CFR 117.37, which has been previously adopted in HSC section 110105.

Why this is important: Personnel must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and contamination of food. Each plant must provide employees with adequate, readily accessible toilet facilities. Without proper cleaning and employee practices, toilet facilities can become a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7750, addresses toilet facilities. The current regulation is relatively short

compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7750. Toilet Facilities.	NSSP Guide Citation and Summary
<p>Every shellfish culling, shucking, packing, or repacking plant shall be provided with clean and adequate toilet facilities conveniently located. * No toilet room shall be used for the storage of garments, food products, containers, or equipment. Construction and maintenance of toilets shall comply with all local and state regulations.</p> <p>* Not a building standard.</p>	<p>Chapters XI – XV .02 D</p> <p>Maintenance of Hand Washing and Toilet Facilities. Toilet rooms doors should be tight fitting, self-closing, and not open directly into processing areas. The dealer shall provide an adequate number of conveniently located toilets and each toilet facility must be equipped with an adequate supply of toilet paper.</p>

Repeal Section 7751, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .02(4) and dealer chapters, Chapters XI to Chapter XV, .02 D. titled “Maintenance of Hand Washing and Toilet Facilities.” In addition, provisions are currently mandated in federal regulation, 21 CFR 117.37, which has been previously adopted in HSC section 110105.

Why this is important: Hygienic practices are necessary to protect against allergen cross-contact and contamination of food. Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) protects consumers and employees from cross-contact and contamination of food. If employees do not have water at a suitable temperature, soap, and in locations convenient to the employees, then employees could transfer diseases and pathogens directly to the food being handled. In addition, when employees touch food contact surfaces (shovels, handles, tables, bins, knives, etc.), the contact surfaces can become contaminated, which would transfer contaminants to any exposed foods handled on those contact surfaces.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7751, addresses handwashing facilities. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7751. Handwashing Facilities.	NSSP Guide Citation and Summary
<p>An adequate number of lavatories shall be provided at locations conveniently to toilet rooms and shellfish handling operations, including running hot and cold water, soap, and individual disposal towels. The use of a common towel is prohibited.</p> <p>All employees shall wash their hands thoroughly with running water and soap on beginning work and after each visit to the toilet. Signs to this effect shall be posted in conspicuous places in the plant and in the toilet rooms.</p>	<p>Chapters XI – XV .02 D Maintenance of Hand Washing and Toilet Facilities.</p> <p>Hand washing facilities with warm water at a minimum temperature of 100F, dispensed from a hot and cold mixing faucet, must be provided. They should be convenient to work areas, separate from sinks used for cleaning equipment, directly plumbed to an approved sewage disposal system, and adequate in number and size for employees. Each hand washing facility should provide hand cleansing soap or detergent, single-service towels or hand drying devices, and easily cleanable waste receptacles. An employee must use adequate hand-washing facility before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated.</p>

Repeal Section 7753, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .02 A (1) and dealer chapters XI - XV.02 A. and dealer chapters XI - XV .03 B. Provisions are currently mandated in federal regulation, 21 CFR 117.37, which has been previously adopted in HSC section 110105.

Why this is important: The water supply must be adequate because any water that contacts food, food-contact surfaces, or food-packaging materials could lead to unsanitary conditions. Physical, chemical, or biological agents cause significant health hazards in the safe production of food. Contamination of water by several pathological microorganisms creates major challenges in food safety and threats to human and animal health. The majority of diseases that are transmitted through contaminated fresh water are caused by pathogenic microorganisms. Whenever water is used as an ingredient in food product, it must be free from undesirable taste, odor, color, and impurities, including pathogenic organisms that could jeopardize consumers' health and gravely affect product quality. The quality of water must be from a potable source.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7753, addresses water supply. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7753. Water Supply.	NSSP Guide Summary
<p>Shucking, packing, or repacking plants shall be provided with an ample supply of water under adequate pressure from a source approved by the State Department of Public Health. The supply shall be accessible to all parts of the plant, adequate in quantity, and of a safe sanitary quality. No cross-connections with unapproved supplies or other possible sources of contamination shall be permitted.</p>	<p>Chapters XI – XV .02 A</p> <p>Safety of Water for Processing and Ice Production. The dealer must provide a potable water supply that meets the federal, state, and local regulations, and have it sampled and tested regularly if it is from a private source. The dealer must use ice that is made on-site from potable water or obtained from a sanctioned facility for processing, storage, or transport of shellfish. The dealer must use potable water or approved growing area water to wash shellstock, and if using a recirculating system, obtain approval, disinfect, and test the water quality daily.</p> <p>The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to prevent contamination of water supplies; any cross-connection between the pressurized potable water supply and water from an unacceptable source. The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.</p> <p>Chapters XI – XV .03 B</p> <p>Plumbing and Related Facilities. The dealer must have proper plumbing and plumbing fixtures, adequate water supply and pressure, and sufficient floor drainage and sewage disposal. The dealer must avoid installing drainage or waste pipes over food processing or storage areas, and ensure that ventilation, heating, cooling, and lighting systems do not contaminate the shellfish products.</p>

Repeal Section 7754, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter XI. Provisions are currently mandated in federal regulation, 21 CFR 117.10 and 117.40, which has been previously adopted in HSC section 110105.

Why this is important: All plant equipment and utensils, such as benches and stands, can become dirty and contaminated during manufacturing, processing, packing, or holding food. Benches and stands can be designed and made of material that makes

them more easily and cleanable. Also, certain maintenance practices can protect against contamination.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7754, addresses benches and stands. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7754. Benches and Stands.	NSSP Guide Citation and Summary
<p>All benches and stands shall be of smooth concrete, metal, or other nonabsorbent material, free from cracks or crevices, and so constructed that drainage is complete and rapid. Shucking blocks shall be removable unless an integral part of the bench and shall be of solid one-piece construction.</p>	<p>Chapter XI – XII .02 B</p> <p>Condition and Cleanliness of Food Contact Surfaces. The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are constructed in a manner and with materials that can be cleaned and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products. They should also be free from any exposed screws, bolts, or rivet heads on food contact surfaces and fabricated from food grade materials. The dealer shall assure that all joints on food contact surfaces have smooth easily cleanable surfaces and are welded. Shucking blocks shall be provided which are easily cleanable, fabricated from safe material, solid, one-piece construction, and easily removed from the shucking bench unless the block is an integral part of the bench.</p> <p>Chapters XI – XV .03 E</p> <p>Equipment Condition, Cleaning, Maintenance, and Construction of Non-food Contact Surfaces. The dealer shall use easily cleanable, corrosion-resistant impervious materials, free from cracks to construct shucking benches and contiguous walls, stands or stalls and stools for shucker, and any non-food contact surfaces in shellfish storage or handling areas. Shucking benches shall drain completely and rapidly and shall drain away from any shellfish on the benches.</p> <p>The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are constructed in a manner and with materials that can be cleaned and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; free from any exposed screws, bolts, or rivet heads on food contact surfaces; and fabricated from food grade materials.</p>

Repeal Section 7755, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapters XI -XII. Provisions are currently mandated in federal regulation, 21 CFR 117.10 and 117.40, which has been

previously adopted in HSC section 110105.

Why this is important: Properly designed equipment and utensils are important because they must be cleanable to protect against contamination. Equipment constructed with materials that cannot be easily cleaned and sanitized will harbor bacteria. Pathogens can settle in cracks and uneven seams of equipment. Illness causing bacteria and other hazards can be transferred directly to the shellstock during employee handling, or indirectly from condensation or airborne movement. Illness causing bacteria also can settle on food through storage. *Listeria sp.*, *Salmonella*, *Vibrio spp.* and other pathogenic bacteria can live on surfaces and grow in a facility under certain conditions.

Physical hazards can be instructed through poorly constructed and maintained equipment as well. Rusted knives, tables, metal shavings, or chipped glassware is also preventable.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7755, addresses construction of utensils and equipment. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7755. Construction of Utensils and Equipment.	NSSP Guide Citation and Summary
<p>All shucking pails, opening knives, blowers, skimmers, tanks, tubs, trays, measures, colanders, paddles, or other equipment or utensils which may come in contact with shucked shellfish shall be made of not readily corrodible, smooth, impervious material and shall be constructed in such a manner as to eliminate grooves, seams, and cracks where foreign particles, dirt, and slime might collect. Perforations in the skimmers, colanders, and blower trays shall be smooth to facilitate cleaning. Skimmers, ladles, and colanders of wire-mesh construction are not permitted. The top rim of every tank, tub, and tray shall be at least 30 inches above the floor.</p>	<p>Chapter XI – XII .02 B</p> <p>Condition and Cleanliness of Food Contact Surfaces. Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall provide adequate cleaning supplies and equipment, including three (3) compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant. Sanitize equipment and utensils prior to the start-up of each day’s activities and following any interruption during which food contact surfaces may have been contaminated.</p>

Repeal Section 7756, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapters XI - XII. Provisions are currently mandated in federal regulation, 21 CFR 117.10 and 117.40, which has been previously adopted in HSC section 110105.

Why this is important: Aprons and other garments can be contaminated with fecal

matter, dirt, grease, and lubricants. Soiled aprons and clothing can harbor bacteria and transfer to food and food contact surfaces. If there are no rooms or lockers for clothing, aprons, and gloves, such articles tend to be stored on the shucking benches or in packing rooms, where they interfere with plant clean up and operations. Employees who have clean outer garments and demonstrate hygienic practices can reduce potential sources of contamination.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7756, addresses aprons and finger cots. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7756. Aprons and Finger Cots.	NSSP Guide Citation and Summary
<p>All persons who handle shucked shellfish shall wear clean aprons and coats of washable and waterproof material. If finger cots or similar shields for protecting the palm of the hand are worn, they shall be of clean, washable, and waterproof material.</p>	<p>Chapter XI – XII .02 B (2)(e)</p> <p>Condition and Cleanliness of Food Contact Surfaces. If used, the finger cots or gloves shall be made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done. Sanitized at least twice daily, properly stored until used, and maintained in a clean, intact, and sanitary condition.</p> <p>Chapter XI .03</p> <p>Other Model Ordinance Requirements. Rooms or lockers should be provided for clothing, aprons, and gloves to eliminate the tendency to store such articles on the shucking benches or in packing rooms, where they interfere with plant clean up and operations.</p>

Repeal Section 7757, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter XI. Provisions are currently mandated in federal regulation, 21 CFR 117.80, which has been previously adopted in HSC section 110105. In addition, provisions mandated in HSC section 110960.

Why this is important: Shellfish are potentially hazardous foods capable of supporting growth of infectious or toxigenic micro-organisms when held at temperatures above 45 degrees Fahrenheit. *Vibrio* are naturally occurring pathogenic bacteria and are commonly found in waters where oysters and other shellfish live. The bacteria thrive in warm temperatures and have exponential growth at temperatures above 50 degrees. Controlling pathogen growth and toxin formation in fish and fishery products is critical to protecting public health. *Vibrio* will grow when held at elevated temperatures. With oysters and other shellfish consumed raw or undercooked, there is not an opportunity to destroy or reduce the bacterial load in the shellfish. Consumers, especially those populations with compromised immune systems, may become ill.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7757, addresses refrigeration. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7757. Refrigeration.	NSSP Guide Citation and Summary
<p>Unless shellfish are delivered to the consumer immediately upon completion of shucking, refrigeration facilities shall be provided capable of cooling the shucked shellfish to a temperature below 50 degrees Fahrenheit within two hours after the shellfish are shucked and keeping them at this temperature until delivered to the consumer. If shucked shellfish are frozen, they shall be kept in a frozen condition until delivered to the consumer. The refrigerator or icebox shall have an impervious lining. The floor shall be graded to drain quickly. An accurate thermometer shall be kept in the refrigerator or icebox. Refrigerators shall be kept clean and sanitary at all times.</p>	<p>Chapter XI .01 A. (2)</p> <p>Receiving Critical Control Point - Critical Limits.</p> <p>The dealer shall ensure that once placed under temperature control and until shucked the shellstock shall be iced; or placed and stored in a storage area or conveyance maintained at 45 °F (7.2 °C) or less; and not be permitted to remain without ice, mechanical refrigeration or other approved methods of storage, for more than two (2) hours at points of processing or transfer such as loading docks.</p> <p>Chapter XI .01 B. (2)</p> <p>Not be permitted to remain without ice, mechanical refrigeration, or other approved methods of storage, for more than two (2) hours at points of processing.</p> <p>Chapter XI .02 B.</p> <p>The dealer shall provide a temperature measuring device accurate to +/- 2 °F for use in monitoring product temperatures.</p> <p>Chapter XI .03 E.</p> <p>Equipment Condition, Cleaning, Maintenance, and Construction of Non-Food Contact Surfaces.</p> <p>All conveyances and equipment (refrigeration units) which encounter stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination.</p>

Repeal Section 7758, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .02 A (1) and dealer chapters XI - XV .02 A. Provisions are currently mandated in federal regulation, 21 CFR

117.80 (c)(16), which has been previously adopted in HSC section 110105.

Why this is important: Ice used on shucked shellfish can be a source of contamination if not produced and handled in a sanitary manner. Ice can be contaminated by producing the ice with non-potable or contaminated water, by coming in contact with fish or other allergens, or when handled with dirty equipment. Ice is a common storage and shipping method to maintain the shellstock at safe temperatures. However, without proper drainage and prolonged storage, the ice will melt at temperatures above 32°F. Shellfish submerged in melted ice will ingest the water around them. They are live animals and excrete waste material as well. Stagnant water becomes a source of contamination, and the shellfish are no longer wholesome and suitable for human consumption. Without proper ice handling, people who eat the tissue of the shellstock may become ill.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7758, addresses ice. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7758. Ice.	NSSP Guide Citation and Summary
Ice used for the processing of shucked shellfish shall be obtained from an approved source and shall be stored and handled in a sanitary manner. No ice shall be allowed to come in contact with shucked shellfish.	Chapter XI .02 A. Safety of Water for Processing and Ice Production. The dealer must use ice that is made on-site from potable water or obtained from a sanctioned facility for processing, storage, or transport of shellfish. The dealer must design, install, modify, repair, and maintain all plumbing and plumbing fixtures to prevent contamination of water supplies and any cross-connection between the pressurized potable water supply and water from an unacceptable source. The dealer must install and maintain in good working order devices to protect against backflow and back siphonage.

Repeal Section 7759, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter X. .02 A (2) and dealer chapters XI - XV.02 B. and chapters XI - XV.03 E. Provisions are currently mandated in federal regulation, 21 CFR 117.35, which has been previously adopted in HSC section 110105.

Why this is important: Proper cleaning and sanitizing of food contact surfaces (such as equipment, utensils, and benches) are essential to remove dirt and contaminants prior to use and between uses. Proper cleaning of non-food contact surfaces (such as floors, walls, and ceilings) is important to maintain a facility in sanitary condition. The cleaning and maintenance of floors, walls, and ceilings leads to the integrity of the facility to keep out pests and to not allow bacteria to colonize under tables and in crevices.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7759, addresses cleaning. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7759. Cleaning.	NSSP Guide Citation and Summary
<p>The floors, walls, and, if necessary, ceilings in the plant shall be cleaned at the end of each day's operations and flushed with water. All equipment, utensils, benches, etc., which come in contact with shucked shellfish shall be thoroughly scoured at the end of each day's operations. The premises shall be kept clean and free of litter and rubbish. Equipment and articles not required in the processing of the shellfish shall be excluded from the plant.</p>	<p>Chapters XI - XV.02 B.</p> <p>Condition and Cleanliness of Food Contact Surfaces. Sanitize equipment prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; and wash and rinse equipment at the end of each day.</p> <p>The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are constructed in a manner and with materials that can be cleaned and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products.</p> <p>Chapters XI – XV.03 E</p> <p>Equipment Condition, Cleaning, Maintenance, and Construction of Non-Food Contact Surfaces. Cleaning activities for equipment must be conducted in a manner and frequency appropriate to prevent contamination of shellfish and non-food contact surfaces. The dealer must use only equipment and approved plastic ware that can be cleaned, sanitized, maintained, or replaced, and easily cleanable, corrosion-resistant, impervious materials to construct non-food contact surfaces in shellfish storage or handling areas. Shucking benches must drain completely and rapidly away from any shellfish on the benches.</p> <p>Non-food contact surfaces shall be cleaned at a frequency appropriate to prevent contamination of shellstock and food contact surfaces. All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency necessary to prevent shellstock contamination.</p>

Repeal Section 7760, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. The intent for this section was to sanitize food contact surfaces and not for sterilization of equipment. Food contact surfaces are, but not limited to, surfaces of knives, tables, ice storage bins, ice manufacturing equipment, slicers, and cutting boards. Sterilization is a validated process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Sanitation is widely practiced

and extensively identified in the NSSP Guide and the CFR.

Provisions for this repealed section related to sanitation are outlined in the NSSP Guide Chapter X .02 A (2) and dealer chapters XI to XV .02 B., which we have incorporated by reference in proposed section 7700. Provisions are currently mandated in federal regulation, 21 CFR 117.35(d), which has been previously adopted in HSC section 110105.

Why this is important: Utensils and equipment that come in direct contact with the shucked shellfish meat and ice can become a source of contamination if not properly cleaned. The proper way to clean these surfaces is to use a cleanser and water to remove dirt and grime. Sanitizing reduces the microorganisms on surfaces. Sanitizer is a chemical agent, such as chlorine bleach and quaternary ammonium, that is used at preset concentrations and have been proven to be effective to reduce pathogens and other microorganisms to a level that is not a public health concern. Cleansing, rinsing, and sanitizing performed within the facility by trained employees reduces contamination.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7760, addresses sterilization of equipment. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7760. Sterilization of Equipment.	NSSP Guide Citation and Summary
All utensils, equipment, or working surfaces coming in contact with shucked shellfish after being thoroughly cleansed shall be sterilized by methods approved by the State Department of Public Health. Sterilized equipment shall be protected from recontamination between usages.	<p>Chapters XI - XV.02 B.</p> <p>Condition and Cleanliness of Food Contact Surfaces. The dealer must use only equipment and utensils that conform to the Shellfish Industry Equipment Construction Guides, are free from any exposed screws, bolts, or rivet heads, and are fabricated from food grade materials. The dealer must ensure that all joints on food contact surfaces are smooth, easily cleanable, and welded, and that all equipment used to handle ice is clean and sanitary.</p> <p>The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are constructed in a manner and with materials that can be cleaned and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products.</p>

Repeal Section 7761, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Ch XI .02 and Ch X .06. Provisions are currently mandated in federal regulation, 21 CFR 117 and 21 CFR 101, which has been previously adopted in HSC section 110105.

Why this important: Cross contamination can occur when food contact surfaces and packaging materials touches shellfish meat. Preventing cross contamination is essential to protect food that will be consumed raw or undercooked. Shellfish packaged in clean, food grade containers will not be a source of contamination and will provide a safe environment for the product. Shipping the shellfish under time and temperature controls also maintains the safety of the product. Additionally, proper labeling allows regulatory agencies to trace the shellfish back to the harvest area and processing dates, should there be a public health issue to address.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7761, addresses packing and shipping. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7761. Packing and Shipping.	NSSP Guide Citation and Summary
<p>Shucked shellfish shall be packed and shipped either in single-service containers made of clean impervious materials or in properly designed, returnable containers* which have received adequate cleansing and bactericidal treatment. All containers shall be stored in a manner that will protect them from contamination. Containers holding one gallon or more must be positively sealed or so sealed that tampering with the container can easily be detected. Each can, container, or package shall bear the name of the shipper, certificate number of the shucking, packing, or repacking plant, and date packed. The date may be in code if the code is registered with the State Department of Public Health.</p>	<p>Ch XI .02 B.(2)(b)-(d)</p> <p>Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling. Containers that may have become contaminated during storage must be washed, rinsed, and sanitized prior to use or discarded.</p> <p>Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling. Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. Shucked shellfish shall be packed in clean covered containers and stored in a manner which assures their protection from contamination: fabricated from food grade materials; and stored in a manner which assures their protection from contamination.</p> <p>At a minimum the dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with CFR 21, Part 101; Part 161, Subpart B (161.130, and 161.136) and the Federal Fair Packaging and Labeling Act. The dealer shall assure that the shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish. The NSSP Guide outlines how the dealer shall label each individual package containing less than and more than sixty-four (64) fluid ounces of fresh or fresh frozen shellfish.</p> <p>Ch X. .06</p> <p>Shucked Shellfish Labeling. Shucked shellfish must be stored in reusable or returnable containers with lot integrity and transaction records. Each package of shellfish must have a legible and indelible label with the dealer's certification number and the relevant dates. The label must comply with the federal regulations and the Fair Packaging and Labeling Act.</p>

Repeal Section 7762, due to the section being outdated and unnecessary because the NSSP Guide is incorporated by reference in the new section 7700. Provisions for this repealed section are outlined in the NSSP Guide Chapter XII. Provisions are currently mandated in federal regulation, 21 CFR 117.80, which has been previously adopted in HSC section 110105.

Why this is important: Cross contamination can occur when food contact surfaces and packaging materials touches shellfish meat. Preventing cross contamination is essential to protect food that will be consumed raw or undercooked. Shellfish packaged in clean, food grade containers will not be a source of contamination and will provide a safe environment for the product. Shipping the shellfish under time and temperature controls also maintains the safety of the product.

NSSP Guide compared to the repealed section: The regulation being repealed, which is section 7762, addresses repacking shucked stock. The current regulation is relatively short compared to the NSSP Guide that has much more detail and rigorous standards (see table below). The NSSP Guide is more protective of public health, and therefore, the regulation being repealed is outdated.

§ 7762. Repacking Shucked Stock.	NSSP Guide Citation and Summary
<p>Repacking of shucked shellfish shall only be done if contamination of the shellfish will not occur. Repacking of shucked stock shall be in conformance with all sections of these regulations dealing with shucking and packing of shellfish.</p>	<p>Ch XII .02 B (2)(b)-(d)</p> <p>Shucked shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling. According to these standards, containers that may have become contaminated during storage must be washed, rinsed, and sanitized prior to use or discarded. Shucked shellfish must be packed in clean covered containers made of food-grade materials and stored in a manner that ensures their protection from contamination.</p> <p>Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling. Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. Shucked shellfish shall be packed in clean covered containers and stored in a manner which assures their protection from contamination: fabricated from food grade materials; and stored in a manner which assures their protection from contamination.</p>

Documents Relied Upon (References)

1. National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 2023 Revision:
<https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>
2. Fish and Fishery Products Hazards and Control Guidance, Fourth Edition – June 2022:
<https://www.fda.gov/media/80637/download>
3. Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive Controls For Human Food, 21 CFR Part 117, Subparts A and B:
<https://www.ecfr.gov/cgi-bin/text-dx?SID=bbe7dfde96b1ffc6f3c5f64ab08f877a&mc=true&node=pt21.2.117&rgn=div5>
4. Fish and Fishery Products, 21 CFR Part 123:
<https://www.ecfr.gov/cgi-bin/text-idx?SID=bbe7dfde96b1ffc6f3c5f64ab08f877a&mc=true&node=pt21.2.123&rgn=div5>
5. Washington Administrative Code 246-282-010
<https://app.leg.wa.gov/wac/default.aspx?cite=246-282-010>
6. Oregon Administrative Rules 603-100-0000
<https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=2760>

Consideration of Reasonable Alternatives

The Department has determined 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.

Statements of Determinations and Economic Impact Assessment

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.

The Department has determined that the regulation 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.

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 public health and safety. The proposed regulations increase and strengthen the public health of California residents by conforming California to the most recent national guidelines.

The Department has determined that there would not be an 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. Updating the regulations will clarify shellstock tagging, wet storage, and depuration procedures, while expanding transparency, formalizing the applications and certification requirements.

The Department has determined that the regulations will have no impact on housing costs.