

Final Concise Explanatory Statement

Sanitary Control of Shellfish, chapter 246-282 WAC

WAC 246-282-006, Vp control plan

Comment Summary	The addition of the words “process” and “processing” in Section 4 can be interpreted to require shucked and post-harvest processed oysters to be reported during the Vp season. Reporting shucked products would distort illness-rate calculations.
Response Summary	Production reporting of shucked and post-harvest processed oysters has always been a requirement in the NSSP Model Ordinance and chapter 246-282 WAC, but illnesses attributed to these do not count towards risk category determinations.
Department’s Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	Subsection (9)(d)(ii) requires oysters in a container or conveyance to be returned to approximately the same tidal level or lower than where they were collected. This will be virtually impossible to enforce. A different approach to consider is specifying maximum tidal elevations for various regions of the state that accounts for the varying tidal amplitudes.
Response Summary	This proposed rule language is intended to add flexibility for the industry and is based off direct industry input during rules workshops. Using approximate tidal levels is protective of public health while minimizing the administrative burden of using specific levels.
Department’s Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	Request that timelines for waiver decisions be outlined in rule, similar to existing timelines for license and control plan reviews.

Response Summary	This is existing rule language. The department makes its best effort to review waivers in a timely manner. The amount of time required to review a waiver depends on the nature of the waiver request, and thus, putting a timeline in rule is not feasible.
Department's Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	The department committed to completing a risk analysis in order to determine whether the Vp Control Plan has been effective in preventing illnesses. It is difficult to assess whether the rule is working if a risk analysis is not completed by the department. Since this has not been done, the reporting requirement should be removed from the rule.
Response Summary	The department is required to do a risk assessment for the Vp Control Plan yearly and report it to the Food and Drug Administration. The NSSP Model Ordinance does not have a set requirement for how a risk assessment should be completed. In the Vp Control Plan, WAC 246-282-006, each growing area is given a risk category based on the average five years of single source illnesses attributed to oyster consumption. The department asked members of the Rulemaking Advisory Committee if the way that risk categories are calculated should be changed, and the response was no. While oyster production is not a part of risk category calculation, production reporting is required in the NSSP Model Ordinance and rule. This was not a proposed change.
Department's Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.

WAC 246-282-010, Definitions

Comment Summary	The definition of "mooring area" should match the 2023 NSSP Model Ordinance, which defines "mooring area" as more than 20 boats with marine sanitation devices.
Response Summary	The mooring area standard differs from the NSSP Model Ordinance. It was developed and implemented in Washington through a Directive Memorandum in 2013 and has been the agency's policy since then. The ten boat standard for marinas and mooring areas is based on the 1993 EPA document "Guidance

	Specifying Management Measures for Sources of Nonpoint Pollution in Coastal Waters.” Development of the 20-boat standard in the Model Ordinance was arbitrary and not based on science.
Department’s Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	The current 1.5-inch threshold for Pacific oysters remains problematic. The 120-day grow-out period adequately protects public health, and no data shows that smaller oysters create additional illness risk.
Response Summary	The NSSP Model Ordinance requires the Shellfish Authority to set the maximum seed size, based on current market size and a minimum of 120 days of growing outside the initial waters, for shellfish moved from unclassified or Prohibited waters to waters in other classifications. The market for Pacific and other oyster species has become smaller in recent years (now ~2 inches). Seed size must be reduced to ensure that the public does not consume shellfish from a Prohibited or unclassified area that has not been in an Approved or Conditionally Approved area for at least 120 days.
Department’s Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	The inclusion of the word “floats” in the “wet storage” definition conflicts with the wet storage permit section.
Response Summary	The word “floats” is in the existing “wet storage” definition. The department does not see a conflict between the proposed definition and the wet storage permit section but can clarify any potential confusion in guidance.
Department’s Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Suggested Change	Remove the following proposed rule language: “The definitions in this section, as well as those in chapter 69.30 RCW and the NSSP Model Ordinance,

	apply throughout chapter 246-282 WAC unless the context clearly requires otherwise. If a definition of the NSSP Model Ordinance or chapter 69.30 RCW is inconsistent with a provision otherwise established under this chapter, then the more stringent definition, as determined by the department, will apply."
Rationale	The above sentence is redundant to language that is already in WAC 246-282-005 and therefore, not needed.
Department's Recommendation	Adopt as amended by the department.
Board Action	The board adopted the rule as amended by the department.

WAC 246-282-012, Certificates of approval

Suggested Change	Remove the clause "or a person acting on behalf of them" from subsections (2) and (4) of this section: (2) "A person engaged in the actions listed in WAC 246-282-005(1), or a person acting on behalf of them, must have a valid shellfish operation license." (4) "A person harvesting a commercial quantity of shellfish or any quantity of shellfish for human consumption or bait, or a person acting on behalf of them, shall have a valid harvest site certificate." This language also appears in WAC 246-282-014, 246-282-020, and 246-282-080. Recommendation to make the change throughout.
Rationale	The definition of "person" in RCW 69.30.050 encompasses "authorized agents of any such entities." The proposed rule language is not needed.
Department's Recommendation	Adopt as amended by the department.
Board Action	The board adopted the rule as amended by the department.

WAC 246-282-016, Aquaculture

Comment Summary	Revise the threshold for seed size variation from 5 percent to 10 percent. Growth within nursery bins is not uniform, and minor variations are natural and not indicative of public health risk.

Response Summary	Wild seed and aquaculture sites located in Prohibited areas are impacted by nonpoint and point sources of pollution. Pollution sources have not been defined in unclassified areas. Actions must exist to ensure that product that exceeds the maximum seed size is not coming out of Prohibited areas. The 5 percent has been in the existing rules for wild seed.
Department's Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	Concern regarding the requirement to deplete shellstock if more than 5 percent of the seed lot is above the maximum seed size. Depletion is not defined and not required by the Model Ordinance. Destruction of the shellstock can amount to tens or hundreds of thousands of dollars of loss. Consider other appropriate corrective actions.
Response Summary	According to the NSSP Model Ordinance, depletion means “the removal, under the direct control of the Authority, of shellstock from a growing area classified as Prohibited.” It is correct that depletion is not required. However, shellfish greater than the defined seed size cannot be collected for human consumption from Prohibited and unclassified areas.
Department's Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	Revise the language in (2)(e) as follows: “Shellfish are moved to Approved or Conditionally approved areas for a minimum of 120 days, excluding days in a confirmed pollution closure.” OR “Shellfish are moved to Approved or Conditionally Approved areas for a minimum of 120 days while in the open status. Days when growing areas are in the closed status due to biotoxins, vibrio or non-confirmed pollution closures can be included in the 120 day minimum.
Response Summary	This is situation-specific and can best be addressed in guidance, rather than in rule.
Department's Recommendation	No change to proposed rule.

Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	The use of the word “lot” in subsection (3) is confusing. It is a common term in the NSSP Model Ordinance that is relative to harvest for sale for consumption (“no more than one day’s harvest”). The seed being planted will be more than a day’s harvest when the crop is ultimately harvested for consumption. Consider using “crop” instead of “lot.”
Response Summary	The Model Ordinance also states that “a lot may also be used to segregate the harvest times and intended uses of shellstock for the purposes of complying with time to temperature requirements.” The department does not use the term “crop” in the existing rules and considers “lot” to be appropriate in this context.
Department’s Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	The 120-day grow-out requirement satisfies public health needs. Weight-based assessment remains a more appropriate metric for determining readiness and survivability.
Response Summary	The waiver process will give shellfish operations the opportunity to use a weight-based assessment if they complete the required study and the results show a comparable level of public health protection.
Department’s Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	Growing area specific studies will be prohibitively expensive. Consider growing region as an alternative.
Response Summary	The department does not currently have enough data to show that a region-wide approach would be sufficient for the purpose of the studies.
Department’s Recommendation	No change to proposed rule.
Board Action	The board adopted the rule as amended by the department.

Suggested Change	Edit the language in subsection (4) as follows: (4) “The department may grant a waiver to seed size as defined in WAC 246-282-010(25) <u>for a shellfish operation to use a measurement other than length when determining seed size if...</u> ”
Rationale	The edited rule language provides clarification on which specific requirement the waiver may be granted for.
Department’s Recommendation	Adopt as amended by the department.
Board Action	The board adopted the rule as amended by the department.
Suggested Change	Refer to the section, rather than the definition, in subsection (4)(a): (4)(a) “It is consistent with the applicable standards and the intent of the definition <u>this section</u> , as related to market size and 120-day grow-out time.”
Rationale	It is more accurate to refer to the aquaculture section here, rather than the definitions section, because the requirements are found in the aquaculture section.
Department’s Recommendation	Adopt as amended by the department.
Board Action	The board adopted the rule as amended by the department.
Comment Summary	Concern that there are differences between seed and cultch, and that the added rule language for seed size will not work for operations that do not utilize a FLUPSY or single seed.
Response Summary	Seed size is set in rule based on market size. Oysters above the maximum seed size cannot be harvested from unclassified or Prohibited areas. In the case of large oysters set on cultch, these oysters are still above maximum seed size. The rule limits harvest of live shellfish larger than seed size attached to, or commingled with, the seed to less than five percent of the total number of live shellfish harvested from the site.
Department’s Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.

WAC 246-282-034, Wild seed permit

Comment Summary	Similar to the aquaculture section, amend subsection (4)(e) to 10 percent, rather than 5 percent.
Response Summary	Wild seed and aquaculture sites located in Prohibited areas are impacted by nonpoint and point sources of pollution. Pollution sources have not been defined in unclassified areas. Actions must exist to ensure that product that exceeds the maximum seed size is not coming out of Prohibited areas. The 5 percent has been in the existing rules for wild seed.
Department's Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.

WAC 246-282-044, Transplant

Comment Summary	Concern regarding the requirement that a conditionally approved area must be in the open status to transplant out of it.
Response Summary	Harvesting from a closed area is not allowed in any circumstance and has never been allowed. If an operation would like to move shellstock from a Conditionally Approved area in closed status, they would have to get a relay permit.
Department's Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.
Comment Summary	Requiring beds be designated on the harvest site certificate as an approved transplant site is unnecessary. Amend subsection (1)(b) to read: "The transplant location is included on a current harvest site certificate."
Response Summary	Revise proposed rule as follows: (1)(c) "The person shall have a <u>valid</u> harvest site certificate showing for the grow-out site(s) as approved transplant site(s)" This revision will address the commenter's suggestion clarifying that the grow out site needs to be on the harvest site certificate, in the appropriate subsection.

Department's Recommendation	Adopt as amended by the department.
Board Action	The board adopted the rule as amended by the department.
Comment Summary	"Transplant method" has no public health relevance and should be removed from subsection (1)(e).
Response Summary	RCW 69.30.050(7)(d) states that the department's certificate of approval to harvest shellfish for purposes other than human consumption shall specify "information about the removal method , transportation method, processing technique, sale details, and other factors to ensure that shellfish harvested from such areas are not diverted for human consumption."
Department's Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.

WAC 246-282-080, Identification and records

Comment Summary	Concerns about the new requirement to list specific harvest sites on shellstock tags: • This requirement exceeds the NSSP Model Ordinance • Provides no demonstrated public health benefit • Concerns about poaching
Response Summary	Chapter 10 of the Model Ordinance states that dealer tags shall have "The most precise identification of the harvest location as is practicable..." The proposed rule language requires the tag to include the growing area name and either the department harvest site application number, harvest ID, parcel number, or other approved harvest site identifier. This information will help the department investigate and stop illness outbreaks quicker.
Department's Recommendation	No change to proposed rule.
Board Action	The board adopted the proposed rule as recommended by the department.

WAC 246-282-082, Export certificate

Suggested Change	Edit the language in subsection (2)(a) from “export” to “be exporting”: (2) “To qualify for an export certificate from the department, a shellfish dealer shall: (a) Export <u>Be exporting</u> the lot to a country that requires a production certificate from a governmental health authority.”
Rationale	This edit helps clarify that the export would not be happening before the certificate is issued.
Department’s Recommendation	Adopt as amended by the department.
Board Action	The board adopted the rule as amended by the department.

Miscellaneous citation and grammatical edits

Suggested changes	- Citation edit in WAC 246-282-016, Aquaculture: (6) “Waiver approval will only be granted for the growing areas evaluated in subsection (4)(b) of this section.” - Correct citation related to adjudicative proceedings in WAC 246-282-100, Notice of decision – Adjudicative proceeding: (4) “An adjudicative proceeding is governed by the Administrative Procedure Act (chapter 34.05 RCW), this chapter, and chapter 246-08 10 <u>246-08 10</u> WAC. If a provision in this chapter conflicts with chapter 246-08 10 <u>246-08 10</u> WAC, the provision in this chapter governs.” - Grammatical edit in WAC 246-282-102, Denial, revocation, suspension of license, certificate or permit – Civil penalties: (1)(a) “Fails to comply with any of the provisions of chapter 69.30 RCW, this chapter, and or <u>or</u> the NSSP Model Ordinance...” - Grammatical edits in WAC 246-282-110, Administrative provisions: (1)(a) “The statement of deficiencies or notice of correction must specify where <u>how</u> the operation fails to comply with chapter 69.30 RCW...” (2) “An authorized representative of the department, fish and wildlife patrol officer or ex officio patrol officer may...”
Rationale	These are non-substantive edits to correct citations and grammatical errors.

Department's Recommendation	Adopt as amended by the department.
Board Action	The board adopted the rule as amended by the department.

Outside the scope of rulemaking

Comment Summary	Six interested parties submitted comments related to the department's fee rulemaking project, which includes shellfish fees.
Response Summary	The comments are outside the scope of this rulemaking project to amend chapter 246-282 WAC, as it is under the authority of the State Board of Health.
Department's Recommendation	No change to proposed rule.
Board Action	No change to proposed rule.
Comment Summary	Concern that without substantial outreach and education by the department, the new transplant section will not serve growers.
Response Summary	The comment is outside the scope of rulemaking, as it relates to implementation. Department staff are incorporating outreach and education on all of the changes to chapter 246-282 WAC, into the implementation plan for this rulemaking project. The department plans to hold five trainings in January, in both English and Spanish, to review the changes. The department is also developing informational handouts and will have inspectors trained on how to answer questions. Finally, department staff are available to meet individually with shellfish operations to discuss how the rule changes will impact them.
Department's Recommendation	No change to proposed rule.
Board Action	No change to proposed rule.



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