



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health

- Preproposal Statement of Inquiry was filed as WSR ; or
- Expedited Rule Making--Proposed notice was filed as WSR ; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

WAC 246-282-005, Minimum performance standards
 WAC 246-282-006, Washington state Vibrio parahaemolyticus control plan
 WAC 246-282-010, Definitions
 Clarify references to the U.S. Food and Drug Administration, National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish.

Hearing location(s):

Washington State Department of Health
 Town Center 3, Room 229
 243 Israel Road SE
 Tumwater, WA 98511

Date: 03/25/2014

Time: 10:00 a.m.

Submit written comments to:

Name: Vicki M. Bouvier
 Address: Post Office Box 47820
 Olympia, WA 98504-7820
 e-mail: <http://www3.doh.wa.gov/policyreview/>
 fax 360.236.2250 by (date) 03/25/2014

Assistance for persons with disabilities: Contact

Vicki M. Bouvier by 03/18/2014

TTY (800) 833-6388 or () 711

Date of intended adoption: 03/26/2014

(Note: This is **NOT** the **effective** date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The purpose of the proposed rules is to clarify references within the chapter to the U.S. Food and Drug Administration, National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish (model ordinance) as adopted in WAC 246-282-005, Minimum performance standards.

Reasons supporting proposal:

During the most recent revision of WAC 246-282-005, the department received a comment that not all references to the model ordinance were consistent throughout the chapter. To address this comment and provide clarity in the rules, this proposed revision makes all references consistent and includes a definition of model ordinance. All proposed changes to the rules are editorial and clarify the language without changing the effect.

Statutory authority for adoption:

RCW 60.30.030

Statute being implemented:

RCW 69.30.030

Is rule necessary because of a:

- Federal Law? Yes No
- Federal Court Decision? Yes No
- State Court Decision? Yes No

If yes, CITATION:

DATE February 18, 2014

NAME (type or print)
 John Wiesman, DrPH, MPH

SIGNATURE

TITLE
 Secretary

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
 STATE OF WASHINGTON
 FILED

DATE: February 18, 2014

TIME: 4:00 PM

WSR 14-05-084

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

None

Name of proponent: (person or organization) Department of Health

- Private
- Public
- Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Vicki M. Bouvier	111 Israel Road SE, Tumwater, WA 98511	360.236.3011
Implementation.... Vicki M. Bouvier	111 Israel Road SE, Tumwater, WA 98511	360.236.3011
Enforcement..... Vicki M. Bouvier	111 Israel Road SE, Tumwater, WA 98511	360.236.3011

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

A small business economic impact statement (SBEIS) was not prepared. Under RCW 19.85.025 and 34.05.310(4)(d), a SBEIS is not required for proposed rules that only correct typographical errors, make address or name changes, or clarify the language of a rule without changing its effect.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No: Please explain: The agency did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(iv) exempts rules that only correct typographical errors, make address or name changes or clarify the language of a rule without changing its effect.

AMENDATORY SECTION (Amending WSR 14-01-002, filed 12/4/13, effective 1/4/14)

WAC 246-282-005 Minimum performance standards. (1) Any person engaged in a shellfish operation or possessing a commercial quantity of shellfish or any quantity of shellfish for sale for human consumption must comply with and is subject to:

(a) The requirements of the ((2011)) U.S. Food and Drug Administration National Shellfish Sanitation Program (NSSP), Guide for the Control of Molluscan Shellfish ((, published by the United States Department of Health and Human Services, Public Health Service, Food and Drug Administration)) (2011) (copies available through the U.S. Food and Drug Administration, Shellfish Sanitation Branch, and the Washington state department of health, office of shellfish and water protection);

(b) The provisions of 21 Code of Federal Regulations (C.F.R.), Part 123 - Fish and Fishery Products, adopted December 18, 1995, by the United States Food and Drug Administration, regarding Hazard Analysis Critical Control Point (HACCP) plans (copies available through the U.S. Food and Drug Administration, Office of Seafood, and the Washington state department of health, office of food safety and shellfish programs); and

(c) All other provisions of this chapter.

(2) If a requirement of the NSSP ((Guide for the Control of Molluscan Shellfish)) Model Ordinance or a provision of 21 C.F.R., Part 123, is inconsistent with a provision otherwise established under this chapter or other state law or rule, then the more stringent provision, as determined by the department, will apply.

AMENDATORY SECTION (Amending WSR 09-08-122, filed 4/1/09, effective 5/2/09)

WAC 246-282-006 Washington state *Vibrio parahaemolyticus* control plan. (1) The Washington state *Vibrio parahaemolyticus* control plan, also known as the control plan, establishes harvest, temperature control, and transportation requirements for oysters intended for raw consumption during the months of May through September. This section does not apply to shucked oyster meats labeled "for cooking only." The requirements of this section are in addition to ((Chapter VIII of)) the ((2007 National Shellfish Sanitation Program)) NSSP Model Ordinance ((NSSP), Requirements for Harvesters, .03 Shellfish Temperature, Control Option 2)) and consist((s)) of:

(a) Time of harvest to temperature control based on the growing area and month of the year;

(b) Harvest record requirements;

(c) *Vibrio* illness response requirements;

(d) Training requirements; and

(e) Hazard Analysis Critical Control Point (HACCP) plan and harvest checklist requirements.

(2) All Puget Sound growing areas, including the Strait of Juan de Fuca, are subject to the requirements of this section. Growing areas in Grays Harbor and Willapa Bay where oysters have been epide-

miologically associated as the source of any *Vibrio parahaemolyticus* illness are also subject to the requirements of this section.

(3) The department may grant an annual exemption to the control plan for Puget Sound growing areas, including the Strait of Juan de Fuca, where there has been no epidemiologically associated *Vibrio parahaemolyticus* illness after review and approval of a written exemption request.

(a) The written exemption request must include the following information:

- (i) Name of the growing area;
- (ii) Description of the harvesting methods;
- (iii) Description of the temperature control methods; and
- (iv) Description of the transportation methods.

(b) The department shall review the exemption request within five business days of submittal.

(c) If approved, the licensed harvester or dealer shall comply with the department-approved exemption.

(d) The department-approved exemption expires October 1 of the calendar year for which it is approved. If the growing area is epidemiologically associated as the source of a *Vibrio parahaemolyticus* illness at any time after approval of the exemption, the department shall issue an order revoking the exemption.

(4) Time of harvest to temperature controls are:

Table 1
Puget Sound Growing Areas
(including the Strait of Juan de Fuca):

Months of Control	Time of harvest to Temperature Control
May	Twelve hours
June and September	Five hours
July and August	Four hours

Table 2
Coastal Growing Areas:

Months of Control	Time of harvest to Temperature Control
July and August	Ten hours

(5) Licensed dealers and harvesters shall maintain harvest records showing the time of harvest and the time oysters are placed under temperature control to demonstrate compliance with the control plan. If ownership of oysters is transferred prior to the time that time of harvest to temperature control requirements must be met, the licensed dealer or harvester shall include in the harvest record date, time, and person or entity to whom the oysters were transferred. If the new owner is a licensed dealer, the dealer shall meet the time of harvest to temperature control requirements established in this section. The harvest times begin as follows:

(a) Intertidal (exposed) time of harvest begins after the first oysters to be harvested are exposed to the air by the receding tide.

(b) Submerged time of harvest begins after the first oysters harvested are exposed to the air and have been placed onto a conveyance, such as a barge or boat. Submerged harvest includes dredge harvesting or retrieval of harvest tubs, bags, baskets, or other containers of oysters previously filled which have been under water for a minimum of

one hour for coastal areas and four hours for Puget Sound growing areas.

(c) Temperature control is achieved when harvested oysters are placed in a controlled environment with an ambient temperature of 45°F (7.2°C) or less.

(6) All licensed harvesters and dealers in a growing area shall reduce the time of harvest to temperature control as defined in Table 1 or 2 of subsection (4) of this section by one hour if oysters from the growing area:

(a) Are epidemiologically associated as the probable source of two sporadic *Vibrio parahaemolyticus* illnesses; and

(b) Were harvested within thirty days of each other.

(7) A growing area shall be closed to harvest and shipment of oysters intended for raw consumption throughout the remainder of the control months for the calendar year when the following conditions are met:

(a) Oysters from the growing area are epidemiologically associated as the probable source of two additional sporadic *Vibrio parahaemolyticus* illnesses;

(b) Oysters from the growing area were harvested in compliance with the reduced time of harvest to temperature control provisions of subsection (6) of this section; and

(c) Oysters from the growing area were harvested within thirty days of the previous illnesses.

(8) If the two additional *Vibrio parahaemolyticus* illnesses specified in subsection (7) of this section are attributed to the same licensed harvester or dealer as the first two illnesses, the department shall conduct an investigation in accordance with the requirements as stated in the ((2007)) NSSP((, Chapter II, Risk Assessment and Risk Management,)) Model Ordinance to determine if the illnesses are the result of harvester or dealer practices or are linked to the growing area as the probable source. If the harvester or dealer practices are reasonably likely to have caused the illnesses:

(a) The harvester or dealer shall retake the training identified in subsection (12) of this section prior to renewal of their next year's license;

(b) The department may take disciplinary action against the harvester or dealer license; and

(c) The department will evaluate whether to associate the illnesses with the growing area.

(9)(a) The department may grant an exemption to closure identified in subsection (7) of this section if the licensed harvester or dealer can demonstrate in a written exemption request that an additional one hour reduction in the time of harvest to temperature control as identified in subsection (6) of this section can be successfully implemented. The written exemption request must include the following information:

(i) Name of the growing area;

(ii) Description of the harvesting methods;

(iii) Description of the temperature control methods; and

(iv) Description of the transportation methods.

(b) The department shall review the request within five business days of submittal.

(c) If approved, the licensed harvester or dealer shall comply with the requirements of the department-approved exemption throughout the remainder of the applicable control months for the particular growing area.

(10)(a) If the required time of harvest to temperature control period is not met, the licensed harvester or dealer shall either:

(i) Destroy the oysters; or

(ii) Remove all oysters from containers, disperse them within the original growing area, and allow a minimum of twenty-four hours for purging before reharvesting.

(b) If the required time of harvest to temperature control period is not met, the licensed harvester or dealer shall record the disposition of the oysters on the harvest record.

(11) In the event of a *Vibrio parahaemolyticus* illness outbreak where oysters from a growing area are epidemiologically associated as the source, the requirements as stated in the ((2007)) NSSP((, Chapter II, Risk Assessment and Risk Management,)) Model Ordinance shall apply.

(12) All licensed harvesters and dealers shall complete an initial department-approved training specific to the requirements of this section prior to harvesting or shipping oysters intended for raw consumption during the months of May through September. All licensed harvesters and dealers shall complete department-approved refresher training following any revision of this section considered significant under RCW 34.05.328. Licensed harvesters and dealers who complete the training shall provide the training to those responsible for the on-site management of harvest activities for their operation, and document the training for responsible employees in their operational records.

(13) Following completion of the training required in subsection (12) of this section:

(a) All licensed harvesters planning to harvest oysters intended for raw consumption from May through September shall develop a harvest plan that describes the harvest, temperature control, and transportation methods that meet the requirements of subsections (4) and (6) of this section. Licensed harvesters shall obtain department approval of the harvest plan prior to harvesting oysters for raw consumption.

(b) All licensed dealers planning to harvest oysters intended for raw consumption from May through September shall amend their Hazard Analysis Critical Control Point (HACCP) plans to define the harvest, temperature control, and transportation methods that meet the requirements of subsections (4) and (6) of this section. Licensed dealers shall obtain department approval of the amended HACCP plan prior to harvesting oysters for raw consumption.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-010 Definitions. The following definitions, as well as those in the NSSP Model Ordinance, apply in the interpretation and the implementation of these rules and regulations.

(1) "Abatement" means an action or series of actions to eliminate a public health hazard or reduce it to a level acceptable to the secretary.

(2) "Approved" means acceptable to the secretary based on the department's determination as to conformance with appropriate standards and good public health practice.

(3) "Approved laboratory" means a laboratory that is in conformance with requirements of the NSSP Model Ordinance.

(4) "Certificate of approval" means a license issued by the department.

(5) "Civil penalty" means a monetary penalty administratively issued by the secretary. It does not include any criminal penalty; damage assessment; wages, premiums, or taxes owed; or interest or late fees on any existing obligation.

(6) "Commercial quantity" means any quantity exceeding:

(a) Forty pounds of mussels;

(b) One hundred oysters;

(c) Fourteen horse clams;

(d) Six geoducks; or

(e) Fifty pounds of other hard or soft shell clams; or

(f) Fifty pounds of scallops.

(7) "Cultch" means any material, other than live shellfish, used for the attachment of seed shellfish.

(8) "Department" means the state department of health.

(9) "Export certificate" means a certificate issued by the department to a licensed shucker-packer or shellstock shipper for use in the foreign export of a lot or shipment of shellfish.

(10) "Harvest" means the act of removing shellstock from a harvest site and its placement on or in a container for transport.

(11) "Harvester" means a shellfish operation with activities limited to growing shellstock, placing shellstock in a container, harvesting shellstock, transporting shellstock within Washington state, and delivering shellstock to a shellfish dealer licensed by the department within four hours of landing it. A harvester does not process shellfish, ship shellfish outside of Washington state, sell shellfish outside of Washington state, sell shellfish to retail outlets, shuck shellfish, repack shellfish, or store shellfish in any location outside of the approved growing area from where the shellfish is harvested.

(12) "Harvest site" means an area of intertidal or subtidal property within a commercial shellfish growing area, that is described by a unique county parcel number, department of fish and wildlife tract number, department of fish and wildlife catch area number, tribal identification number, or other government identification.

(13) "Harvest site certificate" means a type of certificate of approval that designates one or more harvest sites approved for the harvesting of shellfish.

(14) "Hatchery" means an operation where shellfish larvae are produced and grown to the first sessile stage of life.

(15) "Notice of correction" means a document issued by the department that describes a condition or conduct that is not in compliance with chapter 69.30 RCW, this chapter, or the NSSP Model Ordinance and is not subject to civil penalties as provided for in RCW 43.05.110. It is not a formal enforcement action and is not subject to appeal. It is a public record.

(16) "NSSP Model Ordinance" means the U.S. Food and Drug Administration National Shellfish Sanitation Program (NSSP), Guide for the Control of Molluscan Shellfish, as adopted in WAC 246-282-005.

(17) "Nursery" means an operation where shellfish are grown from an early sessile stage of life up to a maximum size meeting the definition of shellfish seed.

((+17+)) (18) "Number of previous violations" means the number of prior violations of the same or a similar nature for which the department has taken a license action or assessed a civil penalty.

((+18+)) (19) "Person" means any individual, firm, corporation, partnership, company, association, or joint stock association, and the legal successor thereof.

((+19+)) (20) "Person in charge" means an individual responsible for the supervision of employees and the management of any shellfish operation.

((+20+)) (21) "Public health threat" is either:

(a) "Low," which means a violation that poses a minor possibility of direct or indirect hazard to public health;

(b) "Intermediate," which means a violation that poses a moderate possibility of direct or indirect hazard to public health; or

(c) "High," which means a violation that poses a known significant hazard or possibility of significant direct or indirect hazard to public health.

((+21+)) (22) "Sale" means to sell; offer for sale; barter; trade; deliver; consign; hold for sale, consignment, barter, trade, or delivery; and/or possess with intent to sell or dispose of in a commercial manner.

((+22+)) (23) "Secretary" means the secretary of the department of health or the secretary's authorized representative.

((+23+)) (24) "Seed" means 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) Nineteen millimeters (3/4 inch) for Olympia oysters;

(d) Nineteen millimeters (3/4 inch) for Kumomoto oysters;

(e) Fifty-one millimeters (2 inches) 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.

((+24+)) (25) "Shellfish" means all varieties of fresh or fresh-frozen oysters, clams, scallops or mussels, either shucked or in the shell, and all fresh or fresh-frozen edible products thereof.

((+25+)) (26) "Shellfish dealer" means a person with a shellstock shipper or shucker-packer license.

((+26+)) (27) "Shellfish growing area" means the lands and waters in and upon which shellfish are grown for harvesting in commercial quantities or for sale for human consumption.

((+27+)) (28) "Shellfish operation" means growing, placing in a container, harvesting, transporting, processing, culling, shucking, packing, and repacking, storing, shipping, or reshipping of shellfish in commercial quantities or for sale for human consumption.

((+28+)) (29) "Shellfish operation license" means a type of certificate of approval applying to the overall activities of a shellfish operation.

((+29+)) (30) "Shellstock shipper" means a shellfish operation that does not shuck shellfish or repack shucked shellfish.

((+30+)) (31) "Shucker-packer" means a shellfish operation that may shuck and pack shellfish.

((+31+)) (32) "Technical assistance" means information provided by the department to a person regarding chapter 69.30 RCW; this chapter; technologies or other methods to achieve compliance with these rules; assistance in applying for a departmental license or permit required by these rules; or the goals and objectives of these rules.

This is not intended to modify the definition of "technical assistance" as provided in RCW 43.05.010(3).

~~((32))~~ (33) "Violation" means the commission of an act or acts prohibited by the provisions of chapter 69.30 RCW, these rules, or the NSSP Model Ordinance.

~~((33))~~ (34) "Wet storage" means the temporary storage of shellstock in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater.

~~((34))~~ (35) "Wild seed" means naturally set seed shellfish.