



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do **NOT** use for expedited rule making

Agency: State Board of Health

- Preproposal Statement of Inquiry was filed as WSR 12-24-036 ; 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 246-282-006, Washington State Vibrio parahaemolyticus (Vp) control plan

Hearing location(s): State Board of Health
Point Plaza East
310 Israel Rd. SE
Tumwater, WA 98501
Room 152/153

Date: 03/11/2014 Time: 2:00 pm

Submit written comments to:

Name: Laura Wigand Johnson
Address: Department of Health
PO Box 47824
Olympia, WA 98504-7824
e-mail: <http://www3.doh.wa.gov/policyreview/>
fax 360-236-2257 by (date) 02/25/2015

Assistance for persons with disabilities: Contact

Michelle Golden by 03/04/2015

TTY (800) 833-6388 or () 711

Date of intended adoption: 03/11/2015

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

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

The State Board of Health (board) is proposing revisions to the Vp control plan rule to include more proactive measures to prevent illness and protect public health. This includes a combination of requirements based on environmental factors to determine the safety of shellfish prior to harvest and consumption. In addition, the board is proposing revisions for clarity and consistency with the National Shellfish Sanitation Program Model Ordinance.

Reasons supporting proposal:

The board adopted revisions to WAC 246-282-006 in March 2009 to better protect shellfish consumers from Vp-related illnesses. Even with the 2009 revisions to the control plan, the number of illnesses has steadily increased. The proposed rule is intended to improve public health by reducing the incidence of Vp related illness.

Statutory authority for adoption:

RCW 69.30.030

Statute being implemented:

Chapter 69.30 RCW

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

DATE 01/26/2015

NAME (type or print)
Michelle A. Davis

SIGNATURE

TITLE
Executive Director

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 28, 2015

TIME: 1:34 PM

WSR 15-04-042

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

None

Name of proponent: (person or organization) State Board of Health

- Private
- Public
- Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Laura Wigand Johnson	243 Israel Rd. SE Tumwater WA 98501	360-236-3333
Implementation.... Laura Wigand Johnson	243 Israel Rd. SE Tumwater WA 98501	360-236-3333
Enforcement..... Rick Porso	243 Israel Rd. SE Tumwater WA 98501	360-236-3302

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: Brandy Brush

Address: Department of Health

PO Box 47824

Olympia, WA 98504-7824

phone 360-236-3342

fax 360-236-2257

e-mail brandy.brush@doh.wa.gov

No. Explain why no statement was prepared.

Is a cost-benefit analysis required under RCW 34.05.328?

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

Name: Brandy Brush

Address: Department of Health

PO Box 47824

Olympia, WA 98504-7824

phone 360-236-3342

fax 360-236-2257

e-mail brandy.brush@doh.wa.gov

No: Please explain:

Small Business Economic Impact Statement
WAC 246-282-006, *Vibrio parahaemolyticus* control plan
January 21, 2015

Describe the proposed rule, including: a brief history of the issue; an explanation of why the proposed rule is needed; and a brief description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

Washington State produces oysters intended for raw consumption for state, national and international markets. According to the Washington Shellfish Initiative, Washington's shellfish industry contributes over \$270 million towards the economy with much of Washington's oysters exported nationally and internationally. The shellfish industry in Washington includes 349 licensees dealing with all types of shellstock, including clams, oysters, geoduck, and others. Approximately 150 of these licensees deal with shellstock oysters during the summer months and so are directly affected by the proposed rule. These licensees include tribal, small and large companies operating in Puget Sound and in coastal areas.

Consuming raw or undercooked oysters can lead to gastrointestinal illness caused by the pathogenic form of *Vibrio parahaemolyticus* bacteria found in oysters. (For the purposes of this document, *Vibrio parahaemolyticus*-associated illness is also referred to as vibriosis.) The *Vibrio parahaemolyticus* bacterium is active in warmer temperatures and is frequently nondetectable in cooler temperatures.

Washington State has experienced two major vibriosis outbreaks; one in 1997 and the other in 2006. The first *Vibrio parahaemolyticus* control plan was adopted nationally in response to the 1997 outbreak. A control plan is designed to reduce the risk of *Vibrio parahaemolyticus*-associated illness using a variety of methods, including time of harvest to temperature control limits, environmental monitoring, illness response measures, and training on effective handling techniques. Since 1999, the control plan has been regularly updated and adopted as part of the National Shellfish Sanitation Program (NSSP) Model Ordinance.

The current rule has held illnesses fairly steady at 40 to 50 reported illnesses per year that are traced back and attributed to Washington state commercial oyster harvest, but occurrences of sporadic illnesses are still prevalent in the warmer months. The state has also seen an increase in coastal illnesses, particularly in the month of September, which indicates that the current control plan is not adequately preventing illnesses.

The proposed rule change utilizes a new approach where *Vibrio parahaemolyticus* controls are based on environmental conditions rather than on the occurrence of illness. The proposed rule uses relative risk to establish harvest controls and increases the stringency of cooling requirements. These changes aim to reduce the post-harvest growth of *Vibrio parahaemolyticus* and restrict harvest when *Vibrio parahaemolyticus* levels in the water may cause illness. The proposed rule establishes new recordkeeping requirements to ensure harvesters and shellfish

dealers are meeting the new requirements. The proposed rule incrementally eliminates the division of controls based on coastal and inland growing areas. Instead controls are established based on historical illnesses rather than geographic region.

The consequences of not adopting the proposed changes would lead to a higher incidence of vibriosis from Washington State oysters. If continued high incidence of illness occurs, harvest of oysters intended for raw consumption could be prohibited during the warmer months to protect public health, or customer demand for raw oysters could dramatically decline as a result of publicized illness. Either reaction would significantly harm a vital industry that is a major contributor to the state’s economic well-being. In addition, the current control plan is out of compliance with requirements established in the NSSP Model Ordinance. The U.S. Food and Drug Administration requires shellfish producing states to implement the most current version of the NSSP Model Ordinance. Failing to update the Washington state control plan could result in licensees being unable to place molluscan shellfish into interstate commerce.

Identify which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS) codes and what the minor cost thresholds are.

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	# of businesses in WA	Minor Cost Threshold = 1% of Average Annual Payroll	Minor Cost Threshold = .3% of Average Annual Receipts
114122	Shellfish Fishing Industry	163	\$1,495	Not available

Analyze the probable cost of compliance. Identify the probable costs to comply with the proposed rule, including: cost of equipment, supplies, labor, professional services and increased administrative costs; and whether compliance with the proposed rule will cause businesses to lose sales or revenue. Identify the cost per business.

The probable costs of compliance include cost of equipment, supplies, labor, and increased administrative costs. Meeting the more stringent time of harvest to cooling requirements may require businesses to purchase ice machines, produce additional ice, or purchase additional ice from a supplier. It could also mean purchasing additional insulated totes to chill oysters while in transit. Based on responses from a key informant questionnaire, the majority of respondents thought that there would be no or minimal costs associated with complying with the time of harvest to cooling requirements.

Most respondents to the questionnaire thought that they would incur additional costs for recordkeeping in order to comply with the calibration recordkeeping requirements and recording temperatures at time of harvest. Many respondents thought there would only be a minimal cost, but many were able to quantify an expected weekly cost associated with compliance.

Businesses are not likely to lose sales or revenue due to the implementation of this rule. In the key informant questionnaire, some respondents thought they may gain sales and revenue due to

being able to harvest oysters more days and/or have a greater perceived value for Washington oysters given the stringent and proactive time to cooling requirements.

The proposed rule will not result in fewer sales for businesses. Businesses are expected to be open more days during the *Vibrio* control plan months. When closures do occur, they are expected to be short-term, which will allow more businesses to shift operation to other species, conduct farm maintenance, or shuck oysters to remain open during the days when they are unable to harvest oysters.

Estimated cost per business

Key informant questionnaires were conducted with small and large businesses to establish the likely costs of this rule. These businesses were selected based on their involvement in the *Vibrio parahaemolyticus* Advisory Committee (VpAC). In addition, the department reached out to an additional 11 companies not involved with VpAC that represented small oyster harvesting businesses operating in Puget Sound and the outer coast. The companies were a mix of harvester and shellstock shipper licensees. Emphasis was placed on harvester licensees because we expect them to be most impacted by the proposed rule. The key respondent questionnaire was sent to a total of 36 companies and 21 responded. Of the respondents, four were large businesses, 16 were small businesses, and one was a tribe. The majority of respondents did not think that the new rule would have a significant impact to their business.

Time of Harvest to Cooling and Time Reductions

One of the four large businesses responded that they would have additional costs associated with meeting the time of harvest to cooling requirements in the proposed rule. This company identified a one-time cost of \$500,000 for ice equipment and an ongoing cost of \$10,000 per season to comply with the rule. When a two hour time of harvest to cooling reduction is in effect, the large businesses identified costs between \$0 and \$70 per day depending on the company and the growing area risk category. When a four hour time of harvest to cooling reduction is in effect, the large businesses identified costs between \$0 and \$145 per day depending on the company and the growing area risk category.

Of the small businesses, 12 of the 16 responded that they would have no additional costs associated with meeting the time of harvest to cooling requirements in the proposed rule. Of the four companies that would have an increased cost, two stated the cost increase would be minimal and they were unable to quantify the cost. One of the four companies believed there would be an increase in labor costs, but was unable to quantify the cost. The fourth company thought there would be an increase in cost of \$600 per week to run a chiller more often.

When a two hour time of harvest to cooling reduction is in effect, all but two of the respondents with category 1 growing areas thought there would be no cost increase. The remaining two respondents thought there would be only minimal increases in costs. Of the respondents with category 2 growing areas, only one believed there would be a minimal increase in costs. Of the respondents with category 3 growing areas, one believed there would be an increase in costs. This company would need to purchase a new ice machine and additional ice totes to comply with this reduction (and any more stringent reductions) at a one-time cost of \$23,000.

When a four hour time of harvest to cooling reduction is in effect, all but three of the respondents with category 1 growing areas thought there would be no cost increase. Of the three companies that believed they would have a cost increase, two thought the increase would be minimal and one company thought it could cost an additional \$100 to \$200 per harvest day. Of the respondents with category 2 growing areas, only one believed there would be a minimal increase in costs. Of the respondents with category 3 growing areas, one believed there would be an increase in costs of \$25 for the season to purchase additional ice.

Closures

All four large businesses would react to closures based on harvest temperatures in the same manner as they currently react to closures based on illnesses. All four large businesses responded that they would shift harvest to an open growing area, conduct farm maintenance, harvest other shellfish species, or post-harvest process oysters in the event of a closure. One company noted that if a closure is for a long period of time, it could cost up to \$15,000 per day due to the inability to support the alternatives mentioned above.

Small businesses tended to be more impacted by closures since many small businesses only operate in one growing area and are therefore unable to shift harvest to an open growing area if their area closes. All of the small businesses would react to closures based on harvest temperatures in the same manner as they currently react to closures based on illnesses. The following information is based on current closure practices based on illnesses that businesses expect to continue under the proposed rule. Of the 16 respondents, six small companies shift harvest to an open growing area, conduct farm maintenance, or harvest other shellfish species. Two companies are able to shift operations, but if closures are long, they are forced to close for the remainder of the season. Five companies close and stop operating when illnesses occur. In addition, two of the companies did not respond to this set of questions and one company voluntarily closes harvest for the summer months. The closure costs included both lost revenue and fixed costs for labor, facilities, etc. Seven respondents were able to quantify these closure costs which ranged from \$150 to \$4,000 per day. A few companies noted that although they close, there is no cost since they could ship the shellfish later.

Harvest Temperature Requirements

Three of the four large businesses would be impacted by the requirement to maintain calibrated thermometers. These companies identified added costs for labor and supplies ranging from \$400 to \$27,000. One company also identified a one-time cost of \$450,000 for the initial cost of equipment and development of a documentation system to track calibration and temperatures. Two of the large businesses identified costs associated with the temperature record keeping requirements. These costs ranged from \$400 to \$1,400 per season.

Ten of the 16 small businesses would be impacted by the requirement to maintain calibrated thermometers. Five small businesses did not believe they would need to change business practices, and one did not respond to these questions. The companies that were able to quantify costs thought this requirement would cost between \$20 and \$200 per. In addition two companies specifically identified one time equipment costs of \$150 and \$250 for thermometers.

Six companies identified costs associated with the temperature record keeping requirements and were able to quantify these costs. The companies thought that this requirement would cost between \$20 and \$200 per week. In addition, two of the respondents included the costs for the temperature record requirements in their cost calculations for calibration requirements, three of the respondents thought the costs associated with temperature records would be minimal, and one respondent was unsure of the cost associated with this requirement.

Analyze whether the proposed rule may impose more than minor costs on businesses in the industry.

<i>Cost per business</i>	<i>\$0 - \$977,825</i>
<i>Minor cost threshold¹- 1% payroll</i>	<i>\$1,495</i>
<i>Minor cost threshold- 3/10% of receipts</i>	<i>Not available</i>

As defined in chapter 19.85 RCW, and based on the calculations above, the proposed rule or portions of the proposed rule may impose more than minor costs on businesses in the industry. The remainder of this document meets the requirements of RCW 19.85.030 and RCW 19.85.040.

Determine whether the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

The information collected through the key informant questionnaire process differs from the NAICS data in terms of the number of large versus small businesses and the number of employees. Based on the questionnaire data, there is a greater number of large businesses and much greater number of employees than reported in the NAICS data. The NAICS data also identifies 163 businesses where Department of Health records indicate there are 349 licensed harvesters and shellfish dealers in Washington. The majority of the industry is made up of small businesses. The rule was developed in close collaboration with small businesses and awareness that the shellfish industry is largely comprised of small businesses. Given the small number of large businesses, it is not possible to determine the top 10% of large businesses.

Based on this inconclusive information, the department could not make a determination of whether there is a disproportionate impact on small businesses versus large businesses. However the department considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses.

- 1) Reducing, modifying or eliminating substantive regulatory requirements;
 - a. The department considered using genetic markers through either requiring lot testing of oysters prior to shipment or environmental sampling prior to harvest. This approach would be prohibitively expensive for small businesses and either requires an increase in fees to cover lab testing or an increase in costs to companies as they procure lab services. In addition to the cost concerns, it was

determined that this was not the best approach to reduce vibriosis illnesses and protect public health.

- b. The department also considered using the time of mean low tide and shellfish bed elevation as a closure criterion. This approach would have required detailed surveys of all shellfish growing areas and resulted in high costs for the surveys and resulting geodatabase to store and reference this information. In addition to the cost concerns, it was determined that this was not the best approach to reduce vibriosis illnesses and protect public health.
 - c. The department did select an approach to *Vibrio* management that should result in fewer days closed. In addition, the closures should be a shorter duration, which allows some small businesses to avoid closure costs by shifting to harvesting other species and conducting farm maintenance. The decision to only trigger harvest temperature closures in July and August, as opposed to all *Vibrio parahaemolyticus* control plan months means there is a greater degree of certainty for how long a closure can last and a greater level of assurance that closures will be timed to be most protective of public health while being least disruptive to the shellfish industry.
 - d. The department added language to the rule to allow a phased in approach for coastal growing areas. As the current rule time of harvest to temperature controls are far less stringent than the proposed rule category 1 time of harvest to cooling, it was determined that all coastal growing areas would initially be categorized as risk category 1. This approach allows small businesses to adjust to the changes in a phased in manner and is still protective of public health.
 - e. The elimination of requirements for May for inland growing areas categorized in the proposed rule as risk category 1 was based on the previous three year's illness data. After a thoughtful review, the department determined that it would be satisfactory to exclude May from category 1. Both category 2 and 3 include time of harvest to cooling requirements for May given the higher likelihood of illness from these areas.
- 2) Simplifying, reducing or eliminating recordkeeping and reporting requirements
 - a. The department determined that weekly calibration was a reasonable requirement. Requiring calibration prior to each harvest, although recommended by some individuals on VpAC, was determined to be too large a burden for businesses. The department also believes that it is reasonable to expect thermometers to maintain accuracy over a week of use. Requiring weekly calibration provides a level of assurance that accurate and precise devices are being used, while not creating an overly burdensome calibration and recordkeeping requirement.
 - 3) Other mitigation techniques suggested by small businesses or their advocates
 - a. Multiple small businesses on VpAC requested that either water or internal tissue temperature be used to meet harvest temperature requirements. The department agreed that providing options for compliance was appropriate in this situation. It allows harvesters the ability to fit the new requirement into their existing harvest practices with minimal disruption. The integrity of the intent is still maintained while providing this option.

Describe how small businesses were involved in the development of the proposed rule.

Small businesses were heavily involved in the rule development. Small businesses comprised of the majority of VpAC which met as a full committee 13 times from January 2013 to September 2014. In addition to these full group meetings, numerous small group meetings to refine draft rule language and subcommittee meetings were held. There were three subcommittees and each subcommittee included representatives from small businesses.

The department worked closely with the Northwest Indian Fisheries Commission, Point No-Point Treaty Council, FDA, individual tribes, and the Pacific Coast Shellfish Growers Association to minimize the burden of this rule. In addition to informal meetings and discussions, the department also engaged with tribes through Tribal Technical Meetings (2013 and 2014) and the shellfish industry through presentations at the PacRim Shellfish Sanitation Conference (2013 and 2014), Pacific Coast Shellfish Growers Association Conferences (2013 and 2014), and West Coast *Vibrio* Management Meeting (2013).

Identify the estimated number of jobs that will be created or lost as the result of compliance with the proposed rule.

The key respondent questionnaire specifically asked whether businesses anticipated a change in the number of employees as a result of the draft rule. Seventeen companies stated that the rule would not result in a change in the number of employees. Three companies thought that this rule could affect the number of employees. One company stated that they might change the number of employees, but did not provide any additional information. Another respondent thought they may add one employee to meet the increased recordkeeping requirements. They also noted that they would need to reduce the number of employee's if the growing area closed for a prolonged time, which is also a possibility of the current rule. The third respondent thought they may be able to increase their workforce by 4-5 employees over the next few years because they expected to be able to operate more days during the year as a result of the proposed rule.

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 the NSSP Model Ordinance and consist 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 epidemiologically 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 NSSP 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 NSSP 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 require-~~

~~ments 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.)~~ (1) This section establishes the Washington state *Vibrio parahaemolyticus* control plan (control plan) for the months of May 1st through September 30th (control months). The requirements of this section are an extension of the NSSP Model Ordinance.

(2) All harvesters and shellfish dealers harvesting or delivering oysters to a certified shucker packer for shucking or postharvest processing (PHP) during the control months must label the oysters with a harvest tag stating "For shucking by a certified dealer" or "For PHP by a certified dealer." Oysters harvested and tagged in compliance with this subsection are exempt from subsections (3) through (20) of this section.

(3) The following definitions apply throughout this section:

(a) "Case" means a laboratory-confirmed *Vibrio parahaemolyticus*-associated illness or illnesses with a common exposure that are reported to the department.

(b) "Control months" means May 1st through September 30th.

(c) "Cool" or "cooling" means to:

(i) Adequately ice or place in a controlled environment with a temperature of 45°F (7.2°C) or less; and

(ii) Reach and maintain an internal oyster tissue temperature of 50°F (10°C) or less.

(d) "Harvest temperature" means the water temperature or internal oyster tissue temperature at the time of harvest. The harvester or shellfish dealer shall state whether they use water temperature or internal oyster tissue temperature for harvest temperature in their harvest plan.

(4) All harvesters and shellfish dealers harvesting oysters during the control months shall report the volume of oysters harvested. This information must be reported by month, oyster species, size class, and growing area for all control months. This information must be reported by December 31st each year. Harvesters and shellfish dealers that do not submit this information to the department may not harvest oysters during the control months during the next calendar year.

(5) Harvesters and shellfish dealers harvesting oysters during the control months shall complete, submit to the department, and keep on file a current *Vibrio parahaemolyticus* harvest plan. In order for the department to review the harvest plan prior to May 1st, the harvest plan must be submitted by March 1st each year unless no changes have been made to the existing harvest plan. Harvesters and shellfish dealers shall sign and date their harvest plan each year and make it available to the department upon request.

(6) The harvest plan must:

(a) Describe the harvest, temperature collection, cooling, and conveyance methods.

(b) Include an example of the harvest temperature record designed to meet the requirements in subsection (11) of this section.

(c) Identify if water temperature or internal oyster tissue temperature is used to meet the requirements in subsection (11) of this section and specifically how this measurement will be taken.

(7) The department shall review and either approve or deny the harvest plan within thirty days of receipt. If the department denies approval of the harvest plan, the department shall notify the applicant of the decision in writing stating the reasons for the denial and providing the opportunity to correct the deficiencies. Harvesters and

shellfish dealers may not harvest oysters during the control months unless the department has approved the plan.

(8) Time of harvest to cooling requirements and harvest controls are based on a risk categorization of each growing area. The department shall assign each growing area a category of 1, 2, or 3 (where 1 corresponds to the least stringent and 3 the most stringent controls) based on the cases attributed to that growing area. The department will attribute cases to a growing area when they:

(a) Are associated with commercially harvested shellstock;

(b) Did not involve documented postharvest abuse;

(c) Are traced back to a single growing area; and

(d) Occurred during the previous consecutive five-year period within the control months.

(9) The department shall categorize coastal growing areas in Willapa Bay and Grays Harbor as Category 1 for the first year of implementation attributing no illnesses to these areas for the years 2010 to 2014. For subsequent years, the department shall categorize coastal growing areas based on the criteria in subsection (8) of this section.

(10) The department shall complete risk categorization and publish a list of all growing areas by risk category no later than February 1st annually. The department shall use a five-year trend to calculate risk categories as follows:

(a) Category 1: One or fewer *Vibrio parahaemolyticus*-associated cases attributed to the growing area over a five-year period.

(b) Category 2: More than one but fewer than five *Vibrio parahaemolyticus*-associated cases attributed to the growing area over a five-year period.

(c) Category 3: Five or more *Vibrio parahaemolyticus*-associated cases attributed to the growing area over a five-year period.

(11) Time of harvest begins after the first oysters to be harvested are exposed to the air. Time of harvest to cooling requirements and harvest controls are as follows:

(a) Category 1:

Requirements:	Time to Cooling:
<u>Except as noted below, the time of harvest to cooling requirement from June 1st through September 30th is:</u>	<u>9 hours</u>
<u>When ambient air temperature at harvest is greater than 90°F, the time of harvest to cooling requirement is:</u>	<u>7 hours</u>
<u>When harvest temperature is between 68°F and 70°F from July 1st through August 31st, the time of harvest to cooling requirement is:</u>	<u>5 hours</u>
<u>Harvest Control: From July 1st through August 31st, harvest is not allowed for twenty-four hours when harvest temperature is above 70°F.</u>	

(b) Category 2:

Requirements:	Time to Cooling
<u>Except as noted below, the time of harvest to cooling requirement from May 1st through September 30th is:</u>	<u>7 hours</u>
<u>When ambient air temperature at harvest is greater than 85°F, the time of harvest to cooling requirement is:</u>	<u>5 hours</u>
<u>When harvest temperature is between 66°F and 68°F from July 1st through August 31st, the time of harvest to cooling requirement is:</u>	<u>3 hours</u>
Harvest Control: From July 1st through August 31st, harvest is not allowed for twenty-four hours when harvest temperature is above 68°F.	

(c) Category 3:

Requirements:	Time to Cooling
<u>Except as noted below, time of harvest to cooling requirement from May 1st through September 30th is:</u>	<u>5 hours</u>
<u>When ambient air temperature at harvest is greater than 80°F, the time of harvest to cooling requirement is:</u>	<u>3 hours</u>
<u>When harvest temperature is between 64°F and 66°F from July 1st through August 31st, the time of harvest to cooling requirement is:</u>	<u>1 hour</u>
Harvest Control: From July 1st through August 31st, harvest is not allowed for twenty-four hours when harvest temperature is above 66°F.	

(d) When a harvester or shellfish dealer places oysters in a container or conveyance, but does not remove them from the tide flat as part of their harvest and the harvest exceeds the time to cooling requirements in subsection (11) of this section, then the oysters in the container or conveyance must be covered by the tide for a minimum of four hours before harvest can be completed.

(12) Harvesters and shellfish dealers shall take the following measurements at the times specified below and record this information in a harvest temperature record for each harvest site for all harvests occurring within the control months. Harvesters and shellfish dealers shall take these measurements with a thermometer that is calibrated weekly using manufacturer specifications or with a method approved in a harvest plan. Calibration must be documented and maintained with operational records. Harvesters and shellfish dealers shall record the following measurements and the date and time they were taken in the record, maintain the record for three years, and make the record available to the department upon request:

(a) Air temperature at time and location of harvest; and

(b) Harvest temperature at time and location of harvest. Harvesters and shellfish dealers using water temperature for harvest temperature shall take water temperature at depth of oysters unless another method is documented in their harvest plan.

(13) Harvesters and shellfish dealers shall initiate cooling as soon as practical from the time of harvest and within the time of harvest to cooling requirements for the growing area where the oysters were harvested to ensure that the maximum number of hours is not exceeded.

(14) If the required time of harvest to cooling requirements are not met after removal from the tide flat, the harvester or shellfish dealer shall dispose of the oysters using one of the methods below and record the disposition on the harvest record:

(a) Destroy the oysters;

(b) Place the oysters within the original growing area or another approved growing area and allow a minimum of fourteen days before re-harvesting; or

(c) Deliver the oysters to a certified shucker packer for shucking or PHP and attach a harvest tag meeting the requirements in subsection (2) of this section.

(15) If ownership of oysters is transferred prior to the oysters being cooled in accordance with the time of harvest to cooling requirements, the harvester shall include in the harvest record required under WAC 246-282-080 the:

(a) Temperatures recorded under subsection (12) of this section;

(b) Date, time, and person or entity to whom the oysters were transferred; and

(c) Growing area risk category for the harvested product.

(d) The receiving shellfish dealer shall meet the time of harvest to cooling requirements for the original harvest time.

(16) *Vibrio parahaemolyticus* training requirements are as follows:

(a) Harvesters and shellfish dealers shall complete an initial department-approved training specific to the requirements of this section prior to harvesting or shipping oysters during the control months.

(b) Harvesters and shellfish dealers shall complete department-approved refresher training within one year following any revision of this rule considered significant under RCW 34.05.328 or at least every five years.

(c) Those responsible for the on-site management of harvest activities must be trained by either:

(i) Harvesters and shellfish dealers at their operation who completed the department-approved training; or

(ii) The department.

(d) Harvesters and shellfish dealers shall record those trained in their operational records.

(17) A harvester or shellfish dealer may request a waiver from specific requirements of this section. The request must:

(a) Be in writing;

(b) Identify the requirement requested to be waived;

(c) State the reason for the waiver; and

(d) Provide supporting information.

(18) The department may grant a waiver request if it:

(a) Is consistent with the applicable standards and the intent of this section; and

(b) Provides a comparable level of public health protection to the requirement being waived.

(19) If the department approves a waiver request, the department shall notify the requestor of the decision in writing.

(20) If the department denies a waiver request, the department shall notify the requestor of the decision in writing stating the reasons for the denial. The requestor shall comply with the provision that was the subject of the waiver request.