



RULE-MAKING ORDER EMERGENCY RULE ONLY

CR-103E (December 2017) (Implements RCW 34.05.350 and 34.05.360)

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STATE OF WASHINGTON
FILED

DATE: May 17, 2023

TIME: 7:29 AM

WSR 23-11-074

Agency: Department of Health

Effective date of rule:

Emergency Rules

- Immediately upon filing.
 Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- Yes No If Yes, explain:

Purpose: WAC 246-282-006, Washington state Vibrio parahaemolyticus control plan. Vibrio parahaemolyticus (Vp) is a naturally occurring bacteria found in marine waters. Molluscan bivalve shellfish acquire Vp through filter feeding. Humans who consume raw or undercooked shellfish containing Vp can develop an intestinal disease called vibriosis.

Chapter 246-282 WAC establishes the minimum performance standards for growing, harvesting, processing, packing, storage, transporting, and selling of shellfish for human consumption. These rules do not apply to persons who conduct activities limited to retail food service, personal use, and transporting as a common carrier of freight.

WAC 246-282-006 establishes the control plan for the months of May 1st through September 30th and are an extension of the NSSP Model Ordinance (U.S. Food and Drug Administration National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish).

Due to current early season high temperatures, this emergency rule making is necessary to protect public health by modifying the existing strictest harvest control requirements which currently start July 1st by setting even more protective measures immediately.

The State Board of Health (board) filed a Preproposal Statement of Inquiry (CR-101) on February 23, 2022, WSR 22-06-034 regarding permanent amendments to the existing rules to address harvest control measures and may also include updating definitions, seed size and other technical and editorial changes as needed.

Until permanent rule making can be completed, the board has delegated emergency rule making authority to the Department of Health if heat-wave conditions occur prior to July 1.

Citation of rules affected by this order:

New: None
Repealed: None
Amended: WAC 246-282-006
Suspended: None

Statutory authority for adoption: RCW 69.30.030 and RCW 43.20.050

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

- That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
 That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: To reduce the threat to public health, amending the “time of harvest to cooling requirements” to a more protective control season immediately is necessary. The current Vp Control Plan, last revised in 2015, establishes a control season between May 1st and September 30th and authorizes enforcement of the rule’s strictest time-to cooling requirements for harvested oysters starting July 1 of the Vp control season. However, recent events demonstrate the need for more flexible rules. From June 26 to July 2, 2021, the National Weather Service in Seattle reported a long-duration, unprecedented heat wave throughout the Pacific Northwest. Shellfish-related Vp illnesses increased sharply. Therefore, due to current early season temperatures and mid-day low tides, this emergency rule is necessary to protect public health.

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency’s own initiative:

New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>

Date Adopted: May 17, 2023

Name: Kristin Peterson, JD for Umair A. Shah, MD, MPH

Title: Chief of Policy for Secretary of Health

Signature:



WAC 246-282-006 Washington state *Vibrio parahaemolyticus* control plan. (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) "Single-source *Vibrio parahaemolyticus* case" or "case" means a laboratory-confirmed *Vibrio parahaemolyticus*-associated illness or illnesses with a common exposure that are reported to the department. The case must:

- (i) Be associated with commercially harvested shellstock;
- (ii) Not involve documented postharvest abuse; and
- (iii) Be traced back to a single growing area.

(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~~) 30 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 number of cases that occurred during the previous consecutive five-year period within the control months and were attributed to that growing area.

(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 rolling five-year average number of cases to calculate risk categories as follows:

(a) Category 1: An average of 0.2 or fewer cases attributed to the growing area over a five-year period.

(b) Category 2: An average of more than 0.2, but less than 1.0 cases attributed to the growing area over a five-year period.

(c) Category 3: An average of 1.0 or more 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:
Except as noted below, the time of harvest to cooling requirement from (June) <u>May 1st</u> through September 30th is:	9 hours
When ambient air temperature at harvest is greater than 90°F, the time of harvest to cooling requirement is:	7 hours
When harvest temperature is between 68°F and 70°F from (July 1st) <u>May 17th</u> through (August 31st) <u>September 14th</u> , the time of harvest to cooling requirement is:	5 hours
Harvest Control: From (July 1st) <u>May 17th</u> through (August 31st) <u>September 14th</u> , harvest is not allowed for twenty-four hours when harvest temperature is above 70°F.	

(b) Category 2:

Requirements:	Time to Cooling:
Except as noted below, the time of harvest to cooling requirement from May 1st through September 30th is:	7 hours
When ambient air temperature at harvest is greater than 85°F, the time of harvest to cooling requirement is:	5 hours
When harvest temperature is between 66°F and 68°F from ((July 1st) <u>May 17th</u> through ((August 31st) <u>September 14th</u> , the time of harvest to cooling requirement is:	3 hours
Harvest Control: From ((July 1st) <u>May 17th</u> through ((August 31st) <u>September 14th</u> , harvest is not allowed for twenty-four hours when harvest temperature is above 68°F.	

(c) Category 3:

Requirements:	Time to Cooling:
Except as noted below, time of harvest to cooling requirement from May 1st through September 30th is:	5 hours
When ambient air temperature at harvest is greater than 80°F, the time of harvest to cooling requirement is:	3 hours
When harvest temperature is between 64°F and 66°F from ((July 1st) <u>May 17th</u> through ((August 31st) <u>September 14th</u> , the time of harvest to cooling requirement is:	1 hour
Harvest Control: From ((July 1st) <u>May 17th</u> through ((August 31st) <u>September 14th</u> , 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 verified weekly using manufacturer specifications or with a method approved in a harvest plan. Thermometer verification 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~~) 14 days before reharvesting; 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.

(21) The department shall review this section to evaluate the effectiveness of the rules and determine areas where revisions may be necessary by November 2017.