



PROPOSED RULE MAKING

CR-102 (June 2004)

(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 08-23-015 ; or
- Expedited Rule Making--Proposed notice was filed as WSR _ ; or
- Proposal is exempt under RCW 34.05.310(4).

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

Title of rule and other identifying information: (Describe Subject)
WAC 246-282-006 Vibrio parahaemolyticus control plan

Hearing location(s): Department of Health
Point Plaza East, Room 152/153
310 Israel Road SE
Tumwater, Washington 98501

Date: March 11, 2009 Time: 2:00 p.m.

Submit written comments to:

Name: Jessie DeLoach
Address: Department of Health
Office of Shellfish Water Protection
Post Office Box 47824
Olympia, WA 98504-7824
Website: <http://www3.doh.wa.gov/policyreview/>
fax 360-236-2257 by (date) 03/04/2009

Assistance for persons with disabilities: Contact

Amber Scott by 03/04/2009

TTY (800) 833-6388 or () 711

Date of intended adoption: 03/11/2009

(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 control plan is to protect public health by revising the state-specific control plan to reduce the incidence of Vibrio parahaemolyticus-related illness (vibriosis). The control plan consists of time-to-temperature controls, training, illness response, record-keeping requirements, and modified Hazard Analysis Critical Control Points plan.

Reasons supporting proposal:

The State Board of Health adopted revisions to the vibrio parahaemolyticus control plan in 2008 to better protect shellfish consumers from vibriosis. There were 44 commercial cases of vibriosis and 3 recreational cases reported for the summer months of 2008. This proposed revision is needed to further clarify rule requirements to provide consistent implementation of the rule for all growing areas in Washington State and to further reduce the number of illnesses associated with vibrio parahaemolyticus.

Statutory authority for adoption:

RCW 69.30.030

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:

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: February 04, 2009

TIME: 10:20 AM

WSR 09-04-096

DATE 02/04/09

NAME (type or print)

Craig McLaughlin

SIGNATURE

TITLE

Executive Director

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..... Jessie DeLoach	Department of Health, 111 Israel Rd SE, Tumwater, WA 98501	360-236-3302
Implementation..... Jessie DeLoach	Department of Health, 111 Israel Rd SE, Tumwater, WA 98501	360-236-3302
Enforcement..... Jessie DeLoach	Department of Health, 111 Israel Rd SE, Tumwater, WA 98501	360-236-3302

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

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 was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

Is a cost-benefit analysis required under RCW 34.05.328?

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

Name: Jessie DeLoach

Address: Department of Health

Office Shellfish and Water Protection

Post Office Box 47824

Olympia, WA 98504-7824

phone 360-236-3302

fax 360-236-2257

e-mail jessie.deloach@doh.wa.gov

No: Please explain:

AMENDATORY SECTION (Amending WSR 08-11-051, filed 5/15/08, effective 5/19/08)

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 ~~((transport))~~ 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 ~~((2005))~~ 2007 National Shellfish Sanitation Program Model Ordinance (NSSP), Requirements for Harvesters, .03 Shellfish Temperature, Control Option 2; and consists of:

- (a) Time ~~((of))~~ of harvest to ~~((of))~~ temperature control ~~((of))~~ 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 ~~((linked))~~ as the source of any *Vibrio parahaemolyticus* ~~((associated))~~ 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 ~~((linked))~~ *Vibrio parahaemolyticus* ~~((associated))~~ illness ~~((if the licensed harvester or dealer can demonstrate safe and effective harvest and transportation methods, as developed in a written agreement))~~ 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 (~~(to assure compliance with the control plan)~~ 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 (~~(---Time must)~~) begins after the first oysters to be harvested are exposed to the air by the receding tide.

(b) Submerged time of harvest (~~(---Time must)~~) 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) (~~In the event of two sporadic *Vibrio parahaemolyticus*-associated illnesses within thirty days where oysters from a single growing area are epidemiologically associated (linked) as the source, all licensed harvesters and dealers in the implicated growing area shall reduce the time-to-temperature control by one hour. The implicated growing area shall remain under the reduced time-to-temperature control throughout the control months for that~~

~~area as defined in Table 1 or 2 of subsection (4) of this section.~~

~~(7) In the event of two additional sporadic *Vibrio parahaemolyticus*-associated illnesses within thirty days under the one hour reduced time-to-temperature control where oysters from a single growing area are epidemiologically associated (linked) as the source, the growing area shall be closed to harvest and shipment of oysters intended for raw consumption throughout the control months as defined in Table 1 or 2 of subsection (4) of this section. If the two additional *Vibrio parahaemolyticus*-associated illnesses 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 2005 NSSP, Chapter II, Risk Assessment and Risk Management, to determine if the illnesses resulted from dealer practices or the growing area.~~

~~(8) An exemption to closure identified in subsection (7) of this section may be granted if the licensed harvester or dealer can demonstrate to the department, as developed in a written agreement, that an additional one hour reduction in time-to-temperature controls can be successfully implemented. If approved, the licensed harvester or dealer shall remain under the reduced time-to-temperature control throughout the control months for that area as defined in Table 1 or 2 of subsection (4) of this section.~~

~~(9)) 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, 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:

~~((a))~~ (i) Destroy the oysters; or

~~((b))~~ (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.

~~((10))~~ (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* ~~(-associated)~~ illness outbreak where oysters from a ~~(particular)~~ growing area are epidemiologically associated ~~(-linked)~~ as the source, the requirements as stated in the ~~(2005)~~ 2007 NSSP, Chapter II, Risk Assessment and Risk Management, shall apply.

~~((11))~~ (12) All licensed harvesters and dealers shall complete an initial department-approved training specific to the ~~(control plan)~~ 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.

~~((12))~~ (13) Following completion of the training required in subsection ~~((11))~~ (12) of this section ~~(7)~~:

(a) All licensed harvesters (~~((intending))~~) ~~planning~~ to harvest oysters intended for raw consumption from May through September shall develop a harvest plan (~~((and checklist))~~) that (~~((defines))~~) ~~describes~~ the harvest (~~((protocols))~~), ~~temperature control, and transportation methods~~ that (~~((will be employed to assure oysters are placed under temperature control as defined in Table 1 or 2))~~) ~~meet the requirements~~ of subsections (4) (~~((of this section,))~~) and (~~((subsection))~~) (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 (~~((other than harvesters))~~) ~~planning~~ to harvest oysters intended for raw consumption from May through September shall amend their Hazard Analysis Critical Control Point (HACCP) plans to define (~~((what))~~) ~~the~~ harvest (~~((protocols will be employed to assure oysters are placed under temperature control as defined in Table 1 or 2))~~), ~~temperature control, and transportation methods~~ that ~~meet the requirements~~ of subsections (4) (~~((of this section,))~~) and (~~((subsection))~~) (6) of this section. Licensed dealers shall obtain department approval of the amended HACCP plan prior to harvesting oysters for raw consumption.