



PROPOSED RULE MAKING

CR-102 (June 2004)

(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).

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

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

WAC 246-282-005, Sanitary control of shellfish - Minimum performance standards; and WAC 246-282-032, Relay permit, to update the reference to the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish (guide), update the name of the Office of Shellfish and Water Protection, and correct a subsection numbering error

Hearing location(s): Department of Health
Town Center 2, Room 530
111 Israel Road SE
Tumwater WA 98501

Date: July 7, 2011

Time: 11:00am

Submit written comments to:

Name: Brandy Brush
Address: Department of Health
Office of Shellfish and Water Protection
Post Office Box 47824
Olympia, WA 98504-7824
Website: <http://www3.doh.wa.gov/policyreview/>
fax 360-236-2257 by (date) 07/07/2011

Assistance for persons with disabilities: Contact

Brandy Brush by 06/30/2011

TTY (800) 833-6388 or () 711

Date of intended adoption: 07/08/2011

(Note: This is NOT the effective date)

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

All shellfish-producing states are required to follow the most current NSSP guide in order to place molluscan shellfish into interstate commerce. Currently, WAC 246-282-005 references the US Food and Drug Administration (FDA) 2007 NSSP guide. FDA has now adopted a 2009 version of the NSSP guide, leaving the current rule out of date. This proposed rulemaking will amend the section to update the reference. The attached document lists the differences between the 2007 and 2009 versions of the NSSP guide. This proposal will also change the office name in WAC 246-282-005(1)(a) to Shellfish and Water Protection and correct a subsection numbering error in WAC 246-282-032(4).

Reasons supporting proposal:

The FDA oversees a cooperative program between the shellfish producing states and shellfish industry for the production and processing of shellfish in a manner specified by the NSSP. The FDA evaluates each states shellfish sanitation control program to ensure compliance with NSSP. An update to 246-282-005 is needed to assure Washington state remains compliant with the NSSP.

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:

DATE 05/25/11

NAME (type or print)

Gregg Grunenfelder for Mary C. Selecky

SIGNATURE

for Mary C. Selecky

TITLE

Deputy Secretary for Secretary

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: May 25, 2011

TIME: 11:41 AM

WSR 11-12-034

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..... Brandy Brush	111 Israel Road SE, Tumwater WA 98501	360-236-3342
Implementation.... Rick Porso	111 Israel Road SE, Tumwater WA 98501	360-236-3302
Enforcement..... Rick Porso	111 Isael Road 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 (SBEIS) was not prepared. Under RCW 19.85.025 and 34.05.310(4)(c), a SBEIS is not required for proposed rules that adopt or incorporate by reference - without material change - federal statutes or regulations, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards;

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)(iii) exempts rules that adopt or incorporate by reference without material change federal statutes or regulations, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards;

2007-2009 MO Crosswalk

Section/Chapter	Citation	Change
Definitions	(53)	Add In-Shell Product Packing
	(61)	Add Lot of In-Shell Product
	(65)	Add Male-specific Coliphage
	(91)	Add Repacking In-Shell Product
	(96)	Add Restricted Use Shellstock
		110
		Definitions now is 115 Definitions
Chapter II	@.02.B.(3)c	Add c Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Federal Regulations Part 7.
	@.02.B.(4)	Add (4) When the Authority determines that the growing area may be the source of pathogens the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7 if the pathogens exceed tolerance levels.
	@.02.B.(5)	Add (5) When the Authority determines that illegal harvesting is taking place, the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of federal Regulations Part 7 for all shellfish that may be falsely represented.
	@.05.B.(4)c	Add Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within 10 hours or less as determined by the Authority after placement into refrigeration during periods when the risk of <i>Vibrio parahaemolyticus</i> illness is reasonable likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within 10 hours or less as determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled " <i>for shucking only</i> ", or other means to allow the hazard to be addressed by further processing.
	@.05.B.(4)c	Change to @.05.B.(4)(d)
	@.05.B.(4)(d)	Change to @.05.B.(4)(e)
@.05.B.(4)(e)	Change to @.05.B.(4)(f)	

Chapter IV	@.02.G.(2)	Substitute Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of: (b) 300 MPN per 100 ml for a three tube decimal dilution test; (c) 173 MPN per 100 ml for a twelve tube single dilution test; or (d) 163 CFU per 100 ml for a MF (mTEC) test.
	@.02.H.(4)	Substitute Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of: (a) 300 MPN per 100 ml for a three tube decimal dilution test; (b) 173 MPN per 100 ml for a twelve tube single dilution test; or (c) 163 CFU per 100 ml for a MF (mTEC) test.
	@.03.A.(5)(b)	Add (iii) (<i>sic</i>) The requirements for biotoxins or conditional area management plans as established in §.04 and §.03 respectively, are met; and (iv) (<i>sic</i>) Supporting information is documented by a written record in the central file.
	@.03.A.(5)(c)	Add (iv) Supporting information is documented by a written record in the central file.
Chapter IX	@.03.A.(3)	Add after "shellfish" temperature or the internal body temperature of in-shell product
	@.04.B.(2)	Add after "temperature" or the internal body temperature of in-shell product Add as (3) In-shell product shipments shall be shipped on pallets
	Requirements for the Harvester/Dealer .04.B	Change to .04.B.(4)
	Requirements for the Harvester/Dealer .04.B.(3)	
Chapter X	.01.C.(2)	Add c Critical control points shall be designed to ensure that shellstock received with restricted use tags is processed consistent with the stated purpose. For Shellstock tagged for restricted use, critical control points shall be included in the Certified Dealer's HACCP plan to ensure that the shellstock is shipped to another Certified dealer with the restricted use tag or processed consistent with the stated purpose.

	.03 Other Model Ordinance Requirements	Add Dialogue Box which contains Additional Guidance - Section IV Guidance Documents Chapter V. Illness Outbreak Investigation and Recall, .02 Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak
	.05 Shellstock Identification	Add E. All restricted use shellstock shall include a tag containing all information required in §.05 of Model Ordinance Chapter X. In addition the tag will include specific language detailing the intended use of the shellstock.
	.05 Shellstock Identification	Change .05.E to .05.F
	.06 Shucked Shellfish Labeling	Change .06.A.(5) to read The dealer shall assure that the shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish
	.07 In-Shell Product or Post Harvest Processed In-Shell Labeling	Add .07.B.(4) When in-shell product intended for retail sale are packed in containers of 5 pounds or less and shipped in a master container which includes a tag in compliance with Chapter X.05.B.(1), the individual containers of 5 pounds or less shall not require tags as specified in Chapter X.05.B.(1) but may be labeled in some other manner with indelible, legible, information which at a minimum is adequate to trace the in-shell shellfish back to the lot of in-shell product it is part of. Consumer advisory information identified in Chapter X.07.B.(1)(j) shall be included on each retail package.
Chapter XI	.01.A.	Add .01.A.(3) In-shell product obtained from a dealer who has: (a) Shipped the in-shell product adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 45°F (7.2°C) internal temperature or less; and [C] (b) Identified the in-shell product with a tag on each container [C]
	.01	Add .01.C In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be: (1) Iced; or [C] (2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less [C]
	.01.C	Change to .01.D
	.01.D	Add .01.D.(5) For in-shell product the internal temperature of meats does not exceed 45°F (7.2°C) for more than 2 hours during processing [C]
	.01.D	Change to .01.E
	.01	Add .01.F Shellstock Shipping Critical Control Point. (1) The dealer shall ensure that Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

	.02.B.(2)(d)	Add (1) Fabricated from food grade materials; and [K] (ii) Stored in a manner which assures their protection from contamination. [K]
	.03.F.(9)	Change to read During storage frozen shellfish shall be maintained frozen. [S k/o]
Chapter XII	.03.F.(1)(g)	Change to read During storage frozen shellfish shall be maintained frozen. [S k/o]
Chapter XIII	.01.A.	Add .01.A.(3) In-shell product obtained from a dealer who has: (a) Shipped the in-shell product adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 45°F (7.2°C) internal temperature or less; and [C] (b) Identified the in-shell product with a tag on each container [C]
	.01	Add .01.C In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be: (1) Iced; or [C] (2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less [C]
	.01	Add .01.F Shellstock Shipping Critical Control Point. (1) The dealer shall ensure that Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.
	.03.F.(1)	Eliminate .03.F.(1)(b)
Chapter XIV	.01.A.(1)(b)	Add after "shellfish" and/or in-shell product
	.01.A.(1)c	Add after "Chapter X.05," identified the in-shell product with a tag as outlined in Chapter X.07, and/or identified the shucked shellfish with a label as outlined in Chapter X.06 [C]
	.01.C	Add .01.C In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be: (1) Iced; or [C] (2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less [C]
	.01.C	Change to .01.D
	.01	Add .01.F Shellstock Shipping Critical Control Point. (1) The dealer shall ensure that Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.
	.02.C.(1)(b)	Change to Shellfish shall be protected from contamination [Sc/k]
	.03.F.(1)	Change to The dealer shall buy shellfish only from sources certified by the Authority or listed in the ICSSL. [K]
Chapter XV	.02.C.(3)(b)	Eliminate (i), (ii), (iii), (iv) and move (v) up to become (b)

Chapter XVI

- A. Eliminate A.(1)(a), A.(1)(b), A.(1)c, A.(1)(d), make A.(1)(e) follow "process." in A.(1), change (i) to (a) and (ii) to (b), and add A.(1)c Analytical results used for validation of a PHP shall come from an analytical laboratory that is evaluated by the State and/or FDA and found to be in compliance with applicable NSSP laboratory requirements.

- A. Insert (2) Validate the process by demonstrating that the process will reliably achieve the appropriate reduction in the target pathogen(s). The process shall be validated by a study as outlined in Guidance Documents Chapter IV, Naturally Occurring Pathogens, Section .04 and be approved by the Authority, with concurrence of FDA. (a) The dealer must demonstrate that the process reduces the level of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* in the process to non-detectable (<30 MPN/gram) and the process achieves a minimum 3.52 log reduction. Determination of *V. vulnificus* and/or *V. parahaemolyticus* levels must be done using the MPN protocols described in Guidance documents, Chapter IV, Naturally Occurring Pathogens, Section .04 followed by confirmation using methods approved for use in the NSSP. (b) For processes that target other pathogens the dealer must demonstrate that the level of those pathogens in processed product has been reduced to levels below the appropriate FDA action level, or in the absence of such a level, below the appropriate level as determined by the ISSC.

- A.(2) Add Dialogue Box which contains Additional Guidance - Section IV Guidance Documents Chapter II. Growing Areas. 10 Approved NSSP Laboratory Tests

Add A.(3) Conduct verification sampling to verify that the validated process is working properly. Verification sampling shall be at least equivalent to the verification protocol found in Guidance Documents, Chapter IV, Naturally Occurring pathogens, Section .04 as determined by the Authority and shall be reviewed annually by the Authority.
- A.(2) Change to A.(4)
- A. Add A.(5) Keep records in accordance with Chapter X.07.

AMENDATORY SECTION (Amending WSR 09-08-116, filed 3/31/09, effective 5/1/09)

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 (~~(2007)~~) 2009 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 (copies available through the U.S. Food and Drug Administration, Shellfish Sanitation Branch, and the Washington state department of health, office of (~~food safety and~~) shellfish (~~(programs)~~) and water protection);

(b) The provisions of 21 Code of Federal Regulations (CFR), 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 or a provision of 21 CFR, 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 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-032 Relay permit. (1) The department will issue a relay permit to a person to move shellfish from a harvest site in a growing area classified as "restricted" or "conditionally approved" in closed status meeting the criteria for "restricted" classification, if all of the following conditions are met.

(a) The person possesses a valid shellfish operation license.

(b) The person possesses a valid harvest site certificate listing both the initial harvest site and the grow-out site.

(c) The initial harvest site and grow-out site meet the requirements for relay specified in this chapter and the NSSP Model Ordinance.

(d) The person submits a completed written application and plan of operations approved by the department completely describing the procedures and conditions of the relay operation.

(e) The person conducts and documents a separate validation study approved by the department for each of the following periods of time when shellfish will be relayed:

(i) May 1 through October 31; and

(ii) November 1 through April 30.

(f) The person pays the department a relay permit application fee or renewal fee as required by this chapter.

(2) Each validation study for a relay permit must demonstrate that shellfish harvested from a specified initial site do not contain excessive levels of fecal coliform bacteria and when relayed to a specified grow-out site for a specified time period consistently purge themselves of bacteria to approved levels. Each validation study must meet all of the following conditions.

(a) It must document that the geometric mean fecal coliform bacteria level in a minimum of five 100-gram tissue samples, representative of shellfish of the same species in the entire initial harvest site, is equal to or less than 1300, with no sample having more than 2300.

(b) It must document that specified relay procedures, times, and environmental conditions reduce fecal coliform bacteria in a minimum of five 100-gram tissue samples, representative of the entire lot of shellfish relayed, to levels that are equal to or less than:

(i) 330, with no more than two samples having greater than 230; or

(ii) Ten percent greater than the geometric mean of a minimum of five 100-gram tissue samples representative of the same shellfish species grown continuously for a minimum of six months at the grow-out site.

(c) It must be repeated a minimum of once every twelve years for a continuing operation and whenever relay conditions change.

(d) All samples must be analyzed by an approved laboratory.

(3) A person operating under a relay permit must follow all procedures in the plan of operations approved by the department, including:

(a) Staking or marking the grow-out site to be easily identified by the person until the minimum relay period of time is passed;

(b) Considering the beginning of the minimum relay time period for a lot to be the moment that the last part of the lot is added to the grow-out site;

(c) Relaying shellfish to a designated grow-out site for a minimum of seven days, or longer period of time as approved by the department; and

(d) Keeping records for each relayed lot of shellfish that show a lot identification number; the species, location, date, and quantity moved from the initial harvest site; the grow-out location; and the date of first harvest of any of those shellfish from the grow-out site.

(4) For each lot of shellfish relayed to a site for a grow-out

period of less than fourteen days, a person must:

~~((i))~~ (a) Collect at least one sample from the shellfish lot at the initial harvest site and have it analyzed by an approved laboratory to demonstrate that the lot contains no more than 2300 fecal coliform bacteria per 100 grams of shellfish tissue; and

~~((ii))~~ (b) Collect at least one sample from the shellfish lot at the grow-out site at the end of the relay period and have it analyzed by an approved laboratory to demonstrate that the lot contains fecal coliform bacteria within the maximum limits determined by a validation study, as described in subsection (2)(b) of this section, before releasing control of the shellfish lot.

(5) A person is exempt from any fees for an initial application and a validation study conducted by the department for a relay permit for the purpose of relaying shellfish from a growing area that the department downgraded from a classification of "approved" or "conditionally approved" to "restricted" within the previous twenty-four months.

(6) A person's relay permit expires on the same date as the person's shellfish operation license.

(7) A person is exempt from the provisions of subsection (1)(e) of this section for the purpose of relaying shellfish to an approved grow-out site for a minimum of six months.

(8) A person possessing a valid shellfish operation license may act as an agent for another person possessing a valid shellfish relay permit for the purpose of harvesting shellfish from the initial harvest site specified in the permit, provided that the agent conducting the harvest is:

(a) Documented in the permit;

(b) In possession of a copy of the permit at the time of harvest; and

(c) Conducting activities described in the written plan of operations approved by the department for the agent's shellfish operation.