



PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: December 18, 2024

TIME: 2:40 PM

WSR 25-02-007

Agency: Department of Health

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR _____ ; or

Expedited Rule Making--Proposed notice was filed as WSR _____ ; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or

Proposal is exempt under RCW _____.

Title of rule and other identifying information: (describe subject) Sanitary Control of Shellfish, Minimum Performance Standards, WAC 246-282-005. The Department of Health (department) is proposing to amend WAC 246-282-005(1)(a) to adopt by reference the 2023 version of the National Shellfish Sanitation Program's (NSSP) Guide for the Control of Molluscan Shellfish (guide). This rulemaking is necessary to update the publication date of the NSSP guide adopted by reference from 2019 to the 2023 version.

Hearing location(s):

| Date: | Time: | Location: (be specific) | Comment: |
|------------------|---------|---|----------|
| February 5, 2025 | 2:00 pm | Virtual Hearing Using Zoom Register in advance for this webinar: https://us02web.zoom.us/webinar/register/WN_j0cKdrAOSGi32iZN3RAv8Q After registering, you will receive a confirmation email containing information about joining the webinar. | |

Date of intended adoption: February 12, 2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name Kseniya Efremova
Address PO Box 47824, Olympia WA 98504-7824
Email shellfishrule@doh.wa.gov
Fax N/A
Other <https://fortress.wa.gov/doh/policyreview/>
Beginning (date and time) Date and time of filing
By (date and time) February 5, 2025 by 11:59 pm

Assistance for persons with disabilities:

Contact Kseniya Efremova
Phone (360) 236-3449
Fax N/A
TTY 711
Email kseniya.efremova@doh.wa.gov
Other N/A
By (date) January 22, 2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The proposed amendment will update the reference to the NSSP guide to ensure that the most current health and safety requirements are in rule as required by the statute. The U.S. Food and Drug Administration (FDA) requires all shellfish-producing states to follow the most current version of the NSSP guide in order to place molluscan shellfish into interstate commerce. The rule currently references an outdated 2019 version of the guide.

Reasons supporting proposal: The FDA oversees a cooperative program between the shellfish-producing states and the shellfish industry for the production and processing of shellfish consistent with the NSSP guide. The FDA evaluates each state's shellfish sanitation control program to ensure compliance with the NSSP guide. Therefore, an update of WAC 246-282-005 is needed so that Washington state remains compliant with the NSSP guide and the molluscan shellfish products from Washington can continue to be placed into interstate commerce.

Statutory authority for adoption: RCW 69.30.030

Statute being implemented: RCW 69.30.030

Is rule necessary because of a:

| | | |
|-------------------------|------------------------------|--|
| Federal Law? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Federal Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| State Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: (person or organization) Washington State Department of Health
Type of proponent: Private. Public. Governmental.

Name of agency personnel responsible for:

| Name | Office Location | Phone |
|-----------------------------|--------------------------------------|----------------|
| Drafting Kseniya Efremova | 111 Israel Rd SE, Tumwater, WA 98501 | (360) 236-3449 |
| Implementation Dani Toepelt | 111 Israel Rd SE, Tumwater, WA 98501 | (360) 890-6054 |
| Enforcement Dani Toepelt | 111 Israel Rd SE, Tumwater, WA 98501 | (360) 890-6054 |

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? Yes No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

- Name
- Address
- Phone
- Fax
- TTY
- Email
- Other

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
- TTY
- Email
- Other

No: Please explain: The department 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, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards.

Regulatory Fairness Act and Small Business Economic Impact Statement
Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:
This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.
Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:

- | | |
|--|--|
| <input type="checkbox"/> RCW 34.05.310 (4)(b) (Internal government operations) | <input type="checkbox"/> RCW 34.05.310 (4)(e) (Dictated by statute) |
| <input checked="" type="checkbox"/> RCW 34.05.310 (4)(c) (Incorporation by reference) | <input type="checkbox"/> RCW 34.05.310 (4)(f) (Set or adjust fees) |
| <input type="checkbox"/> RCW 34.05.310 (4)(d) (Correct or clarify language) | <input type="checkbox"/> RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#). (Does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: *Check one.*

- The rule proposal: Is fully exempt. (*Skip section 3.*) Exemptions identified above apply to all portions of the rule proposal.
- The rule proposal: Is partially exempt. (*Complete section 3.*) The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):
- The rule proposal: Is not exempt. (*Complete section 3.*) No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

- No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.
- Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name
Address
Phone
Fax
TTY
Email
Other

Date: December 18, 2024

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

Title: Chief of Policy for Secretary of Health

Signature:



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 U.S. Food and Drug Administration National Shellfish Sanitation Program (NSSP), Guide for the Control of Molluscan Shellfish ((2019)) 2023 (copies available through the U.S. Food and Drug Administration, Shellfish Sanitation Branch, and the Washington state department of health, office of shellfish and water protection);

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

(c) All other provisions of this chapter.

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