

October 1, 2014

TO: Michelle A. Davis, Executive Director
Washington State Board of Health

FROM: Maryanne Guichard, Assistant Secretary ^{WJ}
Division of Environmental Public Health

SUBJECT: SBOH RULEMAKING AUTHORITY DELEGATION REQUEST
WAC 246-282-005, Sanitary Control of Shellfish, Minimum Performance
Standards

The Department of Health (department) is requesting the State Board of Health (board) adopt an emergency rule and delegate permanent rule-making authority to amend WAC 246-282-005, Sanitary Control of Shellfish, Minimum Performance Standards. This amendment will update the rule reference to the most current version of the U.S. Food and Drug Administration (FDA) National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish (guide). This change will help ensure Washington State remains in compliance with the national shellfish sanitation standards, allowing our state's shellfish producers to place shellfish into interstate commerce.

Federal and State Requirements

Chapter 69.30 RCW directs the board to adopt rules governing the sanitation of shellfish, shellfish growing areas, shellfish processing, plant facilities, and shellfish operations in order to protect the public health. The statute further directs the board to consider the most recent version of the NSSP model ordinance when adopting rules. Chapter 246-282 WAC, Sanitary Control of Shellfish, establishes minimum performance standards for the growing, harvesting, processing, packing, storage, transporting, and selling of shellfish for human consumption. Currently, these rules reference the 2011 NSSP guide. On September 30, 2014, the FDA published a 2013 version of the NSSP guide, leaving the current rules out of date.

The FDA oversees a cooperative program between the shellfish producing states and the shellfish industry for the production and processing of shellfish in a manner specified by the NSSP guide. This guide includes license requirements for growing, harvesting, processing, and shipping molluscan shellfish in a way that is safe for human consumption. States must regulate these activities consistent with the NSSP guide in order for licensees to place molluscan shellfish into interstate commerce. The FDA evaluates each state's shellfish sanitation control plan to ensure compliance with the NSSP guide.

Emergency Rule Making

The FDA recently changed its approach to implementing the guide, making emergency rule making necessary. Washington State must ensure that our requirements immediately align with the 2013 NSSP Guide in order to protect public health and prevent disease, and for FDA to allow interstate commerce of molluscan shellfish from Washington State. The short timeframe between the publication of the 2013 version of the NSSP by the FDA and the required implementation of the NSSP requirements by the state does not allow use of the regular rulemaking process. Therefore, an emergency rule is necessary in order for the state to remain consistent with the requirements of the FDA.

Delegation of Rule-making Authority

In addition to adopting the emergency rule, the department is also requesting the board delegate permanent rule making to the department. The following criteria included in the board's "Policy for Considering Delegation of Rule to the Department of Health" apply to this rule making:

The extent to which the proposed rule seeks to adopt federal requirements in which the state has little or no discretion: The FDA updates the guide biennially to address new and emerging issues in the shellfish industry. The proposed rule amendment will amend the state rule to incorporate by reference the newly published federal requirements.

The extent to which the proposed rule may make significant changes to a policy or regulatory program: Changes to the state regulation will be limited to adopting by reference the 2013 guide. No significant changes will be proposed.

The extent to which the rule revision process would benefit from the board's role as a convener of interested parties: The shellfish industry actively participated in the development of guide. The department does not anticipate any controversy or opposition to this rule change. Stakeholders will be fully involved through program activities to seek input on proposed amendments and the public hearing. The draft rule will be made available through the department's website and email notification to stakeholders and interested parties. The department will distribute the proposed rule to stakeholders and post it on the department's rules comment website during the formal public comment period.

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Attachment

cc: Jerrod Davis