

Office of Shellfish and Water Protection

Preliminary Significant Analysis

of the proposed revision to Chapter 246-282-006 WAC

***Vibrio parahaemolyticus* Control Plan**

January 2009



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Preliminary Significant Analysis

Chapter 246-282-006 WAC *Vibrio parahaemolyticus* Control Plan

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Introduction

Washington State produces oysters intended for raw consumption for state, national and international markets. According to the Pacific Coast Shellfish Growers Association, Washington is the second largest producer of oysters in the United States with 80% of Washington's oysters exported nationally and internationally. The shellfish industry in Washington includes 331 licensees dealing with all types of shellstock, including clams, oysters, geoduck, and others. Approximately 200 of these licensees deal with oysters intended for raw consumption and so are directly affected by the proposed rule. These licensees include Native American, small, and large companies operating in Puget Sound and in coastal areas.

Consuming raw or undercooked oysters can lead to gastrointestinal illness caused by the pathogenic form of *Vibrio parahaemolyticus* bacteria found in oysters. (For the purposes of this document, *Vibrio parahaemolyticus*-associated illness is also referred to as vibriosis.) The *Vibrio parahaemolyticus* bacterium is active in warmer temperatures and nondetectable in cooler temperatures, and has one of the fastest growth rates among human pathogens. As a result, vibriosis occurs primarily during the summer months with an increased incidence of illness during warmer years compared to cooler years. As a result of this temperature-moderated behavior, the pathogen growth can be effectively controlled, and the risk of illness reduced, by placing oysters in a cool environment as soon after they have been exposed to ambient air temperature as possible. Exposure to ambient air begins when the tide recedes and water no longer covers and cools the oysters. This gap between the time of exposure to air and the placement of oysters into a controlled temperature environment is known as time of harvest to temperature control.

Mandatory reporting of vibriosis was established in 1975. Since then, Washington State has experienced two major illness outbreaks; one in 1997 and the other in 2006. The first *Vibrio parahaemolyticus* control plan was adopted nationally in response to the 1997 outbreak. A control plan is designed to reduce the risk of *Vibrio parahaemolyticus*-associated illness using a variety of methods, including time of harvest to temperature control limits, environmental monitoring, illness response measures, and training on effective handling techniques. Since 1999, the control plan has been regularly updated and adopted as part of the National Shellfish Sanitation Program (NSSP) Model Ordinance.

During the summer of 2006, Washington State experienced the second-worst outbreak of *Vibrio parahaemolyticus*-associated illness in the history of the United States, with 113 confirmed illnesses. When the 2006 outbreak occurred, the Washington State rule was based on the 2003 *Vibrio parahaemolyticus* Interim Control Plan outlined in the NSSP Model Ordinance. In 2007, an emergency rule that expanded on the draft 2005 NSSP Model Ordinance was adopted to control vibriosis and it had moderate success; only 57 confirmed illnesses were recorded. Washington State adopted the 2005 NSSP Model Ordinance permanently in September 2007 after the emergency rule expired. However, the 2007 vibriosis outbreak and the significant

increase in the number of sporadic cases of vibriosis demonstrated that the provisions of the 2005 NSSP Model Ordinance and the 2007 rule did not adequately address this public health issue. As a result, the Washington State Board of Health adopted a more stringent rule in 2008 detailing a state-specific *Vibrio parahaemolyticus* control. The adopted rule includes the following:

- Time of harvest to temperature controls based on:
 - Growing area and month of year;
 - Illness incidence; and
 - *Vibrio* illness response;
- Harvest record requirements;
- *Vibrio* illness response requirements;
- Training requirements for harvesters; and
- Modification of Hazard Analysis Critical Control Point (HACCP) plans and creation of harvest checklist requirements.

The *Vibrio parahaemolyticus* control plan outlined in the rule was intended to reduce the risk to the public of acquiring vibriosis from the consumption of raw and undercooked oysters. The rule established shorter harvest time to temperature controls during the months of most concern (May through September) in growing areas most likely to be associated with vibriosis. The rule also established additional time of harvest to temperature controls and potential growing area closure requirements in response to repeated sporadic cases of vibriosis.

The current rule also imposed requirements for records that reflect the time of harvest, in addition to the date and the time the product is placed under temperature control. This record requirement was necessary to verify that the licensed dealer and harvesters were appropriately handling oysters intended for raw consumption in order to limit pathogen growth.

In order for the current rule to be properly implemented by the commercial oyster growers in Washington State, a training requirement for all who intended to commercially harvest raw oysters for human consumption was established.

Finally, the current rule required changes in the Harvest and Hazard Analysis Critical Control Point (HACCP) plans of licensed dealers. Licensed shellstock shipper and shucker packer dealers must amend their HACCP plans to add specific precautions for controlling *Vibrio parahaemolyticus* from May through September, while licensed harvesters must devise harvest plans to add specific precautions to control *Vibrio parahaemolyticus* from May through September.

However, under the current rule, even with the rulemaking that was undertaken to minimize vibriosis, Washington still experienced 45 vibriosis illnesses implicating commercially harvested oysters. Illness investigations determined that four of the confirmed oyster-associated *Vibrio parahaemolyticus* illnesses resulted from a single dealer's practices so the growing area was not closed. These illness investigations, as well as routine inspection findings, revealed three significant changes that need to be made to the current rule to protect public health.

The proposed rule changes are intended to reduce illness by incrementally increasing training and recordkeeping requirements. With these proposed changes, dealers and harvesters will receive appropriate training and will be required to demonstrate compliance with the specific time of harvest to temperature control requirements established in the current rule. The first change creates a recordkeeping requirement for transfer of ownership of oysters prior to when

the time of harvest to temperature control requirements must be met. The second change requires recording the disposition of oysters on the harvest record if the required time of harvest to temperature control period is exceeded. The third change addresses appropriate training. The proposed rule establishes a requirement for a harvester or dealer whose practices are reasonably likely to have caused vibriosis illnesses to retake the training identified in the current rule prior to renewal of the next year's license. The proposed rule also clarifies that the current rule requires an initial training prior to harvesting oysters for raw consumption, and a refresher training any time after a significant rule change is adopted.

Necessity of Significant Analysis

A significant analysis is required for this rule because it creates additional requirements for a regulatory program for the control of vibriosis risk associated with the harvest and transport of raw oysters intended for human consumption.

Statutory Goals and Objectives

The general goal and specific objectives of the statute that this rule implements are stated in RCW 69.30.005, Purpose. "The purpose of this chapter is to provide for the sanitary control of shellfish. Protection of the public health requires assurances that commercial shellfish are harvested only from approved growing areas and that processing of shellfish is conducted in a safe and sanitary manner." Additionally, RCW 69.30.030 requires the State Board of Health to adopt rules to implement chapter 69.30 RCW and states, "Such rules and regulations may include reasonable sanitary requirements relative to the quality of shellfish growing waters and areas ... the handling, storage and refrigeration of shellfish, the identification of containers, and the handling, maintenance, and storage of permits, certificates, and records regarding shellfish taken under this chapter". The proposed rule supports these goals and objectives by establishing additional requirements that further reduce the risk to the public of acquiring a *Vibrio parahaemolyticus*-associated illness from the consumption of raw and undercooked oysters.

Necessity of Rulemaking

This rule is needed to achieve the goal and objectives identified above. The proposed changes to this rule are necessary to assure oysters are harvested and transported in a way that protects public health.

Alternatives to Rulemaking

Since the authorizing statute in RCW 69.30.030 requires rulemaking to implement the statute, and the current rule that incorporates the 2005 NSSP Model Ordinance has proven insufficient to protect public health, there is no alternative to rulemaking.

Consequences of Not Adopting This Rule

The consequences of not adopting this rule would be continued annual outbreaks of vibriosis exceeding the federal standard of one illness per 100,000 meals, and potential illness rates on par with those experienced in 2006. If the proposed recordkeeping requirement for the transfer of ownership of oysters is not adopted, oysters could be inadvertently temperature abused because the gaining licensed owner would not be aware of the elapsed time of exposure to ambient temperature. This would result in the practical incubation of *Vibrio parahaemolyticus* in the oysters, leading to a greatly increased risk of vibriosis. If the proposed recordkeeping requirement to account for the disposition of temperature abused oysters is not adopted, the possibility of oysters with a logarithmic increase in *Vibrio parahaemolyticus* load could enter commerce and create an increased risk of vibriosis for consumers. If the proposed refresher retraining for licensed harvesters and dealers whose practices have been determined to have resulted in vibriosis illnesses is not adopted, these dealers and harvesters will likely continue such practices, leading to increased risk of illness to the consumer.

Any or all of the preceding consequences of not adopting the proposed changes would lead to a higher incidence of vibriosis from Washington State oysters. If continued high incidence of illness occurs, harvest of oysters intended for raw consumption could be prohibited during the warmer months to protect public health, or customer demand for raw oysters could dramatically decline as a result of publicized illness. Either reaction would significantly harm a vital industry that is a major contributor to the state's economic well-being.

Probable Benefits and Probable Costs of This Rule

The goal of the proposed rule is to reduce the incidence of vibriosis to ten or fewer reported illnesses per year, which is calculated based on the suspected vibriosis risk per 100,000 meals as established by federal standard. While the 2008 rule did not meet this goal, it was somewhat effective in reducing vibriosis, with only 45 confirmed vibriosis cases.

In the vibriosis outbreak of 1997, there were 57 confirmed illnesses. In the summer of 1998, without a state or national *Vibrio parahaemolyticus* control plan in place, there were 48 confirmed illnesses equating to a 17.2% decline. This represents the largest single year decline in vibriosis cases since reporting was established in 1975 until 2007. Since the first control plan was not in place in 1998, this decline represents a natural decline associated with yearly temperature change and is not attributable to regulatory action. In the 2006 outbreak, there were 113 confirmed illnesses; in 2007, with a state emergency rule for controlling vibriosis in place, there were 57 confirmed illnesses, a 49.6% decline. This represents a 2.88-fold decrease over the difference in 1997-1998, which demonstrates that the emergency rule played a part in the reduction of vibriosis beyond what would be expected in a natural decline. The 2008 rule, with more comprehensive controls in place, resulted in a decline in confirmed cases of 21% over 2007, again exceeding the 17.2% natural year-on-year decline.

The proposed rule changes establish additional time of harvest to temperature control recordkeeping, establish disposition recordkeeping requirements for disposition of oysters that do not meet the harvest time to temperature control period, and establish new training and recordkeeping requirements for transfer of ownership.

With these revised protective measures in place, the Office of Shellfish and Water Protection (OSWP) expects to see a decrease in the number of reported cases of vibriosis in 2009 compared to the number of cases in 2008 beyond the natural year-on-year decline. With this expected reduction in illness, OSWP also expects to see a decrease in the number of growing area closures and recalls associated with illness outbreaks.

Transfer of ownership recordkeeping requirement: Time of harvest to temperature control.

The current rule does not address transfer of ownership of oysters between the time they are harvested and the time they must be in temperature control. Section (5) currently requires licensed dealers and harvesters to maintain records showing the time of harvest and the time the oysters are placed under temperature control. The proposed rule adds a requirement to account for the transfer of ownership of oysters between licensed harvesters and dealers when that transfer is made prior to the time oysters must be under temperature control. The licensed dealer or harvester shall include in the harvest record the date, time, and person or entity to whom the oysters were transferred. This change increases the ability of licensed harvesters and dealers to comply with the time of harvest to temperature control requirements of this rule by providing needed information, and reduces the risk of temperature abused oysters entering commerce. The risk of vibriosis illness is decreased when the risk of temperature abused oysters reaching the market place is decreased.

Costs:

The department assumes that the increase in time spent on recordkeeping will be minimal over the course of the *Vibrio parahaemolyticus* control months. Assuming the following:

- 153 harvest days during May through September;
 - All 200 companies that the department estimates will be harvesting oysters for raw consumption decide to sell oysters between the time of harvest and the time of required temperature control on each harvest day; and
 - It will take them a minute or less to record the necessary information.
- The result will be an additional 510 hours of recordkeeping time for the entire industry (153 harvest days x 200 companies/60 minutes per hour = 510 hours). At \$13.00 per hour average wage¹, the cost to the entire industry will amount to \$6,630.

Benefits:

The proposed change provides enhanced accuracy in imposing time of harvest to temperature controls for the transfer of ownership of oysters destined for raw consumption. After reviewing the previous two years collecting extensive data on such environmental factors as ambient air temperature, water temperatures at three selected depths, oyster tissue temperatures, tide times and calculated exposures, weather conditions, environmental levels of signature and pathogenic genetic markers, and extensive statistical analyses of how these factors do or do not interact; the department is confident that minimizing exposure to ambient temperatures and maximizing temperature control after harvest are the most effective strategies for decreasing the risk of vibriosis. The proposed change, based on the scientific data referenced, will be more effective and thus more protective of public health, leading to fewer incidents of vibriosis.

¹ Average wage for the Washington oyster industry based on OSWP survey.

Disposition of oysters recordkeeping requirement: Time of harvest to temperature control.

The current rule already requires recordkeeping to document harvest data, time of exposure to ambient air temperature, and time of temperature control. The proposed change requires making one additional entry in a log to record disposition of the oysters that fail to meet the required time from harvest to temperature control.

Costs:

The additional recordkeeping required by the proposed rule is minimal, one minute or less per month per licensed harvester or dealer.

Benefits:

Minimizing the time the oysters potentially containing *Vibrio parahaemolyticus* are exposed to ambient air temperature and before being secured in a controlled temperature environment is crucial to limiting pathogen growth. The department reviews these records during regular inspections. When violations are discovered, inspectors take appropriate corrective action, which may include confiscation and destruction of oysters. Dealers and harvesters will be required to record disposition of the oysters as a record for future inspection. This change contributes to retail marketing of only wholesome oysters which in turn reduces the incidence of vibriosis among consumers and potential growing area closures and oyster recalls due to outbreaks.

Refresher training requirement.

The proposed rule creates a retraining requirement for licensed dealers or harvesters whose practices have been determined by an illness investigation to be reasonably likely to have caused vibriosis. In addition, the rule clarifies the existing requirement that all licensed harvesters and dealers must complete training prior to harvesting or shipping oysters intended for raw consumption. The rule now clearly states that the training is required initially, and that refresher training is required when a significant rule change is made. The proposed change assumes more educated harvesters will result in better compliance with the rule requirements which will reduce incidence of illness.

Costs:

There is no cost associated with this requirement as the training will be offered free of charge by the department in 2009 at times when harvesting is not possible due to tide status. The retraining will be conducted by OSWP staff during technical assistance inspections.

Costs Avoided:

The clarification to the current rule has been interpreted to require annual training. The proposed rule requires an initial training prior to harvesting oysters for raw consumption, and a refresher training any time after a significant rule change is adopted. The department assumes refresher training will be necessary every three to five years and that it will need to be conducted in a timely manner without regard for optimal harvest tides. This could result in the dealers and harvesters having to forfeit a day's, or portion of a day's harvest every three to five years. This creates an overall cost avoidance when compared to an annual training requirement.

To determine an annual cost of training, there are 72 harvesters licensed to harvest oysters by OSWP and, under the proposed change, each would have to attend a half day training in order to be eligible to harvest. There are approximately 140 companies that are dealers licensed as shellstock shippers or shucker packers that also harvest. This requirement would result in approximately 106 days ($72 \times 0.5 = 36$ days, plus $140 \times 0.5 = 70$ days) of lost production. The estimated cost of lost production to attend the mandatory training sessions is \$11,660 (106 multiplied by \$110.00 per day in oyster value). To estimate lost wages associated with this requirement, the department considered only time for shellstock shippers and shucker packers as harvesters are not paid an hourly rate (140×4 hours = 560 hours). The estimated wages are then \$7,280 (560 hours multiplied by \$13.00 per hour). The estimated cost is \$11,660 in lost production and \$7,280 in lost wages totaling \$18,940 for a single training. Based on the department assumption that refresher training will be required once every three to five years rather than annually, the costs avoided would range from \$37,880 ($\$18,940 \times 2$ years) to \$75,760 ($\$18,940 \times 4$ years).

Benefits

The benefit of this requirement is not directly quantifiable; however, the required training will increase knowledge about *Vibrio parahaemolyticus* and emphasize the necessity and importance of following the harvest time to temperature controls established in this rule. This protects the public health by decreasing the risk of exposure to the *Vibrio parahaemolyticus* bacterium which in turn reduces the incidence of vibriosis among consumers and potential growing area closures and oyster recalls due to outbreaks. The more oyster harvesters know about the risk posed by *Vibrio parahaemolyticus*, the more that risk is reduced.

Conclusion

The estimated quantifiable costs associated with the requirements of the proposed changes to rule are \$6,630. Some costs are not quantifiable, including minor recordkeeping time increases and retraining costs conducted during unfavorable tides. Costs avoided for clarifying the existing training requirement range from \$37,880 to \$75,760.

Using the *Codex Alimentarius'* Codex Committee on Food Hygiene² published figures, one case of vibriosis illness costs an estimated \$1,596 and \$18,501 for a hospital admission related to vibriosis. Washington averages 18 cases of laboratory confirmed vibriosis a year, excluding the outbreak years of 1997, 1998, 2006, and 2007. Washington also averages one hospitalization for vibriosis a year, again excluding the outbreak years. Taking the 45 confirmed cases of vibriosis in 2008 and multiplying by the observed natural decline of 17.2% yields a 7.74 or 8 case decline to 37 cases expected for 2009.

Depending on whether these changes result in a minimal change to the average number of 18 vibriosis cases in 2009, or the rule meets the intent of reducing vibriosis illnesses to 10 or fewer cases in 2009, the costs avoided could range from \$48,825 to \$59,997. The costs avoided based on average number of 18 illnesses are calculated by subtracting the annual average of 18 cases from 37. OSWP could expect to see a decrease of at least 19 cases of vibriosis with one requiring hospitalization. Using this method to calculate expected illnesses, the potential costs avoided could be \$47,229 ($18 \text{ cases} \times \$1,596 + 1 \times \$18,501 = \$47,229$). The costs avoided based on the Washington state goal of 10 illnesses or fewer

² Discussion Paper on Risk Management Strategies for *Vibrio spp.* in Seafood, *Codex Alimentarius Commission*, Codex Committee on Food Hygiene, 35th Session, Orlando, Florida, January 27 to February 1, 2003.

are calculated by subtracting the maximum goal of 10 cases from 37. OSWP could expect to see a decrease of 27 cases of vibriosis with one requiring hospitalization. Using this method to calculate expected illnesses, the potential costs avoided could be \$59,997 (26 cases X \$1,596 + 1 X \$18,501 = \$59,997).

In addition to the benefits described above, there is additional non-quantifiable benefit associated with the proposed changes. The shellfish industry is unique in that it relies solely on reputation for advertising and marketing. For this reason, when incidents of illness outbreaks and recalls are publicized, the effect on the industry can be dramatic and severely detrimental because they do not have a mechanism to counter the negative publicity. Controls that reduce the risk of illness outbreak and recall greatly benefit the oyster producers because they reduce or eliminate negative publicity.

Based on the preceding quantitative and qualitative analysis, the State Board of Health determines that the probable benefits of the proposed rule outweigh the probable costs.

Alternatives Considered

DOH staff worked closely with industry and interested constituents such as the Northwest Indian Fisheries Commission, Point No-Point Treaty Council, the U.S. Food and Drug Administration, individual tribes, and the Pacific Coast Shellfish Growers Association, to minimize the burden of this rule. The OSWP had five meetings with a *Vibrio* Advisory Group composed of volunteers from among the interested parties listed above. DOH staff acted in a support role and provided data and scientific analysis as requested by the group, but did not direct the work of the advisory group.

The regulatory requirements recommended by the advisory group and recommended to the state Board of Health were voluntary self-imposed limits dictated by the scientific information available, as well as practical considerations concerning industry practices, many of which were selected for modification by the advisory group in the interest of controlling *Vibrio parahaemolyticus*. As part of their work, the advisory group reviewed requirements of both the emergency rule and the federal *Vibrio parahaemolyticus* interim control plan as contained in the 2007 NSSP Model Ordinance. Ultimately the following alternatives were rejected as too burdensome for licensees or inadequate to control *Vibrio parahaemolyticus*-related illness.

- Less time allowed in the base harvest time to temperature controls;
- Growing area closure as a result of sporadic illness for all shellstock and shucked products;
- Application of the control plan to only areas that have been epidemiologically-linked to a vibriosis illness; and
- Growing area closure for oysters intended for raw consumption during the entire summer season.

Requirements for Private vs. Public Entities

This rule does not impose more stringent performance requirements on private entities than on public entities.

Other Federal or State Law - Violations

This rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Other Federal, State, or Local Law - Differences

This rule does not differ from any applicable federal regulation, state statute, or local law.

Other Federal, State, or Local Law - Coordination

This rule is coordinated to the maximum extent practicable with other applicable laws, as evidenced by the inclusion of the U.S. Food and Drug Administration representatives in the advisory group deliberations over this rule. The U.S. Food and Drug Administration Regional Shellfish Representatives have kept Headquarters, U.S. Food and Drug Administration, through the Office of Seafood and Office of Regulatory Affairs, fully informed of the content and progress of the state Board of Health *Vibrio parahaemolyticus* control plan rulemaking process, as well as making sure that it complied with all applicable federal laws and regulations.