Final Significant Analysis

WAC 246-282-006
Vibrio parahaemolyticus Control Plan

March 2008

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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 internally. The shellfish industry in Washington includes 334 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.) *Vibrio parahaemolyticus* bacterium is active in warmer temperatures and dormant in cooler temperatures, and has one of the fastest reproductive 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-to-temperature control.

Mandatory reporting of vibriosis was established in 1975. Since then, Washington State has experienced two major outbreaks of illness; 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-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, a stricter 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, as well as significantly increased frequency of sporadic cases of vibriosis, demonstrates that the provisions of the 2005 NSSP Model Ordinance and the stricter requirements of the 2007 emergency rule do not adequately address this public health issue. As a result, the Washington State Board of Health (the board) is proposing a rule detailing a state-specific *Vibrio parahaemolyticus* control plan that would be stricter than the 2007 emergency rule. The proposed rule includes the following:

- Time-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 proposed rule is intended to reduce the risk to the public of acquiring vibriosis from the consumption of raw and undercooked oysters. The rule is designed to do this by establishing shorter time-to-temperature controls during the months of most concern (May through September) in growing areas most likely to be associated with vibriosis. This rule also establishes additional time-to-temperature controls and potential growing area closure requirements in response to sporadic cases of vibriosis.

The proposed rule also imposes 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 is necessary to verify appropriate handling that limits pathogen growth in oysters intended for raw consumption.

In order for this rule to be properly implemented and practiced by the commercial oyster growers in Washington State, a training requirement for all who intend to commercially harvest raw oysters for human consumption is established by the proposed rule.

Finally, this rule requires changes in the Harvest and Hazard Analysis Critical Control Point (HACCP) plans of licensed dealers.

Necessity of Significant Analysis

A significant analysis is required for this rule because it creates 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 clearly 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 requirements that 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 on a par with or exceeding those the state experienced in 2006. 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 *Vibrio parahaemolyticus*-associated illness to 10 or less reported illnesses per year, which is consistent with the suspected vibriosis risk per 100,000 meals as established by federal standard. While the 2007 emergency rule did not meet this goal, it was somewhat effective in reducing vibriosis. 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 current rule, which adopts the 2005 NSSP Model Ordinance, requires reduced time-to-temperature controls during summer months and growing area closure based on *Vibrio parahaemolyticus* action levels in the shellfish growing water. The proposed rule further reduces time-to-temperature controls during the months of concern, establishes additional time-to-temperature controls and potential growing area closure requirements in response to sporadic cases of vibriosis, establishes training and record keeping requirements, requires changes in Hazard Analysis Critical Control Point (HACCP) plans of licensed dealers, requires creation of harvest checklists for licensed harvesters, and eliminates growing area closures related to *Vibrio parahaemolyticus* action levels.

With these revised protective measures in place, the Office of Shellfish and Water Protection (OSWP) expects to see a significant decrease in the number of reported cases of vibriosis in 2008 compared to the number of cases in 2007 and a significant decrease in the number of growing area closures and recalls associated with illness outbreaks.

The proposed rule includes five requirements. Each is analyzed individually below in comparison to the current rule and includes the costs of the proposed requirement, avoided costs for requirements of the current rule that are not included in the proposed rule, and benefits of the individual requirement being analyzed. Some costs included in this analysis are calculated based on the similarities between the proposed rule and the 2007 emergency rule to obtain reasonably accurate probable costs.

1. Time-to-temperature control requirements

The current rule allows 12 hours time-to-temperature control for oysters harvested during the summer months. It also relies on two genetic markers; one to determine if *Vibrio parahaemolyticus* is present, and, if the bacteria is present, another to determine if it is a strain of bacteria that has the potential to cause illness (pathogenic). When specific

threshold levels are detected for the pathogenic form of *Vibrio parahaemolyticus*, stricter time-to-temperature control is required. Tissue sampling and laboratory analysis is necessary to determine the levels of *Vibrio parahaemolyticus* and the pathogenic condition of *Vibrio parahaemolyticus*. Laboratory analysis of samples takes 2 to 4 days to yield results, during which time an outbreak can occur. Relying on these genetic markers are thus reactive rather than predictive of illness outbreaks.

The time-to-temperature control and environmental sampling in the current rule does not adequately prevent vibriosis. As a result, sporadic illness and outbreaks occur. The distinction between a sporadic illness and an outbreak is that an outbreak involves two or more related illnesses epidemiologically-linked to a single harvest area. Sporadic illness is a single illness unrelated to any other illness in time and place. Under the NSSP Model Ordinance, outbreaks require investigation to determine the source of the illnesses; growing area closure for all shellfish, not just oysters intended for raw consumption; and recall of oysters intended for raw consumption. This requirement cannot be modified by state rule. A closure can impact large areas of Puget Sound and large numbers of oyster growers and harvesters. The expected result of the proposed time-to-temperature control requirements is significant reduction in the incidence of sporadic illnesses and outbreaks.

The proposed rule requires a more preventative time-to-temperature control based on historical illness data associated with growing areas and the months of the year that *Vibrio parahaemolyticus* is most likely to be problematic. All Puget Sound growing areas, including the Strait of Juan de Fuca, are subject to the requirements of the proposed rule. Growing areas in Grays Harbor and Willapa Bay where oysters have been epidemiologically associated (linked) as the source of *vibriosis* are also subject to the requirements of the proposed rule. The specific time-to-temperature control requirements of the proposed rule are listed in Tables 1 and 2 below.

Table 1
Puget Sound Growing Areas
(Including the Strait of Juan de Fuca)

Months of Control	Time-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-to-Temperature Control
July and August	Ten hours

To further reduce the possibility of vibriosis outbreaks and resulting growing area closure for all oysters, the proposed rule establishes reduced time-to-temperature control based

on sporadic illness. In the event of two sporadic illnesses within thirty days linked to a single growing area, all licensed harvesters and dealers in the implicated growing area must reduce the time-to-temperature control by one hour. In the event of two additional sporadic vibriosis illnesses within thirty days under the one hour reduced time-to-temperature control, the growing area will be closed to harvest and shipment of oysters intended for raw consumption throughout the remainder of the control months. An exemption to closure is allowed if the licensed harvester or dealer can demonstrate to the Department of Health (the department) that an additional one hour reduction in time-to-temperature control can be successfully implemented. The approved procedure must be established in writing.

The proposed rule provides licensed dealers and harvesters the opportunity to store oysters submerged near the beach or in deeper water for pickup and transport at a later time. This is intended to provide additional time beyond the time-to-temperature control to complete harvest without jeopardizing public health.

The proposed rule does not change the federal requirement to close growing areas linked to outbreak illness.

The proposed rule also requires licensed harvesters and dealers to either destroy oysters or return oysters to the original growing area for 24 hours if the required time-to-temperature control period is exceeded.

Costs:
The department assumes that companies will likely choose from two options to comply with the time-to-temperature requirements of the proposed rule: reduce harvest times to only those identified in the control plan for the geographic location and month of year, or submerge oysters for storage and later retrieval. The department further assumes that 50 percent of the approximately 200 licensed companies will choose to reduce harvest times and 50 percent will choose to use submerged harvest techniques. Under this assumption, the compliance costs for the proposed requirements are the opportunity costs of the hours that harvesting is not conducted beyond the specified time-to-temperature control. The costs estimated below are based on annual Puget Sound harvest figures for oysters. Willapa and Grays Harbor would see reduced harvest opportunities with a reduced time-to-temperature control from 12 to 10 hours for July and August only. However, by basing the calculation of costs on annual production rates for the more productive growing areas in Puget Sound, the reduced harvest opportunity for Willapa and Grays Harbor are adequately addressed. Although time-to-temperature control for May is reduced from 36 hours to 12 hours, there are no costs calculated for this change. The department assumes that dealers are meeting this harvest time currently in preparation for warmer weather months.

For those companies that elect to store oysters submerged for later retrieval as provided for in the proposed rule, the harvest curtailment would not apply. However, this method could probably only be employed by about half of the 200 companies identified above because of equipment requirements and location considerations. This means

approximately 100 companies would be able to continue harvesting at normal capacity May through September with no lost revenue.

For those companies who elect to harvest within the time-to-temperature controls specified in the proposed rule, the department assumes available harvest time would be reduced in Puget Sound from 12 hours to 5 hours during the months of June and September, and from 12 hours to 4 hours in July and August. Assuming 28 days of harvest for each of these months, the result is a decrease in hours available for harvest of 392 hours total during June and September, and 448 hours during July and August. Natural tidal cycles limit the amount of time harvesting can occur.

Harvesting can only occur during daylight hours and low tides. Because the low tide for a 24 hour cycle intermittently occurs during the night when harvesting cannot be done, this analysis does not assume a direct reduction in harvest opportunity from 12 hours for all four months of control. (Based on the hours calculated above, direct reductions would be 58% in June and September, and 67% in July and August). Instead, harvest opportunity reductions are calculated based on projected tide cycles for 2008 taking into account the time of day for each low tide. This equates to a 29% reduction in available harvest time for June and September, and a 33% reduction in available harvest time for July and August. Because tide cycles change yearly, these changes will vary from year to year.

The department assumes that 65% of the 31,000,000 pounds of shellfish harvested annually in Washington is oysters harvested from Puget Sound, including those intended for raw consumption (approximately 20,150,000 pounds). The department also assumes equal distribution of harvested oysters across the twelve months (1,679,167 pounds monthly). The total volume of oysters normally harvested during June through September (6,716,668) equates to a retail value of $4,365,834.00 (6,716,668 divided by 5 pounds per dozen, multiplied by $3.25 per dozen). This averages to $1,091,459.00 per month.

Applying the 29% reduction in available harvest time for June and September results in an estimated reduced income of $316,523.00 ($1,091,459.00 multiplied by .50 of companies, multiplied by 2 months, multiplied by 0.29), Applying the 33% reduction in available harvest time for July and August results in an estimated reduced income of $360,181.00 ($1,091,459.00 multiplied by .50 of companies, multiplied by 2 months, multiplied by 0.33). The total estimated annual reduction is $676,704.00

Based on the assumptions identified above, the total estimated cost of compliance for the proposed time-to-temperature control is $676,704.00. However, actual costs are expected to be different due to the following factors: Additional costs for wages associated with transporting oysters after being submerged, reduced costs associated with oysters that don't meet time-to-temperature control that are sold under a "for cook only" label, reduced costs associated with the practice of icing oysters to achieve temperature control while continuing to harvest during the entire low tide, and reduced costs associated with the fact that there is not a strict one-to-one relationship between available harvest time

and income because such factors as weather are being discounted. With these variables, the department assumes the cost estimated in this analysis for reduced time-to-temperature control requirements is overestimated.

There are harvesters for whom the proposed time-to-temperature control would impose a unique cost. Tribal harvesters, whose growing areas are often remote and difficult to access, might have to forego harvest in some instances with a resulting loss in revenue of $110.00 to $220.00 per harvest ($2.20 per dozen oysters harvested, multiplied by a typical daily harvest of 50 to 100 dozen oysters per harvester). There are 14 tribes that harvest oysters in Washington State with approximately 12 harvesters per tribe for a total of 168 harvesters. A second concern of tribal harvesters is the lack of security at some of their growing areas, which are also public beaches or state parks. If they were forced to submerge their days' harvest of oysters prior to delivering them to the buyer, they could lose some to all of their oysters to theft which, again, would amount to $110.00 to $220.00 per harvest for each harvester. The estimated cost of this requirement is based on the percentage of licensed companies that did not harvest oysters for raw consumption in 2007; 10 percent. The estimated cost of this requirement to tribal harvesters ranges from $31,790.00 ($110.00 multiplied by 17 harvesters multiplied by 17 weeks) to $63,580.00 ($220.00 multiplied by 17 harvesters multiplied by 17 weeks).

No costs are attributed to destroying or returning oysters to the original growing area if the required time-to-temperature control period is exceeded. Consequences of not complying with the time-to-temperature requirements of the proposed rule are not considered a cost of the proposed rule.

When an outbreak occurs, the NSSP Model Ordinance requires growing area closure for all species of shellfish and requires recall of all species from that growing area. The proposed state rule does not change this requirement. The proposed rule adds a growing area closure requirement for oysters intended for raw consumption due to sporadic cases of vibriosis. This requirement does not include any other species of shellfish. The department assumes the proposed requirement will likely reduce or eliminate the number of outbreaks, and thus the number of growing area closures and recalls for all species of shellfish related to outbreaks. Since there is no way to predict which growing areas will experience sporadic illness or outbreaks, there is no way to estimate the cost or benefit of this proposed requirement so costs are assumed to be neutral for the purposes of this analysis.

The estimated range of cost associated with reduced time-to-temperature control, including costs for tribal harvesters, is from $679,883.00 to $740,284.00 as illustrated in Table 3 below.

Table 3
Estimated Cost for Reduced Time-to-Temperature Control

Cost Category	Low range	High range
Time-to-temperature	$676,704.00	$676,704.00
Reduced tribal harvest	$31,790.00	$63,580.00
Total	$679,883.00	$740,284.00

Avoided Costs:

Research conducted by OSWP during the 2007 months of concern showed that the methodology of preventing illness by closing growing areas based on *Vibrio* parahaemolyticus presence in the shellfish growing water as established in the current rule is not effective. This is demonstrated by reported illnesses associated with growing areas where no pathogenic *Vibrio parahaemolyticus* was detected; and, conversely, no reported illnesses associated with growing areas with significant levels of pathogenic *Vibrio parahaemolyticus*. Since this requirement is eliminated in the proposed rule, all associated costs are also eliminated, though they are minimal.

Some companies shifted product mix during the summer of 2007 when the risk of vibriosis was the highest, foregoing, for example, the single shell market. This reduced their normal income by 20% to 50%, depending on their normal product mix. As an example of this practice, one company lost $16,000.00 per week (a 40% loss) or $272,000.00 for the 17 weeks of control during 2007.

Approximately 20 companies elected not to harvest at all – or to suspend operations – during the summer when vibrio risk was highest in 2007. This resulted in income losses ranging from $800.00 to $5,000.00 per week depending on the size and type of the company. To calculate the avoided cost, the estimated value of $3,500.00 per company per week is used. The total income loss is estimated at $1,190,000.00 for the 17 week period of vibrio risk. Assuming all these companies will choose to operate during the 2008 summer due to a decreased risk of vibriosis created by the proposed rule, the department assumes the total cost of not operating due to vibrio risk will be avoided.

The proposed rule provides an opportunity for businesses to continue harvesting if they obtain a department-approved exemption to closure. However, there is no clear indication whether this exemption will be used, so there is no way to estimate for these avoided costs.

The most significant cost avoided that can be attributed to the time-to-temperature control and related requirements of the proposed rule is the cost of illness avoided. Using the Centers for Disease Control and Prevention methodology for determining actual disease incidence from reported incidence developed by *Mead et al*[1], it is possible to estimate the actual incidence of *Vibrio parahaemolyticus*-associated illness in Washington State. Then, using the illness cost data provided by the *Codex Alimentarius'* Codex Committee on Food Hygiene[2], the economic burden of *Vibrio parahaemolyticus*-associated illness on the people of Washington State is estimated in Table 4 below. As outlined in the cited authorities, the assumptions are:

[1] Paul S. Mead, Laurence Slutsker, Vance Dietz, Linda F. McCaig, Joseph S. Bresee, Craig Shapiro, Patricia M. Griffin, and Robert V. Tauxe, **Food-Related Illness and Death in the United States**, Centers for Disease Control and Prevention, Atlanta, GA, 2001.

[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.

- Actual *Vibrio parahaemolyticus*-associated illnesses are 20 times greater than reported illnesses;
- The cost of *Vibrio parahaemolyticus*-associated illness for a single case is $1,596.00;
- The cost of a hospitalization due to *Vibrio parahaemolyticus*-associated illness is $18,501.00;
- The average annual reported confirmed *Vibrio parahaemolyticus*-associated illness incidence in Washington State, excluding the outbreak years, is 18; and
- 1997, 1998, 2006, and 2007 were either outbreak years or years of exceptionally high incidence of *Vibrio parahaemolyticus*-associated illness in Washington State.

Table 4
Occurrence and Cost of Illness in Washington State

Year	Reported Illnesses	Actual Illnesses	Cost of Illness
1997	58	1,160	$1,851,360.00
1998	48	960	$1,532,160.00
2006	89*	1780	$2,877,882.00**
2007	53*	1,140	$1,819,440.00
2008	10	200	$319,200.00***

*Reported illnesses for 2006 and 2007 do not include illnesses associated with recreational harvest.
** Two cases resulted in hospitalization, the cost of which is included in the total cost of illness.
*** Projected occurrence and cost of illness calculated for the proposed rule during 2008.

As stated earlier, the goal of the proposed rule requirements is to reduce the incidence of *Vibrio parahaemolyticus*-associated illness to 10 or less reported illnesses, which is consistent with the suspected vibriosis risk per 100,000 meals as established by federal standard. This rate of illness would result in an annual economic burden of $319,200.00 for *Vibrio parahaemolyticus*-associated illness assuming no hospitalization costs. The effect of the proposed rule changes measured in avoided costs of illness could be as much as $2,558,682.00.

The estimated avoided cost associated with reduced time-to-temperature control and related requirements is up to $4,020,682.00.

Benefits:
The proposed rule provides enhanced accuracy in imposing time-to-temperature controls and growing area closures that are likely to result in drastically-reduced illness incidence and the potential elimination of outbreaks of vibriosis. The proposed rule, based on scientific data collected over the previous two years, will be more effective and thus more protective of public health, leading to fewer incidents of vibriosis.

2. Harvest record requirement

The current rule already requires recordkeeping to document harvest data. The proposed rule requires making two additional entries in a log to record time of exposure to ambient air temperature and time of entering temperature control.

Costs:
The additional recordkeeping required by the proposed rule is minimal, one hour 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 growth of the pathogen. The department monitors these logs during regular inspections. When violations are discovered, staff take appropriate corrective action which may include confiscation and destruction of oysters. This requirement 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.

3. Training requirement

The current rule does not include a training requirement. The proposed rule 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 2008 at times when harvesting is not possible due to tide status.

Benefits
The benefit of this requirement is not directly quantifiable; however, the required training would increase knowledge about *Vibrio parahaemolyticus* and emphasize the necessity of following the 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.

4. HACCP plan and harvest checklist requirements

The current rule requires HACCP (Hazard Analysis Critical Control Point) plans for all licensed dealers. Licensed harvesters are not required to have a HACCP plan. The proposed rule requires licensed dealers to modify their HACCP plans and licensed

harvesters to develop a written plan to specifically address harvest protocols that will be used to place oysters intended for raw consumption under temperature control.

Costs:
The cost of this requirement would be minimal; less than 1 hour total. If the company elects to adopt the example provided by OSWP, the total time would be measured in minutes. There is no measurable cost for this proposed rule requirement.

Benefits:
This element of the control plan requires commercial companies harvesting oysters to document the harvest methods and time-to-temperature control measures they will use to reduce the risk of exposure to *Vibrio parahaemolyticus* which in turn reduces the risk of vibriosis and potential growing area closures and recalls due to outbreaks. This provides a guide to risk-reducing behaviors on the part of the harvesters.

5. Conclusion

The estimated quantifiable costs associated with the requirements of the proposed rule range from $679,833.00 to $740,284.00. Some costs are not quantifiable, including growing area closure as a result of multiple sporadic illnesses.

Total estimated quantifiable benefits, including avoided costs, related to reduced time-to-temperature controls are up to $4,020,682.00. Other non-quantifiable avoided costs include those related to growing area closures and recalls that will not occur under the requirements of the proposed rule because of more effective time-to-temperature control, recordkeeping, training, and modified HACCP plans and harvest checklists.

In addition to the benefits described above, there is additional non-quantifiable benefit associated with the proposed rule. The shellfish industry is unique in that it relies solely on word-of-mouth and 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 producers of oysters 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 Office of Shellfish and Water Protection 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 that were adopted by the advisory group and recommended to the state Board of Health were voluntary and self-imposed limits dictated by the extent of 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 2005 NSSP Model Ordinance. Ultimately the following alternatives were rejected as too burdensome for licensees or inadequate to control *Vibrio parahaemolyticus*-related illness.

- More time allowed in the base time-to-temperature controls;
- Use of environmental monitoring for the pathogenic form of *Vibrio parahaemolyticus* as a basis for reduced time-to-temperature control;
- Use of environmental monitoring for the pathogenic form of *Vibrio parahaemolyticus* as basis for growing area closure;
- Use of environmental monitoring for the pathogenic form of *Vibrio parahaemolyticus* as basis for reopening a closed growing areas;
- 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.