# PRELIMNARY SIGNIFICANT ANALYSIS

WAC 246-282-006

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*Vibrio parahaemolyticus* Control Plan

January 21, 2015

**Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.**

Washington State produces oysters intended for raw consumption for state, national and international markets. According to the Washington Shellfish Initiative, Washington's shellfish industry contributes over $270 million towards the economy with much of Washington's oysters exported nationally and internationally. The shellfish industry in Washington includes 349 licensees dealing with all types of shellstock, including clams, oysters, geoduck, and others. Approximately 150 of these licensees deal with shellstock oysters during the summer months and so are directly affected by the proposed rule. These licensees include tribal, 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 is frequently nondetectable in cooler temperatures (DePaola et al 1990; DePaola et al 2002). It has one of the fastest growth rates among human pathogens and can double in about 1.5 hours at 80 degrees Fahrenheit (unpublished data, Dr. DePaola). As a result, vibriosis occurs primarily during the summer months with an increased incidence of illness during warmer years compared to cooler years (Daniels et al 2000; Martinez-Urtaza et al 2010). 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 as possible after they have been exposed to ambient air temperature (Su and Lin 2007). Exposure to ambient air begins when the tide recedes and water no longer covers the oysters or when oysters are removed directly from the water. This gap between the time of exposure to ambient air and the placement of oysters into a controlled temperature environment is known as time of harvest to temperature control. It is important to cool oysters to 50 degrees Fahrenheit once they are in temperature control because *Vibrio parahaemolyticus* no longer grows at this temperature, which reduces the opportunity for post-harvest growth. In addition to these post-harvest strategies, there are conditions where water temperatures allow *Vibrio parahaemolyticus* growth to levels that can cause illness. In these scenarios, post-harvest controls are unable to prevent illness and suspending harvest is the only known measure to prevent illness.

Washington State has experienced two major vibriosis 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 a large outbreak of *Vibrio parahaemolyticus*-associated illness. 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. Washington State adopted the 2005 NSSP Model Ordinance permanently in September 2007 after the emergency rule expired. The Washington State Board of Health adopted a more stringent rule in 2008 detailing a state-specific *Vibrio parahaemolyticus* control plan. The rule established shorter time of harvest 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. In 2009 the rule was revised to increase training and recordkeeping requirements.

Since 2009 Washington has not seen a decline in vibriosis illnesses attributed to Washington oysters. The current rule has held illnesses fairly steady at approximately 40 to 50 reported illnesses per year that are traced back and attributed to Washington state commercial oyster harvest, but occurrences of sporadic illnesses are still prevalent in the warmer months. The state has also seen an increase in coastal illnesses, particularly in the month of September, which indicates that the current control plan is not adequately preventing illnesses.

The proposed rule change uses a new approach where *Vibrio parahaemolyticus* controls are based on environmental conditions. The proposed rule uses relative risk based on the number of illnesses historically associated with each growing area to establish controls for each growing area. The proposed rule incrementally eliminates the division of controls based on coastal and inland growing areas. The rule also increases the stringency of temperature control requirements. These changes aim to reduce the post-harvest growth of *Vibrio parahaemolyticus* and restrict harvest when *Vibrio parahaemolyticus* levels in the water may cause illness. The proposed rule establishes new recordkeeping requirements to ensure harvesters and shellfish dealers are meeting the new requirements.

**Is a Significant Analysis required for this rule?**

A significant legislative rule is defined under 34.05.328(5)(c)(iii) as a rule, other than a procedural or interpretive rule, that:

- Adopts substantive provisions of law pursuant to delegated legislative authority, the violation of which subjects a violator of such rule to a penalty or sanction;
- Establishes, alters, or revokes any qualification or standard for the issuance, suspension, or revocation of a license or permit; or
- Adopts a new, or makes significant amendments to, a policy or regulatory program.

The department evaluated the rule and determined it is a significant legislative rule under the definition provided in statute and requires a significant analysis that includes a cost/benefit analysis.

**Clearly state in detail the general goals and specific objectives of the statute that the rule implements.**

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.

**Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.**

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

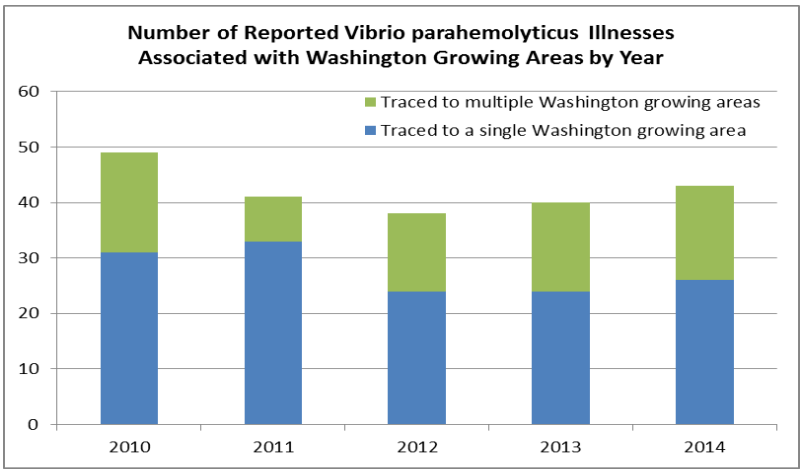
The U.S. Food and Drug Administration (FDA) requires a *Vibrio parahaemolyticus* control plan for the state of Washington and requires that the plan be in compliance with requirements set forth in the NSSP Model Ordinance. The current control plan is out of compliance with this guide. Failing to update the Washington state control plan could result in licensees being unable to place molluscan shellfish into interstate commerce.

Not adopting the proposed changes would lead to a continued high 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.

**Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.**

<u>Introduction:</u>

The goal of the proposed rule is to reduce the incidence of vibriosis illnesses. Since the 2009 rule revision there were a total of 211 confirmed illnesses traced back to and associated with commercially harvested oysters from Washington State. The Centers for Disease Control and Prevention (CDC) estimates that for every laboratory confirmed *Vibrio parahaemolyticus*-associated



illness that is reported, an additional 156.64 illnesses may actually occur (Scallan et al 2011). This broad discrepancy between illnesses that are reported and the actual burden of illnesses is due to under-reporting (factor of 1.1) owing to the passive nature of the illness reporting system and under-diagnosis (factor of 142.4) owing to the steps that need to occur for an individual to become a confirmed illness (Scallan et al 2011). For an illness to be reported, an individual must seek medical care, must submit a specimen to be tested, the *Vibrio* specific lab testing must be requested, and the appropriate test must be used. All of these steps provide an opportunity for under-diagnosis of illness. Using the CDC's methodology for estimating the burden of illness, more than 30,000 illnesses have occurred from commercially-harvested oysters in Washington between 2010 and 2014 with an average of 6,610 illnesses per year.

Given the large discrepancy between reported illnesses and the estimated burden of illness, it is challenging to assess the effectiveness of the current *Vibrio parahaemolyticus* controls in place. Further confounding this issue is the lack of reliably reported oyster production data for the control plan months and the expected year to year variability in *Vibrio parahaemolyticus* levels and populations due to each year's prevailing environmental conditions.

Summary of Proposed Rule Changes:

- Remove current rule exemptions for portions of Grays Harbor and Willapa Bay and for exemptions to the control plan based on the criteria of no illnesses being associated with an individual company. The proposed rule changes do allow harvesters and shellfish dealers to request a waiver from specific requirements in the control plan when the request is consistent with the applicable standards and the intent of the rule section and provides a comparable level of public health protection to the requirement being waived.
- Move from time of harvest to temperature control to time of harvest to cooling. Under the current rule, shellfish harvesters and dealers have a set number of hours to place oysters under temperature control and then ten additional hours to reach 50 degrees Fahrenheit. The proposed rule requires time of harvest to cooling, where shellfish harvesters and dealers must cool oysters to 50 degrees Fahrenheit within a set number of hours. The time of harvest to cooling requirements are based on the relative risk of each area, which is established by the number of illnesses historically associated with the growing area over the previous five-year period. The changes also establish a novel approach to *Vibrio parahaemolyticus* control by using temperature to trigger additional time of harvest to cooling reductions and suspension of harvest.
- Clarify a number of subsections within this rule by removing redundancies with the NSSP Model Ordinance, clarifying unclear language, and adopting national standards set forth in the Model Ordinance.

With these revised protective measures in place, the Department of Health (department) expects to see a decrease in the number of reported illnesses of vibriosis compared to the number of illnesses reported over previous years. Given the confounding factors discussed above and the potential implementation challenges associated with this significant change the decline in illnesses may not be immediate. With this rule revision, the department also expects to see a decrease in the number of growing area closures and recalls associated with illness outbreaks.

Identification of Non-Significant and Significant Rule Changes by Subsection:

| Current Rule Subsection | Proposed Rule Subsection | Significant? | Rationale |
|---|---|---|---|
| 1 | 1 – 2 | No | Clarification |
| 2, 4 – 9 | 8 – 13, 15 | Yes | |
| 3 | 17 – 20 | Yes | |
| 10 | 14 | No | Clarification |
| 11 | | No | Clarification |
| 12 | 16 | No | Clarification |
| 13 | 5 – 7 | No | Clarification |
| | 3 | No | Clarification |
| | 4 | No | Procedural:<br>required in NSSP Chapter 2@.03(B) |

Description of Significant Rule Changes by Subject:

*Current Rule Subsections 2 and 4-9 and Proposed Rule Subsection 8-13 and 15*

*Coastal Growing Areas:* Under the current rule, growing areas in Grays Harbor and Willapa Bay where illnesses have not occurred are not included in the control plan, and growing areas where illnesses have occurred are included in the control plan, but with less stringent controls than inland growing areas. A total of nine growing areas make up the coastal areas of Grays Harbor and Willapa Bay. Of these nine growing areas, seven have been implicated in *Vibrio parahaemolyticus*-associated illnesses between 2009 and 2014. In three of the past five years, a greater number of illnesses have been traced solely to harvest from Grays Harbor and Willapa Bay than traced solely to harvest from the inland growing areas in Hood Canal. Further, the current rule is also very unclear as to what areas the exemption applies to since it does not state which areas within Grays Harbor and Willapa Bay have not been epidemiologically associated illnesses. Given the level of illness occurrence in these areas, all coastal growing areas are included in the proposed control plan and will be categorized using the same criteria as inland growing areas after a brief transition period. (See the description and analysis below for the effects of this change).

*Risk Categorization:* The proposed rule categorizes growing areas based on risk using historic (five-year) illness trends compared to the current rule which categorizes growing areas based on geography (coastal versus inland). This shift in categorization means that there is one plan for the entire state based on risk. Each growing area is placed in a category where the higher the risk the more stringent the controls are for the growing area. These categories mirror requirements in the NSSP MO for states to develop *Vibrio parahaemolyticus* control plans. When a state is implicated in two confirmed *Vibrio parahaemolyticus*-associated illnesses then the state must develop a control plan.

Under the proposed rule, a growing area is in the least stringent control category (category 1) if it had no or one illness over the previous five years. Areas that have had two illnesses, but less than five illnesses over the previous five-year period are in risk category 2. If the area averages one illness or more per year, then that area is in the highest risk category (category 3). There is

one exception to this categorization standard. Grays Harbor and Willapa Bay growing areas will be assigned category 1 for the 2015 control months even if a growing area would otherwise be placed in a different category based on the number of illnesses in the previous five-years. Thereafter, risk categorization for coastal growing areas will be determined based on the preceding five-year illness trend consistent with categorization of other growing areas in the state. This phased in approach recognizes the more stringent category 1 requirements as compared to the current coastal growing area requirements. It will also allow the department to determine if the category 1 requirements will adequately reduce illnesses attributed to coastal growing areas.

For risk categorization, illnesses are included only when they are associated with commercially-harvested shellstock, have occurred in the *Vibrio parahaemolyticus* control months, are not associated with known post-harvest abuse, and are traced to a single growing. By limiting the risk categorization based on these criteria only illnesses that could have reasonably been prevented by the control plan are considered. Illnesses outside of these criteria may be preventable, but not necessarily through a revised control plan. These illnesses include those associated with recreational harvest and multi-source illnesses. At a very basic level, recreational illnesses would not be prevented by a control plan for the commercial industry. Multi-source illnesses are those that potentially involve Washington oysters, but also potentially involve out of state oysters. These types of illnesses may not be preventable through this control plan. By targeting the controls based on illnesses that can likely be prevented, there is additional clarity and objectivity in what the control plan addresses. Illnesses that do not meet the criteria for risk categorization will still be tracked and investigated.

*Time of Harvest to Cooling Requirements:* The proposed rule bases time controls on specific product temperature requirements, not the act of placing product in a temperature controlled environment such as a refrigerator. The proposed rule shifts time controls from time of harvest to temperature control to time of harvest to cooling requirements, where cooling is defined as reaching and maintaining product at 50 degrees Fahrenheit or cooler. This shift to time of harvest to cooling will dramatically reduce post-harvest growth of *Vibrio parahaemolyticus* based on FDA risk modeling. The changes are as follows for coastal areas:

| Current:<br>Coastal | Proposed:<br>Category 1 |
|---|---|
| In July and August, 10 hours from time of harvest to temperature control . | From June through September, 9 hours from time of harvest to cooling. |

The changes are as follows for inland areas:

| Current:<br>Inland | Proposed:<br>Category 1 | Proposed:<br>Category 2 | Proposed:<br>Category 3 |
|---|---|---|---|
| In May 12 hours, in June and September 5 hours, and in July and August 4 hours from time of harvest to temperature control. | From June through September, 9 hours from time of harvest to cooling. | From May through September, 7 hours from time of harvest to cooling. | From May through September, 5 hours from time of harvest to cooling. |

In the current rule, time of harvest to temperature control reductions are in response to illnesses. In the proposed rule, time of harvest to cooling reductions are based on air and harvest temperatures (water or tissue temperature) during the control plan months. Reduction in time of harvest to cooling based on air temperatures is intended to reduce *Vibrio parahaemolyticus* growth during exposure. Reductions in time to cooling based on harvest temperature in July and August is due to the greater likelihood of illness during these months. These reductions are a preventative means of managing *Vibrio parahaemolyticus* compared to waiting for illnesses to occur and then reacting. This approach also serves to manage the pre-harvest risk inherent in warmer months and serves to reduce the post-harvest growth of *Vibrio parahaemolyticus* by reducing the number of hours to cooling based on elevated temperatures. In addition, by allowing harvesters and shellfish dealers to use water temperature or internal oyster tissue temperature to measure the harvest temperature, the proposed rule provides flexibility to accommodate different harvest practices and needs.

The changes are as follows for coastal areas:

| Current:<br>Coastal | Proposed:<br>Category 1 |
|---|---|
| 1 hour reduction in time of harvest to temperature control when 2 illnesses are associated with a growing area and have harvest dates within 30 days of each other. Reduction remains in effect through August. | 2 hour reduction in time of harvest to cooling when air temperature exceeds 90°F from June through September. |
| | 4 hour reduction when harvest temperature is between 68-70°F in July and August. |

The changes are as follows for inland areas:

| Current:<br>Inland | Proposed:<br>Category 1 | Proposed:<br>Category 2 | Proposed:<br>Category 3 |
|---|---|---|---|
| 1 hour reduction in time of harvest to temperature control when 2 illnesses are associated with a growing area and have harvest dates within 30 days of each other. Reduction remains in effect through September. | 2 hour reduction in time of harvest to cooling when air temperature exceeds 90°F from June through September. | 2 hour reduction in time of harvest to cooling when air temperature exceeds 85°F from May through September. | 2 hour reduction in time of harvest to cooling when air temperature exceeds 80°F from May through September. |
| | 4 hour reduction when harvest temperature is between 68-70°F in July and August. | 4 hour reduction when harvest temperature is between 66-68°F in July and August. | 4 hour reduction when harvest temperature is between 64-66°F in July and August. |

Reductions in time of harvest to cooling are not cumulative. The most stringent of the two standards apply when both air and harvest temperature thresholds are exceeded. For example, category 1 growing areas reduce time of harvest to cooling from 9 hours to 7 hours if air temperature exceeds 90°F in July. If under the same circumstances, the harvest temperature is

between 68 and 70°F, the time of harvest to cooling is reduced from 9 hours to 5 hours. The rule does not require cumulative reductions in time of harvest to cooling when both air temperature and harvest temperature thresholds are met.

*Closure requirements:* Similarly, the proposed rule bases closures on harvest temperature rather than based on the occurrence of illness. Harvest will no longer be allowed in July and August when certain harvest temperature thresholds are met rather than waiting for illnesses to occur and then reacting to those illnesses with closures. These closures, similar to time reductions, are a preventative means of managing *Vibrio parahaemolyticus* risk. The temperatures for these closures are based on temperatures at the time of harvest associated with single-source illnesses from 2012 to 2014. These preventative closures are an acknowledgement that there are conditions when *Vibrio parahaemolyticus* levels in the environment will cause illnesses and post-harvest mitigation strategies (such as cooling) are not sufficient to prevent illnesses from occurring. The changes are as follows for coastal areas:

| Current:<br>Coastal | Proposed:<br>Category 1 |
|---|---|
| Growing area closure when 4 illnesses are associated with a growing area and have harvest dates within 30 days of each other. Closure remains in effect through August. | Harvest is not allowed when harvest temperature is above 70°F in July and August. Closure remains in effect for 24 hours. |

The changes are as follows for inland areas:

| Current:<br>Inland | Proposed:<br>Category 1 | Proposed:<br>Category 2 | Proposed:<br>Category 3 |
|---|---|---|---|
| Growing area closure when 4 illnesses are associated with a growing area and have harvest dates within 30 days of each other. Closure remains in effect through September. | Harvest is not allowed when harvest temperature is above 70°F in July and August. Closure remains in effect for 24 hours. | Harvest is not allowed when harvest temperature is above 68°F in July and August. Closure remains in effect for 24 hours. | Harvest is not allowed when harvest temperature is above 66°F in July and August. Closure remains in effect for 24 hours. |

*Harvest temperature record requirement:* To meet these new controls for temperature and closure, harvesters and shellfish dealers will be required to take temperatures at the time of harvest using a thermometer that is calibrated weekly. While the use of a calibrated thermometer is currently required under the NSSP, the proposed rule requires thermometers to be calibrated weekly to ensure accuracy. The temperatures will be recorded in a harvest temperature log to demonstrate compliance with the new requirements. Making informed and thoughtful decisions regarding harvesting and handling oysters is not new to the shellfish industry. Records are frequently used to document compliance with regulations and the record keeping requirements within this rule are consistent with current expectations of the shellfish industry for safe harvest and handling of shellfish.

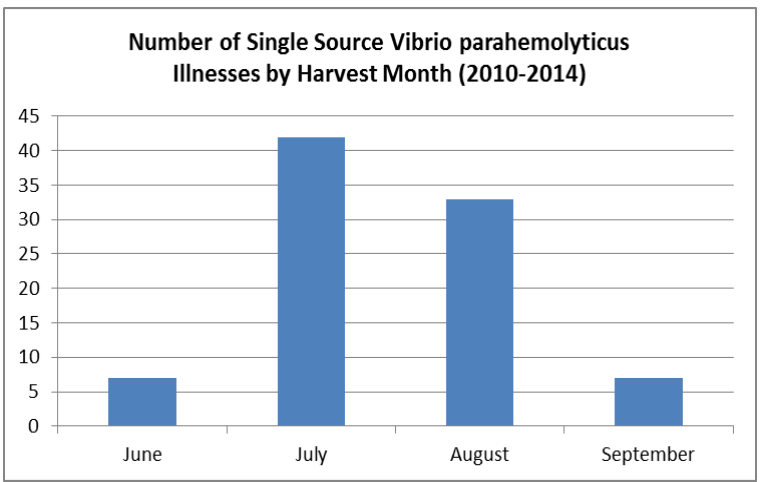
*Waivers:* Under the current rule, there is an exemption process for growing areas based on the criteria of no illness. The department is not allowed to implement this waiver based on FDA guidance as documented in the 2013 PEER Audit. The proposed rule creates a waiver system that allows harvesters and shellfish dealers an avenue for exemption from specific control plan requirements. To obtain a waiver, the harvester or shellfish dealer must show that their request: (a) is consistent with the applicable standards and the intent of this section; and (b) provides a comparable level of public health protection to the requirement being waived. This waiver is intended to accommodate slight variations in harvest practices while maintaining the public health protections provided by the proposed rule.

Benefits of the Proposed Rule:

Illnesses are likely to be prevented by incorporating all Grays Harbor and Willapa Bay growing areas into the rule. The phased in addition of these growing areas provides multiple benefits. It accounts for the far greater stringency of category 1 compared to the current coastal requirements. The current coastal controls apply solely to the months of July and August, while the proposed rule's least stringent risk category applies from June through September. The current coastal time of harvest to temperature control requirement is 10 hours, while the proposed rule's least stringent risk category time to cooling is 9 hours. The proposed rule also provides an opportunity for the department to determine if this change is sufficient to protect public health, and provides harvesters and shellfish dealers the benefit of being placed in a less stringent risk category than what the areas might be placed in based on the risk calculation alone.

Illnesses are likely to be prevented by changing from time of harvest to temperature control to time of harvest to cooling due to the increased stringency in these time controls. All growing areas will cool oysters to 50 degrees Fahrenheit in less than 10 hours. Growing areas in the most stringent risk category will cool oysters to 50 degrees Fahrenheit in 5 hours with a potential reduction to 1 hour under the most risk-prone circumstances identified in the rule. This is far more stringent than the current requirement of allowing 10 hours for shellfish harvesters and dealers to cool product to 50 degrees Fahrenheit. The FDA risk calculator models that this will likely lead to about a 75% reduction in illness (email communication, Dr. Andy DePaola and Dr. John Bowers).

In addition to the stricter time controls, not harvesting in July and August based on harvest temperature is also likely to reduce illnesses. Over the past five years, 84% of single-source illnesses occurred from harvest in July and August. However, the current rule requirements typically lead to closures in August and September when only 45% of the illnesses occurred in these months. By targeting the months of July and August for closure, there should be a further reduction in illnesses.




Under the current *Vibrio parahaemolyticus* control plan,

inland growing areas could be closed beginning in May if illnesses were reported early and associated with the same growing area(s). This closure would remain in effect through September regardless of shifts in environmental conditions and *Vibrio parahaemolyticus* levels. Under the proposed rule, growing areas can only close for a maximum of July and August, the peak risk period. This defined period allows individual businesses a greater ability to plan for potential closures. It also provides public health protection without imposing long and unpredictable closures on the shellfish industry.

An additional benefit to the shellfish industry in the proposed rule is the expanded language allowing companies to apply for a waiver from specific subsections of the rule when they demonstrate that their request: (a) is consistent with the applicable standards and the intent of this section; and (b) provides a comparable level of public health protection to the requirement being waived. The waiver will serve to provide public health protection while accommodating unique needs of specific companies. In addition, it is likely to foster innovation as the industry develops and demonstrates new harvest and cooling methods that meet the rule intent. The preventative and protective nature of the proposed rule is a very different approach compared to the current rule. By encouraging the development of best management practices and creating a process within the rule for implementing these practices, the department expects to see additional unintended benefits due to implementing this rule.

An expansive benefit of this rule is that it raises industry awareness of the factors that contribute to *Vibrio parahaemolyticus* growth and encourages harvesters and shellfish dealers to utilize best management practices in the summer months. Rather than creating an atmosphere where it is advantageous to harvest as much as possible early in the season to prepare for a closure, this rule encourages harvesters and shellfish dealers to reduce the likelihood of illness. A growing area will end up in a lower risk category over time if illnesses decline in that area. Conversely, if illnesses increase in a growing area, than that area will be in a higher risk category. By encouraging innovation and the use of best management practices the gains of this rule go beyond illness reduction and could lead to new ways of reducing *Vibrio parahaemolyticus* growth pre- and post-harvest as well as new methods for rapidly chilling oysters. These shifts in industry practices cannot be directly captured or assessed at this time, but will likely lead us towards a better understanding of *Vibrio parahaemolyticus* and allow us to make improvements in how to manage the risk associated with *Vibrio parahaemolyticus*.

<u>Avoided Costs of the Proposed Rule:</u>
The proposed rule reduces the erosion of public trust in shellfish safety. By focusing on preventing rather than responding to illnesses, the proposed rule demonstrates that the department and the shellfish industry are committed to illness reductions. Shifting the closure periods also provides greater guidance to when shellfish are most risky to consume raw from Washington growing areas. The proposed rule, by restricting harvest when conditions are most likely to lead to illness, should reduce the number of recalls. Recalls are costly to the industry, demand substantial resource expenditures from the industry and the department, and erode public trust in food products.

The FDA risk calculator models that this proposed rule will likely lead to about a 75% reduction in illness (email communication Dr. Andy DePaola and Dr. John Bowers). Even with a more moderate 50% reduction in illnesses, the avoided costs are substantial.

Using the CDC methodology for calculating the number of illnesses, hospitalizations, and deaths from *Vibrio parahaemolyticus*-associated illnesses; the department's illness reports when illnesses have been traced back and attributed to commercial harvest from Washington State; and the U.S. Department of Agriculture's (USDA) Excel spreadsheet for calculating the cost of foodborne illness, it is possible to estimate the likely avoided costs of the proposed rule. The USDA's Excel spreadsheet calculates the annual cost of illnesses based on whether an individual visits a physician, whether the individual is hospitalized, and whether the individual dies (Hoffmann et al 2012; Economic Research Service 2014). The estimates for these categories are derived from the CDC's estimates of the number of individual's with severe and non-severe illnesses that seek care (based on the presence of bloody stools), hospitalization rate, and death rate (Hoffmann et al 2012). Applying the methodologies and calculators provided by the FDA, CDC, and USDA to the average number of illness reports from 2010 to 2014 where confirmed illnesses have been traced back and attributed to commercial harvest from Washington State, the likely current costs of *Vibrio parahaemolyticus*-associated illnesses as well as the predicted avoided costs of the proposed rule can be calculated.

The current estimated annual cost of *Vibrio parahaemolyticus*-associated illnesses for Washington State is $10,483,094. This is based on a total of 6,610 illnesses of which 4,614 do not visit a physician and recover; 1,977 visit a physician and recover; 19 are hospitalized without sepsis; 18 are hospitalized and recover without sepsis; and one dies. Based on a 50% reduction in illnesses $9,577,437 in costs would be avoided. A 75% reduction in illnesses would result in an additional estimated $445,279 avoidance of costs.

| **Avoided Annual Cost Scenarios** | **Total** | **Non-Hospitalized** | | **Hospitalizations** | | **Mortality** |
|---|---|---|---|---|---|---|
| | | **Didn't visit physician; recovered** | **Visited physician; recovered** | **Hospitalized without sepsis** | **Post-hospitalization recovery (non-sepsis)** | **Death** |
| Average number of cases 2010-2014 | 6,610 | 4,614 ($260,817) | 1,977 (1,267,542) | 19 ($286,209) | 18 ($11,168) | 1 (8,657,357) |
| 50% reduction in average number of cases | 3,305 | 2,307 ($130,409 | 989 ($634,092) | 9 ($135,572) | 9 ($5,584) | 0 ($0) |
| 75% reduction in the average number of cases | 1,653 | 1,154 ($65,233) | 494 ($316,725) | 5 ($75,318) | 5 ($3,102) | 0 ($0) |

| **Avoided Annual Costs Scenarios** | **Total Cost of Illness** | **Avoided Cost of Illnesses** |
|---|---|---|
| Average number of cases 2010-2014 | $10,483,094 | None |
| 50% reduction in average number of cases | $905,657 | $9,577,437 |
| 75% reduction in the average number of cases | $460,378 | $10,022,716 |

Costs of the Proposed Rule:

*Summary:* To assess likely compliance costs associated with the proposed rule, the department sent a request to participate in a key informant questionnaire to the interested parties list for this rule. The request reached 25 shellfish companies. An additional 11 companies not on the interested parties list were contacted to ensure adequate coverage of coastal and inland areas; all license types; and all growing area risk categories. Of the 36 companies approached, 15 did not respond and 21 submitted responses in writing or through phone interviews. Most companies that submitted responses in writing required at least one follow-up phone call to clarify responses. Even with this method, some responses were still unclear from a few of the companies or companies elected not to respond to all of the questions. All companies received two email reminders and at least one phone call reminder requesting that they complete the questionnaire.

Of the 21 responders, five companies are licensed as harvesters; five are licensed as shucker packers, and 11 are licensed as shellstock shippers. Four of the companies operate in coastal growing areas; 16 operate in inland areas of Hood Canal, northern Puget Sound, and southern Puget Sound; and one company operates in both coastal and inland growing areas. Twenty of the companies harvest oysters during the control plan months from at least one growing area in risk category 1, nine companies harvest from at least one growing area in risk category 2, and seven companies harvest from at least one growing area in risk category 3.

The majority of companies that responded did not believe this rule would substantially impact their business practices. A few respondents discussed the need to build icing capacity and invest in ice machines, particularly to meet the strictest time to cooling requirements. The majority of respondents thought that the harvest temperature records would be the greatest burden to their operations. Most believed these requirements would have no or minimal increases in costs to their operations, but many respondents did believe there would be costs associated with maintaining calibrated thermometers and the additional record keeping requirements in the proposed rule.

*Time of Harvest to Cooling Requirements:* Overall, the proposed time of harvest to cooling requirements and control plan months were generally considered to have no or very little impact on the shellfish industry across the risk categories. Among licensees, there was not a strong sense that they would need to change harvest practices based on the proposed control plan months and time to cooling requirements.

*Two-hour Time of Harvest to Cooling Requirements:* The proposed time of harvest to cooling requirement reduction of two hours did impact risk categories differently. Most category 1 and category 2 respondents did not think the two hour time reduction based on air temperature would impact their harvest practices. Of category 3 respondents, half thought that there would be a cost associated with the time reduction.

To better quantify what costs could be incurred by the proposed rule, costs were estimated using example growing areas from each risk category and historic weather data for those areas. Based on these example growing areas, category 1 areas had time reductions based on air temperatures for 0-1 days, resulting in $0-$30 of costs for the one company that thought there would be a

$30/day increase in cost. Category 2 areas had time reductions for 9-12 days resulting in $630-$840 in costs for the one company that thought there would be a $70/day increase in costs. Category 3 areas had time reductions for 5-22 days resulting in $250-$1,100 in increased costs for three companies, assuming they each would have a $50/day increase in costs.

| **Two Hour Time to Cooling Reduction** | | | |
|---|---|---|---|
| | **Category 1** | **Category 2** | **Category 3** |
| Number of Responses | 20 | 8 | 7 |
| No Change in Costs | 16 | 6 | 4 |
| Minimal Increase in Costs | 3 | 1 | 0 |
| Increase in Costs | 1 | 1 | 3 |
| Range of Cost Increase (per year) | $0 to $30 | $630 to $840 | $250 to $1,100 |

The third harvester with some category 3 growing areas schedules two to three tribal harvests per month thought they would need to close, costing $20,000/day in lost revenue for harvesters if the time reduction occurred on a day when a harvest was scheduled in one of the category 3 growing areas. The department assumes this cost will be mitigated by not scheduling harvests from category 3 growing areas in July and August and by planning harvests during weeks with early morning low tides when air temperatures and harvest temperatures are cooler. Since only two to three harvests are scheduled per month, avoiding mid-day low tides and predicted heat waves should prevent reaching these temperature thresholds and canceling harvests. The department assumes this will reduce potential cost to within the range of cost for category 3 growing areas described in the Two Hour Time to Cooling Reduction table above and the Four Hour Time to Cooling Reduction described below.

*Four-hour Time of Harvest to Cooling Requirements:* The proposed time of harvest to cooling requirement reduction of four hours based on harvest temperature led to a slightly greater impact to category 1 areas, no change in the impact to category 2 areas, and a much greater impact to category 3 areas in terms of the expected increase in costs.

Based on the example growing areas historic water temperature data, category 1 areas had time reductions for 0-1 days. This resulted in $0-$200 of costs for the two companies that thought there would be a $110/day or $100-$200/day increase in cost. Category 2 areas had time reductions for 0-3 days resulting in $0-$210 in costs for the three companies, assuming they all had a $70/day increase in costs. Category 3 areas had time reductions for 8-9 days resulting in $1,160-$1,305 in increased costs for the four companies, assuming that they all had a $145/day increase in costs.

| **Four Hour Time to Cooling Reduction** | | | |
|---|---|---|---|
| | **Category 1** | **Category 2** | **Category 3** |
| Number of Responses | 20 | 9 | 7 |
| No Change in Costs | 16 | 5 | 2 |
| Minimal Increase in Costs | 2 | 1 | 1 |
| Increase in Costs | 2 | 3 | 4 |
| Range of Values for Cost Increase (per year) | $0 to $200 | $0 to $210 | $1,160 to $1,305 |

Two companies highlighted the need for large one time equipment purchases to either accommodate the time to cooling requirements or to have the capacity to operate under reduced time of harvest to cooling requirements. One large company (300 employees) identified a need to expand their ice capacity in order to meet the rule requirements. They estimated a $500,000 expenditure on ice making equipment. A mid-size company (25-30 employees) that operates in risk category 3 growing areas identified the need to expand their ice capacity in order to operate during times when there are time reductions in place due to air or harvest temperatures. They would need to purchase an ice machine at $20,000 and additional totes for transporting oysters at $3,000 to operate within these time controls.

*Closure requirements:* Nineteen respondents provided cost information related to closures. All would react to closures based on harvest temperatures in the same manner they currently react to closures based on illnesses. These reactions to closure vary. Ten shift harvest to open areas, shift to farm maintenance tasks during the closure, or shift harvest to other species during the closure. Three of the respondents initially shift their harvest activities, but will close if the closure is long-term or expanded into a number of growing areas where they operate. Six of the respondents close. Many of these respondents only have one growing area to harvest from, therefore shifting to another growing area is not an option for their business. In addition, one respondent stops harvesting oysters in the summer months and another voluntarily closes based on environmental conditions.

The costs for closures varied quite considerably by response. Of the 19 responses, eight do not currently have costs associated with closures based on illness while eight indicate they do. For the proposed rule, seven of the respondents do not expect to have any costs associated with closures based on harvest temperature, while nine believe they will have costs. Three of the respondents were unsure of the costs now and based on the proposed rule.

To estimate the costs of the proposed rule, the department considered both current and expected costs of closure provided by the 19 respondents. These costs range from $150-$15,000/day. These costs include fixed costs associated with business operations as well as lost revenue, the cost to their businesses of deferring revenue, and challenges associated with maintaining cash flow during closures. Although the shellfish can be sold once the area opens, the demand may have changed during the closure, the oysters continue to grow and may not be marketable to the more lucrative half shell market, and buyers may have moved on to other suppliers during the closure.

| **Closure** | | |
|---|---|---|
| | **Current Rule** | **Proposed Rule** |
| Number of Responses | 19 | 19 |
| No Change in Costs | 8 | 7 |
| Unsure of Costs | 3 | 3 |
| Increase in Costs | 8 | 9 |
| Range of Cost (per day) | $150 to $15,000 | $150 to $15,000 |

To better quantify what the cost differences would be between the current rule and proposed rule, closure costs were estimated using example growing areas for each risk category, historic water

temperature data from 2014, and actual closures based on illness in 2014. Based on the example growing areas, neither category 1 nor category 2 growing areas had any illness closures or harvest temperature closures. There would be no new costs imposed by the proposed rule to category 1 or category 2 growing areas based on these examples. For the category 3 areas, one example had eight fewer days closed when closures were based on harvest temperatures compared to illness closures, while the other example had 10 additional closure days compared to the illness closures in 2014. Based on these examples and a per day cost of $150 to $15,000/day, there could be an estimated cost savings of $1,200 to $120,000 with more days open or an added cost of $1,500 to $150,000 with more days closed.

*Harvest Temperature Record Requirements:* The majority of respondents intend to change their calibration practices based on the proposed rule. Of the 21 respondents, seven did not think there would be a change in cost for their business. Fourteen respondents thought they would need to change their practices to calibrate thermometers more frequently, purchase new equipment, and accommodate additional record keeping.

Eleven of the 14 respondents who indicated a need to change practices as a result of the proposed rule provided values for these changes. Costs involved one time equipment costs for thermometers ranging from $150 to $450,000 with an average cost of $93,971 and a median cost of $363. The difference between the average and median equipment costs reflect the effect of the proposed change for two large companies reporting costs. One company reported $450,000 and another reported $112,700 in increased costs. The remaining companies had a range of costs $150 to $400 with an average of $281 and a median of $288. Respondents also thought there would be ongoing weekly costs associated with compliance ranging from $20/week to $270/week with an average cost of $154/week and a median cost of $150/week.

Another component of the proposed rule is the additional cost of recordkeeping associated with measuring and recording air and harvest temperatures. Over half of the respondents (11) thought the additional record keeping requirements would have no or minimal additional costs and one respondent was unsure of the added costs for this requirement. Eight respondents thought there would be an added cost and estimated this cost. Of the respondents that provided values for the additional recordkeeping costs, one included the costs in the calibration requirement costs above. The remaining seven respondent costs ranged from $20/week to $200/week with an average cost of $92/week and a median cost of $100/week.

| **Harvest Temperature Record Requirements** | | |
|---|---|---|
| | **Calibration** | **Recordkeeping** |
| Number of Responses | 21 | 20 |
| No Change in Costs | 7 | 11 |
| No Change in Costs Provided | 3 | 1 |
| Increase in Costs | 11 | 8 |
| Range of Values for Cost Increase (one time purchase) | $150-$450,000 | None |
| Range of Values for Cost Increase (per week) | $20-$270 | $20-$200 |

Benefit and cost determination:
To make the benefit and cost determination, the department assumed a company had one harvest site in each growing area risk category and used the range of costs provided by respondents to the questionnaire. We used the example scenarios to calculate the costs associated with time reductions of two hours, time reductions of four hours, and closures. We used the range of costs provided by companies for the required harvest recordkeeping requirements.

Using the costs identified above, the department calculated the range of annual costs of the proposed rule.

| | Cost Range | High Cost Estimates | Low Cost Estimates |
|---|---|---|---|
| **Time of Harvest to Cooling** | | | |
| Category 1 | $9,600-$10,000 | $ 10,000 | $ 9,600 |
| Category 2 | $ - | $ - | $ - |
| Category 3 | $ - | $ - | $ - |
| **Two Hour Reduction** | | | |
| Category 1 | $30/day | $ 30 | $ - |
| Category 2 | $70/day | $ 840 | $ 630 |
| Category 3 | $50/day | $ 1,100 | $ 250 |
| **Four Hour Reduction** | | | |
| Category 1 | $100-$200/day | $ 200 | $ - |
| Category 2 | $70/day | $ 210 | $ - |
| Category 3 | $145/day | $ 1,305 | $ 1,160 |
| **Closure** | | | |
| Category 1 | $ - | $ - | $ - |
| Category 2 | $ - | $ - | $ - |
| Category 3 | $150-$15,000/day | $ 150,000 | $ (120,000) |
| **Recordkeeping** | | | |
| Calibration (equipment) | $150-$450,000 | $ 450,000 | $ 150 |
| Calibration (ongoing) | $20-$500/week | $ 10,000 | $ 400 |
| Recordkeeping | $20-$200/week | $ 4,000 | $ 400 |
| **Total Range** | | **$ 627,685** | **$ (107,410)** |

Based on these estimates, a company could incur increased costs and lose revenue as a result of proposed rule to total $627,685. Conversely, a company could *avoid* costs by an *increase* in revenue as a result of the proposed rule to total $107,410. This increase in revenue is due to additional days open under the proposed rule as compared to the 2014 closure time based on the current rule. Additionally, the proposed rule is expected to create an avoided cost of illness of

$9,577,437. Based on this analysis, the department has determined the probable benefits of revising the *Vibrio parahaemolyticus* control plan proposed in the rule are greater than the probable costs.

**Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.**

In developing the proposed *Vibrio parahaemolyticus* control plan, the department considered many alternatives. A *Vibrio parahaemolyticus* Advisory Committee (VpAC) was convened to develop the proposed rule. The first year of meetings focused first on identifying potential preventive approaches to *Vibrio parahaemolyticus* management, while the second year of meetings refined the selected approach and drafted the proposed rule language. A number of ideas were discussed such as closures based on the:

- Physical site characteristics of sites such as bed elevation/depth, and substrate composition
- Weather and temperatures such as forecasts of heat waves, the amount of sunshine and cloud cover, air temperature, and water temperature
- Tidal exposure, time of day, size of tide, and tidal elevation of sites
- Amount of *tlh* and/or *trh* in environmental sampling results
- Harvest methods and practices being employed

A common theme consistent in all of the controls considered, including those in the proposed rule, is to move from a reactive illness-based approach to a preventative environment-based approach. VpAC wanted to move away from a reactive management approach and manage the risk proactively. All of the proposed controls acknowledged that *Vibrio parahaemolyticus* is best confronted when the risk is the greatest—in terms of growing areas and seasonality of illnesses. Some of the discussed alternatives were too challenging to develop a rule that could be easily understood and implemented consistently, such as developing controls around cloud cover. Although data suggests that there is greater *Vibrio parahaemolyticus* growth on sunny days compared to cloudy days, it is difficult to turn that information into actionable requirements for the shellfish industry. The proposed rule does address the amount of sunshine to some degree by reducing time of harvest to cooling requirements based on air temperatures. Air temperatures can be measured and recorded at the time of harvest using quantitative measures, while percent cloud cover cannot. Other alternatives lacked enough data to develop reasonable controls. For example, although substrate composition likely plays a role in warming and heat retention, there is not enough data to suggest what appropriate controls could be. The proposed rule is based on science and can be both implemented and enforced as written. Two alternatives that VpAC considered are:

<u>Alternative 1:</u>
British Columbia (BC) began a new management strategy where oysters are tested for the *tlh* gene. If it is present and exceeds 100 MPN/g, then the oysters cannot be shipped. VpAC considered creating a similar trigger either based on lot testing of oysters (similar to BC) or

based on weekly environmental sampling results. Although there was broad agreement that this approach could prevent illnesses, there were also many issues with this approach. Most notably, *tlh* is an indicator for the presence and level of *Vibrio parahaemolyticus* as a species, not for pathogenic strains. As the majority of *Vibrio parahaemolyticus* strains are not associated with human illness and there is not a clear relationship between total *Vibrio parahaemolyticus* and pathogenic *Vibrio parahaemolyticus*, there were concerns that this is not the most appropriate genetic marker to use for closures (Zimmerman et al 2007). There was also discussion of using *trh*, or *tdh*, or both *trh* and *tdh*. Both genetic markers are associated with pathogenic strains. The challenge with these markers is that the dose required is not known—there is no guidance for what to use as a closure level. In addition to this issue, the *trh* gene is also found in *Vibrio anginolyticus*. There is evidence that Alaska, California, and Washington have these *trh*+ stains of *Vibrio anginolyticus*, which confounds the results of environmental sampling (González-Escalona et al 2006). We could end up closing growing areas based on the presence of *Vibrio anginolyticus* rather than *Vibrio parahaemolyticus*. Finally, neither the *trh* nor *tdh* genes are specifically associated with the mechanism that causes illnesses; these genes tend to be present when illness occurs (Paranjpye et al 2012; Klein et al 2014). We do not have enough information on strain shifts and potential changes in virulence, do not have complete markers associated with illness, and do not have complete information on dose relationships. There are also some unresolved issues with how *Vibrio parahaemolyticus* behaves in the environment. We know that it doubles rapidly and has a large degree of natural variability. Unlike biotoxins, maintaining temperature control of samples and processing samples within 24 hours is required. An environmental sample-based approach to *Vibrio parahaemolyticus* management would require a great expenditure of resources to increase the Public Health Laboratory's capacity both in terms of employees and analytical tools and resources. Given these concerns with the state of the science for *Vibrio parahaemolyticus* and the logistical and capacity challenges associated with this approach, the department determined the cost prohibitive with a high likelihood of failing to adequately protect public health.

<u>Alternative 2:</u>
Another alternative that was discussed in detail by VpAC was to restrict harvest on days with mid-day low tides based on the tidal elevation of shellfish beds. VpAC discussed implementing this rule based on tidal exposure, time of day, and air temperatures. One idea that was developed in a small group at the July 2013 meeting was to "Close growing area when there is a -3' tide and $\geq 80^0$ air temperature between 11am and 5pm in July and August." Although there is agreement that all of these factors likely contribute to the occurrence of illnesses, a rule that could be easily understood and implemented consistently could not be developed. Establishing the -3' tide height for each harvest site would be cumbersome given the current data sets on bed elevation and staff resources. It was also agreed that this sort of closure would require harvesters to track too many variables—bed elevation, time of day, air temperature, and month. This alternative is not a reasonable approach to control *Vibrio parahaemolyticus* risk.

Based on this analysis, the department determined the proposed rule is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives of the statute that the rule implements.

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

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

**Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.**

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

**Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.**

The proposed rule does not differ from any applicable federal regulation or statute.

**Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.**

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 ensuring that it complies with all applicable federal laws and regulations.

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