Proposal Subject

Reduction of Time - Temperature Matrix Levels 2 & 3 for *Vibrio parahaemolyticus*

Specific NSSP Guide Reference

NSSP Model Ordinance, Chapter VIII. Control of Shellfish Harvesting, Requirements for Harvesters, .03 Shellstock Temperature Control, Option 2

Text of Proposal/ Requested Action

Reduce the time to temperature control for *Vibrio parahaemolyticus, Option 2.* The basis for this reduction in time of exposure is due to the *Vp* risk associated with consumption of raw shellfish from growing areas that have AMMAT temperatures at these levels. *Vp* numbers multiply faster as temperatures increase. The intent is to shorten the period from harvest to temperature control to further reduce the risk of *Vp* with raw oyster consumption.

Time-Temperature Matrix for *Vibrio parahaemolyticus*:

Action Level	Average Monthly Maximum Air Temperature	Maximum Hours from Harvest to Temperature Control
Level 1	<66 °F (18 °C)	36 hours
Level 2	66 °F - 80 °F (19 °C - 27 °C)	~~12~~ **10** hours
Level 3	≥81 °F (≥27 °C)	~~10~~ **8** hours

Public Health Significance

During the summer of 1997, the Pacific coast experienced a significant increase in the number of *Vibrio parahaemolyticus* (*Vp*) illnesses attributed to shellfish consumption. *Vp* was never found to exceed the NSSP action level in the growing waters associated with these illnesses. Recognizing the inadequacy of the NSSP action levels, the ISSC developed the current Interim Control Plan (ICP) for *Vp*.

Due to either low *Vp* levels in the water since or the stronger provisions in the ICP, or both, Vp related illnesses remained at low levels until the summer of 2006, Last year, the northwest experienced the highest number of *Vp* related illnesses in recorded history. Product recalls extended into many states and countries. The affected industry and regulatory control agencies are determined to prevent this from occurring again, and met extensively over the intervening period to discuss possible actions to accomplish this goal. It was acknowledged that stricter controls were needed and that time and temperature controls were key.

The ICP has retained its 'interim' status, acknowledging that the tighter controls resulting from the 1997 illnesses might yet have to be revisited. This Proposal is one component of a multi-pronged response to the 2006 *Vp* illnesses.

Vp numbers are known to multiply faster as temperatures increase. Shortening the period from harvest to temperature control should reduce the number of *Vp* in oysters when they reach temperature control.

While replacing all time values in this table with zeros would maximize the impact of this time-temperature control effort, practicality in the field has also been taken into consideration. These new time values are being proposed as significant reductions to the existing allowances, after extensive consultation with the industry, to ensure that compliance is possible, though in some cases, it may require considerable effort.

Acknowledging that a scientific basis is frequently the preferred method to arrive at numeric limits, we ask that you accept our proposed numbers, and give appropriate credit for the significant reduction they represent, and the practicality component that was also considered.

Cost Information (if available)

Specific cost information has not been calculated as it would vary significantly by operation and location. The west coast industry and regulatory agencies, tribal and non-tribal, have all been parties to this effort and generally believe that this is a workable part of a solution to this problem.

Substitute Proposal Submitted to 2007 Task Force II

Chapter VIII Control of Shellfish Harvesting – Requirements for Harvesters
.03 Shellstock Temperature Control

For Options 1, 2 and 3, wherever appropriate to accomplish the objective, change language so that in each Time - Temperature Matrix, the time begins once the first shellstock harvested is no longer submerged, i.e. when the shellstock is no longer able to take in and expel water, which naturally prevents internal logarithmic bacterial growth.

The following language is intended to reflect the changes being proposed:

OPTION 1

Introduction: " ... the Authority shall adopt the following ~~harvest~~ **exposure** time to temperature controls in the time - temperature matrix below ..."

Table: "Maximum Hours from ~~Harvest~~ Exposure to Temperature Control"

OPTION 2

Introduction: " ... the Authority shall adopt the following ~~harvest~~ **exposure** time to temperature controls in the time - temperature matrix below ..."

Table: "Maximum Hours from ~~Harvest~~ **Exposure** to Temperature Control"

OPTION 3

Table: "Maximum Hours from ~~Harvest~~ **Exposure** to Temperature Control"

Since it is NOT the intent of this Proposal to reduce the total allowable Time to Temperature Control, the Authority in any state, with the concurrence of FDA, may add the time that it typically takes to gather shellstock, to the currently allowable time to temperature control.

PUBLIC HEALTH SIGNIFICANCE:

On a nationwide level, for many years, numerous efforts have been undertaken to address the problem of *Vibrio* bacteria in shellstock. Two main approaches have been adopted 1. Time - Temperature Control, which seeks to limit bacterial growth within shellstock, and; 2. Post Harvest Processing, which seeks to eliminate bacteria once the process of harvesting has been completed. This proposal seeks to improve efforts in the first approach by standardizing the time when 'the clock starts ticking'.

Submerged, undisturbed shellstock typically filter large volumes of water to respire and feed. Food and bacterial concentrations within shellstock are therefore related to the levels of food and bacteria in the surrounding water. Once this process is interrupted, either naturally as the tide recedes, or artificially as shellstock are removed from the water as part of the harvest process, additional bacteria do not enter the shellstock and bacteria already within it, for the most part, do not leave. Unfortunately, the number of internal bacteria does not remain fixed. Bathed in a stable, nutrient-rich medium, bacteria multiply, at a rate that increases as temperature increases. This is the basis behind the 3 Time - Temperature Control Matrixes.

Ever since the matrixes were adopted, it has been accepted that if illnesses continue to occur, a reduction in the time to temperature control would reduce the number of illnesses. For the industry, a certain amount of time reduction was initially not too difficult to incorporate, and only involved improving efficiency. At some point however, efficiency can no longer be improved and any further reduction in time to temperature control becomes impossible. The result is either a shut-down of harvesting or operating outside the matrix. Neither is desirable.

With last year's *V. parahaemolyticus* outbreak on the west coast, there was much focus on the requirements in Option 2, and it became obvious that the time requirement was flawed.

One type of harvest consists of waiting until the tide has started to go out, collecting & placing shellstock in containers, and then removing the containers before the tide returns. The time between high tides is roughly 12 hours and shellstock high on the beach may be out of the water for 8-10 hours before those containers are removed from the beach. Since 'Harvest' is defined as 'the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport', the TIME component of the Time - Temperature Matrix, may not start until bacteria in some of the shellstock has been multiplying for 8-10 hours.

Assume that a company harvests as described above one day, and the next day, due to a rush, or small order, that same company has its harvesters follow the tide out collecting all needed shellstock as they become exposed. All collection on day 2 could be completed within an hour. Even if matrix requirements are met on both days, if *Vibrio* is in the water, it is not difficult to imagine shellstock from the 1st day resulting in illness and a subsequent questioning as to whether the matrix time requirements are inadequate. Total adherence to the Matrix, even though its specified times may be adequate to protect public health, could still result in illnesses, financial loss, loss of reputation and added regulatory scrutiny.

Another type of harvest consists of gathering submerged shellstock from the bottom. Here too, a long day of harvest with possibly a break before leaving the harvesting area, could result in much bacterial multiplication before the time component of the Matrix even starts.

The intent of this Proposal is:

- to start the clock ticking as soon as the first shellstock is no longer in the water and conditions for bacterial multiplication become favorable, and;
- NOT to shorten the currently allowed time to temperature control
  i.e. if gathering or collecting shellstock in a state currently takes 6 hours (for example), and the Authority acknowledges this, it would be appropriate, with FDA's concurrence, to add this time to the allowable time in the Matrix.

COST INFORMATION:

Additional cost is not anticipated.

Action by 2007 Task Force II

Recommended adoption of Proposal 07-204 as substituted by the submitter; and add to the NSSP Guide Model Ordinance Chapter II Risk Assessment and Risk Management as follows:

@ .05 The Time When Harvest Begins.

For the purposes of time to temperature control time begins once the first shellstock harvested is no longer submerged.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action.