Proposal Subject: *Vibrio parahaemolyticus* Control Plan Guidance

Specific NSSP Guide Reference: Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens
.03 *Vibrio parahaemolyticus* Control Plan Guidance

Text of Proposal/ Requested Action In accordance with the ISSC Constitution, Bylaws, and Procedures and in keeping with the spirit and intent of the Conference, the ISSC Executive Board approved Interim Guidance on September 11, 2008, as follows:

> Insert the following after "for cooking only": **or for shucking by a certified dealer, or other mechanism such as a variance, to allow the hazard to be addressed by further processing.**

This proposal, as amended by the *Vibrio* Management Committee at its meeting on May 6, 2009, is submitted to the Conference for adoption as required by the ISSC Constitution, Bylaws, and Procedures.

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I. Risk Evaluation
The determination of Reasonably Likely to Occur should be conducted as follows:

1. A risk evaluation as described in Proposal 07-202 (with the understanding that ISSC has not adopted nor endorsed the FDA *Vp* Risk Assessment); or

2. The risk factor decision tree under development by the VMC using the risk factors included in Proposal 07-202; or

3. Other approaches approved by the State Authority that provide at least an equivalent level of protection and reduce the risk so that it no longer constitutes an annual occurrence.

II. *Vibrio parahaemolyticus* Control Plan

A. Triggers
A plan for an area(s) or a state must include control measures for the month(s) in which:

1. The total number of *Vp* illnesses is two or more in a three (3) year period; or

2. The area was epidemiologically linked to an outbreak within the prior five (5) years and the plan must also apply to the period 30 days prior to the first day of harvest of the outbreak and 30 days after the last day of harvest associated with the outbreak; or

3. The average water temperatures representative of harvesting conditions exceed 60 °F for states bordering the Pacific Ocean and 81 °F for states bordering the Gulf of Mexico and Atlantic Ocean (New Jersey and south). See exemption in the NSSP Model Ordinance Chapter II.@.05.B.2.; or

The regulatory authority to administer this plan is [To be filled in by the Authority].

B. Control Measures

1. Post Harvest Processing (PHP).

2. Closing the area to oyster harvest.

3. Restrict oyster harvest to product labeled ~~"For Cooking Only".~~ **for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing.**

4. Limit time from harvest to refrigeration to no more than five (5) hours or other times based on modeling and sampling in consultation with FDA.

5. Limit time from harvest to refrigeration such that levels of total *Vp* after completion of cooling to 60 °F do not increase more than 0.75 log from levels at harvest. Calculations for 0.75 log increase can be based on the table as shown below or based on validation studies. The authority may use the FDA Risk Assessment to determine the initial "at harvest" levels.

6. The term refrigeration is storage in a container that is capable of dropping and maintaining ambient air temperature of 45 °F (7.5 °C).

7. Other control measures based on appropriate scientific studies.

C. Plan Effectiveness as Demonstrated by:

1. Post Harvest Processing.

   Conduct end product testing consistent with PHP verification protocol as provided in the NSSP Guide for the Control of Molluscan Shellfish. Test results shall demonstrate the level of total *Vp* in the final product does not exceed the average levels found in the area at times of the year the state had determined *Vp* illness is not reasonably likely to occur.

   Data may be shared between states or other entities as may be appropriate considering the characteristics of the harvest area(s), such as temperature, hydrological patterns, etc. In the absence of such state data, use 100/gm for the Pacific and 1000/gm for the Atlantic/Gulf as provided in the FDA Risk Assessment.

   Note: These levels are significantly higher than those allowed in validation/verification to non-detectable. Labeling "for added safety" would not be permitted unless the lower levels were reached.

2. Closing the area to oyster harvest.
   Issue a legally binding closure order(s). Conduct Patrol and maintain Patrol records for the area(s) in accordance with the NSSP MO requirements.

3. Restrict oyster harvest to product labeled ~~"For Cooking Only"~~ **for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing** or "For PHP Only".

The authority must notify harvesters and dealers of those areas restricted to harvest ~~"For Cooking Only"~~ **for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing** or "For PHP Only." Harvesters must include on the tag of all product harvested in these areas the statement ~~"For Cooking Only"~~ **for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing** or "For PHP Only." Dealers must establish a ~~"For Cooking Only"~~ **for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing** or "For PHP Only" labeling Critical Limit as part of their HACCP plan for receiving. A shipping Critical Control Point must include ~~"For Cooking Only"~~ **for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing** or "For PHP Only" labeling requirement.

4. Limit time from harvest to refrigeration to no more than five (5) hours or other times based on modeling and sampling in consultation with FDA. Compliance may be documented by State restriction orders, harvester records, dealer records, field records, storage records, harvester education/inspections, records of capable and operating refrigeration.

5. Limit time from harvest to refrigeration such that levels of total Vp after completion of cooling to 60 °F do not increase more than 0.75 log from levels at harvest. Calculations for 0.75 log increase can be based on the table as shown below or based on validation studies. The authority may use the FDA Risk Assessment to determine the initial "at harvest" levels.

6. The term refrigeration is storage in a container that is capable of dropping and maintaining ambient air temperature of 45°F (7.5°C).

7. Other control measures based on appropriate scientific studies

D. Plan Modification

Cost Benefit Analysis (Optional)

Public Health Significance:

Cost Information (if available):

Action by 2009 Task Force II: Recommended adoption of Proposal 09-234 as submitted.

Action by 2009 General Assembly Adopted recommendation of 2009 Task Force II on Proposal 09-234.

Action by USFDA 02/16/2010 Concurred with Conference action on Proposal 09-234.

Temperature Specific *Vp* Growth Rates and Doubling Times for Calculating Cumulative Growth Based on Hourly Temperature Observations					
Oyster Temperature (degree F)	Growth Rate (logs/hr)	Doubling Time (hrs)	Oyster Temperature (degree F)	Growth Rate (logs/hr)	Doubling Time (hrs)
50	0.008	35.8			
51	0.011	28.4	76	0.147	2.05
52	0.013	23.1	77	0.156	1.93
53	0.016	19.2	78	0.165	1.83
54	0.019	16.1	79	0.174	1.73
55	0.022	13.8	80	0.183	1.64
56	0.025	11.9	81	0.193	1.56
57	0.029	10.4	82	0.203	1.48
58	0.033	9.14	83	0.213	1.41
59	0.037	8.11	84	0.224	1.34
60	0.042	7.24	85	0.235	1.28
61	0.046	6.50	86	0.246	1.23
62	0.051	5.87	87	0.257	1.17
63	0.056	5.33	88	0.268	1.12
64	0.062	4.86	89	0.280	1.07
65	0.068	4.45	90	0.292	1.03
66	0.074	4.09	91	0.304	0.99
67	0.080	3.77	92	0.317	0.95
68	0.086	3.49	93	0.330	0.91
69	0.093	3.24	94	0.343	0.88
70	0.100	3.01	95	0.356	0.85
71	0.107	2.81	96	0.370	0.81
72	0.115	2.63	97	0.383	0.79
73	0.122	2.46	98	0.397	0.76
74	0.130	2.31	99	0.412	0.73
75	0.139	2.17	100	0.426	0.71

Note: Growth rate (in logs/hr) = (0.01122*Temp – 0.4689) ^2