ISSC

I. CALL TO ORDER

The meeting was called to order by Mike Hickey.

II. ROLL CALL

Ken Moore conducted roll call.

Board members in attendance were:

Kathy Brohawn	Task Force I Chair
Paul DiStefano	FDA Representative
Bill Eisele	Office Manager
Steve Fleetwood	Industry - Region 2
William Hastback	Regulatory - Region 2
J. Michael Hickey	Regulatory Region 1
Bill Kramer	EPA Representative
Terri Gerhardt	Non-Producing State
Ken B. Moore	Executive Director
Debbie Rouse	Regulatory - Region 3
Angela Ruple	NOAA
Ed Watson	Non-Producing State
Robin Downey	Industry - Region 6
David Fyfe	Northwest Indian Fisheries Commission
David Guilbeau	Regulatory – Region 5
Lori Howell	Industry - Region 1
Dan Leonard	Industry - Region 4
Charles Newell	Regulatory – Region 4
Angela Ruple	NOAA
Manny Soares	Regulatory Region 6

Board members absent were:

Donna Garren	National Restaurant Association (Consumer Advisor)
Spencer Garrett	NOAA
Johnathan Gerhardt	Non-Producing State
John Jenkins	Patrol Advisor
Doris Nelson	Industry – Region 5
Larry Simns	Industry - Region 3
Keith Skiles	Vice Chairman / Task Force II Chair
Robert Wittman	Program Chairman

III. APPROVAL OF AGENDA

A motion was made by Lori Howell and seconded by Bill Kramer to approve the Agenda. The motion carried with a voice vote.

IV. AGENDA ITEM FOR DISCUSSION

FDA *Vp* Control Plan Guidance Template

Lori Howell advised that the appointed work group recommended approval of the FDA *Vp* Control Plan Template as revised:

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 risk per serving exceeds $1x10^{-5}$ (one in 100,000 servings). Risk is calculated as shown in the FDA Risk Assessment. However, it is recognized that because of the uncertainty associated with the Risk Assessment a predicted risk of 1×10^{-4} may in fact represent an actual risk as low as 1×10^{-5}.~~
4. The average water temperatures representative of harvesting conditions meet or exceed 60^{o}F for states bordering the Pacific Ocean and 81^{o}F for states bordering the Gulf of Mexico and Atlantic Ocean (New Jersey and south). See exemption in proposal 07-202 in summary of actions (to be incorporated into the 2007 NSSP Model Ordinance as Chapter II.@.05.B.2.); or

   The regulatory authority to administer this plan is: (To be filled in by the Authority)

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

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.
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

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. In the FDA risk assessment, these levels correspond to a risk of $1x10^{-5}$.
   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" or "For PHP Only".
   The authority must notify harvesters and dealers of those areas restricted to harvest "For Cooking Only" or "For PHP Only." Harvesters must include on the tag of all product harvested in these areas the statement "For Cooking Only" or "For PHP Only." Dealers must establish a "For Cooking Only" or "For PHP Only" labeling Critical Limit as part of their HACCP plan for receiving. A shipping Critical Control Point must include a "For Cooking Only" 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. 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

E. Cost Benefit Analysis (Optional)

Table xxx. 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

A motion was made by Bill Kramer and seconded by Bill Eisele to adopt the FDA *Vp* Control Plan Template.

- Charles Newell noted that A. 4. should now read A. 3.

- Comments were received by Paul DiStefano. FDA disappointed the risk level was taken out of the document. FDA is willing to go along with the revised document. FDA, through the specialists, will be working with the States.
- Ken Moore recommended that the Board agree to have FDA report its findings and progress at the Fall Board meeting.

Robin Downey made a motion for a friendly amendment, which Lori Howell accepted, and seconded by Kathy Brohawn, to make editorial edits as follows:

- C. Plan Effectiveness **as Demonstrated by:**
- C. 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.

After a brief discussion, Steve Fleetwood made a motion to eliminate the five (5) hour requirement in B. 4. and C. 4. which was seconded by Bill Eisele for discussion purposes.

In response to Charles Newell, Paul DiStefano confirmed that the Plan does not require anything less than five (5) hours.

A further discussion ensued and it was determined that the motion was out of order due to Conference approval of Proposal 07-202 at the 2007 Biennial Meeting which included the five (5) hour requirement. Ken Moore explained the reason the motion is out of order is because the Executive Board can only act on behalf of the Voting Delegates of the Conference when their action is consistent with the intent of the Voting Delegates and it is clear the Voting Delegates intended for this requirement to be five (5) hours.

The motion to approve the amended *Vp* Control Plan Template passed with a voice vote by the Board.

Board Action (VMC Recommendations)

Lori Howell made a motion, seconded by Ed Watson, to adopt suggested changes in the VMC report below after reconsideration of its action at the April 3, 2008, meeting in St. Louis.

A. Request Martha Iwamoto and Marc Glatzer to review the cases included in the baseline and provide COVIS form information to the Vv Illness Review Work Group. The work group will complete the "Criteria for Including Vv Cases in Illness Reduction Calculations and Determining Source States."
B. Request FDA to provide a Vv Refrigeration Illness Reduction Refrigeration Curve.

C. That Source States must have *Vv* Illness Reduction Plans (Vibrio Management Plans) authorized and in place so that controls become effective on May 1, 2010.

D. Source States shall submit, no later than August 15, 2008, their Action Plans for implementing their Vibrio vulnificus Management Plans. The plan submitted by the state shall include what actions will be taken for various levels of illness rate reduction to achieve the goal.

E. Accept the recommendations of the Vibrio Education Subcommittee as follows:

1. Continue its efforts to improve and enhance *Vv* education.
2. Request Flying Fish provide additional information to enable the Subcommittee to analyze the impact of Online Vv Education Course offering.
3. Expand the Subcommittee's charge to include communication of information to retailers and consumers as well as harvesters and dealers.
4. Prepare a DVD and brochure to communicate information to harvesters, dealers, retailers, and consumers regarding risks associated with post harvest growth of *Vibrio parahaemolyticus*.

F. Adopt interim guidance, as amended by the Board, for use by state authorities in developing and by FDA in evaluating *Vp* Control Plans.

"Reasonably likely to occur" as referred to in Proposal 07-202 may be determined by utilizing:

1. A risk **<u>evaluation</u>** ~~assessment~~ as described in **<u>Proposal 07-202</u>** ~~the *Vp* Control Plan Template~~ (with the understanding that ISSC has not adopted nor endorsed the FDA *Vp* Risk Assessment); or
2. The risk factor decision tree **<u>under development by the VMC</u>** 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.
4. Appoint a work group to further develop No. 2.

G. Adopt the **<u>amended</u>** *Vp* Control Plan Template (attached).

H. In order to assist with implementation of the *Vp* Control Plan Template C. 1., authorize the Validation/Verification workgroup convene to quickly develop a protocol that firms or states can use this summer to implement this aspect of the *Vp* Control Plan.

I. Approve the following recommendation:

The VMC recognizes that without additional action there is near statistical certainty that the *Vv* illness reduction goals will not be reached. The VMC recognizes that the *Vp* Control Measures that will be taken by the source states consistent with the provisions of Proposal 07-202 and the interim guidance will reduce the risk of *Vv* illness by an estimated 10-15%. The VMC finds that this is an appropriate step and thus, no additional *Vv* control measures are necessary at this time.

J. Adopt VMC recommendation that the Interstate Shellfish Sanitation Conference encourage states to investigate pre-dawn harvesting as a public health tool to decrease potential illness.

The motion carried with a voice vote by the Board.

III. ADJOURNMENT

A motion to adjourn was made by Larry Simns and seconded by Bill Hastback. With no further discussion the meeting was adjourned.