

**Interstate Shellfish Sanitation Conference
Minutes of Executive Board Meeting
Whispering Woods – Olive Branch, MS
September 11, 2008**

I. CALL TO ORDER

The meeting was called to order at 8:00 AM by Chairman Mike Hickey.

II. ROLL CALL

Roll call was conducted by Ken Moore with the following Board members in attendance:

Kathy Brohawn	Task Force I Chair
Robin Downey	Industry - Region 6
Paul DiStefano	FDA Representative
Bill Eisele	Office Manager
Steve Fleetwood	Industry - Region 2
David Fyfe	Northwest Indian Fisheries Commission
Maryanne Guichard (Alternate)	Regulatory – Region 6
David Guilbeau	Regulatory – Region 5
J. Michael Hickey	Regulatory Region 1
Lori Howell	Industry - Region 1
Bill Kramer	EPA Representative
Dan Leonard	Industry - Region 4
Ken B. Moore	Executive Director
Chris Nelson (Alternate)	Industry – Region 5
Charles Newell	Regulatory – Region 4
Debbie Rouse	Regulatory - Region 3
Spencer Garrett	NOAA
Larry Simms	Industry - Region 3
Ed Watson	Non-Producing State

Board members absent were:

Donna Garren	National Restaurant Association (Consumer Advisor)
Johnathan Gerhardt	Non-Producing State
Terri Gerhardt	Non-Producing State
William Hastback	Regulatory - Region 2
Doris Nelson	Industry – Region 5
Keith Skiles	Vice Chairman / Task Force II Chair
Manny Soares	Regulatory Region 6
Robert Wittman	Program Chairman

Others Present:

Committee chairs, regulatory members, industry members, and others were also present.

III. EXECUTIVE BOARD MEMBERSHIP

Ken Moore advised the Board of several Executive Board vacancies.

- A. Region 6 Regulatory representatives recommended the Executive Board appoint Maryanne Guichard to serve as the alternate for Region 6. A motion to approve was made by Bill Eisele, seconded by Paul DiStefano, and approved by the Board with a voice vote. Ken and Manny will discuss Manny's retirement and continued representation on the Board. Ken will advise Board members.
- B. Region 5 Industry Board member Doris Nelson asked for Board approval for the elected alternate to assume her position on the Board. The region will seek another alternate representative and advise. A motion to approve was made by Lori Howell, seconded by Bill Kramer, and passed with a voice vote by the Board.
- C. Region 5 Regulatory representative David Guilbeau asked for Board approval to replace the former alternate Raymond Burditt, who is now employed by FDA. The Region recommended Kirk Wiles (Texas) as the replacement. A motion to approve was made by Bill Eisele, seconded by Ed Watson, and passed with a voice vote by the Board.

NOTE: Spencer Garrett joined the meeting at this point.

- D. Region 3 Industry Board member Larry Simns asked for Board approval to confirm Pete Jensen as the Board alternate to represent Region 3 Industry. A motion to approve was made by Bill Eisele, seconded by Lori Howell, and passed with a voice vote by the Board.

IV. APPROVAL OF AGENDA

Mike Hickey asked for a motion to approve the agenda. The motion was made by Bill Eisele, seconded by Lori Howell, and carried with a voice vote by the Board.

V. MINUTES

Mike Hickey asked for a motion to approve the Executive Board minutes of April 3, 2008; May 13, 2008; June 5, 2008; and July 17, 2008. A motion to approve all minutes was made by Bill Eisele and seconded by Paul DiStefano. Following a request by Paul DiStefano to amend the April 3, 2008, minutes by deleting the confidential information under Item X. Old Business B. PICC Legal Matter, the motion was approved by the Board with a voice vote.

VI. INTRODUCTORY COMMENTS

- A. **ISSC Executive Board Chairman Mike Hickey:**
 - Mike asked that a moment of silence be observed to reflect on the seventh anniversary of 9/11 and the people that perished during the acts of terrorism in New York, at the Pentagon, and in Pennsylvania.
 - Mike expressed thanks to the *Vibrio* Management Committee members for their hard work the past two days.

B. FDA Board Member Paul DiStefano

- Raymond Burditt is now at FDA's Center for Food Safety and will be the new national Plant Standards and is expected to be a great addition to the team.
- FDA is also in the process of hiring an additional engineer to assist with a growing work load of hydrographic studies that have been requested by the States.
- An increase in staff should enable FDA to timely complete specific programmatic requests from States.
- Hired a Central Region Specialist, John Jaworski, who will work out of the Cincinnati Office.
- The Southeast Region is in the process of hiring a fourth specialist to replace Miles Motes who was recently diagnosed with lung cancer. Ken responded that the organization will be contacting Miles.
- Initiative within FDA titled "Beyond Our Borders" is an effort by FDA to expand its presence in the world. Agency recognizes that business cannot be conducted from just within our country anymore. In process of setting up satellite offices with first in China. Plans to set up offices in Latin America, India, Middle East, and Europe. Persons placed in these countries will be working directly with counterparts in that country.
- Paul will be attending an EU workshop in England next week which will be specifically aimed at growing area classification. FDA will be working with a number of countries to exchange information regarding individual program operations. Paul will be giving presentation on the National Shellfish Sanitation Program (NSSP).
- The Workshop is a joint effort between FDA and Center for Environment Fisheries and Aquaculture Science (CEFAS).
- The Fish and Fisheries Products Hazards and Controls Guide, 4th Edition, should be forwarded to General Counsel next week for final review. Release is anticipated by the end of 2008.

Andy Depaola provided a report on the CODEX meeting.

- Japan hosted a CODEX meeting in June. A Code of Hygiene Practices for Vibrio Species in Seafood is being developed. General document has been developed.
- A recommendation was made to develop a separate code for molluscan shellfish in international trade.
- Andy will check on the availability of the draft report for distribution to the Board by the ISSC Executive Office.
- Lori Howell expressed concern regarding a mechanism for input to CODEX. Paul DiStefano commented that prior to each of the CODEX meetings there are public meetings that anyone can attend. He believes it is important for ISSC to be involved at some level. A request was made by Lori Howell to have ISSC placed on the mailing list for CODEX meetings and that ISSC follow up with notices of CODEX meetings to the ISSC Executive Board and membership.

C. NOAA/NMFS Board Member Spencer Garrett

- Provided a brief update on financial situation.
- Advised he would like to have staff member Dr. Calvin Walker serve on some of the ISSC committees as a matter of expertise to the organization.
- NOAA is expanding its inspection program for assessing import products by assigning personnel in five countries. These staff will work with counterparts to ensure quality and safety of products.

- NOAA relationship with FDA now is the best it has been in 40 years.
- Urged ISSC to apply for funds under the Saltonstall-Kennedy Grant Program.

D. EPA Board Member Bill Kramer

- EPA desires to continue working with the ISSC to improve the Measure and the basis for its calculation. The PAM for Shellfish in the 2006-2011 Strategic Plan is:
- “By 2011, maintain or improve the percentage of state-monitored shellfish-growing acres impacted by anthropogenic sources that are approved or conditionally approved for use. (2003 baseline: 65 to 85 percent of the 16.3 million acres of state-monitored shellfish-growing acres estimated to be impacted by anthropogenic sources are approved or conditionally approved for use.)”
- Because of the uncertainty of the ability of the CWA to correct non-anthropogenic impacts, EPA deducted acres impacted only by wildlife (5% estimated in 1995) from the 1990 baseline of 17.2 million (peak classified acres on a national basis) resulting in 16.3 million acres; 85% was selected because it is what was originally reported in 2003 (85% of 1990 baseline of 16.3), and the 65-85% range reflects uncertainty in CWA ability to effect waters with a mix of wildlife and anthropogenic impacts (24% in 1995)
- A recalculation of the measure using the revised 2003 and 2005 acre totals yields 81% for both years. Additionally, both years are new historical high classified acreage totals: 2003 = 22,973,000; 2005 = 23,594,000. This suggests the need for EPA to consider revising the Measure baseline, acreage, and target.
- Access to Shellfish Data - Calculating the national PAM currently depends on historical and the 2005 State acreage data from the ISSC’s “Inventory of State Classification”; and in the future, will depend on a access to data such as found in the Shellfish Information Management System (SIMS). The ability of systems like SIMS to locate program data in time and space (e.g., maps) allows the overlay of data from other Programs to facilitate coordination. EPA would like to continue to work with the ISSC to include in the ISSC Work plan a way to establish the long-term availability of shellfish data for states’ program management and to guide EPA’s nationwide Programs; and to discuss the availability of state 2007 shellfish harvesting acreage data. This data could also fill gaps on molluscan shellfish data in EPA’s series of Coastal Condition Reports (next report has case studies on North Atlantic and Gulf HABs impact on shellfish, but no national shellfish component in addition to the benthic metric); as well as EPA’s Report on the Environment, and NOAA-led Aquaculture, Fish Habitat, and Ocean Initiatives, and Fiscal Year 2009 National Water Program Guidance.
- Vibrio Education - The 2009 Fish Advisory Conference [Mid Oct; Portland OR]. EPA would like the ISSC to provide an abstract of a presentation on how to reach at-risk consumers and their health care providers and how to evaluate the effectiveness of those efforts.
- Water Quality Criterion for Recreational Exposure – Designed to protect swimmers from illnesses due to exposure to pathogens in recreational waters, the existing criteria are more than 20 years old. Scientists have since learned much about molecular biology, virology, and analytical chemistry. This new information will help build a stronger scientific foundation for up-to-date recreational water quality criteria.

- EPA is in the process of collecting input from the scientific and technical community on research and science needs to develop up-to-date, scientifically defensible criteria to protect people from exposure to contaminated recreational waters. Near-term needs were defined as specific research and science activities that could be accomplished in 2 to 3 years to support development of new or revised criteria by 2012.
- The March 2007 Experts Scientific Workshop was a forum for discussion of critical research and science needs for developing new or revised recreational ambient water quality criteria in the near-term.
- The Critical Path Science Plan (August 2007) describes the high priority research and science that EPA intends to conduct to establish the scientific foundation for the development of new or revised recreational water quality criteria recommendations. The Criteria Development Plan (August 2007) describes the process and timeline EPA intends to follow to develop and publish.

Joel Hansel provided the Board with a report on EPA Research to support new/revised recreational water quality criteria.

- Overall objectives are to provide an update on EPA's research efforts to support the development of new/revised recreational WQC.
- EPA's Current Focus is developing the science foundation for publication of new/revised recreational water quality criteria by 2012. This focus is to ensure that new/revised recreational water quality criteria are sufficiently protective of public health.
- EPA's Critical Path Science Plan for New/Revised Criteria describes research and science for establishing the scientific foundation for new/revised criteria and is an integrated approach to answering key science questions for scientifically sound criteria.
- Settlement of BEACH Act Litigation.
 - NRDC, NACWA, and LA County sued EPA, regarding completing new or revised CWA Section 304(a) water quality criteria for recreation.
 - Settlement includes Conducting specific studies necessary to meet the obligations under the BEACH Act.
 - Parties settled suit in August 2008; settlement addresses most studies in EPA's Critical Path Science Plan and some additional studies and workshops.
- Things to Expect – Now - 2010:
 - Additional Research into Indicators, Methods, and Epi Studies
 - Indicators: Enterococci, *E.coli*, bacteroides, coliphage
 - Biomarkers: human, bovine
 - Methods: culture, qPCR, other
 - Epi studies: California, Alabama, Rhode Island, more...
 - Fate & Transport Studies
 - Predictive Modeling
 - Site Characterization Studies: sanitary surveys, use of Quantitative
 - Microbial Risk Assessment
 - Research to Support Extrapolation to Inland Waters
 - Engaging Stakeholders on Implementation
- Things to Expect 2010 – 2012
 - Development of New Recreational Water Quality Criteria
 - Continued Engagement with Stakeholders on Implementation

- New Criteria Published for Use by States and Tribes
- Bill Kramer will provide the ISSC Executive Office with EPA links that will be posted on the ISSC website for access to the various EPA documents. Ken Moore suggested the Sanitary Survey and BEACH Act as possible topics for the Thursday forum of the 2009 Biennial Meeting.

VII. PROGRAM CHAIRMAN'S REPORT

- A. 2009 Spring Meeting
- B. 2009 Biennial Meeting

In Rob Wittman's absence, Ken Moore presented the Program Chairman's Report on Items A. and B.

- Rob has submitted proposals to the Chambers of Commerce in Providence, Rhode Island and Boston, Massachusetts.
- Direction previously given by Board at the April 2008 meeting to hold the 2009 Biennial meeting in the latter half of October due to federal budgets and the Northeast meeting location was confirmed.
- Robin Downey and Larry Simms expressed concern with conflicting regional meetings.
- Ken assured Board members that efforts will be made to identify dates, a facility, and a location by January 2009.
- Information will be shared with the Board and Conference members as soon as available.

VIII. COMMITTEE REPORTS

- A. Executive Committee
- 1. Grant Updates

- a. **FDA Cooperative Agreement**

Ken Moore advised the Board that the Notice of Award for the FDA Cooperative Agreement Continuation Grant had been received July 1, 2008, in the amount of \$325,000. The award amount will be reduced by \$4,500 for Year 17. A complete new application and review is due every five (5) years. There are three (3) years remaining in the current grant period that will end June 30, 2011. The funding is not guaranteed for five (5) years but is an annual decision made based on funding resources.

- b. **Gulf & South Atlantic Fisheries Foundation**

- (1) **Vv Public Health State Facilitator**

Ken Moore advised the Board that this contract was amended to include additional funding for extension of the Vv State Facilitator contract that will expire December 31, 2008. Additional monies were also provided for printing of ISSC educational brochures and fact sheets.

- (2) **Vv Workshops**

Ken Moore explained that in June he had been requested by representatives of the Gulf industry to hold regional Vv Workshops. Following discussions with the GSAFF funds were made available to host the workshops to assist the Gulf States in developing their Vv Management Plan. Funding was also provided to host a meeting in

Biloxi for regulatory and industry representatives from the Gulf States. Approval to use the remaining funds for travel assistance was granted by GSAFF.

2. **Current Financial Statement**

A current financial statement was presented to the Board as information.

3. **2008 Expense Report**

A statement of actual income and expenses to date for the calendar year 2008 was presented to the Board as information.

4. **2009 Budget**

The ISSC 2009 calendar year budget was submitted to the Board and received without objection. Robin Downey will email the Executive Office a revised format for suggested changes to the budget format.

5. **2009 Membership Fees**

After review of the 2008 membership fees of \$600.00 for a state membership and \$60.00 for an individual membership, Ken Moore recommended no changes for 2009. A motion was made by Bill Kramer and seconded by Ed Watson, that membership fees remain the same for the year 2009. The motion passed with a voice vote by the Board. Ken informed the Board that there is a significant reduction in membership in non Biennial Meeting years. He reminded the Board that a proposal will be submitted at the 2009 Biennial Meeting that will address this issue by proposing a two-year membership.

6. **2009 Biennial Meeting Registration Fees**

The Board also reviewed Biennial Meeting registration fees for all categories. As recommended by Ken Moore, a motion was made by Maryanne Guichard and seconded by Robin Downey to increase the non-member registration fee to \$475.00 and to increase the at conference non-member registration fee to \$575.00. The motion passed with a voice vote by the Board.

7. **2009 Work Plan**

After a brief discussion and positive feedback from members on improvements in the 2009 Work Plan presentation, a motion was made by Lori Howell and seconded by Dan Leonard to approve the 2009 ISSC Executive Office Work Plan as submitted. The motion carried with a voice vote by the Board.

B. *Vibrio* Management Committee

Lori Howell presented the following reports and recommendations to the Board.

1. ***Vibrio* Education Subcommittee Report & Recommendations**

A motion was made by Spencer Garrett and seconded by Ed Watson that the Board consider the following recommendations (a. – g.) for approval as one item. The VMC recommended approval contingent upon funding.

- a. Direct Executive Office to distribute a mass mailing to physicians in GOM states (focus on Gastroenterology and Internal Medicine) to encourage use of online education courses.

AMENDED RECOMMENDATION:

The Executive Office will investigate the availability and the cost of a mass mailing to Gulf State specialty physicians to advertise the online education course. Upon completion this item can be resubmitted to the Board by email for approval.

- b. Endorse a request from the *Vibrio* Education Subcommittee that Sally Soileau and Tori Stivers survey physicians at the National Association of Gastroenterologists meeting to estimate the effect of education. Recommend that the Executive Office assist Dot Leonard with design of the survey.
- c. Each Committee member will receive a minimum of 100 *Vv* brochures to leave in doctors' offices and emergency rooms. Additional brochures, fact sheets and other educational materials can be downloaded from the ISSC website to be distributed by committee members.

AMENDED RECOMMENDATION:

Advise *Vibrio* Education Subcommittee members to contact the ISSC Executive Office if they would like to receive educational materials to voluntarily distribute to local physicians in their community.

- d. Request FDA and ISSC to expand educational opportunities and encourage more participation from the Conference for Food Protection and National Restaurant Association.

Ken Moore agreed to explore ways to engage better participation from these types of organizations.

- e. Consumer surveys (2002 and 2004) showed that most oyster consumers received their *Vv* information from TV. Depending on availability of funding, request the Executive Office prepare a public service announcement and distribute as widely as possible.

AMENDED RECOMMENDATION:

Direct the *Vibrio* Education Subcommittee and the ISSC Executive Office to research grant possibilities to fund creating public service announcements for *Vv* education. Ken Moore will investigate the costs and possible funding sources to produce a PSA and report the findings to the Subcommittee and the Board

- f. Determine the percentage that *Vv* education has contributed to the decline in *Vv* cases using 2002/2004 survey results, 20 years data on the increase in the immunocompromised population and performing one or more case studies.

AMENDED RECOMMENDATION:

Ken Moore will contact FDA to try to find sources of information to pursue methods of determining what percentage of the decline in *Vv* illnesses can be attributed to *Vv* educational efforts of consumers. This information will be shared with the *Vibrio* Education Subcommittee.

Dan Leonard will locate information on a similar Sea Grant award two years ago for a study on this same issue to share with the Subcommittee.

Ken will seek information from FDA on how to factor the effect, if any, of education into the risk calculator for risk reduction.

- g. PCSGA has received a grant for *Vp* education but reduction in award eliminated funds for printing. PCSGA will coordinate with the Executive Office to produce consistent product that can be printed and distributed. Either develop a separate brochure for retail/restaurants/consumers or cover audience in harvester brochure. Distribute the new *Vp* education DVD and brochure by March 2009.

AMENDED RECOMMENDATION:

Distribute the new ISSC *Vp* Harvester Education DVD and brochure by March 2009 and collaborate with the PSCGA in developing two educational *Vp* brochures; one for retailers/restaurants/consumers and one for harvesters.

The amendments were accepted as part of the original motion by Spencer Garrett and second by Ed Watson. The motion passed with a voice vote by the Board.

- 2. ***Vibrio vulnificus* Illness Criteria Review Subcommittee**
- 3. **FDA's *Vv* Refrigeration Illness Reduction Refrigeration Curve**

Lori Howell presented the following report on Items 2. and 3. to the Board as information. No action was required by the Board.

- a. The VMC will ask the *Vv* Illness Review Subcommittee to further review the following cases using FDA assistance as appropriate and report to VMC as soon as possible.
 - DAL – 09132 (which was apparently included in the 2001 database)
 - FLA – 9351 (which was apparently included in the 2001 database)
 - New Florida case for baseline year (per Roberta Hammond)
 - 8 cases in which subcommittee found insufficient evidence
- b. In reviewing the cases in (8) above, if the *Vv* Illness Review Subcommittee finds that there is insufficient information on which to make a case determination the case shall not be counted toward the illness reduction goal and a rationale shall be presented.

The Illness Review Subcommittee reviewed a recompiled baseline. The list of cases reviewed was compiled by CDC working with FDA and has now been cross referenced against a January 2001 list of cases believed to be the source of the original baseline.

Item 1 on the instructions for completing the Criteria for Including *Vv* Cases in Illness Reduction Calculations and Determining Source States form could not be followed, with regard to COVIS Form because the Subcommittee did not have access to COVIS forms due to confidentiality restrictions. It is noted that although the original COVIS forms could not be used, the information on the spreadsheet provided by FDA was compiled from COVIS forms, or other original information.

The VMC voted to recognize the *Vv* Risk Calculator as a tool to project illness reduction. Don Kraemer offered to provide the committee with a reference from Carl Klontz explaining how the at risk population was calculated. Spencer Garrett

requested that the stated assumptions upon which the calculator is premised be included in the records. Andy Depaola advised that all of the assumptions are available in the Risk Assessment which is on the FDA website.

Al Rainosek explained that the *Vv* Risk Calculator takes into account only three inputs as far as reducing cases: time to refrigeration; cool down time, and number of servings.

In response to an inquiry by Chris Nelson, Ken Moore explained that any changes to the baseline recommended by the VMC would involve Board action and be referred to the Voting Delegates at the 2009 Biennial Meeting.

Chris Nelson asked that the appropriate body develop a proposal to change the Model Ordinance to reflect using risk reduction rather than illness reduction as the management tool for the *Vv* Risk Management Plan. Ken Moore suggested that this item be placed on the agenda at the next VMC meeting for a recommendation to the Board.

4. *Vibrio vulnificus* Management Plans

Lori Howell reported the VMC had received the Gulf States' *Vv* Management Plan and is now asking that the Gulf States communicate and provide a report to the VMC by December 15, 2008, with a plan describing the measures that will be implemented to achieve the *Vv* Illness Reduction Goals. The plan will include:

- a. Measures for 10%, 20%, 30% & 40% reduction.
- b. Estimated time for each state to implement measures.
- c. Interim steps that can be used to achieve implementation by May 1, 2010.

The ISSC Executive Office will distribute Paul DiStefano's Report (FDA Summary of Control Measures Implemented) to the Committee and State Regulators.

This report was for information and no action by the Board was required.

5. *Vp* Control Plan

Lori Howell presented the following items to the Board.

- a. The VMC recommended to the Executive Board that the VMC be charged to write a proposal that would substitute the following in the place of "for cooking only" (Proposal 07-202):

For shucking by a certified dealer, or other mechanism such as variance, to allow the hazard to be addressed by further processing.

A motion to approve this item was made by Bill Kramer and seconded by Ed Watson. The motion carried with a voice vote by the Board.

Charles Newell said he had been asked by David Heil that the following comment be reflected in the Board minutes.

- David Heil – Florida
Had this original “for cooking only” verbiage not been in the original proposal, at least one state would not have voted in support of the proposal and perhaps more, which could have influenced the outcome.

FDA recognizes the concerns raised in their letter of July 8, 2008, will be addressed through a new proposal. ISSC will communicate Conference actions related to FDA concerns outlined in the July 8, 2008, letter.

- b. The VMC recommended interim guidance be adopted on the following:

In proposal 07-202 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.

In accordance with the ISSC Constitution, Bylaws, and Procedures, Lori Howell made a motion, seconded by Bill Kramer that the Board vote to take interim action on this item as it is in keeping with the spirit and intent of the Conference.

A motion was made by Maryanne Guichard and seconded to Paul DiStefano, to adopt the interim guidance as recommended by the VMC. The motion carried with a voice vote by the Board.

- c. Lori Howell presented the following VMC recommendation for approval.

Interim guidance shall be adopted as follows:

In order that the labeling of “For Cooking Only” shucked product is consistent between states using as a *Vp* control measure, the container will be labeled on the lid and side panel and the label must be obvious, clear, legible, indelible, and not next to or over lapping other text. “For Cooking Only” product shall be in a master container separate from product that is not required to be so labeled.

After a lengthy discussion, Chris Nelson suggested a notification to the Conference that in it’s deliberations of Item b. above, the Executive Board also discussed that should an individual company in compliance with *Vp* controls choose to continue to use “for cooking only”, labels on shucked product containers that that label would need to be in compliance with existing label requirements of the NSSP. No action was taken by the Board.

6. Vv Workshops

Ken Moore reminded the Board, as discussed earlier that Vv Workshops were held in Apalachicola, Florida; New Orleans, Louisiana; and Dickerson, Texas during August. The agenda and notes were provided in the Board notebooks. This item was provided as information to the Board and no action was necessary.

7. Saltonstall-Kennedy Grant Program

Ken Moore informed the Board that the ISSC Executive Office intends to submit a grant proposal for education funding and/or possibly PHP under Utilization of Resources. This item was provided as information to the Board and no action was necessary.

8. Annual VMC Work Plan

Lori Howell advised the Board that the VMC Annual Work Plan was discussed during the VMC meeting but not finalized because of pending actions expected to be taken by the Board. The ISSC Executive Office will share the Plan with the Board upon receipt of the final report from the Chairperson.

IX. OLD BUSINESS

A. FDA Letter of February 7, 2008 Regarding Summary of Actions

Ken Moore reminded the Board of the action taken at the April 2008 meeting on Proposals 05-107 Real Time PCR Methods for Determining Levels of V_p and V_v and Proposal 05-113 Microbiology Checklist, Isolation of Male -Specific Coliphage, MSC as follows:

Mike Hickey explained to the Board that these two proposals addressed laboratory methods and the actions by the Voting Delegates was no action, but directed the Conference advise the submitter to resubmit. FDA asked that this be treated as “referred to Committee”. Pending resubmission of necessary information, the Executive Office interpreted conference action as is being recommended by FDA.

A motion was made by Spencer Garrett and seconded by Lori Howell that the Board approved the FDA recommendation on Proposal 05-107 and Proposal 05-113. The motion carried with a voice vote by the Board.

Ken recommended that the Conference recognize “No Action” to allow proposals to be removed from our agenda. In these cases the ISSC needs to inform the submitter in writing that no action was taken due to inadequate information and prior to further consideration additional information is required from the submitter. The submitter should be given a time limit of one (1) year to submit the additional information. If information is not received within one year it is a “No Action” item and should be deleted from the list of referred proposals. In response to Paul DiStefano, Ken advised that if the additional information is received within the one (1) year time frame, the proposal will be resubmitted to the Conference for approval. Ken will review Procedure XVI for clarification and will also be specific in giving direction to Task Force I in 2009.

A motion was made by Ed Watson that this item be reconsidered by the Board. The motion was seconded by Lori Howell and passed with a voice vote by the Board.

A motion was made by Kathy Brohawn to rescind the Board April 2008 action on this item. The motion was seconded by Ed Watson and passed with a voice vote by the Board.

B. FDA Response to 2007 Summary of Actions

Reconsideration of Concurrence with Proposal 07-202

Ken Moore advised the Board that the action taken by the Board on the VMC recommendations has addressed this item completely. A lengthy discussion ensued concerning procedures for ISSC Summary of Actions concurrence by FDA. This item was reported as information to the Board and no action was necessary.

C. 2007 Update NISSP Guide for the Control of Molluscan Shellfish

Paul DiStefano reported that the first draft of the 2007 Guide has been completed by FDA's IT department. FDA staff is in the process of reviewing the official document for posting on FDA's website. This item was reported as information to the Board and no action was necessary.

D. Follow Up to Intergovernmental Coordination Discussion

Spencer Garrett reported that this effort has grown and is now known as SIMOR (Subcommittee on Integrated Management of Ocean Resources). A recommendation will be made that EPA, FDA, and NOAA develop a Memorandum of Understanding (MOU) which will allow access of information through local databases. This is still a work in progress and appears to be more user-friendly, less expensive, and have more utility than SIMS. There was a consensus of the Board that Congressional funding is needed to pursue this project. Spencer Garrett will continue the efforts, with the assistance of Al Rainosek, to design a survey for distribution to states by the ISSC Executive Office. This item was reported as information to the Board and no action was necessary.

E. California Voting Censure

Ken Moore advised the Board that a follow up letter had been sent to California on August 27, 2008, requesting an update on the status of state regulations to change California's post harvest processing <3 MPN requirement. Rufus Howell of the California Department of Health Services responded by telephone and explained that the California budget cuts had slowed the process and the Department will follow up with a letter to ISSC. The Executive Office will share the letter with the Board upon receipt. This item was received as information to the Board and no action was necessary.

F. Jellett Rapid Test Concerns

Ken Moore presented background information on this issue. A letter from John Tennyson (NOAA) expressing his concerns regarding the Jellett Rapid Test kits had been furnished to Board members. There are concerns that changes made to the kits in an attempt to change the detection level are not consistent with original approval that was granted by the Conference. Ken advised the Board that he would work with other parties to write a letter to Jellett which addresses these concerns. The letter will request a quick response from Jellett for additional information on changes to the kit and documentation that the results obtained are consistent with the approval granted by the Conference. An update will be furnished to the Board upon receipt of information.

G. Dockside Testing (George's Bank)

Paul DiStefano advised that two pilot runs have been made out to the George's Bank area. The Jellett Rapid Test kits were used for both runs and tests were positive. Shellfish were not harvested for commercial use. Another run will be made on September 18, 2008. This item was reported as information to the Board and no action was necessary.

H. Research Needs Proposal 07-RN-200

Ken Moore reminded the Board that this research need proposal had been approved by the Conference at the 2007 Biennial Meeting based on availability of funding. Ken advised that this laboratory procedure is used to determine the level of thermal processing applied to shellfish meats, either in shell, half shell, or frozen. The funds have been disbursed to the Pennsylvania Department of Agriculture to complete this project. In response to Paul DiStefano, Ken said he will ask the Northeast states to share their experiences using this method.

I. Use of Press Committee Meeting with FDA

Ken Moore reported on the ISSC Use of Press Committee meeting held April 30, 2008, with FDA staff in College Park, Maryland. The four-hour meeting involved:

- Presentations by FDA staff on activities associated with outbreaks and recalls.
- Explanation as to how FDA makes decisions on press releases.
- Concluded that all can benefit from more precise and more rapid communications to determine the extent of closures and the need for recalls and press releases.
- Committee needs to continue to discuss how best to provide guidance about the kinds of information needed and the time frames.
- Bill Kramer suggested the Committee develop a list of items to be addressed and present the concerns to FDA.

This item was reported as information to the Board and no action was necessary.

J. Letter to MD and VA Regarding Product Recalls

Ken Moore reported that a response letter had been sent to the States of Maryland and Virginia on May 12, 2008. This matter has been sent to a committee to review protocol for recall and the Committee will report their findings and recommendations to the Board. This item was reported as information to the Board and no action was necessary.

K. Letters to Congress and States Regarding Economic Analysis

Ken Moore reported that response letters had been sent to the US Congressional Delegation and the States of Florida, Louisiana, and Alabama concerning the request that ISSC conduct economic studies on the implementation of the *V_p* and *V_v* Management Plans. Copies of the March 2000 ISSC study performed by Research Triangle Institute and the August 2005 FDA study were also furnished to the recipients. The letter asked that funding be made available to ISSC should a determination be made that an additional study was warranted. Ken advised that no responses have been received. This item was reported as information to the Board and no action was necessary.

L. Procedures for Executive Board Interim Approval Items

Ken Moore advised the Board that Paul DiStefano had requested this item be added to the Board agenda. Paul explained that at times the Board acts on behalf of the Conference and grants interim approval. These approvals can mean that a change in the Model Ordinance will be required. Paul asked for guidance by the Board as to the most appropriate way for this to be handled. He questioned appropriateness of including Board approved interim guidance included in the Model Ordinance prior to the item going to the Conference for adoption.

Ken explained that historically any interim guidance approved by the Board has been included in updates to the NSSP Guide if available. After further discussion, Board

members agreed that no changes in procedures are necessary at this time and requested that all interim guidance be posted on the ISSC website.

X. NEW BUSINESS

A. Executive Board Patrol Advisor Vacancy

Ken Moore advised the Board that John Jenkins had accepted a position as Director of the Alabama Marine Police Division and would no longer be able to serve as Patrol Advisor to the Board. Ken recommended the Board approve Bruce Buckson from Florida to fill the position. Bruce has acted as Patrol Committee Chair in John's absence in the past. A motion was made by Lori Howell and seconded by Ed Watson for the Executive Director to write John a letter thanking him for his service to the Board. The motion was approved with a voice vote by the Board.

B. Executive Board Consumer Advisory Position

Ken Moore advised the Board that the Consumer Advisory Representative's position has expired and is vacant. The Board was asked to advise Ken of any recommendations to fill this position. This item was reported as information to the Board and no action was necessary.

C. *Vibrio* Methods Workshop

Ken Moore informed the Board that he had been contacted by Steve Otwell, University of Florida, concerning funds available to bring together the research community that has been working on *Vibrio* methods. Steve asked if ISSC would be interested in working with him and Ken responded affirmatively. Steve will follow up with a proposal which Ken will share with the Board for comments and approval. Lori Howell asked that industry be included in participation. Joel Hansel also asked that the ISSC Laboratory Methods Review Committee Chairman be included in notification of the workshop. Ken recommended discussion of ISSC's method approval process at the workshop. This item was reported as information to the Board and no action was necessary.

D. EPA Grant Request

Ken Moore advised the Board that an inquiry and a scope of work had been sent to EPA requesting a determination of available funding for the collection of 2007 shellfish harvesting water classification survey and report. Ken will advise the Board of EPA's response. This item was reported as information to the Board and no action was necessary.

E. FDA PHP Validation Approval

Ken Moore advised that two additional companies have received PHP validation approval from FDA (one for *Vp* and one for *Vv*). Following a discussion, Board members agreed that in the future the name of the firm and the PHP method shall be posted on the ISSC website and any other detailed information should not be provided to the Board.

F. Accounting Services

Ken Moore explained that after discussion by the Executive Committee, the Executive Office is considering a new bookkeeping system (Quick Books) with a CPA firm on retainer. The fees being charged are not in line for services rendered for the present online bookkeeping system. This item was reported as information to the Board and no action was necessary.

G. Committee Travel Assistance

Ken Moore advised that this item had been added to the Board agenda at the request of Robin Downey. Robin asked for an explanation as to the parameters involved in approving travel funding assistance requests. Ken furnished background on travel policies of the ISSC and the current criteria used for approving travel funding assistance. Ken explained that there is a line item in the ISSC budget for travel that travel funds are distributed to requestors equally. Spencer Garrett recommended that the Executive Committee develop a transparent written policy. A motion was made by Maryanne Guichard directing the Executive Office to draft the general principles and guidelines regarding the travel assistance approval process to share with the Board at its next meeting. The motion was seconded by Spencer Garrett and carried with a voice vote by the Board.

H. Board Conference Call Participation

Chris Nelson asked if Conference members could listen in during Executive Board conference calls. Maryanne Guichard said that any member can contact their Board representative for input or participation in meetings. Maryanne Guichard made a motion to post approved Executive Board minutes, notices of Board meetings, and Board agendas on the website. The motion was seconded by Robin Downey and passed with a voice vote by the Board.

XI. OTHER INFORMATION

A. FDA Request to Expand Closure of Federal Waters

Ken Moore advised the Board that the following notice from FDA was furnished as information only. FDA formally requested that the National Marine Fisheries Service (NMFS) expand the existing closure of federal waters in the northwest Atlantic Ocean to include a restriction on the harvest of all species of bivalve molluscan shellfish in an area previously closed to whole and roe-on scallop harvest only.

B. EPA Solicitation of Public Comments (NPDES Vessel Permits)

Ken Moore advised the Board that information had been posted on the ISSC website and emailed to members at the request of Bill Hastback concerning EPA solicitation for public comment on two proposed NPDES vessel permits. This proposed permit incorporates the Coast Guard's mandatory ballast water management and exchange standards and supplemental ballast water requirements for vessels that carry ballast water. Furthermore, for all covered vessels, this permit also would establish requirements for twenty-seven other discharge types including deck runoff, bilgewater discharge, and graywater discharge. In addition to these standard or common requirements, the permit outlines further requirements for eight specific classes of vessels, such as cruise ships, research vessels, and large ferries. Bill commented the issue of ballast water management and exchange standards is relevant to shellfish sanitation because pathogenic microorganisms and harmful algae can be transported through ballast water.

C. LSU Raw Oyster Survey Participation

Ken Moore advised that a request had been received from LSU asking for assistance in distributing a survey involving regulating the raw oyster industry to protect human health. The ultimate goal of the study is to aid policymakers in the development of more efficient regulation to protect the at-risk population. The Executive Office provided a list of persons for the LSU contact. This item was reported as information to the Board and no action was necessary.

D. ICSR and ICMSS

Dot Leonard expressed her thanks to the Board for past support of the Restoration Conference held in Charleston, South Carolina. Dot asked that the Board consider what role ISSC would like to play in the International Society that is being formed. Ken asked that Dot furnish updates as they become available. No action was required by the Board.

XII. EXECUTIVE SESSION

A motion was made by Lori Howell that the Board go into Executive Session. The motion was seconded by Charles Newell and carried with a voice vote by the Board.

A motion was made by Bill Eisele that the Board reconvene in open session. The motion was seconded by Charles Newell and carried with a voice vote by the Board.

A. PICC vs. ISSC Update

An update was provided to the Board and this item was received as information. No action was required by the Board.

B. Executive Director Contract

A motion was made by Steve Fleetwood and seconded by Bill Eisele that the Board retains Ken Moore as an employee to serve as Executive Director at an annual compensation package as recommended by the Executive Committee and that the Executive Committee will finalize the agreement. The motion carried with a voice vote by the Board.

C. Staff Salaries

A motion was made by Lori Howell that in recognition of outstanding performance, that the Board award Nancy Daniel and Heather Thomas a salary increase, as agreed upon by the Board in Executive Session, effective retroactive to April 2008. The motion was seconded by David Guilbeau and carried with a voice vote by the Board.

XIII. ADJOURNMENT

A motion was made by Ed Watson to adjourn the meeting. The motion was seconded by Lori Howell and carried with a voice vote by the Board.