

**Interstate Shellfish Sanitation Conference
Denver, Colorado
Executive Board Meeting Minutes
March 10 and 11, 2010**

I. CALL TO ORDER

Mike Hickey called the meeting to order at 12:45 PM.

II. ROLL CALL

Ken Moore conducted roll call with the following members present:

Bruce Buckson	Lori Howell
Bob Connell	Bill Kramer
Robin Downey	Ken Moore
Bill Eisele	Chris Nelson
Paul DiStefano	Debbie Rouse
Steve Fleetwood	Spencer Garrett
David Fyfe	Larry Simms
Johnathan Gerhardt	Keith Skiles
Maryanne Guichard	Al Sunseri
David Guilbeau	Tommy Ward
Bill Hastback	Ed Watson
David Heil	Kirk Wiles
Mike Hickey	

The following members were absent:

Terri Gerhardt
Greg Pallaske
Rob Wittman

Office staff present:

Nancy Daniel, ISSC
Heather Thomas, ISSC

III. MINUTES

A. October 2009 Meetings

David Heil asked for editorial changes as follows:

“abeyance” 10/23 page 4; editorial changes effectiveness 10/23 page 4.

Ken Moore commented that the discussion by the Voting Delegates was clear and they chose not to give any direction.

B. February 1, 2010 Conference Call Meeting

A motion to approve the minutes was made by David Heil and seconded by Maryanne Guichard. The motion carried with a voice vote by the Board.

IV. INTRODUCTORY COMMENTS

A. Chairman Mike Hickey
Welcome

B. FDA

Paul DiStefano briefed the Board on the following:

- Staff
- Saxiton PSP funding extended for another year.
- PHP
- Recognized Andy DePaola for CODEX Report; Post documents on ISSC website; Working Group will meet in September

C. NMFS

Spencer Garrett briefed the Board on NMFS matters regarding staff and minor budget increases.

D. EPA

Bill Kramer updated the Board on water quality criteria for swimming and asked that the new links be posted on the ISSC website. He also reported on the small vessel discharges comment period which ends April 7th and nutrient criteria for fresh water.

V. APPROVAL OF COMMITTEE ROSTERS

The following committee charge memos and rosters were presented to the Board for approval.

- A. Audit Committee
- B. Biotxin Committee
- C. Communications Committee
- D. Education Committee (includes *Vibrio* Education)
- E. Foreign Relations Committee
- F. Import Assessment Committee
- G. Laboratory Methods Review & Quality Assurance Committee & Workgroup
- H. NSSP Evaluation Criteria Committee
- I. Patrol Committee
- J. Plant Standardization Advisory Committee
- K. Post Harvest Processing Committee & Workgroup
- L. Product Recall Committee & Workgroup
- M. Proposal Review
- N. Research Guidance Committee
- O. Resolutions Committee
- P. Shellfish Restoration Committee & Workgroup
- Q. Time Temperature Technology Committee
- R. Use of Press Committee
- S. *Vibrio* Management Committee & *Vv* Illness Review Subcommittee

Ken Moore explained the committee appointment process and discussed requests for committee member substitutes if a member was unable to attend a meeting. He suggested that committee quorums could be based on the number of members attending the Biennial Meeting rather than the roster. Al Sunseri suggested the Board develop a proposal for the 2011 Biennial Meeting that deals with replacing committee members unable to attend a particular meeting. Ken added that the Board could write a policy which makes members aware of ramifications of not attending. Following further discussion, David Heil made a motion that the ISSC Executive Board develop a policy for use in the future that the Chairman of the Executive Board will not chair any committee. Al Sunseri seconded the motion. There was a show of hands vote (Favor 7 Opposed 8) and the motion failed.

Lori Howell made a motion to accept the committee charge memos and rosters as submitted. Spencer Garrett seconded the motion and the motion carried with a voice vote by the Board.

VI. PROGRAM CHAIRMAN'S REPORT

- A. 2010 Fall Meeting will not be postponed until January 2011 as directed by the Conference.
- B. 2011 Biennial Meeting will be held in the Pacific Region.

VII. COMMITTEE REPORTS

- A. Executive Committee -- Mike Hickey
Ken reported on the status of the items listed below and materials were furnished to the Board members:
 - 1. Grant Update
 - 2. Financial Statement
 - 3. Annual Legal Retainer
 - 4. Renewal of Director's and Officer's Liability Insurance Policy
- B. Audit Committee Report -- Lori Howell
 - 1. Audit Report Year Ending 12/31/2009
Final report will be sent by email to Board members
 - 2. Bid Solicitation for Audit Services 2010 -- 2012
Proposals being prepared for distribution after receipt of 2009 final audit.
- C. Use of Press Committee Report
Bill Dewey chaired and recognized Bob Rheault. Use of Press committee Report- Work in Progress. Draft decision tree being developed.
- D. *Vibrio* Management Committee Report

The VMC reported the following and no Board action was required.
 - 1. The VMC voted to accept Tommy Ward as an alternate for Kevin Begos.
 - 2. FDA will provide a proposal for review at the next VMC meeting.
 - 3. FDA shared with the VMC their concerns associated with 00-201.
 - 4. The ISSC Executive Office will develop a Work Plan from the action of VMC and share it electronically for review and comment.
 - 5. No further action needed to encourage collection of environmental data. The ISSC should continue to support efforts to enhance the collection of epidemiological data. This would include recommending to States that the Supplemental *Vv* illness reports be completed for each *Vv* case.

6. Continue to encourage industry-implemented post-harvest controls to reduce Vv levels.
7. Provide incentives to post-harvest process oysters intended for raw, half-shell market.
8. Continue assessment of capacity of operational plants and those under construction.
9. The Executive office should share data from most recent survey with Vv source states.
10. The VMC will continue efforts to compile and review data on rates of illness.
11. The following Vv Illness Data report was presented to the VMC by Al Rainosek.

Marc Glatzer has indicated that of the current reported 17 Core States Vv cases for 2009, at least 11 are clearly countable. Below is a table giving the **2009 Illness Rate Reductions from Baseline** for 11 to 17 cases.

Baseline (1995-1999) Illness Rate (IR) = 0.278/mil

Estimated (based on US Bureau of Census data) 2009

Core States population = 84,669,386

Av 2007/2008 IR Reduction from Baseline = 35.2%

<u>Cases</u>	<u>Illness Rate/mil</u>	<u>Illness Rate Reduction</u>
11	0.130	53.2%
12	0.142	48.9%
13	0.154	44.6%
14	0.165	40.6%
15	0.177	36.3%
16	0.189	32.0%
17	0.201	27.7%

Note: For each case, there is (allowing for round-off) about a 4.3% change in Illness Rate Reduction.

12. Evaluation Criteria for Vp Requirements of Model Ordinance Chapter II. The next VMC agenda will include an item to review Vp illness data. Data will be obtained from CDC to allow for comparison of 2008 and 2009 illness data.
13. Recommend a workgroup be formed to work with NMFS and USDA (corrected) data collectors to provide information and data needed for 05-100. ISSC Executive Office will develop a survey and contact the states and report back to the Committee. Maryanne Guichard made a motion to approve adding ISSC will work with RTI and Lori Howell seconded the motion. The motion carried with a voice vote by the Board.
14. Development of Criteria for Evaluating Effectiveness of 2010 State Vv Management Plans:
 - a. The VMC will use the following criteria in determining the effectiveness of State Vv Management Plan control in 2010.
 - b. How many cases do we have relative to other years May through December at this same point (date) in the year?
 - c. How effective have the source states been in implementing the time-temperature control strategy?
 - d. Effectiveness means levels of enforcement, rate of compliance, recognition of problems in implementation.
 - e. Any extraordinary factors which may be contributing to increase or decrease in number of illnesses e.g. compliance downstream with

retail food code or extraordinary non-compliance in a non-core state, which contributes to illnesses in core states.

- f. All cases will be reviewed by the *Vv* Illness Criteria Review Subcommittee.

Maryanne Guichard made motion to accept recommendation and the motion was seconded by Lori Howell. The motion carried with a voice vote by the Board.

15. Current Status of Economic Impact Analysis Recommendations:

Request that the Economic Impact Analysis workgroup appointed in Manchester be charged with developing an RFP for a consumer, wholesaler, retail study and solicit a minimum of three competing proposals for consideration. Request the workgroup be further charged with reviewing and selecting the best proposal, identifying funding to complete the study and getting the study done as soon as possible. The ISSC Executive office will coordinate discussion between RTI, Steve Otwell, Joe Jewell, LSU Sea Grant and workgroup.

16. Proposal 09-207:

Request workgroup be formed to continue to (added by Spencer) explore implementation of Proposal 09-207 and to look at types of controls and determine the risk reduction they might achieve with each type of control. USFDA has stated that they will be withdrawing their non concurrence. Spencer Garrett mad a motion to include "continue to" and adopt recommendation. The motion was seconded by Robin Downey and carried with a voice vote by the Board.

17. Validation/Verification Guidelines for Shellfish without *Vv* Labeling Claims:

Request a subcommittee be appointed to develop a draft proposal for review at the next VMC meeting. Lori Howell made a motion to accept the recommendation and Maryanne Guichard seconded the motion. The motion carried with a voice vote by the Board.

18. FDA Industry Interaction Sessions in the Gulf:

Recommend that FDA have at least three interaction sessions: Two in the Gulf and one on the East Coast and to include the fishermen in (both Gulf) sessions. Arrange opportunities for FDA to visit individual facilities to better understand industry. Recommend that in each of cities where these sessions are being held, include a session with wholesalers and restaurateurs. The ISSC Executive Office will share the FDA Interaction Session summaries with the VMC upon completion. A motion was made by Maryanne Guichard and seconded by Lori Howell with a friendly amendment by Al Sunseri accepted. Following a discussion, the recommendation was approved by the Board with a voice vote.

19. *Vp* Illness Data:

Request CDC provide *Vp* Data Illness tables on all sources for the next VMC meeting. Request that FDA ask CDC to continue to prepare the pie chart that shows harvest areas in total vibrio cases and the percentage by species for each area of the country.

The ISSC Executive office will request that CDC present this data at the

next VMC meeting. The ISSC Executive Office will form a workgroup to gather information and report back to the committee to address *Vp* issues. Workgroup will be formed to review and analyze data and report back to VMC. Maryanne Guichard made a motion with correction of recommendation. The motion was seconded by Lori Howell and carried with a voice vote by the Board.

20. PHP End Point Testing:

Arrange a meeting for statisticians and microbiologists to meet and discuss end point and validation/verification issues. The group will look at sample size for validation end point testing for processes not intended for labeling. Prior to this meeting the ISSC will form a workgroup to determine the appropriate approaches for measuring process effectiveness. The workgroup will convene via conference call. A motion was made by Lori Howell to accept the recommendation and seconded by Johnathan Gerhardt. The motion carried with a voice vote by the Board.

21. Discussion of VMC Actions for 2011

No action taken.

22. Collaboration with Education Committee

The ISSC Executive office will take recommendations from the VMC Committee for Education Committee charges and establish charges for the Education Committee. No board action required. Email will be sent out to VMC for recommendations.

23. The Board agreed that the fall meeting be moved to January 2011.

VIII. OLD BUSINESS

- A. EU Audit
Paul DiStefano Response to questions from each due next week.
- B. Proposal 07-303 Guidance on Equivalence Criteria for Food
Paul and Ken to develop language for document.
- C. GAO Audit Request
Ken Moore – no additional information at this time. Chris said another letter will be coming from the Gulf asking that other areas be addressed in the Audit.
- D. Shellfish Restoration Proposal (The Campbell Foundation)
Discussions with Dot.
- E. No response on California Regulation Regarding Raw Oysters Update
- F. International Society on Molluscan Shellfish Safety Membership
- G. *Vibrios* in the Environment Meeting November 2010 in Biloxi
 - Added Item Andy DePaola
 - Post additional information on website
 - Asked ISSC to be sponsor and financial support \$5,000 (speaker/travel, etc.).

- Board will be provided copy of agenda and discuss
- Andy asked for funding for state personnel to travel to meeting
- Registration \$400 early \$500 late program participation will waive registration \$150 Day; \$360,000 budget
- ISSC will be listed as sponsor. Focus on food safety. Send request of who is interested and look at all requests received.

Maryanne Guichard made a motion to spend \$5,000 to send members of ISSC that are presenting, participating, or attending. Robin Downey seconded the motion. The motion carried with a voice vote by the Board.

- G. FDA Reformulation of Vv Policy
Attachments: FDA Letter 10/16/2009; ISSC Letter 11/02/2009; FDA Press Release 11/19/2009; FDA Letter 01/26/2010; ISSC Draft Letter 02/11/2010).furnished to the Board. Ken recommended consideration of this item after the Board receives and acts on the VMC report on Thursday.

THURSDAY DISCUSSION AND ACTION:

Ken referred to February 10th letter drafted to FDA. No action was taken by the Board.

IX. NEW BUSINESS

- A. FDA Response to the 2009 Summary of Actions
1. Proposal 09-205 Investigation during a Suspected Oyster Related Outbreak of *Norovirus*
Spencer Garrett made a motion to refer proposal 09-205 to a committee and pointed out that in the future FDA's response should be in accordance with the CBP Procedure X. Section 3. Johnathan Gerhardt seconded motion. Motion carried.
 2. Proposal 09-207 *Vibrio vulnificus* Risk Management for Oysters
Kirk expressed concern over FDA not following CBP in response. Paul DiStefano. FDA wishes to officially withdraw non-concurrence of 09-207
 3. Proposal 00-201 *Vibrio vulnificus* Risk Management Plan
No action required by the Board.
 4. Proposal 05-100 *Vibrio vulnificus* Risk Management Plan for Oysters
Exemption for Licensed Shellfish Harvesters & Dealers
Board agreed with FDA response. Exceptions are not appropriate.
 5. Proposal 05-114 Microbiology Method to Determine the Presence of Male Specific Coliphage in Shellfish Meats and the Microbiology

Maryanne Guichard made a motion to reject FDA's recommendation in their response to Summary of Actions. Executive Director will add section for clarification in Summary of Actions. Robin Downey seconded the motion. Guidance should be developed for NSSP Guide for the Control of Molluscan Shellfish. The motion carried with a voice vote by the "Board.

6. Proposal 09-107 Saxitoxin (PSP) Elisa Kit
Resubmit proposal with additional information. A motion was made by Robin Downey and seconded by Maryanne Guichard that the ISSC write a letter and ask for additional information. The motion carried with a voice vote by the Board.

- B. Proposal for Acceptance Study for PHP Oysters
Requested that the workgroup appointed in Manchester be charged with developing a RFP for a consumer, wholesaler, retail study and solicit a minimum of three competing proposals for consideration. Request the workgroup be further charged with reviewing and selecting the best proposal, identifying funding to complete the study and getting the study done as soon as possible. The ISSC Executive office will coordinate between RTI, LSU Sea Grant and workgroup.

- C. Conference for Food Protection Issue (Consumer Advisory)

Following a lengthy discussion, a motion was made by Al Sunseri and seconded by Lori Howell that Ken Moore will attend the biennial meeting of the Conference for Food Protection in Providence, Rhode Island the week of April 11, 2010, to represent ISSC's position opposing the issue and with the following direction. The motion carried with a voice vote by the Board.

The ISSC Executive Board on behalf of the membership of the organization opposes the adoption of Issue #007. The ISSC Executive Board believes that the current Consumer Advisory language for hazardous foods which includes shellfish and the requirement to "inform *consumers* by brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means of the significantly increased *risk* associated with certain especially vulnerable *consumers* eating such *foods* in raw or undercooked form" are adequate. Requiring a unique consumer advisory message specifically for Gulf oysters sets precedence for other hazardous foods that could result in multiple confusing messages for consumers. And further, shellfish (oysters) should not be singled out as the only food item to be included for this requirement. Further the ISSC Executive Board believes the National Shellfish Sanitation Program suggests that a point of sale consumer information message as written on an oyster tag, or an equivalent message be carried forward to retail as currently provided in the Model Retail Food Code.

For these reasons, the ISSC opposes Issue #007 and believes that the current language in the Model Retail Food Code addresses this issue adequately.

- D. 2009 NSSP Guide for the Control of Molluscan Shellfish
Paul DiStefano reported ISSC continues to work on updating the Guide.
- E. FDA Status of States Program Report

Paul DiStefano reported the following:

- Number of states visited and programs evaluated
- Pilot program report requested by NSSP Evaluation Criteria Committee.
- Ken asked for information for Paul so ISSC can share with the Committee.
- FDA checklist for Vp control plans. Assure all inspectors are inspecting states with vp control plans equally.

- Board can ask VMC to comment or ask NSSP Eval Criteria to comment; or both. Paul recommends committee hold conference call. Mike asked for comments from Board on sending this matter to committee. Lori Howell made a motion to send to committee. The motion was seconded and carried with a voice vote by the Board.
- Ken informed Board of Letter to State of Illinois and content. Letter will follow to certified dealers.

- F. Executive Committee Members and Procedure
Al Sunseri requested this item on the Agenda. Al Sunseri mad a motion that ISSC develop a policy for executive committee industry member recommendations to committee with term limits and staggering terms, option for no limit on term. Announce Executive Committee meetings and agendas.
- G. 2009 ISSC Work Plan Evaluation
Will send draft for comments.

X. OTHER ITEMS

Ken presented information to the Board on the following:

- A. MSI Meeting Report Ken Moore brief report
- B. ISSC/Industry Meeting January 18, 2010 Ken Moore brief report
- C. State of Rhode Island Resolution

XI. EXECUTIVE SESSION

A motion was made by Lori Howell that the Board go into Executive Session (10:50 AM) the motion was seconded by Johnathan Gerhardt.

- A. Staff Evaluations
The Board reconvened at 11:35AM. A motion was made by Spencer Garrett to recognize the truly outstanding efforts of office staff. Steve Fleetwood seconded the motion and the motion carried with a voice vote by the Board.
- B. Executive Director Employment Status
A motion was made by Lori Howell to hire Ken Moore as full time executive director in June and the motion was seconded Ed Watson and carried with a voice vote by the Board.
- C. Other
A motion was made by Lori Howell and seconded by Maryanne Guichard that an Executive Committee succession plan be developed.

XI. AJOURNMENT

The meeting was adjourned at 5:20 PM