

I. CALL TO ORDER

The meeting was called to order at 1:00 PM by Chairman Keith Skiles.

II. ROLL CALL

Ken Moore conducted roll call and determined a quorum was present to conduct business. Ken advised the Board that effective October 12, 2012, Congressman Rob Wittman had resigned as Program Chairman of the Executive Board.

Board Members Present:

Keith Skiles
Maryanne Guichard
Ken Moore
William Eisele
Mike Hickey
Lori Howell
Cali Alexander
Steve Fleetwood
Julie Henderson
Patti Fowler
Joe Jewell
Mike Voisin for Al Sunseri
Margaret Barrette
Ed Watson for Johnathan Gerhardt
Quincy Boyce for Terri Gerhardt
Bruce Flippens
Paul DiStefano
Spencer Garrett
David Fyfe
Chris Nelson
Kirk Wiles

Representing:

Chair
Vice Chair / Region 6 Regulatory
ISSC Executive Director
Conference Office Manager
Region 1 Regulatory / Past Chair
Region 1 Industry / Task Force II Chair
Region 2 Regulatory
Region 2 Industry
Region 3 Regulatory / AFDO Representative
Region 4 Regulatory
Region 5 Regulatory
Region 5 Industry
Region 6 Industry
Non-Producing State
Non-Producing State
Non-Producing State
FDA
NOAA
Northwest Indian Fisheries Commission
Task Force I Chair
Task Force III Chair

Board Members Absent:

Larry Simms	Region 3 Industry
Tommy Ward	Region 4 Industry
David Guilbeau	Region 5 Regulatory
Bill Kramer	EPA
Greg Pallaske	Conference for Food Protection Representative
Christopher Blankenship	Patrol Advisor

ISSC staff and others were also present.

III. EXECUTIVE BOARD

- A. Board Vacancies
Ken Moore advised that the Board continues to have a vacancy for the Consumer Advisory Representative and he is still trying to identify a person that would be willing to serve. Paul DiStefano suggested asking Kevin Smith (FDA). Chris Nelson suggested someone from the Conference for Food Protection, the National Restaurant Association or the Food Marketing Institute. Ken will propose options for discussion at the next Board meeting and Keith Skiles asked for suggestions from the Board.
- B. Conflict of Interest Statement
Following review of the Conflict of Interest Statement, a motion was made to reconsider this item at a future Board meeting. The motion was seconded and approved with a voice vote by the Board.

IV. MINUTES

Following a motion and a second, the Board approved the minutes of the meetings listed below:

- A. September 13, 2012
- B. August 7, 2012
- C. April 13, 2012
- D. March 6 & 7, 2012 (Joe Jewell will be added as present at this meeting.)

V. INTRODUCTORY COMMENTS

- A. Keith Skiles, Executive Board Chair welcomed Board members.
- B. Paul DiStefano, FDA, provided updates on the following issues that had previously been brought to the attention of the Board.
 - 1. The 2nd International Workshop on Molluscan Shellfish Area Classification and Management was held in Rhode Island September 24-28, 2012. Eleven countries participated. Exchange of program systems was presented.
 - 2. FDA is continuing to work with the EU to establish agreement to reopen trade between the countries.
 - 3. FDA continues to work on a signed seafood safety agreement with New Zealand to seafood safety agreement. There is currently an MOU between FDA and New Zealand.
 - 4. The State of Hawaii is interested in coming back into the NSSP program as a producing state.

Ken Moore informed the Board of Phil Busby's illness and the Executive Office will mail a card on behalf of the Board.

- C. Spencer Garrett, NOAA, provided updates on the following:
 - 1. Informed the Board that he hopes to be retired by January 3, 2013.
 - 2. Expressed concerns with NOAA budget issues and the effect it could have on future ISSC annual funding of \$75,000.
- D. Bill Kramer, EPA
No comments were provided in Bill's absence.

VI. PROGRAM CHAIRMAN'S REPORT

Ken Moore advised that the 2013 Biennial Meeting is scheduled for the Gulf Region. Bill Eisele reported on the progress in identifying hotels in Mississippi and Texas. The Executive Office will update the Board as information becomes available. The 2013 Spring Board meeting may be held in a different location due to funding issues.

VII. COMMITTEE REPORTS

A. Executive Committee

1. Grant Updates

Ken Moore advised that the 2013 grant award letter for our Cooperative Agreement with FDA had been furnished to Board members. No Board action was required.

2. Financial Statement

Ken Moore advised that the Board had been furnished a current Financial Statement and no action was required by the Board.

3. 2013 Budget

Ken Moore advised that the 2013 budget had been furnished to Board members. Following a motion and a second the Board approved the 2013 budget as submitted.

4. 2013 Membership Fees

a. Individual

b. State (Proposal 11-302)

Ken Moore presented information on current individual membership fees. Following a discussion a motion was made to delay action on a decision regarding individual and state membership fees until the 2013 Spring Board meeting. The motion was seconded and approved by the Board.

5. 2013 Draft Work Plan

Ken Moore reported that the Board had been furnished a copy of the 2013 ISSC Work Plan and asked Board members to review and furnish comments by email to the Executive Office no later than December 1, 2012.

B. Audit Committee

Lori Howell advised that the draft audit reports for 2010 and 2011 had been reviewed by the Audit Committee and there are no concerns or deficiencies. She advised the Board that approval was needed so final reports could be issued. Following a motion and a second the Board approved the 2010 and 2011 audit reports.

C. Use of Press Committee

Ken Moore provided an update on information submitted to FDA. Paul DiStefano explained there had been a delay but the information has been forwarded to an internal FDA group that is developing protocol. A motion was made and seconded that the Board ask FDA for a progress report on the protocol and provide a report to the Board in March. The motion was approved by the Board.

D. Depuration Review Committee

Ken Moore advised that in response to a letter from Tom Howell, the Board had previously approved a motion to appoint a work group to address modernization of depuration and how depuration-like processes apply. The work group was to include non-depuration persons. Ken said he had reviewed Tom's letter and developed a charge and a roster. Following a motion and a second, the Board approved the Depuration Review Committee charge and roster. Steve

Fleetwood requested that he be replaced on this committee by Cali Alexander. There was no objection by the Board.

E. Import Assessment Committee

Ken Moore advised that Sandy Shepherd had requested additional information on NOAA on fisheries import data and asked if NOAA and FDA are communicating on NON-MOU product entries. Following a discussion Spencer Garrett agreed to discuss this item with FDA and provide an update to the Board at the March meeting. A motion was made and seconded to send a letter to quality control staff of major broad line distributors in the US to make them aware of imported product from non MOU countries is from an unapproved source and a State in the NSSP can take action. Ken said a distribution list needs to be identified before the letter can be sent. FDA and States will be copied on the letter. Margaret Barrette asked that the letter include an invitation to attend a future Board meeting for further discussion. The motion was approved by the Board. Lori Howell suggested renewing the charge of the Import Assessment Committee.

VIII. Old Business

A. California Regulations Update

Ken Moore reported on California's efforts to change their regulations regarding <30 MPN/gram non-detect. He said that California had to revise the Fiscal Impact form that goes with the package to change the regulations and that is now back in their budget shop. California said they are still making slow but steady progress. A motion was made and seconded that the Board direct the Executive Director to write California a letter stressing the importance of participation and voting in the Conference. The motion was approved by the Board.

B. Virginia Vv Case Reconsideration Request

Keith Skiles passed the gavel to Vice Chair Maryanne Guichard during discussion of this item. Ken Moore reported that a letter had been received from the Virginia State Health Commissioner. Senator Richard Stuart was in attendance and Congressman Rob Wittman joined the meeting by phone. Congressman Wittman and Senator Stuart presented information to the Board on new evidence on a Vv illness case attributed to Virginia and asked the Board to consider the new evidence and return this case back to the Vv Illness Review Subcommittee for due diligence and reconsideration. Following discussion, a motion was made to send this request for reconsideration related to this illness back to the Vv Illness Review Subcommittee for further review and deliberation and report the findings of the Subcommittee at the next Board meeting. The motion was seconded and failed by a show of hands (Yes 5; No 6) of the Board.

C. Proposal 05-310 (NSSP Evaluation Criteria Committee Shellfish Sanitation Plant Element Evaluation Criteria)

Ken Moore reported on the background of this proposal that was adopted by the Conference in 2005 and advised that a letter had been sent to States advising that the ISSC Voting Delegates adopted Proposal 05-310 which established Plant Sanitation Evaluation Criteria of the National Shellfish Sanitation Program (NSSP). He said the letter also advised that FDA had concurred with the Conference adoption of this proposal and would be using these criteria in evaluating State programs in 2012. FDA has used these criteria for the past two (2) years in a pilot to test and refine the criteria. States were advised to review these criteria recognizing the possible impact for their program. Paul DiStefano reported on results of the criteria and said that the majority of States were in compliance with these criteria. Following a lengthy discussion by the Board no action was required by the Board.

D. Proposal 11-201 Part A (*Vibrio vulnificus* Risk Management of Oysters)

1. FDA Concurrence Update

Ken Moore advised that a letter had been received from FDA informing the ISSC of FDA's concurrence with adoption of the Conference's Proposal 11-201A to initiate a new plan to reduce illnesses and deaths resulting from *Vibrio vulnificus* in raw oysters. Following a discussion a motion was made and seconded that the ISSC request evaluation criteria from FDA, which will be distributed to the Board for comments, prior to implementation in the FDA compliance program. The motion was approved by the Board. A motion was made and seconded to choose implementation date of December 1, 2012. The motion was approved by the Board.

2. Vv Illness Review Subcommittee Charge

Ken Moore explained to the Board that the review of Vv cases will be different under risk per serving criteria. He suggested that the Subcommittee charge be revamped and said additional elements need to be reviewed. Ken Moore, Keith Skiles and Lori Howell will develop a new charge and the Subcommittee will be charged to go back several years and review all cases. There was no objection from the Board.

E. Proposal 11-201 Part B (Time/Temperature Requirements) Model Ordinance

Margaret Barrette presented a PCSGA letter and concerns with a motion for suspension of all changes for time temperature requirements. The motion was seconded. A substitute motion was made that in response to PCSGA, between now and March 1, 2013, all clarifications be complete and the ISSC meet in each region to discuss the implementation of these requirements. The substitute motion was seconded and the substitute motion carried with a voice vote by the Board. Ken Moore agreed to develop a questions and answers page for time temperature requirements and post on the ISSC website. Further discussion was tabled by a motion and a second. The Board approved the motion. Mike Voisin asked for a definition of "receipt". The following day Ken Moore presented the Board with a revised document for discussion on Chapter VIII A. 3. Matrix Deleted Level 4 Revised Level 3; Page 2 of 11 Chapter XI. B. (2); B. 2. (c) Reject changes; and Page 2 of 9 Chapter XIII. B. (4). Following a lengthy discussion, a motion was made and seconded to keep the current documents in place and postpone any changes to language until the next Biennial Meeting. A substitute motion was made and seconded that the Board refer the documents back to the Shipping & Receiving Committee and task that Committee to review the suggested changes and further directed this document be brought back to the Board for discussion at the March 2013 meeting. The Board voted by a show of hands with eight (8) voting yes and five (5) voting no. The substitute motion passed.

F. Online Vv Courses for Physicians, Nurses & Dieticians

Ken Moore updated the Board on the costs involved with maintaining and updating the online Vv courses. Following a discussion and a second a motion was made to continue funding of these courses if the funds are available and seek other grant funding to support the courses. Ken said a cost analysis can be developed and provided to the Board. The Board approved the motion.

G. FDA Dilution Policy 1000:1

Ken Moore advised that the Board had previously been furnished a letter from to ISSC to FDA regarding FDA's program application of the 1000:1 Dilution Policy for classifying waters adjacent to sewage wastewater treatment plants. As a follow up to the discussion the Executive Board requesting that FDA revisit the agency's position on its 1000:1 Dilution Policy. This specific policy is not currently a part of the National Shellfish Sanitation Program (NSSP). There was agreement that a guidance document should be submitted as a proposal for incorporation into the NSSP. The Executive Board is not opposed to the use of dilution studies

for determining appropriate classification for growing water adjacent to sewage treatment plants, it is imperative that recommended dye study standards be reviewed by ISSC. However, until formally recognized by the ISSC for incorporation into the NSSP, FDA is requested to instruct shellfish specialists and States that use of the 1000:1 Dilution Policy is not a mandatory requirement. A motion was made and seconded that ISSC send a letter to the States advising that this is not a mandatory requirement but rather a recommendation by FDA. The motion was approved by the Board.

H. Korean Update

Paul DiStefano provided an update to the Board on the Korean product recall and said he will provide a progress report to the Board at the next meeting. Paul said that no timeline has been set for Korean recertification. FDA will respond directly to Cali Alexander in reference to questions on Korean product she has embargoed. There was further discussion regard FDA and MOUs with foreign countries. No action was required by the Board.

I. Laboratory Approval for PHP Validation & Verification

Ken Moore reported that in 2001 the ISSC Executive adopted interim criteria for laboratories, involved in PHP validation and verification and States are responsible for assuming laboratory compliance with these criteria. He said FDA is now evaluating state programs using these criteria and are finding laboratories that are not in conformance with the criteria. Following discussions with the FDA, the ISSC Executive Board recommended that effective January 1, 2013 that validation and verification analytical data will only be allowed from laboratories meeting the ISSC adopted laboratory criteria. He said States which have licensed, permitted, or certified PHP processors would be requested to advise these processors within their states of these requirements and the effective date of implementation. Ken advised the Board that he would send a letter to the States and will furnish costs of sampling at the next Board meeting.

J. ISSC Issue to Conference for Food Protection (Retail Food Programs)

Ken Moore reported that a request had been received from the Conference for Food Protection asking ISSC to co-write a letter to States asking them to educate retail food establishment operators in their jurisdiction on the proper methods of handling raw molluscan shellfish, and to take enforcement action where applicable to ensure the requirements are followed. Ken said he would review the letter again and suggest alternate language in the letter and Board members could review and provide comments on the letter. No action was required by the Board.

K. PHP Oyster Sensory Final Report

Ken Moore reported that the final report had been received for this project and the report will be posted on the ISSC website. No action was required by the Board.

L. ISSC Grants Final Reports for *Vibrio* Technology Projects

Ken Moore reported that the findings of these projects had been received. He said the reports had been distributed to a group for review and did the reports meet the scope of the project. Ken asked for suggestions on how to best use this information. A motion was made and seconded that Steve Otwell's report be expanded into more of a publication and for the technical terms needed to be defined. The motion was approved by the Board.

IX. New Business

A. Shellfish Control Authority Contact on ISSC Web Site

Ken Moore presented background on the State Shellfish Control Authority contact page on the ISSC website and explained that there is only one contact per category. No action was required by the Board.

B. Placement of Program Compliance Evaluation Criteria

Ken Moore explained that one set of program compliance evaluation criteria placement is in the ISSC Constitution, Bylaws, and Procedures one set is in the Model Ordinance and another set is in the Guidance Documents. Ken advised that he would like to postpone discussion of this item until March meeting. No action was required by the Board.

C. Connecticut House of Representatives Member Inquiry

Ken Moore reported that a letter from a Connecticut House of Representatives Member had been received inquiring about *Vp* control responses to outbreaks. He said this letter was provided to the Board as information and no action was required by the Board at this time.

D. New Jersey Borough of Highlands (Highlands Depuration Commission) Inquiry

Ken Moore referred the Board to the letter from Highlands dated July 3, 2012. Gef Flemlin spoke to the issue and provided handouts. Dennis Kavanaugh of Sandy Hook Waterman's Alliance also presented information to the Board. No action was required by the Board. Ken advised Mr. Flemlin and Mr. Kavanaugh that they needed to submit a proposal at the 2013 Biennial Meeting and the forms would be provided by the Executive Office. Ken also offered his assistance in putting a proposal together.

E. State Survey Proposal 09-212 (Training Requirements for Harvesters & Dealers)

Ken Moore asked the Board if they would like to see a proposal on how a program can be developed and delivered. Following a discussion, a motion was made to pursue development of harvester and dealer education courses and present this item to the Board at the March meeting. The motion was seconded and approved by the Board.

F. Proposal 11-114 (Requirement for the Authority During a Suspected Oyster Related Outbreak)

Ken Moore all states should be included in and closure notification from ISSC. States are required to notify us of recalls but there are not requirements⁰ that closures be included in notification to ISSC. No action was taken by the Board. This item will be brought back to the Board in March 2013.

G. Re-submerging Shellfish Harvested under *Vibrio* Plans

Ken Moore reported on this item and said an interest had been expressed in resubmerging shellfish harvested under *Vibrio* Plans. Following a discussion, Maryanne Guichard said she supports a group to look at this issue and more data is needed. A motion was made to form a workgroup to discuss and develop standards for equivalent controls for resubmerging for *Vibrios*. The motion was seconded and approved by the Board.

H. Standards for Equivalent Controls

Ken Moore reported that we have no standards for equivalent controls and we need a committee to develop guidelines. It was agreed that we need more data and members were supportive of having a group look at this issue. A motion was made and seconded to develop a committee to discuss and develop standards for equivalent controls for *Vibrios* and address the issue of resubmerging with some guidelines that can be used. The Board approved the motion. . Following a discussion, another motion was made and seconded to do a call for data-Motion carries. The Board also approved this motion. Sections of the Guide to be reviewed are:

1. Model Ordinance Chapter II. @ .06 B. (4) (b) (vi) [*Vp* Controls] 0

2. Model Ordinance Chapter II. @ .05 E. (1) (b) (iv) [Vv Controls]
3. Proposal 09-231 PHP Handling

Board action on this item will also address Item G. above.

I. Status of FDA 2012 State *Vibrio* Plan Evaluations

Paul DiStefano presented some of the findings as information to the Board. Paul agreed that no state names would be used and he would use generalities in his report.

- *Vibrio* reports will be separate from state evaluations
- On board temperature control not doing what it is supposed to do
- Logs indicating white tag product that does not meet requirements
- Not meeting harvest times segregation of product not achieving internal temperature 50 / 10 hour
- No efforts to have dealers demonstrate coolers are capable to achieve this.
- No effort to ensure dealers are complying
- State's control plan does not include requirement for 50 /10 hour
- Greatest deficiency cool down from harvest to 50 when in the cooler
- Most state plans met minimum requirements of program.
- States are capable of meeting current requirements of plan
- Plans are consistent with requirements for establishing a plan
- Seeing significant improvement in terms of regulatory compliance to take immediate action when they see deficiencies and bring product back into control.
- Seems to be significant improvements in efforts by states to see that states are in compliance
- Evaluations are better as far as States and industry compliance

No action was required by the Board.

J. ISSC Voting

1. Foreign Country Participation in ISSC

Ken Moore advised the Board that foreign countries have expressed an interest in participation in the ISSC unresolved issue process. Ken said the countries want to use this process to protest FDA evaluations. No action was taken by the Board.

2. State Vote Allocation

In response to an inquiry from Margaret Barrette, Ken Moore explained the state vote allocation process of the ISSC. Following a discussion, no action was taken by the Board.

K. Foreign MOU Requirements

Ken Moore suggested that ISSC provide input to FDA on what MOU requirements should be regarding foreign countries. Paul DiStefano will make a presentation at the March Board meeting on procedures used by FDA to grant MOUs to foreign countries. No action was required by the Board.

L. AOAC Approved Methods

Ken Moore advised that he and Patti Fowler will submit a proposal at the 2013 Biennial Meeting to reduce the level of requirements associated with Conference adoption of methods validated by the AOAC. He said that the AOAC criterion exceeds the requirements of the ISSC. He said this item will be brought back to the Board in March for reconsideration. No action was required by the Board at this time.

M. 9th International Conference on Molluscan Shellfish Safety (Australia)

Ken Moore asked for direction from Board on attendance at this meeting to represent the ISSC. Paul DiStefano recommended that Ken or Keith attend. A motion was made to send one person to participate in the meeting in Australia. The motion was seconded and approved by the Board.

X. Other Information

- A. NOAA Proposed Rule to Re-Open Georges Bank
Ken Moore advised that information on this item was submitted as information to the Board and no action was required by the Board.

- B. Department of Justice News Release (Traffic in Illegal Oysters NJ)
Ken Moore advised that information on this item was submitted as information to the Board and no action was required by the Board

XI. Adjourn

A motion was made to adjourn the meeting at 12:06 PM.

NOTE: All referenced documents had previously been furnished to Board members and are available from the ISSC Executive Office upon request.