

I. CALL TO ORDER

Johnathan Gerhardt, Executive Board Chairman, called the meeting to order at 1:00 PM.

II. ROLL CALL

Ken Moore, Executive Director, conducted roll call.

Board Members Present:

Johnathan Gerhardt
Ken Moore
William Eisele
Mike Hickey
Lori Howell
Dave Carey
Steve Fleetwood
Kathy Brohawn
A.J. Erskine
Shannon Jenkins
Barry Hurt for Tommy Ward
Kirk Wiles
Kim Stryker
Margaret Barrette
Bruce Flippens
Melissa Abbott
Jon Bell
Bill Kramer
David Fyfe
Patti Fowler
Mike Pearson
Keith Jackson
Keith Skiles

Representing:

Chair and Non-Producing State Member
ISSC Executive Director
Conference Office Manager & Program Chair
Region 1 Regulatory
Region 1 Industry
Region 2 Regulatory
Region 2 Industry
Region 3 Regulatory
Region 3 Industry
Region 4 Regulatory / Task Force I Chair
Region 4 Industry
Region 5 Regulatory
Region 6 Regulatory
Region 6 Industry
Non-Producing State
FDA
NOAA
EPA
Northwest Indian Fisheries Commission
Past Chairman
Patrol Advisor
Retail Advisory Representative
Vibrio Management Committee Chairman

Board Members Absent:

Chris Nelson

Region 5 Industry

Others present included:

Quentin Forrest
Laurie Farmer
Bob Rheault
Miranda Ries
Aaron Wozniak
ISSC Executive Office Staff

FDA
FDA
East Coast Shellfish Grower's Association
National Fish & Oyster Company (Olympia, WA)
FDA Regional Shellfish Specialist

Ken Moore advised the Board that Jerrod Davis, representing Region 6 Regulatory had resigned his Board seat. Ken asked Jerrod to poll Region 6 for a replacement recommendation. Kim Stryker of Alaska was recommended to fill the vacancy for Jerrod's term which expires this year. A motion was made and seconded to approve the Region 6 Regulatory recommendation. The motion was approved with a voice vote by the Board.

III. Approval of November 2 and 3, 2017, Minutes

Melissa Abbott indicated Bill Jones was not present at the November meeting and asked that the minutes be corrected. A motion was made and seconded to approve the minutes of the November 2 and 3, 2016, Board meeting as corrected. The motion was approved with a voice vote by the Board.

IV. Introductory Comments

A. Executive Board Chairman Johnathan Gerhardt
Johnathan said he was excited and honored to fulfill the remainder of Patti Fowler's term as Executive Board chair.

B. FDA

Melissa Abbott reported on the following items:

- FD245 Sanitation course was held in Rhode Island.
- FD243 Shellfish Control course is being finalized for posting online.
- There is a link on the FDA website with a listing of other general courses offered relevant to the shellfish program.
- FD242 Shellfish Growing Area course to be held in FY 2018
- They are working on advanced Sanitary Survey of Shellfish Growing Areas course. The purpose of this course is to fill in gaps and enhance participant skills in the methods of shoreline surveys and sanitation concepts for shellfish growing and harvesting areas. The course will go beyond the basic concept which will teach advanced techniques. Growing area course was last taught in 2007. Hope to have this course ready in 2018.
- Focusing on efforts related to laboratory training. Creating a Division of Human Resources and Development (DHRD) course (OTED is new acronym for Office of Training Education and Development) for LEOs and Lab Management.

C. NOAA NMFS

Jon Bell reported on the following items:

- Broaden and incorporate more NOAA NMFS expertise into the ISSC.
- Searching for Angela's Ruple's (now Lead Analyst) replacement as Lead Microbiologist.
- Tony Lowrey (NSIL) has retired.
- Seafood Inspection Program has the lead on international efforts.

D. EPA

Bill Kramer reported on the following:

EPA, in addition to implementing the Clean Water Act programs for: bacterial pathogen standards, monitoring, permits, assessment, TMDLs and enforcement; is engaged in these topics:

1. Clean Water Act Recommended Water Quality Criteria for Recreational Waters (Swimming) [John Wathen]
2. Development of Recreational Water Quality Criteria for Coliphage [Sharon Nappier]
3. EPA Development of Recreational Ambient Water Quality Criteria (AWQC)
4. Water Treatment Optimization for Cyanotoxins Document
5. Harmful Algal Blooms (HABS) [Lesley D'Anglada]
6. Microplastics in Shellfish - Trash Free Waters Program [Margaret Murphy]
7. Fish and Shellfish Program Newsletter [Sharon Frey]
8. 2017 EPA-FDA Advice about Eating Fish and Shellfish
9. Beach Marine Sanitary Survey Tool Demonstration [Samantha Fontenelle]
10. EPA International Cooperation Website [Bill Kramer]

V. PROGRAM CHAIRMAN'S REPORT

- A. 2017 Biennial Meeting
Bill Eisele reported that the 2017 Biennial Meeting will be held at the same location as the Board meeting (Sheraton Hotel and Convention Center in Myrtle Beach) during October 14 – 19, 2017. A draft agenda for the Biennial Meeting is available on the ISSC Website. Ken Moore stated an email will be sent soliciting suggestions for symposium topics. He mentioned a possible federal government shutdown and how it could affect the Biennial Meeting. He indicated he will discuss this situation with the hotel regarding any possible penalties.
- B. 2017 Call for Proposals
Bill Eisele advised the Board that June 16, 2017, is the deadline to submit proposals for consideration at the 2017 Biennial Meeting. Ken Moore said he will schedule conference calls thirty (30) days prior to the Biennial Meeting for each task force to review proposals.

VI. EXECUTIVE COMMITTEE REPORT

- A. Travel Policy
Ken Moore reminded the Board that State membership fees were increased in 2013 and the Board agreed that any monies collected that were not needed for operation costs could be used for travel funding assistance. He then provided background information on the development of the draft travel policy and explained that criteria to attend Board meeting and hardship conditions were included in this draft. In response to Kim Stryker, Ken stated that travel committee members will be anonymous. A motion was made and seconded to approve the draft travel policy submitted. The motion carried with a voice vote by the Board.
- B. Grant Updates
1. 2017 FDA Cooperative Agreement
Ken Moore advised the Board that the second year continuation application for the five-year grant period will be completed and submitted.
 2. FDA 2017 Scientific Small Conference Grant
Ken Moore advised the Board that the grant application had been completed and submitted and expects approval. The \$25,000 award is used to assist State regulators with travel costs to the Biennial Meeting.
 3. NoroCORE Contract
Ken Moore updated the Board on the NoroCORE projects that ISSC had completed:
 - MSC Workshop;
 - Dealer and Harvester Training Programs;
 - State Boater Education; and
 - Overboard Discharge Education for Recreational Boaters. ISSC attended boat shows in Myrtle Beach, SC, Baltimore, MD, Eugene, OR, Biloxi, MS, and Mobile, AL. The final report will be shared with the Board.Ken said he would like to research additional opportunities for grants to continue sponsoring an exhibit booth at boat shows throughout the country for educating recreational boaters in the dangers of overboard discharge.
- C. 2017 Budget
Ken Moore asked Board members to review the 2017 draft budget for approval at tomorrow's meeting. He explained the increases in special projects and research. Ken explained why the budgets were separated into a fiscal year basis and a calendar year basis. Bill Kramer asked for a comparison of the 2015 to 2017 budgets with the percentage change.

Ken said the document would be handed out at tomorrow's meeting. The current financial statement was presented to the Board as information. The following day a motion was made to approve the budget as submitted. The motion was seconded and approved with a voice vote by the Board.

D. 2016 Work Plan Evaluation

Ken Moore said the 2016 Work Plan Evaluation had been provided to Board members in the meeting materials and there were no program deficiencies for 2016. A motion was made and seconded to approve the 2016 Work Plan Evaluation as presented and to post the document on the ISSC Website. The motion carried with a voice vote by the Board.

E. 2017 Work Plan Draft

Ken Moore asked that Board members review the 2017 ISSC Work Plan draft that was included in Board materials and provide any comments to the ISSC Executive Office no later than June 23, 2017. The Work Plan will be considered final within thirty (30) days after comments are received.

VII. OLD BUSINESS

A. AFDO Milk & Shellfish Cooperative Agreement Update

Ken Moore briefed the Board on the background of this grant proposal and award. He said after the grant was awarded to AFDO, the ISSC was asked to participate in the Joint Advisory Group (JAG). Following additional comments, Ken reported the information below on the AFDO Milk/Shellfish Agreement for Training and Equipment:

- \$ 675,000 available for FY2017
- \$ 303, 750 allocated to Shellfish
- \$ 1.3 Million requested from States
- \$ 438,548 requested for Shellfish

Shellfish Training

- Available: \$237,000
- Requested: \$303,455
- All Priority 1 and 2 requests funded: \$195,691
- Priority 3 requests funded: \$47,475 (\$107,445 requested)

Shellfish Equipment

- Available: \$66,250
- Requested: \$135,412
- All "Achieve Compliance" requests funded: \$24,326
- "Maintain Compliance" funded: \$35,944 (\$63,851 requested)

Laurie Farmer said she would like to recognize the ISSC Training Committee for their efforts. Kirk Wiles requested information on how many States had applied for funding. Several members commented on the AFDO grant procedure stating some States that did not apply for this funding due to the administrative burdens associated with the small amount of monies available. Ken Moore mentioned exploring other procedures that could be used to assist States in obtaining these funds. Ken said historically FDA has made monies available for States to attend regional meetings. He said if we are going to fund attendees for training that the regional meetings need to have a training component. Mike Hickey asked which States declined the funding because of the amount of funding available or the application process. Ken said this item will be carried over the next Board meeting and so additional information can be brought back to the Board on these concerns. Additionally, he will determine how to provide feedback to AFDO.

B. US/EU Equivalency Agreement (Melissa Abbott, FDA)

Melissa Abbott reported that FDA is moving forward with plans to file a Federal register notice within a month or two. They are working through the remaining administrative processes. She said the initial MOU will involve Massachusetts, Washington, The

Netherlands, and Spain. They have developed a streamlined process to add more States and countries in the future without onsite evaluations. All details have not been worked out on procedure States will follow to be added to the MOU. EU will not allow any product to be sent by States that operate under a V.v. Plan. FDA and the EU agreed to form a workgroup to talk about how they might be willing to consider PHP product. FDA will be having discussions with the EU to consider allowing canned product. Lori Howell asked that deperated product be included as accepted product. Agreement language will come after the Federal Register Notice. Melissa said she thinks the initial group will be a five-year agreement and it will probably be a year before the process is complete.

C. Vibrio Research Projects

1. Existing Contracts – PSI Final Report Ken Moore advised the Board that there are three (3) outstanding Vibrio Research contracts.

- a. Pacific Shellfish Institute (PSI) – The Vibrio Research Committee has reviewed the final report. The ISSC Executive Office is working with PSI to make the changes. Final report should be completed within the next fourteen days.
- b. Massachusetts Division of Marine Fisheries – Mike Hickey presented the following update to the Board.
 - Massachusetts conducted all the sampling described in its proposal to and contract with ISSC.
 - Oyster samples were collected from multiple field sites (n=5) to determine background levels of total and pathogenic *V.p.* in oysters, and for comparison to levels of total and pathogenic *V.p.* in re-submerged oysters following air drying and following transplant from Katama Bay to an adjacent open water site.
 - Data recording sondes were deployed adjacent to all *V.p.* oyster sampling locations and recorded environmental conditions (water temp, salinity, Chl a, turbidity, etc.) at 15 minute intervals.
 - Oyster samples were processed following Standard NSSP enumeration protocols and tiered analysis for total *V.p.*, tdh and trh.
 - Additional genetic sequencing and strain typing (prp/flp, pathogenicity island via end point and qPCR, and WGS and PFGE) from trh or tdh positive enrichments or cultured isolates was conducted.
 - Lysates from oyster enrichments that tested positive for *V.p.* and either tdh or trh, but could not immediately be analyzed for strain specific markers, were frozen and are pending analysis for the presence and quantification of pathogen specific markers (prp/flp, pathogenicity island).
 - Preliminary analysis of 2016 data for total *V.p.*, tdh and trh show below normal (as compared to 2014 and 2015 DMF monitoring data) levels of total *V.p.*, tdh and trh, which is consistent with the observed decline in clinical cases of *V.p.* in Massachusetts.
 - Multivariate PCN analysis comparing levels of total *V.p.* and pathogenic markers to environmental conditions and illness occurrence is on-going.
 - Massachusetts is on track to provide ISSC with a final report by August 2017.
- c. State of Washington Department of Health – Ken Moore informed the Board that we were unable to obtain a recent report from Washington but based on their last quarterly report they are on track with their project.

2. Future ISSC Funded Research

Ken Moore said he wanted to reserve discussion of this item until after discussion of the ROP Workshop and the *V.p.* Workshop.

- D. 2015 NSSP Guide Revision
 Ken Moore reminded the Board reported that the Guide had been finalized and posted on FDA's website February 2017. He thanked FDA staff for their diligence and complimented the staff that worked on the review and editing for the 2015 Guide update.
- E. MSC Guidance Document
 Ken Moore reported that work was continuing for the guidance document that will be submitted as a proposal at the Biennial Meeting. The guidance document addresses classification of waters adjacent to waste water treatment plants. He said this document will be of great benefit to everyone that classifies growing waters.
- F. Reduced Oxygen Packaging (Proposal 15-208)
 - 1. ROP Workshop Report
 Ken Moore reported that the ROP November 1 & 2, 2016, workshop report was included in the Board materials.
 - 2. FDA Letter December 8, 2016
 Ken Moore advised the Board that a letter was received from FDA requesting additional action by the ISSC to include ROP controls in the NSSP Model Ordinance.
 - 3. The Executive Board voted to reconsider previous Executive Board action on the ROP Committee recommendations.
 - 4. A motion was made and seconded to delay further action on the ROP Committee recommendations until FDA has completed a packaging study and determined the appropriateness of including ROP controls into the Model Ordinance
- G. Laboratory Committee
 Ken Moore briefed the Board on the activities of the Laboratory Committee. He said the Committee had sent over forty (40) letters concerning laboratory method approvals since the last Biennial Meeting. He complimented Stacey DeGrasse (current Chair) and Patti Fowler (past Chair) for the exceptional work that has been done by the Laboratory Committee.
- H. V.v. Illness Review Committee (Lori Howell, Committee Chairperson)
 Lori Howell presented the following report to the Board:

On August 3, 2016 the *Vibrio Vulnificus* Illness Review Committee made the determination that case number FL05042015 was attributable to Washington State. Washington State appealed that decision and following the procedure approved by the Executive Board for appeal of a determination of the *Vibrio vulnificus* Illness Review Committee, filed an appeal. Washington alleged that the case should not have been considered a septicemia case and also argued that the Washington oysters did not cause the illness. After discussion, the committee voted to affirm the previous decision. Ms. Laura Johnson made the presentation on behalf of Washington. Factors discussed included the lack of new information, lack of information indicating that the previous decision was incorrect; review of information contained on the COVIS form, discussions about how one fishes the Indian River, where the patient fished. Also discussed were the symptoms experienced and disease progression of the patient, how similar symptomology was adjudicated in previous cases and many other factors. When Committee discussions ended, there was no motion to reconsider the August 3, 2016 decision, therefore, the appeal was denied.

Following Executive Board discussion, David Fyfe made a motion that the Board delay a decision on this item so further information can be submitted and reviewed. The motion was seconded by Margaret Barrett. The motion failed with a voice vote by the Board.

Following further discussion, Ken Moore suggested delaying posting of the report for ninety (90) days. A motion was made and seconded that there be a ninety (90) day period waiting period before any V.v. illness cases are posting on the ISSC website. The motion failed with

a voice vote by the Board. A request for show of hands on the vote was requested and the motion failed by a vote of seven (7) to six (6). Jon Bell (NOAA NMFS) abstained from the vote. A motion was made by Kirk Wiles to accept the report and decision of the V.v. Illness Review Committee's decision on the Washington State countable case appeal. The motion was seconded by Bruce Flippens. The motion carried with a voice vote by the Board.

- I. Biotoxin Workshop.
Ken Moore informed the Board that a Biotoxin Workshop was held in Washington, D.C. on March 14 & 15, 2017. Nine (9) States were in attendance and presented information on issues that affect each State. He said the meeting was very informative. States provided overviews of their Biotoxin Programs. Ken said there was an abundance of information presented at the meeting and no two States manage in the same manner. The workshop recommendations and a report will be presented to the Biotoxin Committee.
- J. Other Committee Activities
Ken Moore said he would like to talk about the Aquaculture Committee is working to rewrite Model Ordinance Chapter VI.
- K. ISSC Website Update
Ken Moore reported that the new ISSC website went live on January 9, 2016. He explained that we were still looking for additional pictures to enable rotating slides for each program element in the program. He said all comments are welcomed and will be considered.
- L. Chandler vs. ISSC
Ken Moore informed the Board that a complaint had been filed against the ISSC for failure to provide financial information requested in a timely manner. He said ISSC has filed an Answer in accordance with the advice received from the ISSC attorney. After speaking with the Clerk of Court in Florida, Ken believes this is one of many frivolous complaints brought by this individual and the complaint will be dismissed without prejudice. Ken said he will keep the Board updated.
- M. FDA Compliance Program Review (Melissa Abbott, FDA)
Melissa Abbott reported that the document is still in draft form with one section left for final review. She said it should be available soon.
- N. Shellfish Models for AFDO HACCP Training
Ken Moore reported to the Board that the ISSC Executive Office had assisted the AFDO Seafood HACCP Alliance with development of two oyster models for training courses. The two models were shellstock shippers and shucked shellfish.
- O. FDA Transportation Rule
Ken Moore reported when FDA proposed the rule for Sanitary Transportation of Human and Animal Food we commented on July 30, 2014 to the Federal Register. In one of the comments in the letter he stated that Section H.3. included potential waivers for companies with valid permits that are inspected under the National Conference on Interstate Milk Shipments and Food Establishments holding valid permits when engaged in certain types of operations. These potential waivers should be extended to shippers, carriers, and receivers of shellfish that hold valid State permits. Ken said the same rule should apply to retail, milk, and shellfish programs. There are only two states (Maine and Massachusetts) that inspect trucks. He said FDA will involve the ISSC after developing guidance and how it will be implemented. FDA will engage ISSC if this requirement is optional or a requirement that will be incorporated into the Model Ordinance. Will be broader discussion in the future on exemption ISSC requested.

VIII. NEW BUSINESS

- A. 2017 Task Force Appointments
Ken Moore asked the Board to review the 2017 Task Force Rosters for approval after distributing a corrected copy.

- B. *V.p.* Workshop
- C. CDC Data Sharing

Ken Moore reported that he was having some difficulty in obtaining data from CDC. He said he had reminded CDC that prior to 2007 that the Model Ordinance required that States report all *V.p.* illnesses to ISSC. At the request of CDC, the ISSC stopped collecting the data and there was agreement that CDC would share their *V.p.* illness data with ISSC in exchange for ISSC discontinuing collection of *V.p.* illness information. Ken then read information that had been sent to CDC that said “A small team of ISSC members met at CDC in early October. At that meeting and a similar session held with the full Subcommittee in Duluth, the CDC indicated it can and will provide *Vibrio* illness data parsed into data sets and analyses most useful to the ISSC. Further, the CDC is open to requests from the ISSC for additional data collection, e.g., shellfish harvest date and location, species, or other information important to determining cause or source of the illness. These requests will be considered and carried forward by CDC, recognizing that any changes in *V.p.* illness case investigation and data collection will likely involve changes to the agency’s officially approved protocols and forms, a process in itself. Ken said the point he made to CDC is ISSC is the primary user of this information and the controls to address *Vibriosis* in this program is this Conference. He said a conference call is being scheduled with CDC and FDA to discuss data sharing.
- D. Washington State Norovirus Outbreak

Ken Moore updated the Board on this item and said communication with Washington State had been successful. He said notices were posted on the ISSC website and there was a concern on the number of outbreaks. Laurie Farmer said she was aware of this situation and familiar with the outbreaks. He said Washington plans to cooperate with the concerns over timing, retroactive closures, and sizes of areas closed. Melissa Abbott said FDA needs to send a letter to Washington and has offered to assist Washington with field issues.
- E. Training Committee/Training Presentations

Ken Moore reported that he had communicated to groups at the regional meetings that this is an opportunity to gather information. He said the epidemiologists don’t understand how we use the COVIS forms. Kirk Wiles asked if the presentations could be made available to the States so they could education within their State.
- F. Status of States Report Follow Up

Ken Moore reminded the Board of the discussion at the November 2016 meeting that FDA provide the names of States in their Status of States report to the Board each year.
- G. Catalina Sea Ranch

IX. EXECUTIVE DIRECTOR ACTIVITIES

Ken Moore updated the Board on his activities with a brief discussion of the meetings attended.

- A. PAC RIM
- B. ISS
- C. NESSA
- D. GSASSC
- E. Seafood HACCP Alliance
- F. AFDO Conference

X. OTHER INFORMATION

In response to a question by Barry Hurt asking if all States were reporting production data, Ken Moore responded that we are still working on this item. He said intervals being reported are pounds, bags, bushels, etc. and we need a conversion to risk per serving. Ken will keep the Board updated on the progress.

XI. EXECUTIVE SESSION

A motion and a second was made that the Board convene in Executive Session at 10:50 AM Wednesday, May 24, 2017. The motion was approved with a voice vote by the Board.

XII. RETURN TO OPEN SESSION

A motion was made and seconded that the Board reconvene in open session at 11:17 AM. The motion was approved with a voice vote by the Board.

A. Staff Evaluations

Johnathan Gerhardt asked for a motion to approve a 5% salary increase, as discussed by the Board in Executive Session, for Nancy Daniel and Cathy Mantooth. The motion was seconded and approved with a voice vote by the Board.

B. Executive Director Evaluation

Johnathan Gerhardt asked for a motion to approve a 7.5% salary increase with a survey comparison study to be completed by the fall Board meeting, as discussed by the Board in Executive Session, for Ken Moore. The motion was seconded and approved with a voice vote by the Board. Ken Moore said in the future the Executive Director's evaluation will be shared with all Board members for review and comment.

XIII. ADJOURN

A motion was made and seconded to adjourn the meeting at 11:25 AM on Wednesday, May 24, 2017. The voice was approved with a voice vote by the Board.