



MINUTES

I. CALL TO ORDER

Johnathan Gerhardt called the meeting to order at 1:00 PM

II. ROLL CALL

Board Members Present:

Johnathan Gerhardt
Kohl Kanwit
Ken Moore
William Eisele
Mike Hickey
Lori Howell
Bob Schuster
Steve Fleetwood
Kathy Brohawn
Pete Jensen
Mike Pearson
Barry Hurt (for Tommy Ward)
Kirk Wiles
Jennifer Jenkins
Kim Stryker
Margaret Barrette
Jon Strauss
Melissa Abbott
Laurie Farmer
Bill Kramer
Jon Bell
David Fyfe
AJ Erskine

Representing:

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

Board Members Absent:

Patti Fowler
Keith Jackson
Bruce Flippens
Erin Stokes
John Tesvich

Past Chairman
Retail Advisory Representative
Non-Producing State
CDC Liason
Task Force I Chair

III. APPROVAL OF MAY 17-18, 2018 MINUTES

A motion was made and seconded to approve the minutes of the May 17-18, 2018 Board meeting. The motion was approved with a voice vote by the Board.

IV. INTRODUCTORY COMMENTS

- A. Chair Johnathan Gerhardt
Welcome and additional welcome to John Strauss to the Executive Board.
- B. FDA Melissa Abbott
 - Staff updates for CFSAN
 1. Pete Koufopoulos – still acting as Shellfish & Aquaculture policy branch director
 2. No approval for filling vacant positions at this time
 - Budget update
 1. The 2019 budget has been reduced by 20%
 2. Participation of staff at regional meetings and other shellfish related meetings will be reduced
 3. CFSAN priorities will focus on critical activities such as laboratory evaluations in 2019
 - Foreign audits
 1. Taiwan HACCP audit occurred in August and included one shellfish firm. No concerns were indicated.
 2. Canada audit occurred in September. Washington and Oregon were visited as those states are Canadian primary exporters. Canada did identify gaps with the NSSP but implementation of NSSP was found to be comparable to CSSP. A draft report is expected in 60 days. The ISSC may be interested in including a presentation by Canada during the information session of the biennial meeting that explains their HACCP-based approach to handling *Vibrio parahaemolyticus*.
 - 3.
 - Training items
 1. FD246 course laboratory methods being offered June 10-14, 2019
 2. FD245 Plant standardization being offered in July 2019
 3. Developing advanced growing area course
 4. Patrol course expected early in 2019 for FDA specialists online
 - GARB studies
 1. Dye study in NJ done in April produced additional recommendations for classification
 2. Dye study in MD conducted in September; data is being analyzed
 3. WA is writing a draft report and requested study be continued in Hammersley Inlet & Oakland Bay
 4. MA study completed in June; FDA will present draft of data analysis to MA and will provide training on analysis and assist in developing draft report
 5. Budget cuts may affect approval of future GARB requests.

Laurie Farmer

- ORA Update
 1. Budget is similar to last year.
 2. The key priority is uniformity for FDA evaluations;

developed peer templates that align NSSP requirements to deficiencies.

3. Luis Solorzano will be conducting field meetings to address training and standardization.
4. Laurie Farmer advised that states interested in having program manager meetings should contact her office.
5. 2017 Model Ordinance was published and evaluations will be based on the new requirements.
6. A track change version of Guide in 2019 will help with continuing changes and implementations associated with the national field program including assessments of program and standardizing evaluations.

- C. NMFS Jon Bell
- Aquaculture in federal waters currently has little structure; NOAA is actively hiring for this program
 - No budget approved yet but funds expected to support safety in federal waters
 - NOAA will get more involved with ISSC and the NSSP
- D. EPA Bill Kramer
- See attachment which was distributed to the Board.

V. PROGRAM CHAIRMAN'S REPORT

- A. 2019 Executive Board Spring Meeting will occur in late March or early April in San Diego, CA
- B. A motion was made and seconded to hold the 2019 Biennial Meeting October 5-10, 2019 in San Diego, CA at the Intercontinental Hotel. Motion was approved by a voice vote by the Board.

VI. COMMITTEE REPORTS

- A. Executive Committee Report
 - Grant Updates
 - 2019 FDA Cooperative Agreement has been awarded and is the same as previous year.
 - 2019 FDA Small Conference Grant will be applied for to cover travel expenses for state representatives attending the 2019 Biennial Meeting
 - 2019 Membership and Registration Fees
 1. A motion was made and seconded to leave individual membership fees at \$60.00. Motion was approved by a voice vote by the Board.
 2. A motion was made and seconded to leave state membership fees at \$1100.00. Motion was approved by a voice vote by the Board.
 3. A motion was made and seconded to give the ISSC Executive Office the option to raise the registration fee by \$25 if necessary. Motion was approved by a voice vote by the Board.
- B. Laboratory Committee
 - Meets monthly in addition to several monthly subcommittee meetings
 - Tremendous amount of work is being done
- C. Time/Temperature Committee
 - Surf Clam Subcommittee
 1. Industry Background document including harvesting, handling, and processing practices. (See attachment provided to the Board)

2. A study needs to be designed to trace shellfish from harvest through processing to determine if and what time temperature controls may be needed.
- D. Research Management Committee
- The following entities have been notified of the intent to award research contracts:
 1. Virginia Institute of Marine Sciences
 2. University of New Hampshire
 3. Auburn University
 4. University of North Carolina
 5. State of Maryland
 - Contracts have been initiated with 3 entities and the other 2 will be initiated soon. Total funding is around 242K.
 - Research is being expanded beyond vibrio now and ideas can be presented at next board meeting for next request for proposal cycle
- E. Training Committee
- Discussed training requirements. Currently there are requirements for LEO, HACCP and Standardized Inspector but there are no training requirements for Growing Area Classification and poorly defined requirements for patrol.
 - There are training requirements in the Model Ordinance for some program elements while other elements have none defined. To continue to expect funding from outside sources, training requirements will need to be defined. Expect to see training proposals at the next Biennial meeting.
 - Topics for training sections at the regional meetings need to be decided. Record keeping for traceback in the event of a recall has been suggested. All suggestions for topics for thirty minute training sessions at regional meetings should be submitted to the ISSC Executive Office.

VII. OLD BUSINESS

- A. US/EU Equivalency Agreement
- Comment for federal register notice closed May 23rd. A final determination is expected by the end of 2018 at which time trade can resume.
 - EU procedure requires a final vote to add US to list of 3rd country importers. Washington and Massachusetts are the only approved states.
 - Additional states will have to be voted on by the EU for addition to the program.
 - FDA plans to hold a WebEx meeting to demonstrate how to use the Export Listing Module. Further discussions need to be held addressing who will be invited to these meetings.
 - Much concern was expressed regarding the fairness of the agreement.
- B. 2017 Work Plan Evaluation
- Executive Board members have 30 days to provide comments to the ISSC Executive Office.
- C. 2018 Work Plan Approval postponed until Executive Session
- Executive Board members have 30 days to provide comments to the ISSC Executive Office.
- D. AFDO/FDA Cooperative Agreement
- The portal has been set up and \$843,750.00 is available for the two programs. The split of the money between the milk program and the shellfish program was determined by the amount of funding requested in previous years by members of each program.
 - Funding for travel to training can be applied for now and monies for equipment will be made available at a later date.

- Not all states are able to benefit from this grant process. A motion was made and seconded to ask FDA to look at future funding be made available in ways to accommodate all states. Motion was approved by a voice vote by the Board.
- E. 2017 NSSP Guide Revision
- The guide was published to the FDA and ISSC websites on October 17, 2018.
- F. V.v. Illness Review
- FDA and CDC believe more decision documentation is needed as there is no guidance for making medical determinations and no one on the Committee is clinically able to make a determination.
 - CDC believes a case definition can be developed for anyone to use in making a septicemia determination on V.v. cases. A motion was made and seconded to request CDC to develop a case definition of septicemia for V.v. Motion was approved by a voice vote by the Board.
- G. Impact of CIDT for Reported V.p. Cases
- A technical committee involving CDC has been formed to discuss the impacts of the recent increase in the use of culture independent diagnostic tests (CIDT). The discussion at a minimum should address:
 1. The impact of CIDT on the effectiveness of the V.p. controls included in Chapter II @.02 Shellfish Related Illnesses Associated with V.p.
 2. The impact that CIDT on trend data that is currently being used by the ISSC to evaluate the effectiveness of NSSP V.p. controls.
 Additionally, the technical committee's charge will be expanded to include the identification of available tools and techniques and illness data information that could be used to enhance the effectiveness of the NSSP. These tools, techniques and additional illness information discussions should involve all illnesses associated with the consumption of raw molluscan shellfish. These discussions should address the roles of illness reporting entities and their ability to share data both real-time and long term.
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VIII. NEW BUSINESS

- A. Proposal 17-119 Implementation
- This proposal was intended to address aquaculture in federal waters. States assumed it was applicable to aquaculture.
 - The requirement now says all product from federal waters will require a dockside testing program. Currently every boat harvesting surf clams and every state in which it is landed, is now out of compliance.
 - The Federal Water Subcommittee is meeting with FDA on October 22, 2018 to discuss how to incorporate federal water requirements into the program. The meeting is being held in College Park to attempt to develop an implementation strategy and better understand the positions of FDA and NOAA.
 - Motion was made and seconded to recommend to FDA to delay implementation of 17-119 until after ISSC has a strategy that addresses the concerns of all parties. Motion was approved by a voice vote
- B. Laboratory Evaluation Criteria Guidance
- During the review of the 2017 NSSP Guide, conflict found in criteria from the checklist not matching the Model Ordinance. The wording in question is “more than” and “less than” statements.
 - A motion was made and seconded that should a discrepancy exist, the FDA will use criteria from the checklist. Motion was approved by a voice vote by the Board,

- C. Committee Structure and Process
 - Committees should be making recommendations and have reports prepared prior to the Biennial Meeting. The recommendations should be included in the proposal package and all debate on the recommendations should occur at Task Force.
 - Further discussion needs to be had by the Board concerning why participation is not occurring in Task Force
- D. Status of the States
 - Control of Harvest was presented by Raymond Burditt.
 - Plant Evaluation Report was presented by Raymond Burditt.
 - Growing Areas Report was presented by Quentin Forrest.
 - Laboratory Evaluation Report was presented by Lizzie Evans.
 - Vibrio Evaluation Report was presented by Lizzie Evans.
 - Foreign Evaluation Report presented by Melissa Abbott.

IX. EXECUTIVE DIRECTOR ACTIVITIES

- A. The Executive Director recently performed a site visit to hotels in San Diego, CA and participated in a HACCP Alliance meeting.

X. EXECUTIVE SESSION

- A. The following items were discussed during Executive Session
 1. Moore, Beauston, Woodrow LLP (Accounting Firm Update)
 2. Audit/Financial Report
 3. Executive Office Financial Procedures Policy (Attachment 14)
 4. ISSC Employee Manual
 5. N. Daniel Update
 6. Executive Director Evaluation
- B. A motion was made and seconded that for the years 2012-2017 no external audit will be conducted. The motion was approved by a voice vote by the Board.
- C. A motion was made and seconded that the Executive Office and the Executive Committee will develop procedures for additional financial controls and they will be implemented immediately. The motion was approved by a voice vote by the Board.
- D. A motion was made and seconded that the Executive Office and the Executive Committee will revise the Employee Handbook. The motion was approved by a voice vote by the Board.