MINUTES

I. CALL TO ORDER

Johnathan Gerhardt called the meeting to order at 8:10 AM PST

II. ROLL CALL

Board Members Present:	Representing:
Johnathan Gerhardt, Chairperson	Non-Producing Regulatory
Ken Moore	ISSC Executive Director
Mike Hickey	Region 1 Regulatory
Lori Howell	Region 1 Industry
David Carey	Region 2 Regulatory (Alternate)
Steve Fleetwood	Region 2 Industry
Kathy Brohawn	Region 3 Regulatory
Pete Jensen	Region 3 Industry
Mike Pearson	Region 4 Regulatory
Barry Hurt	Region 4 Industry (Alternate)
Kirk Wiles	Region 5 Regulatory
Jennifer Jenkins	Region 5 Industry
Kim Stryker	Region 6 Regulatory
Margaret Pilaro	Region 6 Industry
Bruce Flippens	Non-Producing State
Jon Strauss	Non-Producing State
Melissa Abbott	FDA
David Fyfe	Northwest Indian Fisheries Commission
Keith Jackson	Retail Advisory Representative
Lesley Price	ISSC Executive Staff
Cathy Mantooth	ISSC Executive Staff
Kohl Kanwit, Vice Chairperson	Task Force II Chair
Jon Bell	NOAA
AJ Erskin	Vibrio Management Committee Chairman

Board Members Absent:	
Bob Schuster	Region 2 Regulatory
Tommy Ward	Region 4 Industry
Laurie Farmer	USFDA/ORA Advisory (Joined by WebEx)
Erin Stokes	CDC Liason (Joined by WebEx)
Bill Kramer	EPA Representative
Patti Fowler	Past Chairman
John Tesvich	Task Force I Chair

III. INTRODUCTORY COMMENTS

A. Chair — Johnathan Gerhardt

Welcome and explanation of meeting schedule.

B. FDA — Laurie Farmer

- Explained the continuing changes and implementations associated with the national field program including assessments of program and standardizing requirements.
- States are asked to communicate regularly and to respond more timely to evaluation findings.
- FDA is conducting cross training within the Cooperative Program to familiarize staff with the NSSP and the history.
- FDA is in the process of hiring three (3) new specialists.
- Participation of laboratory personal in regional meetings and the ISSC Biennial Meeting is needed.
- FDA is discussing holding SSO meetings

Melissa Abbott

- Staff updates for CFSAN
    1. Mark Mormman – New Executive Director CFSAN
    2. Pete Koufopoulous – also acting as Shellfish & Aquaculture policy branch director
    3. Quentin Forrest – Growing Area contact person
- Training items
    1. FD245 Plant standardization being offered in Spring 2019
    2. Growing area course being offered in Mid 2019
    3. FD243 patrol being offered online
- Field studies
    1. Dye study in NJ, data analyzation underway
    2. MD proposed dye study being reviewed by growing area personnel
    3. WA is conducting a study to better understand bacteria at different dilutions in Hammersly Bay & Oak land
    4. MA is reviewing and assessing effluent discharges at WWTPs
- NSSP Advisory audits from Canada occurred September 2018 in the states of Washington and Oregon.

C. NMFS — Jon Bell

- No major changes for NOAA.
- John Jacobs continuing to work on vibrio modeling applications.
- NOAA will receive even funding for 2019.
- Federal aquaculture projects require considerable planning. Mussels at Catalina Sea Ranch are being harvested. NOAA sees role as helping with siting.

D. CDC — Erin Stokes

- Provided Vibrio illness data for 2017.
- Explained CDC reasons for not yet providing a case definition for Vv septicemia illness. Additional information is forthcoming.

IV. PROGRAM CHAIRMAN'S REPORT (GIVEN BY KEN MOORE)

- William Eisele, "Bill", suffered a heart attack and is no longer able to travel long distances. His retirement is effective immediately. We will be seeking someone to replace Bill.
- The 2019 Biennial Meeting is on October 5-10, 2019 in San Diego, CA at the InterContinental Hotel.
- The 2019 Call for Proposals is April 23, 2019. The deadline for all requests is June 7, 2019. The package will be distributed no later than July 5, 2019.

V. COMMITTEE REPORTS

A. Executive Committee Report

- Grant Updates
  - 2019 FDA Cooperative Agreement ends August 31, 2020.
  - FDA Cooperative Agreement Application is due July 1.
  - FDA Small Conference Grant application has been submitted for 2019 Biennial Meeting.
  - AFDO Milk & Shellfish Cooperative Agreement grant application includes a role for the ISSC in making funds available to states that are unable to apply through AFDO portal.
- A motion was made and seconded to accept the 2019 Budget. Motion was approved by a voice vote by the Board.
- Draft 2018 Work Plan Evaluation (Attachment 2)
  - Executive Board comments requested by May 18, 2019.
- 2019 Work Plan Draft (Attachment 3)
  - Executive Board comments requested by May 18, 2019.
- The ISSC Executive Office is meeting the deadlines set out in the 2019 Work Plan
- 2018 Tax Return and 2018 Financial Review Engagement letters with Moore Beauston & Woodham , have been signed. This work is expected to be completed by the beginning of June 2019.
- Development of the Executive Office Financial Procedures Policy is currently in progress.
- ISSC Employee Manual needs to be updated.
- Assistant Executive Director Hiring (Attachment 4) On April 22, 2019 an E-Letter will go out announcing the hiring of the position of an Assistant Executive Director.
- Additional members have been added to the Assistant Executive Director Selection Committee. The Committee includes Johnathan Gerhardt, Bruce Flippens, Steve Fleetwood, Pete Koufopolous, Margaret Pilaro, Patti Fowler and, Ken Moore.

B. Laboratory Committee

1. Continues monthly calls with several monthly subcommittee calls.

C. Time/Temperature Committee

1. Surf Clam Subcommittee

- Study Design Committee is continuing conference calls to develop study plan.

D. Training Committee postponed until New Business
- The Committee has determined that there should be additional training requirements. The Committee is expected to present a training curriculum as an ISSC Proposal.

E. V.v. Illness Review Committee
1. This committee has not reviewed any Vv cases in two (2) years. The FDA and CDC expressed concern during the 2017 Biennial Meeting regarding ISSC procedure for reviewing reported Vv illnesses. The concerns have been discussed with FDA and CDC.
2. CDC expressed concerns regarding the use of surveillance data for clinical decisions and had agreed to develop a new definition.
3. FDA concerns involved documentation of review and will be addressed by the committee
4. A motion was made and seconded to proceed with the requirements in Chapter II of the Model Ordinance. Motion was approved by a voice vote by the Board.

F. Biotoxin Committee postponed until Old Business (See New Business Section F.)

VI. OLD BUSINESS

A. US/EU Equivalency Agreement
1. Comment for federal register notice closes May 23rd. Supplemental information has been developed by FDA. A link can be provided to anyone that needs it. Once closed, FDA will develop responses. ISSC will provide comments to the notice.
2. Export Listing Module will interact with the ICSSL to automatically send notice to EU for their listing requirements. EU will require a separate list from the ICSSL that shows firms shipping from approved growing areas. All exports will require a NOAA certificate.
3. There are procedures to allow approved States to be added later to the module.
4. Approved growing areas will be added to the module on a quarterly basis.
5. States will be responsible for notifying the industries of the approved growing areas.
6. FDA has set up a mailbox that is designated for state authorities and shippers with questions at shellfishequivalence@fda.hhs.gov.
7. ISSC and FDA are working together to establish communication with states before the module is in place. There will be an announcement to states.
8. Herpes virus a concern in the US/EU agreement.
9. There is a concern associated with how the EU is deciding what type of processed shellfish products will be shipped to the EU. The EU will only accept raw shellfish products of any kind from Massachusetts and Washington. The FDA is trying to negotiate this with the EU regarding processed shellfish products from other states. It is considered unfair trade and is presented a challenge.
10. There is a substantial amount of illegal product being shipped in from Mexico. Border Patrol regards this as public health issue and is taking this activity seriously.

B. ISSC Website Updates
- We are finalizing an internal auditing of the website and are ready soon to have an ISSC Committee review it and offer suggested changes.

C. Research Projects
1. Virginia Institute of Marine Science

2. University of New Hampshire
3. Auburn University
4. University of North Carolina
5. State of Maryland

D. CIDT
- ISSC will post the project descriptions on the website to inform the public of the types of research we fund.

E. Conference calls for the CIDT Workgroups will be scheduled in two weeks.

VII. NEW BUSINESS

A. 2019 Task Force Appointments
- A motion was made and seconded to accept the 2019 Task Force Assignments. It is expected that changes will occur later. Motion was approved by a voice vote by the Board.

B. Center for Oceans and Human and Climate Change Interactions ($OHHC^2I$)
- The ISSC is collaborating with the Arnold School of Public Health, University of South Carolina on research that addresses toxic algae and Vibrios.
- ISSC will share the research results from this project 2021 Biennial Meeting.

C. Committee Report Session The Board discussed scheduling a Committee report session prior to Task Force meetings

D. FDA Plant Standardization Field Guide
- The FDA is using this document as a resource training tool and an "interpretation guide". It is not a replacement for the MO and the FDA does not wish to incorporate it into the MO.
- States are concerned that the field guide includes requirements that are not included in the NSSP Model Ordinance.
- States with concerns will be asked communicate their concerns to the ISSC. These concerns will be shared with the FDA.

E. Remote Participation
- A motion was made and seconded to develop a committee to explore the technology and equipment needed to incorporate remote conferencing options for future Executive Board Meetings. Motion was approved by a voice vote by the Board.

F. FDA Federal Water Subcommittee & Proposal 17-119 Implementation
- During the fall Executive Boarding Meeting a motion was adopted to request the FDA to delay implementation of 17-119 until ISSC and FDA could develop an implementation strategy to address concerns. FDA responded to ISSC. (See attachment 1)
- The Federal Water Subcommittee met in College Park and discussed types of controls that need to be in place prior to implementing 17-119 for wild harvest in Federal Waters.
- The Subcommittee agreed that FDA and NOAA should address issues involving federal responsibilities.
- A list of 12 action items was developed. Due to the Government shutdown there has been not a lot of opportunity for work on these items but additional discussions will be scheduled soon.
- FDA and Abraxis have been working together to identify the source of challenges

observed by certain users of the Abraxis PSP Shipboard ELISA Kit for conducting pre-harvest paralytic shellfish poisoning (PSP) toxin screening for molluscan shellfish harvested from federal waters.

- FDA and Abraxis have ongoing investigation planned to help better understand and identify discrepancies in performance.
- ISSC would like an update from FDA on this Abraxis kit in sixty (60) days.
- It is likely the Biotoxin subcommittee will develop a proposal to address this issue.
- A motion was made and seconded to extend the December 2018 interim approval for an additional 90 days.

G. FDA Evaluation MO Chapter II

H. Canada had two (2) separate Norovirus outbreaks without issuing recalls. The Canadian non-compliance with the MO affected dealers on the west coast. Canada has now implemented new requirements but it is not clear if the new requirements address recalls.

- A motion was made and seconded to request the FDA discuss with Canada why the guidelines set forth in the MO on recalls with Norovirus are not being followed. The motion was approved by a voice vote.

I. CFSAN needs more communication from ISSC before evaluating cleansing studies. There is a need for more information prior to FDA developing a policy and evaluating state programs.

- A motion was made and seconded that Ken will discuss with the FDA compliance associated with cleansing studies and that states will not be found in noncompliance until compliance guidance is provided. Motion was approved by a voice vote.

J. Concern was expressed regarding how FDA is addressing the determination of acceptable thermometers.

- It was the general consensus that every thermometer should be calibrated.

K. Following the comments of Laurie Farmer (FDA) members of the Executive Board expressed concern regarding the contentious relationship which has developed between FDA and States. The Executive Board requested the Executive Director explore steps that could be taken to address the concerns. A meeting of FDA Leadership and state regulatory members of the Board was held in Charlotte, North Carolina on September 10 and 11, 2019. A report of that meeting is attached.

IX. OTHER INFORMATION

- Conference calls for the CIDT Workgroups will be scheduled in two weeks.

VII. EXECUTIVE SESSION

A. Staff Evaluations

- A motion was made and seconded to accept the Executive Committee recommendation of a three percent (3%) cost of living increase for all ISSC staff and to grant Cathy Mantooth and Lesley Price a one thousand dollar ($1,000.00) bonus as recommended based on Staff Evaluations. This becomes effective on the next pay period. The motion was approved by a voice vote by the Board.
- A motion was made and seconded to approve the Payment to the Executive Director of thirty one (31) days of accrued vacation time. Motion was approved by a voice vote by the board.

VIII. ADJOURN

- A motion was made and seconded to adjourn the meeting at 5:50 PM PST on Thursday, April 24, 2019. The motion was approved with a voice vote by the Board.

Meeting adjourned 5:50 PM PST