## I. CALL TO ORDER

Mike Hickey called the meeting to order at 1:15 PM.

## II. ROLL CALL

Ken Moore conducted roll call with the following members present:

Bruce Buckson Pete Jensen (for Larry Simns)

Bill Dewey (for Robin Downey)

Bill Kramer

Bill Eisele

Ren Moore

Paul DiStefano

Steve Fleetwood

Chris Nelson

Debbie Rouse

David Fyfe Angela Ruple (for Spencer Garrett)

Johnathan Gerhardt Keith Skiles
Maryanne Guichard Al Sunseri
David Guilbeau Tommy Ward
David Heil Ed Watson
Mike Hickey Kirk Wiles

Lori Howell

Board members absent were:

Cali Alexander Larry Simns Robin Downey Rob Wittman

Bill Hastback

## III. EXECUTIVE BOARD

## A. Board Vacancy

Ken Moore advised the Board that Bob Connell had resigned as a result of his retirement. The ISSC Region 2 Regulatory members were polled and recommended Board Alternate Cali Alexander as Bob's replacement. Lori Howell made a motion to approve which was seconded by Steve Fleetwood and the motion carried with a voice vote by the Board.

# B. AFDO Representative

Ken Moore advised the Board that this position had been vacant for some time and recommended the Board appoint Julie Ray of Virginia. A motion to approve the recommendation was made by David Heil and seconded by Ed Watson. The motion carried with a voice vote by the Board.

### IV. MINUTES

Lori Howell made a motion to approve the March and July minutes as submitted. The motion was seconded by Maryanne Guichard and carried with a voice vote by the Board.

## V. INTRODUCTORY COMMENTS

- A. Chairman Mike Hickey
  - Welcome
- B. FDA Paul DiStefano

Paul reported that Amy Fitzpatrick will be replacing Peter Koupoulous and Lizzie Evans has been hired to work with Linda Chandler. Paul also gave an update on the EU Audit.

- C. NMFS Angela Ruple for Spencer Garrett
- D. EPA Ken Moore for Bill Kramer

#### VI. PROGRAM CHAIRMAN'S REPORT

A. 2011 Spring Meeting Ken Moore

Maryanne Guichard - Question Task Force Appointments
Al Sunseri motion not to hold spring Board meeting, seconded by Maryanne Guichard. Motion carried with a voice vote.

B. 2011 Biennial Meeting

Ken Moore briefed the Board on bid solicitations and proposals received. Maryanne Guichard made a motion to hold the Biennial Meeting in Seattle at the most accommodating hotel. A second was made the motion carried with a voice vote by the Board

C. 2011 Call for ProposalsKen Moore furnished dates.

# VII. COMMITTEE REPORTS

A. Executive Committee

Ken Moore reported on the following items and no action was required by the Board. Furnished materials will be identified as exhibit files.

- 1. Grant Updates
  - a. FDA Cooperative Agreement
  - b. FDA Carryover Funds
  - c. FDA Shellfish Safety Assistance Project
  - d. FDA Vibrio Illness Reduction Program
  - e. Small Conference Grant
  - f. The Nature Conservancy
  - g. Gulf & South Atlantic States Fisheries Foundation
- 2. Financial Statement
- 3. Annual Legal Retainer
- 4. Renewal of Director's & Officer's Liability Insurance Policy

- 5. Renewal of Employee Bond Coverage
- 6. 2012 Membership Fees

Chris Nelson made a motion to investigate methods of funding biennial meeting costs and reduce registration fees to attend the biennial meeting for members. A work group will be formed to report back to Board at a later date. Maryanne Guichard seconded the motion which carried with a voice vote by the Board.

- 7. 2010 Work Plan Evaluation. Ken asked the Board members to follow up with any comments or suggestions.
- 8. 2011 Work Plan is being developed and will be send to the Board for comments or suggestions.
  - Ken asked for items for work plan.
- 9. 2011 Budget

The budget was discussed by Board members. A correction needs to be made in the Communications item total. Lori Howell made a motion to approve the budget as correction and Maryanne Guichard seconded the motion. The motion carried with a voice vote by the Board.

#### B. Audit Committee

Lori Howell advised that Spencer Garrett and Maryanne Guichard are new members. The Committee was provided a copy of audit and had met by conference call with the auditor.

- C. *Vibrio* Management Committee
  Bill Dewey, Vice Chair, presented the VMC Report to the Executive Board.
  - 1. Maryanne Guichard made a motion that the Board approve the VMC recommendation that ISSC abolish the use of the supplemental *Vv* Data Collection form that was being used to collect additional epidemiological data. Following discussion, David Heil seconded the motion which carried with a voice vote by the Board.
  - 2. The VMC was presented with the 2009 Vv Illness Data and the 2010 Vv Illness data to present. The VMC concluded that the 60% Illness Rate Reduction Goal had not been achieved. The VMC further concluded that the 2010 controls implemented by the Gulf States from May through October were not adequate to accomplish the 60% Illness Rate Reduction Goal. For the purpose of achieving the 60% Illness Rate Reduction Goal the VMC recommended that the Executive Board accept the following modifications to the 2010 State Vv Management Plans.
    - a. The establishment of additional temperature controls in November and April in the Gulf States.
    - b. FDA focus in their annual state evaluations on compliance with the time temperature controls of the State *Vv* Management Plans. Ken Moore and Paul DiStefano will review the Patrol Evaluation Criteria and offer the ISSC Patrol Committee an opportunity to review and comment.

c. Require HACCP implementation (to include harvesters) of the time temperature controls and that enforcement efforts increase to ensure better compliance with HACCP as well as time temperature controls from harvest to refrigeration.

Chris Nelson made a motion to adopt which was seconded by Johnathan Gerhardt and carried with a voice vote by the Board.

- 3. Johnathan Gerhardt made a motion that the Board adopt the VMC recommendation that the VMC should meet again in June or July to develop options needed for potential proposals for consideration at the 2011 Biennial Meeting and that a subcommittee (represented equally by geographic regions) be appointed to develop potential options for VMC consideration. The motion was seconded by Lori Howell and carried with a voice vote by the Board.
- 4. Bill Dewey made a motion that the Executive Board make a recommendation to FDA that FDA proceed to conduct industry interactive sessions this year regarding the challenges to further implementing Post Harvest Processing (PHP). These interactive sessions should provide a summary of the results from the RTI analysis of implementing PHP technology and sensory analysis (Otwell et al) and a discussion of overcoming the challenges identified by these studies and further recommended the formation of a workgroup to work with FDA and the findings of these interactive sessions to develop a proposal for consideration by the Conference.

Al Sunseri made a substitute motion that the Executive Board make a recommendation that FDA proceed to conduct industry interactive sessions this year regarding the challenges to further implementing PHP. These interactive sessions should provide a summary of the results from the RTI analysis of implementing PHP technology and sensory analysis (Otwell et al) and a discussion of overcoming the challenges identified by these studies.

Following discussion, the substitution motion carried with a vote by the Board.

- 5. Lori Howell made a motion to adopt the VMC recommendation that existing illness data be reviewed to determine if other states or foreign countries have been the source of 2 or more etiologically confirmed shellfish borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested, raw or undercooked oysters that originated from the waters of that state or foreign country. The motion was seconded by Maryanne Guichard and carried with voice vote by the Board.
- Bill Dewey advised the Board that the following items were discussed by the VMC and submitted to the Board as information with no Board action required.

- a. RTI presented preliminary findings of the Economic Impact Analysis funded by FDA.
- b. Steve Otwell and Bill Huth presented the preliminary findings of the Consumer Acceptance Study funded by ISSC.
- c. The Committee discussed implementation strategies for proposal 09-207.
- d. The Committee will continue to develop validation criteria for PHP that will not utilize a labeling claim.
- e. The Committee was provided *Vp* data from CDC. Subcommittee will review data and make recommendations.

Maryanne Guichard requested sufficient time (2 full days) at future meetings and add other V*ibrio* discussions to agenda.

D. Laboratory Methods Review Committee

Ken Moore reported on the following:

- Jellett Test Kit concerns resolved.
- Concerns over lab methods submission.
- Data not available that meets ISSC criteria.
- Submitter benefits from ISSC approval. In cases where states would like to use methods where we don't have data, we assist states in generating data. Abraxis method discussed.
- LMRC would like to communicate with entities concerning data collections. States need methods approved.
- Lori Howell more rapid approval of methods needed by Conference and industry. Report provided to Board as information.
- Ken briefed Board on Section A10 in Guidance Documents.

## VIII. OLD BUSINESS

- A. ISSC Consumer Acceptance Survey Report presented by Steve Otwell and Bill Huth. No action required by the Board.
- B. RTI Report Mary Muth presented a report on the Economic Analysis
- C. California Regulations Update Maryanne Guichard commented that California wants to participate in the ISSC but they are having extreme budget issues.
- D. Dockside Biotoxin Testing in Federal Waters
   Ken briefed Board on background of the Dockside Biotoxin Testing Protocol
  - Paul DiStefano said a proposal will be submitted at the Biennial Meeting.
  - Tom Allspock representing Sea Watch International in New Bedford. ½ of resources on George's Bank.
  - Maryanne Guichard said pilot successful. Looking forward to proposal. Can be used in other areas of country.

- Abraxis, Sea Watch and Mass working to gather data and make it available at Biennial Meeting which would strengthen the proposal and approval of the method. On board screening is a fish/no fish use.
- E. 2009 NSSP Guide for the Control of Molluscan Shellfish Ken Moore reported that the 2009 update of the NSSP Guide was taking longer than anticipated to get final version to FDA. Ken explained the reformatting of A10. for Approved Lab Methods. Maryanne urged FDA to make this a priority.

# F. GAO Audit Update

Leo Acosta gave an update on the GAO Audit:

- Review of Vv Risk Management Plan.
- Review arm of Congress after final draft.
- Has held meetings with states and industry to discuss goals, control measures, education, economic impact, consumer survey.
- Time frame is now 6-8 weeks of field week.
- Will conduct In-depth discussions with FDA and hopefully finish in July.
- Draft report to will be furnished to FDA for comment.
- FDA comments will be addressed but not necessarily incorporated into report.

Bill Dewey made a motion that the Executive Board request FDA share a draft of the GAO Audit Report with Board members for solicitation of comments. A second was made by Tommy Ward and passed with a voice vote by the Board. Bill Jones said the report will be shared if allowed by FDA. The motion carried with a voice vote by the Board.

# G. Traceability Committee

Ken advised Bill Dewey has requested this item be added to the Board agenda. Bill advised that proposals for funding have been submitted in the past and new technology is available. Request a study if trace back is an issue and can be improved. Bill Dewey made a motion to recharge the Traceability Committee. Chris Nelson seconded the motion. Lori Howell - Industry is moving in new direction and this matter needs to be revisited. Al Sunseri suggested reaching out to National Restaurant Association, AFDO, CFP, etc. Can closures and recalls be condensed with better traceability. Motion carried with voice vote by Board.

## IX. NEW BUSINESS

## A. FDA Status of States Report Paul DiStefano

Paul will check on classification status for area in Louisiana. LA says FDA regional specialist if holding up approval. Increase in number of violations at plants from 2009 to 2010. Bill Dewey asked if there was any particular area that stood out for an increase in violations. Paul read some of violations found. Ken agreed to advise states of HACCP requirements associated with handling of restricted use shellstock. Ken is working with Lizzie Evans on Lab Evaluation

protocol document which will be shared with Board and the Board will be asked to grant interim approval.

Inspection worksheet developed and inspectors have been using form and states are consistently compliant with requirements. Requirements are for vulnificus and parahaemolyticus. Board/Conference may ask for additions to evaluation form

Bill Dewey made a motion that the Executive Boardrequest that FDA include anonymous industry interviews in annual audit of States. Chris Nelson seconded motion. The Intent of motion is that FDA is looking for input from industry that could be validated. FDA will share how they will accomplish procedurally. The motion passed with voice vote by Board.

- B. ISO Standards for Traceability of Shellfish Ken Moore - Standardization already in place.
- C. Retail Distribution Interpretation
  Ken Moore advised that ISSC will be submitting interpretation through the process and will report back to the Board.
- D. FDA Training
  Ken asked Paul DiStefano if FDA is continuing to provide prerequisite courses or
  are they involving center in Battle Creek only. This is not direction of FDA. Paul
  said expenses for training of standardization officers for states was paid for.
- E. Gulf States Meeting to discuss 2010/2011 Vv Control Plans
- F. Gulf Oil Spill Reopening Protocol

Ken Moore addressed reopening criteria not in NSSP. FDA forced protocol during oil spill. Chris Nelson commented that right people did not get on group that developed reopening protocol that primarily impacted shellfish growing areas. Group was not well represented in group that worked on protocol. Chris would like ISSC brought in in the future. Don Kraemer – federal agencies must to through appropriate communications cycle. Heads of state health departments were very involved by FDA. FDA has to be careful how they interject ISSC into these matters. Protocol specifically written for the Deep Horizon Spill. Good reason not to put in ISSC. Al Sunseri – have a committee look at protocol and make suggestions at a later date to state and federal agencies using industry's expertise. Kirk Wiles...hours of collaboration; started on wrong foot; further discussion extremely collaborative effort. Would be misuse of docment to use it for any other situation. Don Kraemer could be interesting analysis on what went right and what went wrong. Think about how to do it next time. Mike Hickey – drill in Mass month prior to oil spill. Persons involved in protocol assisted in Mass drill. Maryanne suggested presentation of lessons learned during oil spill DEWEY). Recommendation specific to Deep Water Horizon (Gulf States). ISSC has expertise. MFAC interim until ISSC can address.

Mike Voisin expressed lack of communication to shellfish programs. Need communication protocols for situations. Important to look at and ISSC does play role. Compliments to FDA. Ken Moore encouraged Maryanne's suggestion to present to membership is a good idea. Al would rather see information prior to being presented to membership. Mike Hickey – have people involved in developing and using protocol present data/information...give overview...then have ISSC group look. Lot of science involved. Need group to come back with something meaningful. Paul DiStefano said there is some utility in asking group to review protocol and develop general guidance for states to consider during an oil spill. Reopening in Guide for deleterious substances.

- G. East Coast Shellfish Growers Association *Vibrio* Education Workshops Ken, project and amount of funding 1,029.00
- H. Conference Communications
  - Regional Board Conference Calls
     David Heil request. Ken logistics are a nightmare but the concept is good.
  - 2. Meeting Participation by Conference Call Use of conference calls during meetings rather than personal attendance. Input from Board on how to deal with requests. Lori Howell made motion appoint workgroup to address needs of conference related to members participating via conference calls. Maryanne Guichard seconded and the motion carried with voice vote by the Board

## X. OTHER INFORMATION

Ken Moore gave a brief report to the Board on attending the following meetings:

- A. Conference for Food Protection
- B. FMI Retail Food Safety Committee
- C. HACCP Alliance Meeting
- D. AOAC Meeting
- E. *Vibrios* in the Environment Meeting

## XI. EXECUTIVE SESSION

Staff Evaluations will be submitted at the next meeting.

# XII. ADJOURNMENT

The meeting was adjourned at 1:05 PM.