I. CALL TO ORDER

Mike Hickey called the meeting to order at 3:36 PM.

II. ROLL CALL

Tom McGee conducted roll call with the following members present:

Quincy Boyce for Ed Watson
Kathy Brohawn
Bruce Buckson
Paul DiStefano
Robin Downey
Bill Eisele
David Fyfe
Steve Fleetwood
Johnathan Gerhardt
Terri Gerhardt
Maryanne Guichard
David Guilbeau
Bill Hastback
David Heil for Charles Newell
Mike Hickey
Lori Howell
Bill Kramer
Ken Moore
Chris Nelson
Debbie Rouse
Angela Ruple for Spencer Garrett
Larry Simns
Keith Skiles
Al Sunseri
Tommy Ward

The following members were absent:

Donna Garren
Gregg Pallaske
Rob Wittman

Executive Office staff, Committee chairs, regulatory members, industry members, and others were also present.

III. MINUTES OF MAY 7, 2009 MEETING

It was the preference of the Board to delay approval of the referenced minutes until its meeting on Friday, October 23, 2009.

IV. INTRODUCTORY COMMENTS

A. Chairman

Mike Hickey welcomed the Board.

B. FDA (Paul DiStefano)

1. Paul said he understood that Ken would be leaving our organization in the near future and wanted to say a few words on behalf of FDA and himself. He said FDA wishes to extend its appreciation to Ken for his efforts as ISSC Executive Director. Paul said Ken's ability to bring together the industry and regulatory components of this Conference has carried us through some extremely difficult times and under his leadership the Conference has truly matured. Paul said that without a doubt we will all miss his presence and leadership and FDA wishes

Ken success in all his future career endeavors. Paul added, on a personal note, he has grown to appreciate Ken not only for his leadership abilities, but also for his candor, his sense of humor, his ability to move folks forward even when things appear to be at their worst, and for his unyielding dedication to improving public health.

2. Employee Changes
Jessie DeLoach has been hired as the new Shellfish Specialist in Pacific Region; and Peter Koufopoulos is no longer the Northeast Shellfish Specialist. FDA will be filling this vacancy.

3. Thursday Information Forum
Greg Goblick will be presenting at the Thursday Open Forum to discuss the FDA Dilution Guidance and FDA encouraged everyone to attend.

4. ISSC Grant
FDA approved year 17 of the Shellfish Safety Assistance Grant with ISSC for $325,000; and FDA supplemented the grant this year with an additional $81,250 for *Vibrio* control and outreach activities.

5. FDA has entered in contract with MA Division of Marine Fisheries to conduct PSP monitoring in federal waters of the northwest Atlantic Ocean.

6. FDA has funded a study by Research Triangle Institute to examine the cost to the Gulf industry to implement *Vv* controls. The study was to originally look at the cost associated with implementing reduced time to refrigeration and time from initial refrigeration to cool down to 50F. Given the Agency's redirection relative to *Vv* and the need to ensure that controls are in place to eliminate the risk at the highest possible level we have redirected RTI to focus their efforts on the costs associated with implementation of PHP by the Gulf oyster industry. FDA anticipates that the study findings will be available by late winter or early spring. We will be meeting with RTI at the conclusion of this Conference to apprise them of recent ISSC actions and to develop a final time line. FDA hopes that states and industry will offer RTI their fullest cooperation when contacted for information. FDA has directed RTI to begin refocusing their efforts nationally to look at retail and examine consumer confidence in post harvest product.

7. Efforts to conduct a pilot of the Onboard Screening and Dockside Testing Protocol for managing PSP in offshore federal waters have resumed.
   - In accordance with the support from the ISSC, use of the Abraxis test kit has been incorporated into onboard screening efforts.
   - As a result, for the first time a lot of shellfish (surf clams) was harvested under the Protocol
   - Surf clams from Georges Bank were harvested in September
   - Results from the onboard Abraxis screening test enabled the harvest
   - Dockside samples were analyzed by MBA and demonstrated acceptable PSP levels and the product was released into commerce.
   - Results of both Abraxis and MBA demonstrated a high level of consistency.
   - Efforts to pilot test the Protocol will continue as weather permits.

8. EU Audit
   - At the last Board meeting Paul indicated that the EU audit of the US Shellfish Program had been conducted and the Board had previously been provided with preliminary findings as presented at the audit close out meeting.
   - FDA has since received the draft audit report
   - FDA has shared it with the states involved in the audit (ME, RI, WA) for their comments
   - The audit identified 6 areas of concern where the US program did not meet requirements of EU directives
     - Failure to monitor federal waters for marine biotoxins
     - Failure to monitor for all marine biotoxins of concern to the EU (DSP, Azaspiricids) as well as lack of control of echinoderms (urchins, sea cucumbers), tunicates (sea squirts) and gastropods (snails, conch, whelk)
     - Failure to control the Vibrio vulnificus hazard in Gulf shellfish and concern that it may be shipped to Europe
     - Failure to implement mandatory phytoplankton monitoring
     - Failure to conduct product testing to ensure safety
     - Failure to require ISO accreditation of shellfish labs

9. Retail Oyster Study
   - Provided to Executive Board for review and comment
   - Currently under final review in FDA
   - Will publish in the Journal of Applied Environmental Microbiology

C. NMFS

Angela Ruple advised the Board that Spencer Garrett would be in attendance at the Friday, October 23, 2009, meeting and would provide his introductory comments at that time.

D. EPA (Bill Kramer)

Bill expressed his desire to elaborate on Paul DiStefano's earlier statement regarding Ken. He said the ISSC needs strong process and trust and that he has always found Ken to be able to provide both. Bill said it is important to have an open working relationship such as he has always had with Ken and that he has enjoyed working with Ken and has learned a lot. Bill expressed his appreciation to Ken for introducing him to the hierarchy of learning and said it helps in working with others and understanding yourself.

Bill Kramer provided an updated presentation to the Board which included the following:

EPA's Objective: New recreational water criteria for all waters by 2012
- Including freshwater rivers, streams and lakes
- 2012 is Consent Decree deadline
- BEACH Act requires new criteria for coastal rec. waters
- Incorporate new science—over 20 long years since 1986 criteria; CWA requires updates "from time to time"
- Improve scientific foundation and implementation based on what we've learned over the past 20 plus years

- Ease implementation for BEACH Act states: no double standards
- Makes providing protection for downstream rec. waters easier

EPA's Major Research Areas per Critical Path Science Plan

- Epidemiology Studies and Quantitative Microbial Risk Assessment (QMRA)
- Site Characterization: Sanitary Surveys
- Indicators/Methods Development and Validation
- Modeling
- Addressing Application to:
  - >Coastal (marine) waters
  - >Great Lakes
  - > Inland Waters- rivers, streams, lakes

EPA Research & Activities Related to Indicator/Methods

- Performance of QPCR signal (fate & transport) (P8)
- Evaluate multiple indicator/method combos to develop quantifiable relationships (P15)
- Sample holding time/preservation (P16)
- Develop, refine, validate, publish one or more new ambient test methods (P17a)
- Develop, refine, validate, publish one or more new wastewater test methods, provided results of P8 and P18 indicate need (P17b)
- Evaluate the suitability of individual combos of indicators and methods for different CWA purposes (P18)
- Re-analyze archived NEEAR samples using molecular methods for other indicators, provided samples have not degraded per outcome of P16 (P22)

EPA-Supported Epi Studies

- 2007 and 2008 SCCWRP Studies at Avalon Beach, CA
- droppings, urban runoff, and leaking sanitary sewers (human source)
- 2008 SCCWRP Continuation Study at Doheny Beach, CA
- EPA Epi Studies Conducted in 2009

Opportunities & Challenges (2)

- EPA will need to synthesize data from a wide assortment of studies which may have conflicting or inconsistent results regarding indicator/method relationship to illness.
- Culture-based methods require 24-48 hours to obtain results. qPCR is a faster method to assess recreational water quality and predict swimming-related illnesses,
  – Even with rapid testing method, beach notification decisions could not be made for 4-6 hours after sample collected.
- EPA is considering the use of predictive models to supplement beach monitoring, but not to replace it.
- EPA is considering developing a process/methodology for incorporation of new methods into future criteria development in the absence of an epi study.

V. PROGRAM CHAIRMAN'S REPORT

Ken Moore recommended postponing this report until Friday, October 23, 2009, given the motion made at the Opening General Assembly to hold a special 2010 meeting. Ken advised that due to Rob Wittman's Congressional responsibilities the Executive Office has assumed the Program Chairman's duties for meeting planning.

VI. OPENING GENERAL ASSEMBLY MOTION

Ken Moore advised that the following motion made at the Opening General Assembly had previously been distributed to Board members.

Part one of the motion read:

> Request that FDA present their specific concerns related to the Conference's present position on Proposal 00-201 to the VMC for consideration. In this discussion, it is requested that FDA specifically identify the elements of 00-201 that the FDA feels are inadequate. The VMC is requested to consider the FDA concerns in its deliberations of 00-201 and make recommendations to Task Force II as appropriate.

Mike Hickey advised that the Board will be dealing with the second part of the motion that read:

> I further move that the Executive Board be directed in its first meeting of the Biennial Meeting to discuss with FDA the impacts and concerns associated with their approach to implementing a reformulated policy on the control of *Vv* and the implications that this action will have on the future relationship between the USFDA and the ISSC.

Ken asked Lori Howell to read the recommendations that the VMC will be making to Task Force II. The recommendations are as follows:

1. Recommended that FDA submit a proposal for deliberation by a Special ISSC conference to be held in 2010. In the interim, it is requested that FDA, in coordination with ISSC fund a robust economic impact and consumer acceptance analysis to inform the ISSC deliberations on the proposal. An impacts analysis guidance committee will be appointed to guide and make recommendations on the components of the impacts analysis study.

2. Recommended that a workgroup be established as soon as possible to develop criteria for an economic analysis. The workgroup will use the criteria for an economic impact analysis for rulemaking as a guide. The study should include a taste acceptance component. The workgroup should include, but not be limited to, at least one industry member and one regulatory member from the east, west and gulf coasts.

3. Recommended that May 1, 2011, be set as date for implementation of Model Ordinance Section II @ .04, *Vibrio* Management Plan for Oysters.

4. Recommended that the *Vibrio* Management Committee meet at the spring 2010 Executive Board meeting.

5. Recommended that the findings of the *Vibrio* vulnificus Illness Review Subcommittee be accepted. The Subcommittee found that 17 cases in 2007 met the criteria and 13 cases in 2008 met the criteria. After adjusting for population changes, the illness rate reduction was calculated to be 35.2% from the baseline period.

Following a lengthy discussion, the Board members agreed to postpone further discussion on this item until the Friday, October 23, 2009, Executive Board meeting.

VII. PROPOSAL REVIEW COMMITTEE

Lori Howell reported that the Executive Board had directed the Proposal Review Committee to recommend "No Action" on proposals that had been deliberated previously and did not contain new supporting information and that all "No Action" recommendations must include a rationale. The Committee was requested to use careful consideration in ranking proposals submitted by an ISSC Committee. Lori said that the members of the Committee had reviewed all proposals and submitted a ranking form with incorporated comments. The Committee submitted a document with recommendations for the order in which the new proposals should be addressed taking into consideration linkages with related proposals as well as recommendations of no action and referral of proposals to other task forces. Lori also informed the Board that the Committee wishes to discuss the numbering system used to rank proposals as well as investigate additional ways this committee can assist the conference. A motion was made by Paul DiStefano and seconded by Maryanne Guichard that the Board approve the recommendations of the Proposal Review Committee. The motion carried with a voice vote by the Board.

VIII. RESOLUTIONS COMMITTEE

Ken Moore reported that the Committee recommended that the Board approve the following meritorious resolutions for adoption by the Voting Delegates:

- Resolutions 09-002 – 09-007 Memorial Resolutions;
- Resolution 09-008 Resolution of Appreciation of Staff; and
- Resolution 09-009 Resolution of Appreciation of Chairman's Reception sponsors.

Ken said that Resolution 09-001 Educational Outreach Common Carrier Associations was substantive in nature and asked the Board to approve referral of this resolution to Task Force II. A motion was made by Maryanne Guichard and seconded by Johnathan Gerhardt to approve the Resolutions Committee recommendations. The motion carried with a voice vote by the Board.

IX. RECIPROCITY COMMITTEE

Ken Moore recommended that reporting and discussion of this agenda item be carried over to the October 20, 2009, Executive Board meeting. The Board concurred.

X. OLD BUSINESS

A. Task Force Vacancies

Ken Moore advised that some of the previously appointed Task Force members were unable to attend the Biennial Meeting and asked the Board to approve the following replacements as recommended by the Board Chairman.

- Task Force I Tom Howell to replace David Relyea;
- Task Force II Pete Jensen to replace Dave Wallace;
- Task Force III Bill Dewey to replace Clifford Hillman as Chairman;
- Task Force III John Tesvich to replace Mike Voisin; and
- Task Force III Joe Lacotte to replace Steve Wegh.

A motion was made by Chris Nelson and seconded by Lori Howell to approve the amended Task Force rosters. The Board carried with a voice vote by the Board.

B. Proposals

1. Proposal No. 07-103 Lab Methods and *Vv* and *Vp* Post Harvest Processing

Ken Moore advised the Board that the methods in Proposal 07-103 had previously been given interim approval by the Board. The Laboratory Methods Review Committee will not make a recommendation for these two methods to be approved by the Conference. Board interim approval will remain in effect. Ken suggested the Board could renew interim approval but it is not necessary. The Committee is on track to recommend approval at a later date. No action by the Board required at this time.

2. Proposal No. 05-200 Post Harvest Processing

Ken Moore advised the Board that this proposal was not included in the proposal package. He explained that Recommendations No. 1, 2, and 4 have been dealt with but the Post Harvest Processing Committee is continuing to work on Recommendation No. 3. Angela Ruple suggested that the Executive Office appoint a small workgroup to address this charge. The Committee will report their recommendations at the October 23, 2009, Board meeting. No action by the Board was required.

3. Proposal No. 05-308 ISSC Policy Statement on Consumption of Raw Oysters

Ken Moore advised that no progress has been made on this proposal. Task Force III had asked for discussions with FDA on how to incorporate post harvest processing into the ISSC policy statement on the consumption of raw molluscan shellfish. Ken will report to Task Force III that there is no recommendation at this time from the Executive Board. Ken said this issue is becoming more complex and will require Executive Board review as the Conference continues to address *Vv* controls. No action by the Board was required.

4. Proposal No. 05-310 Plant Element Evaluation Criteria

Ken Moore explained that at the 2007 Biennial Meeting after a discussion concerning plant element evaluation criteria, the Voting Delegates adopted a recommendation that FDA use field tests as criteria and for FDA to also go back and apply that criteria for the past two evaluations. FDA responded in the 2007 Summary of Actions that they did not think going back would be meaningful or useful and that they wanted the field testing to continue going forward. The Executive Board agreed with that recommendation. FDA is not prepared to present the information at this time. The two year period just ended and FDA will be reporting their findings and making recommendations regarding these criteria at a later date. Paul DiStefano said that at the NSSP Evaluation Criteria Committee meeting held yesterday and it was agreed that FDA would provide Committee members with an interim report of FDA findings. The Committee will need to review the findings and make recommendations at the next Executive Board meeting. Ken said the Committee will need to resubmit the criteria at the next Conference meeting. No action required by the Board at this time.

5. Proposal No. 07-303 Guidance on Equivalence Criteria for Food

Ken Moore advised that discussions of this proposal with FDA will continue but has recently not been a priority for FDA. He said at some point in the future this proposal will be brought back to the Board for discussion. Ken will report to Task

Force III that no progress has been made on Proposal 07-303. No action required by the Board at this time.

XI. NEW BUSINESS

A. Late Proposals

Ken Moore advised the Board that no late proposals were submitted and no action was required.

B. Executive Board Elections

Ken Moore announced the results of the Executive Board elections as follows:

- Region I Industry Lori Howell; Alternate Virginia Olsen
- Region 3 Industry Larry Simns; Alternate Pete Jensen
- Region 5 Industry Al Sunseri; Alternate Mike Voisin
- Region 2 Regulatory Bob Connell; Alternate Callie Alexander
- Region 4 Regulatory David Heil; Alternate Patti Fowler
- Region 6 Regulatory Maryanne Guichard; Alternate Dawn Smith
- Non-Producing States Johnathan Gerhardt and Terri Gerhardt; Alternate Martina Kief

XII. ADJOURN

A motion was made by Steve Fleetwood and seconded by Paul DiStefano to adjourn the meeting. The motion carried with a voice vote by the Board. The meeting was adjourned at 5:15 PM.