

I. CALL TO ORDER

Chairman Keith Skiles called the meeting to order at 11:00 AM on January 31, 2014.

II. ROLL CALL

Ken Moore conducted roll call. The following members were present:

Board Members Present: Representing:

Keith Skiles Chair Maryanne Guichard Vice Chair

Ken Moore ISSC Executive Director
William Eisele Conference Office Manager
Mike Hickey Region 1 Regulatory / Past Chair
Lori Howell Region 1 Industry / Task Force II Chair

Bruce Friedman for Dave Carey
Steve Fleetwood
Region 2 Regulatory
Region 2 Industry

Julie Henderson Region 3 Regulatory / AFDO Representative

A.J. Erskine Region 3 Industry

Patti Fowler Region 4 Regulatory / Task Force I Chair

Tommy Ward Region 4 Industry Joe Jewell Region 5 Regulatory Chris Nelson Region 5 Industry Jerrod Davis Region 6 Regulatory Margaret Barrette Region 6 Industry Terri Gerhardt Non-Producing State **Quincy Boyce** Non-Producing State **Bruce Flippens** Non-Producing State

Paul DiStefano FDA
Calvin Walker NOAA
Bill Kramer EPA

David Fyfe Northwest Indian Fisheries Commission

Kirk Wiles Task Force III Chair Mike Pearson Patrol Advisor

Bill Dewey Vibrio Management Committee Chairman

Board Members Absent:

Greg Pallaske Conference for Food Protection Representative

ISSC staff and others were also present.

III. MINUTES

Ken Moore advised Board members that a copy of the draft minutes for the March 6 and 7, 2013, meeting was provided in the materials provided. A motion was made to take up approval at the next Board meeting. The motion was seconded and approved with a voice vote by the Board. Mr. Moore asked that members review the minutes and provide any comments prior to the next meeting.

IV. INTRODUCTORY COMMENTS

A. FDA

Paul DiStefano provided introductory comments at the January 27, 2014, Board meeting.



B. EPA

Bill Kramer provided the following report and asked that materials from his presentations be posted to the ISSC website. Ken Moore commented that the ISSC Executive Office can share information with entire membership if requested.

- a. Clean Water Act Recommended Water Quality Criteria for Recreational Waters (Swimming)
 - EPA published final recreational water quality criteria in December November 2012.
 - Section 303(i)(1)(B) of the Clean Water Act (as amended by the BEACH Act of 2000) directs each state with coastal recreational waters to adopt and submit to EPA new or revised water quality standards for those waters for all pathogens and pathogen indicators for those waters to which the new or revised water quality criteria are applicable.
 - The deadline for state adoption and submittal to EPA of revised WQS is three years from EPA publication of new recommended criteria, thus states should complete this action by December 2015.
 - EPA is preparing implementing guidance. http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/index.cfm
- 2. EPA Development of Ambient Water Quality Criteria for Viruses Bacteriophage-Viral Indicators
 - In 2014, EPA is:
 - Oconducting three literature reviews collaborating with FDA and reviewing literature on: bacteriophage, norovirus and adenovirus in 2014. Collaborations with FDA are facilitating more robust viral estimates.
 - Evaluating multiple approaches to derive the bacteriophage criteria and exploring implementation considerations.
 - In 2015, EPA anticipates a draft criteria could be released for public comment.
 - Throughout the process, EPA will also be collaborating on the use impact of future criteria on Clean Water Act (CWA) programs including: research, water quality standards, permits, and enforcement to protect designated uses including shellfish harvesting.
- 3. Ocean Acidification (OA) Study of Water Quality Parameters for Criteria and Standards
 - EPA and NOAA held an information exchange to promote better understanding of local, non-atmospheric sources leading to coastal acidification. This meeting provided a forum for the two agencies to examine the role that the CWA and existing voluntary programs could play in addressing acidification-related pollution in U.S. coastal waters and to see how lessons learned from efforts to address OA might be transferable amongst regions of the United States encountering ocean and coastal acidification.
 - EPA and NOAA have an ongoing collaborative research program that is examining coastal acidification in Narragansett Bay. The program, which is scheduled to run through 2014, will collect data that will enable scientist to better understand the role of land-based pollution sources (e.g., nutrients) in contributing to coastal acidification and the impact of coastal acidification on the health of economically important shellfish species.
 - EPA is participating in the Interagency Working Group on Ocean Acidification established pursuant to the Federal Ocean Acidification Research and Monitoring Act of 2009. This working group was created to coordinate OA activities across federal agencies and is charged with developing a strategic plan for federal research and monitoring on ocean acidification.



- EPA has committed to participate in seven actions identified in the National Ocean Policy Implementation Plan that pertain to OA and to resiliency and adaptation to climate change.
- EPA Region 10 is participating in the State of Washington's Blue Ribbon Panel on Ocean Acidification, which continues to develop a strategic response plan to address the causes and consequences of acidification.

4. Beach Sanitary Survey Tool Demonstration

• EPA is going to schedule a webcast this spring on the new marine version of the Beach Sanitary Survey Tool. As not all state Beach Programs are co-located with Shellfish Programs, Mr. Kramer asked if there was preference for EPA to notify the ISSC of the presentation time for posting or notification of the States; or for EPA to contact State Shellfish Programs individually?

V. PROGRAM CHAIRMAN'S REPORT

A. 2015 Meeting

Bill Eisele reported that the last Biennial Meeting will be held in a non-producing member State in 2015. The Conference will return to annual meetings beginning in 2016. according to the rotation schedule.

B. Executive Board Meeting Schedule

Bill Eisele reported that the next Executive Board meeting could possibly be a conference call. Ken Moore explained that with regard to items that will need Executive Board action including the budget. Mr. Moore advised the Board that the final budget could be approved during a conference call. He also said that he does not feel like a sit down face-to-face meeting is needed until late summer or early fall of 2014.

A motion was made and seconded that the Spring Executive Board meeting be held by means of a conference call. The motion was approved with a voice vote by the Board.

Following a brief discussion on locations for the 2015 Biennial Meeting, Ken Moore said he will have additional information available for the next Board conference call.

VI. COMMITTEE REPORTS

A. Executive Committee

- 1. Grant Updates
 - a. FDA Cooperative Agreement
 - b. FDA Carryover Funds
 - c. Small Conference Grant
- 2. Financial Statement
- 3. 2014 Draft
- 4. 2013 Work Plan/2014 Proposed Work Plan

B. Foreign Relations Committee

David Fyfe presented the Foreign Relations Committee report to the Board. He said that FDA had presented a thorough verbal review of Agency activities pertaining to its International Shellfish Program and written copies of FDA's report were made available to the Committee membership. Mr. Fyfe also reported that he had outlined activities regarding China's recent ban of west coast bivalve shellfish and Washington State's response as well as NOAA's efforts to help resolve the situation. He said the Committee



members concluded that these regular reports by FDA are very informative and serve to generate a number of subsequent discussion item. Mr. Fyfe said the Committee had also discussed the following issues:

- Chile may conduct a dye study in conjunction with ICMSS2015.
- Virginia and Maryland oyster producers are exploring the possibility of exporting to Japan.
- Due to the passing of long time New Zealand representative and Foreign Relations Committee member, Phil Busby, other New Zealand representatives in attendance were encouraged to sign up for the Foreign Relations Committee
- At least two representatives from Mexico were in attendance and they were also encouraged to become Committee members.

This report was received as information. No action was required by the Board

C. Import Assessment Committee

Ken Moore presented the Import Assessment Committee report in Sandy Shepherd's absence. Mr. Moore said the Committee had requested that the Board to revive efforts and research needs to complete validation for the Thermazyme ACP Test. He said this test will allow enforcement decisions to be based on rapid, quantitative methods rather than sensory related methods. Mr. Moore explained that funding had previously been provided to assist in developing this method. He said due to staff changes the work was not completed and was inadequate for Committee review. Linda Chandler commented that the company involved did not support the work of the group that conducted the research. The Board did not take any action on this item.

The Committee report indicated that States are still reporting incidences of Non-MOU product being imported during their own field inspections or through FDA Alerts with mixed enforcement actions. Instances include Non-MOU product as well as product labeled as "cooked" are still entering without any enforcement action. There has been a noticeable increase in product labeled as "cooked" from Non-MOU countries. It is likely that much of this product is mislabeled.

The Committee concluded that State Shellfish Control Authorities have no conclusive tools to properly assess the safety and disposition of mislabeled or questionable raw imported product. Without any conclusive validated testing method State shellfish Authorities are unable to assure consumers that imported Non-MOU product which may be intentionally labeled as "cooked" are safe.

D. Program Review

Ken Moore reported for Mike Hickey that the Program Review Committee had met by means of a conference call on October 3, 2013, with the following recommendations for Board approval.

- 1. Recommended the ISSC Executive Office assist the Committee in the development of a Model Ordinance document which can be easily edited to track changes.
- 2. Recommended Committee participation by the ISSC Executive Director.
- 3. Recommended changing the name of the committee from Program Review Committee to Model Ordinance Effectiveness Review.

Mr. Moore said the Committee recommendation to place more emphasis on the importance of providing cost information with submission of new proposals had been



addressed by the Proposal Review Committee. He said these are things we do as a matter of record and no action was required by the Board.

E. Research Guidance Committee

Bob Rheault presented the Committee report as follows and reported that there are significant needs for research to inform regulatory decisions made by the ISSC. Ken Moore asked Board members to advise the Executive Office of any other entities they would like to see included on this list. The recommendations of the Committee are:

- The ISSC should annually present research needs to the USDA National Institute of Food and Agriculture (NIFA), Ecology and Evolution of Infectious Disease (EEID) and National Institute of Health (NIH), NOAA, Sea Grant and other pertinent groups that support relevant research to inform these organization's funding committees of the value of the industry and the research needs that have been identified by the ISSC Research Committee.
- 2. Identified the following research needs:
 - a. Alternative PHP methods of reducing Vibrios that retain the product attributes of live shellfish such as treatment in: ozone, probiotics (bdellavibrios or vibriovax), ethyl pyruvate, cold high salinity relay.
 - b. Rapid detection methods for pathogenic strains of Vibrio.
 - c. Determine the infectious dose/response for the various pathogenic Vibrio strains.
 - d. Investigate how environmental conditions (beyond just temperature and salinity) and cultivation practices impact Vibrio levels and the production of hemotoxins.
 - e. Identify more accurate genetic markers for pathogenicity of Vibrios.
 - f. Determine how environmental strains relate to clinical strains, in order to better define outbreaks and improve outbreak response.
 - g. Identify the processes that impact the uptake and elimination of Vibrios and viruses in shellfish such as: attachment mechanisms, role of digestion, role of temperature and pumping/feeding activity, impact of food or lack of food in the water, mechanisms of elimination.
 - h. Identify how tidal state, turbulence and depth interact to influence Vibrio uptake and retention.
 - i. Refine all elements of the Vibrio Risk Calculator by refining the estimates of serving size, percent served raw/cooked, and estimated ratio of confirmed to unreported cases. Include regional considerations if appropriate.
 - j. Validate the use of ice slurry on a regional basis and evaluate shelf life impacts.
 - k. Evaluate the impact of prescription and over-counter proton pump inhibitors (such as Prilosec and Nexium) and antacids on the risk of Vibrio infection by evaluating COVIS records and determine if a consumer advisory label for such products would be appropriate.
 - 1. Develop a training module to educate public health and epidemiology staff on how to properly investigate and document Vibrio illnesses including guidance on patient interview, COVIS forms, and retail evaluation.
 - m. Vibrio-related issues identified by the ISSC
 - Is total V.v. a valid indicator of risk?
 - Are there differential effects of validated PHP on virulent subpopulations?
 - How do environmental factors affect levels of virulent subpopulations?
 - Compile a collection of *V.v.* strain samples for future virulence research.
 - Do other bacterial species react to controls the same as *V.v.* and *V.p.*?



- What are baseline Vibrio (total and virulent) levels at harvest (in oysters and clams)?
- How much Vibrio (total and virulent) growth results from the current time/temperature controls (in oysters and clams)?
- 3. Recommended the following research priorities:
 - a. What regional information is needed to refine risk assessments and risk calculator tools for implementation of effective control plans?
 - b. What is the significance of salinity to Vibrio levels in shellfish.
 - c. Is there a salinity/temperature matrix that determines Vibrio levels?
 - d. What are the key virulence factors (or combination thereof) for V.v. and V.p.?
 - e. What are the regional differences in pathogenic strains of V.v. and V.p.?
 - f. What is the percentage of pathogenic strains of Vibrio in growing waters?
 - g. Should the "viable but not culturable" state in pathogenic Vibrios be a concern?
- 4. Recommended developing a rapid test for ASP biotoxin and validation of the DSP rapid test that is currently under review.
- 5. Recommended that the ISSC continue to develop additional information to inform the use of MSC as an indicator of enteric viruses including the retention times and seasonal fluctuations.
- 6. Recommended that the ISSC develop better tools to evaluate whether shellfish have been fully cooked (especially for evaluating imports). The acid phosphatase test has not been fully validated. A quantitative test would be a significant improvement over current organoleptic tests.
- 7. Recommended development of tools to allow the culture of Norovirus for enumeration.

A motion was made and seconded that the Board adopt the recommendations of the Research Guidance Committee. The motion was approved with a voice vote of the Board.

F. Traceability

Bill Dewey advised the Board that the Committee had reviewed Executive Board action on the four recommendations from the October 2, 2011, meeting in Seattle. Following a discussion, a motion was made and seconded that the Board approve the following recommendations:

- Request the FDA to incorporate shellfish traceback in their Train the Trainer course and also ask FDA and ISSC to develop a standalone course and request FDA to request federal, state, and local inspectors get training on shellfish traceback and make it available for continuing education units. A motion was made and seconded to add a request that the ISSC Executive Office contact CDC to explore possibility of receiving CDC COVIS state evaluation for Committee review. The motion was seconded and passed with a voice vote by the Board.
- 2. Appoint a committee to look at the COVIS investigation form to improve traceback and request the ISSC executive office explore the possibility of receiving CDC state evaluations to share with Traceability Committee.



3. Write a letter to ask the Conference for Food Protection to emphasize annually the importance of retaining the tags in an orderly and chronological fashion, noting the dates of consumption, while prefacing this with our appreciation of their efforts on our behalf to date.

VII. OLD BUSINESS

A. California Regulations

Ken Moore reported that California is progressing with regulation amendments.

B. Vibrio Technology Project

Ken Moore reported that a presentation of study was presented during the Thursday Symposium. The study demonstrated that cooking does reduce Vibrio. This study offers ways for restricted use shellstock to be used. He said the ISSC membership will be advised of the final report.

C. Harvester & Dealer Education Program Proposal 09-212

Ken Moore reported to the Board that most states will not be in compliance this year. He said that within the next thirty days a draft training program could be available for review. Mr. Moore said the template is ready and the cost of the program is \$1200 for a sole user. Materials could be used today if necessary. Requirement will need FDA evaluation criteria. A motion was made and seconded to form a committee to evaluate the minimum requirements for Harvester/Dealer training. The motion passed with a voice vote by the Board.

VIII. NEW BUSINESS

A. FDA Status of States Report

Paul DiStefano presented the following general information to the Board.

- The fiscal year 2013 Molluscan Shellfish Evaluation Compliance Program covered the period October 1, 2012 through September 30, 2013.
- Evaluations of all NSSP elements (Growing Area, Control of Harvest, Plants and Shipping, Vibrio and Laboratory) were conducted. The number of states evaluated under each element varied based on the defined level of risk for each program element.
- Evaluations Conducted Included:
 - o Growing Area 18 States and 159 Growing Areas Evaluated
 - Control of Harvest 19 States and 128 Patrol Areas Evaluated
 - o Plant and Shipping 14 States Evaluated and 148 Certified Dealers Visited
 - Vibrio 22 States Evaluated, three of the 22 states voluntarily implement Vibrio Controls
 - Laboratory 10 Laboratories in six states were evaluated

Julie Anabarchian presented the following Growing Area Element report:

- 18 states evaluated
- 808 growing areas; 159 growing areas evaluated (20%)
- 1 state on an Action Plan
- 2 significant deficiencies
- 2 states were on Action Plans last year the deficiency of not meeting sampling requirements has been resolved, but the deficiency of not completing all reports on



time remains; the deficiency of upwardly classifying growing areas to conditionally approved without sufficient data to support the classification has been temporary resolved.

- Deficiencies or Potential Issues:
 - o 1 state 1 overdue 12-year sanitary survey report area to be closed under Action Plan; lack of effective controls to provide direct supervision of shellfish harvested from restricted and conditionally restricted areas for relay pursuant to NSSP MO Chapter V .@04(A) the state actually requested to be placed on an Action Plan for the relay deficiency to increase likelihood of funding from their legislature to address the issue.
 - o 1 state the deficiency of upwardly classifying growing areas to conditionally approved without sufficient data to support the classification has been temporary resolved by downgrading the growing area of concern back to its original classification of conditionally restricted, but this could potentially become an issue if the same area is upwardly reclassified again in the spring without the data to support the upgrade.

Raymond Burditt presented the following reports to the Board.

Control of Harvest Element General:

- 19 states evaluated
- 1059 Patrol Areas in those 19 States; 128 patrol areas evaluated (12%) Patrol Areas may not be defined the same as a classified Growing Area
- No states on Formal Action Plans
- Three state was identified with deficiencies in 2013

Significant Deficiencies:

- Not meeting patrol frequencies
- States lack direct oversight of shellfish relay program

Plant and Shipping Element General:

- 14 states evaluated
- 148 certified dealers were included as part of this evaluation
 - o 2 PHP
 - o 26 SP
 - 5 RP
 - o 73 SS
 - o 42 RS
- This includes 55 in the NER, 75 in CER, 13 in SER, 0 in SWR, 5 in PAR
- 7 SSO's were standardized
- 8 SSO's had maintenance
- 5 states were in Conformance

This means that the state programs complied with all of I.1, I.2, I.3, I.4, I.5, I.6 and 0% of firms failed the I.7 In-field Plant Criteria.

- 6 states were in Conformance w/ Deficiencies
 - This means the state programs complied with all of I.1, I.2, I.3, I.4, I.5, I.6 and 25% or less of firms failed the I.7 In-field Plant Criteria.
- 1 state was in Non-conformance
 - Does not comply with I.3 (Inspection Frequency) and I. 7 (31%, or 4 of 13 plants failed the In-field Criteria.)
- 2 states were in Major Non-conformance



- O Does not comply with criterion I.1(Legal Authority) and I.7 (36%, or 4 of 11, failed the In-field Plant Criteria)
- Does not comply with criterion I.1(Legal Authority), I.3 (Inspection Frequency), I.5 (Compliance Schedule Follow-up) and I.7 (40%, or 2 of 5, failed the In-field Plant Criteria)
- o Action plans requested from one (1) state
- Two Action Plans Requested 1.) I.7 In-field criteria and 2.) I.3 Inspection Frequency
- Two states under previous Action Plan
 - State does not have administrative laws/rules in place that provide authority to require dealer certification requirements.
 - State does not have administrative laws/rules in place that provide authority to require dealer certification requirements.

Significant Deficiencies: These are representative violations at multiple certified dealers within each state.

- Failure to have appropriate Critical Control Points within HACCP Plans
- Failure to have appropriate Critical Limits within HACCP plans
- Failure to have appropriate Verification within HACCP plans
- Failure to have appropriate Corrective Actions within HACCP plans
- Failure to maintain adequate HACCP records
- Failure to maintain adequate sanitation records
- Failure to protect water supply from contamination
- Failure to properly maintain and clean food contact surfaces
- Failure to protect shellfish from cross-contamination
- Failure to protect shellfish from adulteration
- Failure to properly label, store and use toxic compounds
- Failure to maintain control of pests from entering facility
- Failure to properly tag or label shellfish
- Failure to maintain hand washing/hand sanitizing
- Failure to maintain appropriate shipping documents and records
- Failure to have Written Recall Procedures

Shellfish Plant Inspections

Lizzie Evans reported the following report on State Evaluations of Vibrio Plans

- 22 states have Vibrio plans; 18 states are required to have Vibrio Plan
- Time temperature non-compliance most noted during inspections
- Compliance issues found in Gulf region
- *V.p.* issues of concern and permitting issues found in Northeast and Mid-Atlantic regions
- HACCP critical limits most addressed issue in Pacific region
- Regions have requested FDA assistance
- 209 visits by specialists
 - o Pacific 37
 - o Gulf 82 with 45 vessel boarding
 - o Mid-Atlantic 65
 - Northeast 25
- States are continuing to develop education programs, management strategies.
- Demand is overwhelming to FDA for demos, etc.
- Calculator use effective
- 2 states have actions plans



Paul DiStefano commented that states will have to do their own risk per serving calculation. Bill Dewey asked for an update from FDA on clarification of serving size. Ken Moore informed the Board that the subcommittee that had previously been working on this issue had been disbanded. He stated that FDA is working on risk per serving size and that a number was agreed upon but is not in program. Kirk Wiles state that the number being used in risk assessments is 196 grams for serving size. Following further discussion, Ken Moore suggested that the ISSC request FDA share its recommendation on risk per serving size and action was needed to create a level of uniformity. In response to Lori Howell, Mr. Moore said the appropriate place to address a motion on portion size would be during discussion of Proposal 13-204.

Linda Chandler reported on laboratory inspections as follows:

- 16 labs evaluated in 6 states
- 1 foreign 1 domestic –
- did one desk audit due to extensive personnel changes,
- few non-conform
- egregious action caused action plans
- action plan for desk audit
- Backlog issue Should be in compliance by end of 2014

A motion was made and seconded requesting FDA report their compliance schedule and whether or not the frequency of that schedule is being met by FDA. The motion carried with a voice vote by the Board. Paul DiStefano stated that he would share the information with the Executive Office.

B. Election of Board Officers

Bill Eisele reported that the Nominating Committee had met and recommended Maryanne Guichard as Executive Board Chair and Patti Fowler as Executive Board Vice Chair. A motion and a second was made to adopt the recommendation by acclamation. The motion was passed by the Board.

C. Proposals

1. Proposal 11-201-A *Vibrio vulnificus (V.v.)* Controls Ken Moore reported that the *V.v.* illness database will be transferred to the CFSAN Office. Mr. Moore said he will work with Lori Howell to determine standards for a database. Mr. Moore also said he hopes to share this information with FDA within thirty days.

2. Proposal 11-207 Vibrio cholera (V.c.)

Ken Moore advised the Board that the Pathogen Review Committee recommended that *Vibrio cholera* O75 should be treated as a naturally occurring pathogen unless the Authority determines there is evidence of association with pollution. Mr. Moore said he would research the Model Ordinance and make a recommendation for action by the Board at a future meeting.

3. Proposal 13-204 Vibrio Control Plans

Ken Moore advised the Board that the Conference has tasked the Board to work with states to seek and obtain funding for the purpose of assessing the efficacy of time and



temperature controls on post-harvest Vibrio growth. The following issues were discussed by the Board:

- Proposal 13-204 states that efforts shall be directed at developing robust science to define the combination(s) of prevention and post-harvest time and temperature controls that, when fully implemented, will minimize post-harvest Vibrio growth. The proposal directs the ISSC Executive Director, ISSC Chair, in consultation with an appropriate work group including some members of the Vibrio Management Committee, to provide guidance and administrative oversight to promote a coordinated effort among states, industry and the FDA to:
 - 1. Assess regional and environmental differences that may better define the combination(s) of post-harvest time and temperature controls that will be most effective for a given region or state and;
 - 2. Ensure that the results of research efforts will be fully considered by the membership of the ISSC.
- In addition to new research activities directed at scientifically defining effective time and temperature controls, the Executive Office shall request that states and industry submit to the VMC data and information relative to efforts in their respective state associated with time and temperature assessment and control activities. This work shall be conducted over the next one to two years and the science that is generated and compiled shall be used to compose an ISSC Proposal for consideration at the 2015 Biennial Meeting of the ISSC for controlling the post-harvest growth of Vibrios. The Executive Board shall be briefed at each of its semiannual meetings regarding all ongoing work associated with this effort.

Following this discussion a motion was made and seconded to assist states in implementing and carrying out the direction of the Conference in Proposal 13-204. The motion carried with a voice vote by the Board.

As a result of discussion during the FDA Status of States report, a motion was made and seconded that further work be conducted with regard to serving sizes of both oysters and clams (mercenaria), distinguishing regional consumption patterns and species difference, including Northeast, Southeast, Gulf, and Pacific. The motion carried with a voice vote by the Board.

4. Proposal 07-305 Press Releases

Ken Moore reported that the Use of Press Committee will continue to report its findings as they monitor use of press. Following a discussion a motion was made and seconded that ISSC share the FDA's final document for CORE SOP with all Conference members. The motion carried with a voice vote by the Board.

- 5. Proposal 11-305 Executive Board Interim Changes to NSSP Model Ordinance Ken Moore advised the Board that a work group would be appointed to develop instructions on the cost field of the ISSC proposal submission form. A report will be provided to the Board at a later meeting.
- 6. Proposal 13-306 Return to ISSC Annual Meetings Ken Moore suggested the Executive Board look at the possibility of condensing the meeting. Following a discussion, a motion was made and seconded to form work



group to work with the Executive Office to develop recommendations for future meeting formats. The motion carried with a voice vote by the Board.

D. FDA Consumer Advisory Copano Bay, Texas

Ken Moore gave background on the situation. The Board discussion addressed follow-up to the FDA issued Consumer Advisory for Copano Bay Texas. The discussion led to several questions. Such as: Is Texas out of compliance? Does conference need to know more about FDA expectation from States in these situations? What is interpretation of Texas violation by FDA?

Paul DiStefano explained FDA position. The agency felt the recall should have involved all shellfish from the growing area not just one distribution chain. FDA felt evidence was strong for recall of all shellfish from entire growing area. FDA was asked if it was their intent to notify Texas they were out of compliance? Paul indicated yes and the findings would be included in the PEER report. Chris Nelson and Ken suggested the current language is not clear. Kirk indicated that a determination of implicated product must be made. Ken asked if additional guidance is needed. A motion was made and seconded that the Board appoint a committee to investigate an interpretation of what is the definition of implicated product and to form committee to work on Model Ordinance language clarification in Chapter II.

Background:

Disagreement between FDA & Texas on how broad the recall should be. Following discussions between the two, Texas felt its actions were appropriate but FDA disagreed and released a statement saying shellfish were unsafe for consumption. Chapter II requirements following an outbreak include closing and investigation within 24 hours to find out if illegal harvesting or post-harvest contamination were responsible for the illnesses. The next step involves recalling of all implicated product. It was the opinion of FDA that all product from the entire growing area should have been recalled. Additional information came in and analysis showed NV in the gut which shows that the growing area was the cause of the contamination. Ken reminded the Board that this issue does not require Board action at this time.

IX. OTHER INFORMATION

The Executive Board will address the 2014 budget at the next meeting.

X. EXECUTIVE SESSION

A motion was made and seconded that the Board to into Executive Session. The motion passed with a voice vote by the Board.

A motion was made and seconded that the Board reconvene in open session which passed with a voice vote.

A motion was made that the Board approve the personnel recommendations made in Executive Session. The motion was seconded and carried with a voice vote by the Board.

XI. ADJOURN

A motion to adjourn the meeting was made and seconded. The motion carried and the meeting was adjourned.