

**I. Call to Order**

Mike Hickey called the meeting to order at 1:35 PM Eastern time. (Agenda Attachment 1)

**II. Roll Call (Attachment 2)**

Ken Moore conducted roll call with the following members present:

Bruce Buckson	Mike Hickey*
Bob Connell*	Lori Howell*
Robin Downey*	Ken Moore
Bill Eisele	Chris Nelson
Melissa Ellwanger for Paul DiStefano*	Gregg Pallaske
Steve Fleetwood*	Debbie Rouse*
David Fyfe	Angela Ruple for Spencer Garrett*
Terri Gerhardt*	Keith Skiles
David Guilbeau*	Al Sunseri*
Bill Hastback	Ed Watson*
David Heil*	

The following members were absent:

Johnathan Gerhardt*	Tommy Ward*
Maryanne Guichard*	Kirk Wiles
Bill Kramer	Rob Wittman
Larry Simms*	

Others Present were:

Bill Dewey, Region 6 Alternate  
 Nancy Daniel, ISSC  
 Heather Thomas, ISSC

*\*Indicates voting members of the Executive Board.*

**III. Discussion of End Use of Shellstock Harvested Outside of Model Ordinance Time/ Temperature Matrixes**

- Ken Moore
  - This will be complicated discussion involving 2 -3 things
  - Ken will give explanation of where he thinks we are and will make suggestions on how he thinks it should be handled as quickly and as transparently as possible.
  - At the end Ken will suggest putting a small work group together to develop additions to the MO and to the Guide to address the disposition of shellstock harvested outside the time/temperature matrixes.
  - Possible changes in Model Ordinance Chapters X, XIII, and XIV discussed with Kirk Wiles.

- July 8, 2010 memo (Attachment 3) sent by email to Executive Board:

This week I was notified by the USFDA that there were two (2) *Vv* related deaths in Washington, DC possibly from green tag oysters shipped to retail by a Virginia certified dealer. The investigation has not confirmed that the deaths were associated with green tag oysters. However, green tag oysters were observed in retail outlets in Washington, DC for raw oyster consumption sale. Green tags are used as a control measure by States in their *Vv* Management Plans and strict enforcement is critical to the success of the National Program in meeting the 60% goal established by the ISSC. It is imperative that the ISSC address this situation immediately.

I suggest the first step in addressing this situation is for the ISSC Executive Board to establish an effective date for the removal of “for cooking only” which was adopted in Proposal 09-210 and Proposal 09-234. Although this language is part of the *Vp* Control Plan it does allow oysters from the Gulf of Mexico to be shipped that have not met the controls established by the Gulf States to address *Vv*. I recommend establishing an effective date of July 11, 2010, for the removal of “for cooking only”. The present effective date is the publishing of the 2009 NSSP Guide for the Control of Molluscan Shellfish. In discussions with FDA it is likely that the Guide would not be available on FDA’s website until the fall of 2010.

FDA has previously indicated that a certified dealer can not ship green tag oysters to a retailer and be in compliance with the NSSP and the Seafood HACCP Regulation. The rationale is that a hazard can not be passed on to the consumer or end user. Restaurants are considered end users and processors can not rely on retail establishments to address food safety hazards such as *Vibrio*. I concur with FDA’s position and although the establishment of an implementation date for removing “for cooking only” does not completely address the enforcement issue, it may help certified dealers to understand that selling to a restaurant which indicates they plan to cook the product is not acceptable practice.

I have discussed this with ISSC Executive Board Chairman Mike Hickey. The Executive Board can handle this in one of two ways. We can schedule a conference call or you can agree to vote by email to establish an implementation date. Please advise us of your preference no later than 5:00 PM Tuesday, July 6, 2010. I realize this is short notice but given the magnitude of this problem I think it is important that the Conference act decisively and without delay. I will be contacting you next week to schedule a conference call to discuss enforcement of shipping requirements for green tag product. I think it imperative that we communicate to all States the expectations of ISSC as it relates to shipping requirements of oysters harvested and labeled with green tags.

Motion by Lori Howell: I find that the recommendation of the Executive Director to establish an earlier effective date for removal of “for cooking only” is consistent with the actions of the voting delegates. Based on that information and a review of the actions taken by the conference I make the following motion:

That July 11, 2010 shall be established as the effective date for the removal of “for cooking only” from Proposal 09-210 and 09-234 and that an Executive Board conference call be scheduled to begin discussions/precautions pertaining to the use of green tags.

The motion was seconded by David Guilbeau and approved with an email vote by the Board.

- Ken referred to FDA letter of July 12, 2010 to ISSC (Attachment 4)

This letter is to follow-up on a recent occurrence that FDA reported to the ISSC and which we believe warrants a full dialogue with the Interstate Shellfish Sanitation Conference (ISSC).

In early June, a visit by the State Standardization Officer (SSO) for the District of Columbia and FDA to the Wharf retail seafood markets in Washington, DC, found shellstock for sale at three retail businesses. Each of the three locations was offering for sale raw untreated oyster shellstock harvested from Texas and/or Louisiana. The oyster shellstock had been purchased from Louisiana and Texas by a single NSSP certified dealer in Virginia, who then sold the shellstock to the three DC retail establishments. Each container of shellfish displayed the original Texas or Louisiana dealer's tag. The Louisiana tags were green and stated, "For Shucking by a Certified Dealer or Post Harvest Processing Only". The Texas tags stated in bold red lettering, "For Cooking Only or PHP." Each retail establishment was selling the oysters as live shellstock for raw consumption. None of the retail establishments were certified under the NSSP to either shuck or Post Harvest Process the oysters. They serve only as retail seafood establishments.

Subsequent to the time of that visit in June, two *Vibrio vulnificus* (Vv) deaths have been attributed to consumption of oysters purchased at the DC Wharf retailers. In both instances oyster shellstock associated with the deaths came from the Virginia dealer referred to above. In one instance the oysters were labeled with a Louisiana tag that stated, "For Shucking by a Certified Dealer or Post-Harvest Processing Only". In the other instance the oysters were labeled with a Texas tag that stated, "For Cooking Only or PHP". Sale of this product by the Virginia dealer to retail outlets is clearly in violation of the NSSP Model Ordinance. The fact that a certified dealer would sell product intended for shucking or treatment by a NSSP certified dealer is extremely troubling. The Louisiana and Texas tags were intended to ensure that the oysters were not sold for raw consumption in accordance with NSSP controls for *Vibrios*. Failure by the Virginia dealer to adhere to NSSP requirements for controlling *Vibrios* questions the ability of the NSSP to ensure that measures for controlling *Vibrio* illnesses are carried forward from dealer to dealer and state to state.

In addition to the tags bearing the "For Shucking by a Certified Dealer or Post-Harvest Processing Only" or "For Cooking Only or PHP" language, the tags also included the NSSP Consumer Advisory statement. This raises another question relative the labeling of oyster shellstock not intended for raw consumption. Is inclusion of the advisory on such product contradictory and does it create some level of confusion?

FDA requests that the ISSC engage in a deliberative discussion regarding the issues identified above. Because of the obvious ability to jeopardize ISSC efforts to control *Vibrios*, it is necessary that the Conference immediately address these issues and prevent future occurrences and the continued undermining of state and industry efforts to control *Vibrio* illnesses.

Ken referred to Proposal 07-202 (Attachment 5) and FDA's letter of July 8, 2008 (Attachment 6) rescinding concurrence of this proposal. ISSC pointed out that procedurally that was inappropriate and that FDA could not rescind concurrence. The Board recognized that Seafood HACCP regulation does not allow hazards to be passed on to consumers. Conceptually the Conference agreed with FDA but said that procedurally FDA could not withdraw its concurrence so the Board asked the VMC to develop language, which they did and the Board adopted the language and changed the language from "for cooking only" and basically said for shucking or PHP. Consistent with the Constitution, Bylaws, and Procedures a proposal was submitted at the 2009 Biennial Meeting taking "for cooking only" out and leaving for shucking for a certified dealer or PHP only. The intent was that raw shellstock would not be sent to retail and that obviously happened here.

Received letter from Keith Skiles, State of Virginia (Attachment 7). The statement in the letter is correct that while the Conference intended for it to be the case, there is not an NSSP requirement that prohibits a certified dealer from selling product harvested outside of the matrix and tagged for cooking only, for shucking only, or for PHP only to a retailer. If this is the case, it is time to put language into the Guide that talks about disposition of this product and who receives the product. Language could be inserted in Chapters XIII and XIV under Critical Control Points on who can receive the product. Other than the original shipper, if you don't ability to shuck or to PHP maybe you should never receive product. Customers may have ability. Also, add requirements about disposition of products and in Chapter X require record keeping showing what kind of product was received and what the disposition was. Records check would indicate how much "green tag" product was received by a dealer and how they disposed of it. There is currently no differentiation in the NSSP regarding how product that is harvested outside the matrix is to be handled differently from product that has a regular shipping tag. We can now see what the implications are when that product is being sold as the same product.

Ken suggested appointing a small work group and letting that work group present the Board with language which could be adopted on an interim basis because time is critical. Within the next 7-10 days should have language that can be submitted to the Board for adoption. David Heil made a motion to approve Ken's suggestion and the motion was seconded by Lori Howell.

Keith Skiles would like to serve on work group.

Chris Nelson offered a friendly amendment to David Heil's motion that Ken write a letter to all 50 states to explain what has happened and say that it was never the intent for this product to be sold to retail and that the ISSC Executive Board is considering adopting interim language to address this issue but in the meantime it is the expectation of the ISSC that each State will find a way to deal with this and we recommend that you contact your dealers and make them aware of this. The friendly amendment was accepted by David Heil and Lori Howell (second to original motion). The motion passed with a voice vote by the Board.

#### **IV. Possible Solutions**

- A. Model Ordinance Changes and**
- B. FDA Interpretation(s)**

Ken will share the draft letter with Board members and asked that Board members think about where in the Guide the language should be inserted controlling the distribution of shellstock. Kirk Wiles and Ken discussed whether to put the language in as a critical control point or as a .03 Other Requirement. Refer to FDA's Fish and Fisheries Product Guide has a control for fish that deals with parasites as a hazard and it allows for parasites to actually be passed on to restaurants if the product is not intended to be eaten raw. Need to make sure no conflict is created with this Guide. Will ask work group to look and Guide to be sure no conflict is created.

Refer to Question and FDA Response of April 2, 2010 (Attachment 8). FDA's response is laid out quite well and wishes everyone in conference had seen this correspondence earlier in the spring. An FDA interpretation could be another way to deal with this issue but given the nature of the issue and also the criticality of controlling this and the impact of the success of the Vibrio Management Plan, language needs to be in the NSSP Guide.

#### **V. Possible Effective Dates**

Ken With the removal of for cooking only on tags, LA has already removed for cooking only. Emails sent to other gulf states asking how complicated would implementation be and one of the things could be as simple as taking a magic marker and striking it out. Implementation dates when it comes to tags has always been a sensitive issue because of reprinting, etc. associated with tags. Outside of the issue of having regulatory authority for States, if we change the MO and ask states to take immediate action, some states may have difficulty and may have to go the emergency regulation rule making. Condition of permitting. Could be problematic for some states. Effective date can be chosen when adopted. How quickly can states put this into effect?

David Heil

Stressed that letter should make absolutely clear that it was never the intent of the ISSC to have this product sold at retail. Do not want to give CSPI ammunition for a loop hole.

Bill Eisele

May need some language in shucking Chapter XI.

Workgroup:

Keith Skiles

Chris Nelson

Kirk Wiles

Mike Hickey

#### **VI. Adjournment**

A motion was made by Lori Howell and seconded by Melissa Ellwanger to adjourn the meeting at 2:10 PM Eastern time.