

# Gulf & South Atlantic States Shellfish Conference

August 15-19, 2010

Island House Hotel

Orange Beach, Alabama



Ken B. Moore  
Executive Director



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● Lori Howell (ME)	Industry	Region 1
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Task Force I Chair (non-voting)  
Task Force II Chair (non-voting)  
Task Force III Chair (non-voting)



# 2009 ISSC Proposal Package

**22 Proposals Referred from Previous Conferences**

**65 New Proposals**



Task Force I (Growing Area Classification)	New 8	Previous 14
Task Force II (Harvesting/Processing/ Distribution)	New 38	Previous 3
Task Force III (Administrative)	New 9	Previous 5
Resolutions	New 10	Previous 0



# Conference Adopted Proposals Resulting in Program Changes



Growing Area Classification	6
Harvesting/Handling/ Distribution	26
Administrative	3

# Conference Adopted Proposals Resulting in Program Changes

## Growing Area Classification



05-105	Re-Opening criteria based on new indicator (Male-Specific Coliphage) of sewage-borne viral pathogens 50/100 grams shellfish
05-113	Microbiology Checklist, Isolation of MSC
05-114	Microbiology method to determine the presence of MSC in shellfish meats and the microbiology.

Conference Adopted Proposals Resulting in Program Changes

# Growing Area Classification

07-107	Deletions and additions to Table I action levels, tolerances and guidance levels for poisonous or deleterious substances in seafood
09-103	Alternative analytical method for Vv. Quantitative Real-Time PCR
09-104	Method for the determination of Paralytic Shellfish Poison Post Column Oxidation

# Conference Adopted Proposals Resulting in Program Changes



## Harvesting/Handling/Distribution

07-200	Model Ordinance requirements to conduct product recall Presence of pathogens or illegal harvesting
09-200	Incorporating In-shell product concept into Model Ordinance definitions
09-202	Prohibit Commingling of In-shell Product
09-206	Defined product to be included in a recall & requirements for recall status reports

# Conference Adopted Proposals Resulting in Program Changes

## Harvesting/Handling/Distribution

09-207	Converts <i>Vibrio vulnificus</i> Management for oysters to a risk based plan effective January 1, 2012
09-208	Revised Post Harvest control standard for <i>Vp</i> control plans
09-209	Time requirement for achieving internal oyster temperature of 50°F (10°C) for <i>Vp</i> control
09-210	Deleted “For Cooking Only” as an option for restricted use shellstock in <i>Vp</i> control plans
09-213	Established In-shell product transportation requirements

# Conference Adopted Proposals Resulting in Program Changes

## Harvesting/Handling/Distribution

09-215	Modified shucked shellfish labeling
09-217	Clarified master carton labeling
09-218 09-223 09-225	Incorporating In-shell product concept (Shucking & Packing, Shellstock Shipping, & Reshipping)
09-219	Food contact equipment storage (Shucking & Packing)
09-220	Clarified plumbing & water supply requirements Chapters XI, XII, XIII, XIV, XV

# Conference Adopted Proposals Resulting in Program Changes

## Harvesting/Handling/Distribution

09-221	Frozen shellfish storage and handling
09-222	Removed references to shellstock in Chapter XII (Repacking of shucked shellfish)
09-224 09-228	Removed references to shucking (Shellstock shipping & Depuration)
09-226	Deleted requirement to add name & certification number to containers of shellstock when reshipping only
09-229	Modified Post Harvest Processing validation and verification requirements

# Conference Adopted Proposals Resulting in Program Changes

## Harvesting/Handling/Distribution

09-233	Created verification for process studies for Time and Temperature requirements related to <i>Vibrio</i> Management Plan Controls
09-234	Further defined requirements for Restricted Use Shellstock harvested under <i>Vp</i> Control Plans
09-236	Created an Illness Outbreak Investigation and Recall Guidance Chapter
09-237	Created a new section for Public Health Reasons & Explanations for Post Harvest Processing

# Conference Adopted Proposals Resulting in Program Changes

## Administrative



09-301	Adopted electronic Shellfish Sanitation Program Records
09-302	Modified requirements for standardization classroom training
09-308	Clarified time of Spring ISSC Executive Board meeting

# 2009 Summary of Actions Review Process

**Summary of Actions Submitted to FDA**  
November 20, 2009

**FDA Review Required in 60 Days**  
(Completed February 16, 2010)

- FDA Response to ISSC**  
**Summary of Actions**
1. Refer to Executive Board for further discussion; or
  2. Refer to next Biennial Meeting for consideration.

**2009 Version of NSSP**  
Effective upon posting of updated NSSP Guide on the FDA Website



**FDA Website Link**  
<http://www.fda.gov/default.htm>



**ISSC Website Link**  
[www.issc.org](http://www.issc.org)  
Click on “NSSP Guide”

# FDA's Response to 2009 Summary of Actions

## Proposal 09-205 Investigation During a Suspected Oyster Related Outbreak of *Norovirus*

FDA did not concur with action by the Conference to adopt Proposal 09-205 which defined the requirements for investigating a suspected *Norovirus* outbreak. FDA stated that it is incumbent upon health officials and the industry to act promptly and not delay prudent public health measures until clinical confirmation. FDA recommended that this Proposal be referred back to the Conference for further deliberation. The ISSC Executive Board concurred with the FDA.

## Board Concurrence with FDA's Response to 2009 Summary of Actions (continued)

Proposal 00-201  
*Vibrio vulnificus*  
Risk Management  
Plan

FDA concurs with recommendations of the Conference as outlined in Proposal 00-201. FDA stated its desire to maintain an open dialog with the ISSC and its commitment to a process to ensure that the essential elements will be in place for the Executive Board to take action during its fall 2010 meeting to protect consumers from *Vv* illnesses and deaths. Toward that end, FDA is contracting with Research Triangle Institute to conduct an assessment of Post Harvest Processing implementation by the Gulf industry. Efforts to conduct a consumer acceptance component of that study will be conducted through an ISSC contract.

# Board Concurrence with FDA's Response to 2009 Summary of Actions (continued)

Proposal 05-100  
*Vibrio vulnificus*  
Risk  
Management  
Plan for Oysters  
Exemption for  
Licensed  
Shellfish  
Harvesters &  
Dealers

FDA stated that exemption of any harvester or dealer, regardless of operational size, from NSSP *Vv* controls is not an appropriate public health approach. FDA believes it would be more prudent for the Executive Board to take no action on Proposal 05-100, or at least table further consideration pending consideration of Proposal 00-201. This Proposal was referred to Committee by the ISSC voting delegates.

# Board Concurrence with FDA's Response to 2009 Summary of Actions (continued)

Proposal 05-114  
Microbiology  
Method to  
Determine the  
Presence of  
MSC in Shellfish  
Meats and the  
Microbiology

FDA concurs with Conference action to adopt the male specific coliphage (MSC) method as a NSSP Type IV lab method for determining the presence of MSC in soft shell clams and oysters. However, the Summary of Actions states that its use is only for determining impacts of raw sewage associated with wastewater treatment plant effluent *spills*. It was not intended that its application be limited in this regard. FDA recommended that the restriction be removed from the Conference action. The Executive Board did not concur with this recommendation. The Executive Board acknowledged that States can use this method for other non regulatory purposes.

# Board Concurrence with FDA's Response to 2009 Summary of Actions (continued)

Proposal 09-107  
Saxitoxin (PSP)  
ELISA Kit

The Laboratory Methods Review Committee determined that Proposal 09-107 lacked sufficient data necessary for the Committee to make a determination regarding the efficacy of the proposed saxitoxin test method for use under the NSSP. The General Assembly voted "No Action" on the proposed analytical method. FDA recommended the Conference request that additional data from Abraxis, LLC to advance a thorough examination of this method for saxitoxin screening. The Executive Board concurred.

# *Vibrios in Shellfish*

*Vibrio vulnificus*  
*and*  
*Vibrio parahaemolyticus*



# *Vibrio vulnificus*

## Proposal 00-201

- A 49.4% reduction in *Vv* illnesses was achieved for 2005 & 2006 (combined), exceeding the 40% reduction goal for 2005 & 2006.
- The 2007 & 2008 goal is a 60% reduction in *Vv* illnesses.



2007/2008 reduction from baseline was 35.2%. The 2009 reduction (not final) is 36.3%. These reductions suggests the 60% goal will not be achieved.

## Status of States *Vibrio* Management Plans

- The *Vv* Source States have *Vv* Illness Reduction Plans (*Vibrio* Management Plans) authorized and in place that becomes effective on May 1, 2010.
- The effectiveness of the Plans will be evaluated by the VMC at its next meeting early 2011. Should the 60% goal not be achieved additional controls will be implemented in 2011.

# *Vibrio Parahaemolyticus*

*Outbreaks associated with Vp  
continue to be of significant concerns*

- Proposal 07-202 was adopted in 2007 by the Conference to establish a more comprehensive *Vp* Control Plan. The Plan requires all states to assess *Vp* risk and establish a Control Plan where appropriate.



This Plan is a shift toward more stringent post harvest controls. At the board meeting in Denver, FDA reported that all states were in compliance with the exception of two. These states were not following their written plans.

# Restricted Use Shellstock

## ISSC Board Action-August 11, 2010

- Proposal 00-201
- Proposal 09-210 and 09-234
- **Restricted Use Shellstock** - Shellstock that is harvested under conditions that do not allow the sale of the shellstock for direct marketing for raw consumption. Restricted use shellstock is identified with a tag indicating that the shellstock is intended for further processing prior to distribution to retail or food service.

# Restricted Use Shellstock

## ISSC Board Action- August 11, 2010

### Chapter X .01 C. (2) (c)

Critical control points shall be designed to ensure that shellstock received with restricted use tags is processed consistent with the stated purpose. For Shellstock tagged for restricted use, critical control points shall be included in the Certified Dealer's HACCP plan to ensure that the shellstock is shipped to another Certified Dealer with the restricted use tag or processed consistent with the stated purpose

# Restricted Use Shellstock

## ISSC Board Action- August 11, 2010

### Additional language for Chapters X, XI, XIII, and XIV.

#### Chapter X General Requirements for Dealers

##### .05 Shellstock Identification

A. ...

B. Tags.

(1)

(2)

(3)

(4) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.05 B. If the shellstock is received bearing a restricted use tag all specific use language shall be transferred to the new shipping tag.

C. ...

# Restricted Use Shellstock

## ISSC Board Action- August 11, 2010

- D. Tagging of a Lot of Shellstock During Intermediate Processing.
  - (1)
  - (2)
  - (3)
  - (4)
  - (5)
- E. All restricted use shellstock shall include a tag containing all information required in § .05 of Model Ordinance Chapter X. In addition the tag will include specific language detailing the intended use of the shellstock.
- F. Transaction Record. If shellstock are sold in bulk, the dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in §.05 B. with the addition of the name of the consignee.

# Restricted Use Shellstock

## ISSC Board Action- August 11, 2010

### Chapter XI Shucking and Packing

01. Critical Control Points
  - A. Receiving Critical Control Point
  - B.
  - C.
  - D.
  - E. Shellstock Shipping Critical Control Point – The dealer shall ensure that Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

# Restricted Use Shellstock

## ISSC Board Action- August 11, 2010

### Chapter XIII Shellstock Shipping

#### Critical Control Points

- A.
- B.
- C. Shellstock Shipping Critical Control Point
  - (1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

## Chapter XIV Reshipping

### Critical Control Points

A.

B.

C.

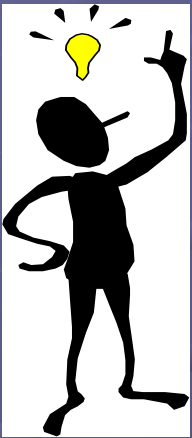
D. Shellstock Shipping Critical Control Point

(1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.



- Physicians/Nurses/Dieticians Online Vv Training Courses will continue.
- ISSC is looking at ways to facilitate and enhance validation for Post Harvest Processing
- ISSC will continue its activities to facilitate implementation of Proposal 00-201 (Vv Management Plan)

# Other ISSC Activities



- The ISSC continues to work with FDA, NOAA, and States to implement the Dockside Testing program for George's Bank.
- Continued development of the ISSC Website.
- The ISSC continues efforts to approve and review laboratory methods for use in the NSSP.

# ISSC Committees

- **Audit**
- **Biotoxin**
- **Communications**
- **Education**
- **Foreign Relations**
- **Import Assessment**
- **Laboratory Methods Review & Quality Assurance**
- **NSSP Evaluation Criteria**
- **Patrol**
- **Plant Standardization Advisory**
- **Post Harvest Processing**
- **Product Recall**
- **Proposal Review**
- **Research Guidance**
- **Resolution**
- **Shellfish Restoration**
- **Time-Temperature Technology**
- **Unresolved Issues**
- **Use of Press**
- **Vibrio Management Committee**
  - **Vv Illness Review Subcommittee**

*Membership forms and Committee sign-up sheets  
can be downloaded from the ISSC Website.*

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