



# **FDA Update 2010**

## **Gulf & South Atlantic States Shellfish Conference**

M. Lizzie Evans  
CFSAN  
Office of Food Safety  
8-18-2010



# Overview

- *Vibrio* management
- Recent *Vibrio* Illnesses
- European Union Trade Issues
- Other Items of Interest
- New personnel and changes in College Park, MD

# Mitigating the risk: the Good the Bad and the Ugly

- The burning issue... PHP
  - ISSC biennial meeting FDA announced intent to change position *V.v.* control policy
  - *V.v.* control more closely follow Seafood HACCP
  - Change to FDA's Fish and Fishery Products Hazards and Controls Guide
    - “prevent, eliminate, or reduce the hazard to an acceptable level”

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm>

# Mitigating the Risk continued...

- Current efforts under the NSSP have not been successful (60% illness reduction)
- ISSC (VMC) meet in January
  - Further review and discussion
- What is FDA/ISSC doing to determine efficacy and impact?

# Determining Impact: in the works.

- GAO audit in response to congressional inquiry
- ISSC contracted a Consumer Acceptance Study
- FDA contracted Research Triangle Institute Impact Study-implementation in the gulf
- Further discussion... possible meetings between top officials and stakeholders
  - FDA intent to hold meeting in the gulf and on the Atlantic coast
  - Oil spill, agency held off
  - Time frame not yet established still intent to move forward
  - Regional listening meetings with industry; discuss ideas
- Communication is KEY!

# Intention

- Methods that fall short of HACCP, where time and temperature controls exist, is not acceptable.
- Food Safety Hazards risk based approach
  - Equivalent risk reduction as determined by VMC
- FDA heard loudly and clearly concerns from States, Industry and Congress... TIMING



# So What Happens Next?

- Policy decisions are placed in abeyance while studies are being conducted
- Utilize information to examine policy and implementation



# New Guidance For Validations: options for PHP

- FDA involved in developing a couple of documents to assist industry and labs in PHP and verification work, shared with ISSC.
- Ken Moore will be setting up committee or work group to forward through the conference. Look forward to feedback.

# Recent Illnesses

## D.C. illnesses/deaths

- Untreated raw product sold to retail establishments
  - product labeled to be shucked by a certified dealer or PHP
  - 2009 to remove for cooking but until MO is published old one stands so for cooking was allowed, until....
  - A few weeks ago for cooking taken out of language after incident.
  
- None were certified under NSSP – retailers not dealers!!!
  
- FDA is working with the ISSC to develop language to clarify restricted use of product for certified dealers.

# European Union Trade Issues

- As of July 1, 2010 E.U. will no longer allow U. S. shellfish imports
- Confusion... raw or processed i.e.. cooked product.
  - Even on EU's part.
- We are currently working through a process to review each others program to determine equivalent level of health protection
  - FDA never looked at EU program in detail.... EU performed US audit 3/2009.
  - FDA does not believe one to be dependant upon the other.



# What do I do as an exporter?

- FDA recommends contacting your importer prior to sending
- More information to follow as soon as it becomes available

# Other Items of Interest:

- *Vibrio* evaluation worksheets
  - Will be part of evaluation process.
  - NSSP MO requirements
  - *Vv* and *Vp* risk management control plan implementation
  
- FD 241 State Shellfish Standardization Officer Course being taught November 2-3, 2010 in Battle Creek Michigan.

# Personnel in College Park

- Julie Mayer
  - Works with water quality engineers to do water quality assessments and dye dispersion studies for growing area classification
  
- Me!
  
- Personnel Changes: Donald Kraemer and Roberta Wagner acting deputy center director
  - Bill Jones acting deputy director of Office Food Safety
  - Melissa Ellwanger acting director of the division of seafood safety.

# QUESTIONS?



Pity the poor fool who with  
his eyes alone doth judge an oyster,  
he who would refuse gold because  
it were too shiny. But of course, that  
leaves more for the rest of us  
to enjoy.

---

From an article in the January 1997  
issue of *Hemispheres* by Kevin Keating

---

**Raymond Burditt**  
[floyd.burditt@fda.hhs.gov](mailto:floyd.burditt@fda.hhs.gov)

**Lizzie Evans**  
[melissa.evans@fda.hhs.gov](mailto:melissa.evans@fda.hhs.gov)