



# ***National Shellfish Sanitation Program***

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# ***Presentation Objectives***

- ✱ National Shellfish Sanitation Program (NSSP)
- ✱ Imported shellfish control measures



# MOLLUSCAN SHELLFISH

Shellfish<sup>1</sup> Means All Species of :

- (a) Oysters, clams or mussels, whether:
  - (i) shucked or in the shell;
  - (ii) fresh or fresh frozen; and
  - (iii) whole or in part: and
- (b) Scallops in any form, except when the final product form is adductor muscle only

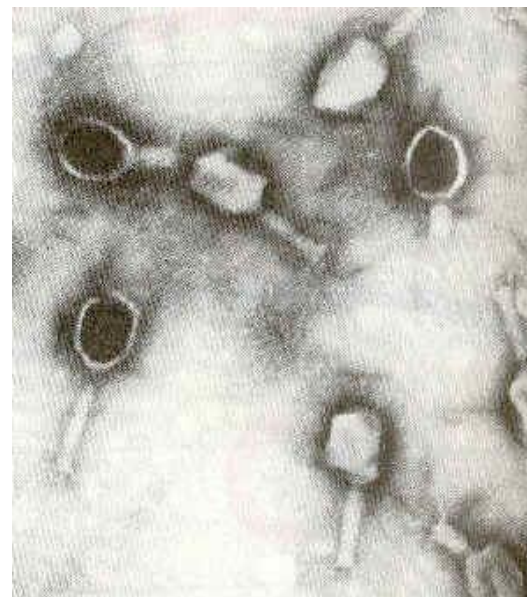
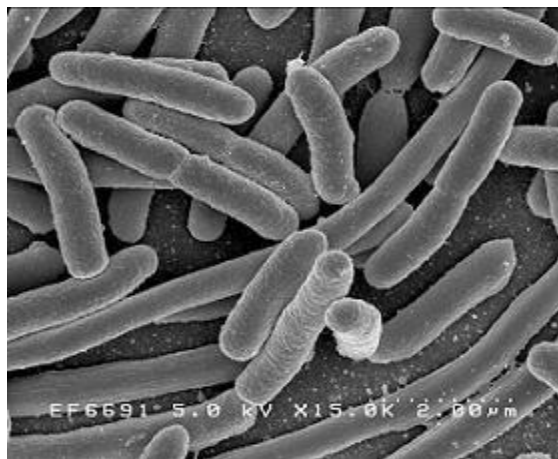


<sup>1</sup> Model Ordinance definition



# WHY SHELLFISH? FUNCTION

- Shellfish do not discriminate
  - Pathogenic bacteria
  - Viruses
  - Phytoplankton/diatoms
  - Chemicals/metals





# Pathogens of Concern

## Enteric Pathogens Transmitted by Fecal Contamination:

**Norovirus**

**Hepatitis A virus**

***Salmonella* spp.**

***Shigella* spp.**

## Naturally Occurring Bacterial Pathogens:

**Pathogenic *Vibrio* spp.**

**(*V. vulnificus*, *V. parahaemolyticus*, *V. cholerae*)**

# **Naturally Occurring Toxins of Concern**

**Known as “marine biotoxins”**

- **Produced by certain species of phytoplankton**
- **Occur during phytoplankton blooms**

**(1) Paralytic shellfish poison (PSP)**

**(2) Amnesic shellfish poison (ASP or Domoic Acid)**

**(3) Neurotoxic shellfish poison (NSP or Brevetoxins)**

**(4) Diarrhetic shellfish poison (DSP or Okadaic Acid)**





# National Shellfish Sanitation Program

- **The National Shellfish Sanitation Program (NSSP) based on public health principles and controls – growing, harvesting, processing, shipping**
- **Designed to prevent illnesses associated with the consumption of raw fresh and fresh-frozen bivalve molluscan shellfish**
- **Cooperative, voluntary, tripartite program (ISSC)**
- ***NSSP Guide for the Control of Molluscan Shellfish* –principles, guidelines, and requirements for controlling shellfish safety and regulating shellfish industry.**



# NSSP RISK ASSESSMENT STRUCTURED APPROACH

## Element

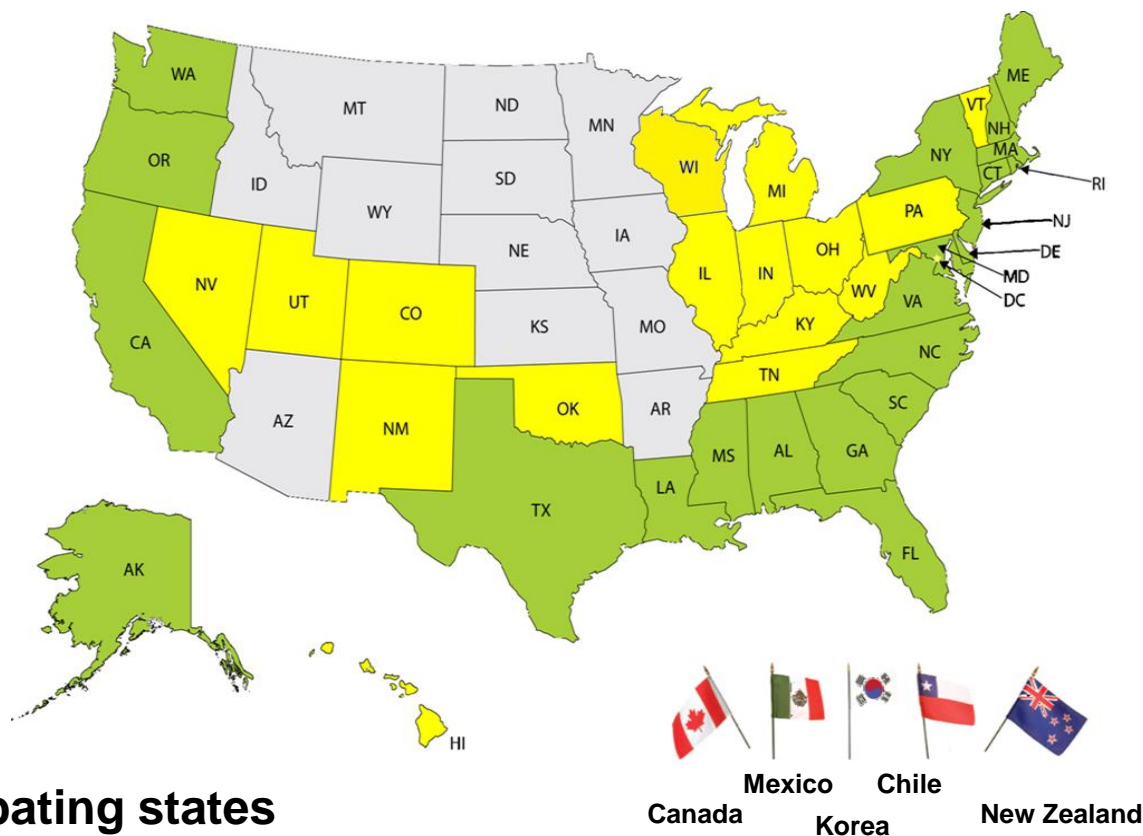
- Vibrio Management
- Growing Area
- Control of Harvest (Patrol)
- Plant Sanitation

## Program Risk

- High
- High
- Medium to high
- Low to Medium



# ISSC STATE/COUNTY PARTICIPATION



# **Acceptable Imported Shellfish**

- **Only fresh (raw) or fresh frozen shellfish shipped from dealers listed on FDA's Interstate Certified Shellfish Shippers List (ICSSL) – Canada, Mexico, Korea, New Zealand.**
- **Properly labeled, including the Dealer's Certification Number**

# Four Active Exporting Countries



# **MOU Country Imports**

- **MOU stipulates responsibilities of the exporting country - requires conformance to NSSP requirements or demonstration of equivalent/comparable safety**
- **FDA conducts periodic program audits of MOU country program to ensure continued compliance and safety**

# **Non-MOU Country Concerns**

- **Polluted Harvest Waters**
  - **Bacterial and viral pathogens**
  - **Chemical and metal contaminants**
- **Marine Biotoxins**
- **Insanitary Processing**
- **Unsafe Handling**
- **Lack of Oversight by Responsible Government Agency**



# **Raw Molluscan Shellfish Imports Fresh and Fresh Frozen**

**Must meet both Federal standards  
(Regulations) and State enforced  
NSSP requirements to gain free  
access to U.S. markets**



# **Regulatory Authority**

## **States:**

- **NSSP requirements (Model Ordinance) – state law, regulation, ordinance, etc.**

## **FDA:**

- **Public Health Service Act**
- **FD&C Act**
- **Fair Labeling and Packaging Act**
- **Seafood HACCP Rule**
- **COOL (w/USDA)**
- **Lacey Act (w/NMFS)**
- **Food Safety Modernization Act**





# **FDA Compliance Programs and Sample Collection/Analysis of Imported Shellfish**

- **Molluscan Shellfish Compliance Program (7318.004) – domestic and international shellfish compliance administered by ORA Shellfish Specialists**
- **Import Seafood Products Compliance Program (7303.844)**

## **Lacey Act**

- **On July 7, 1986, FDA and NMFS entered into an MOU (see FDA Federal Cooperative Agreements Manual, 1996 edition, pg. 4-4) to increase and improve cooperation on the enforcement of the Lacey Act...**
- **Against the illegal harvest, transport, export, import, sale, and purchase of molluscan shellfish in violation of any law or regulation of any state or any Indian tribal law**



## **Imported Shellfish Labeling**

- **21 CFR Part 101 - Food Labeling**
- **NSSP Labeling Requirements:**
  - **Dealer's certification number (e.g. NZ-49-SP)**
  - **Indicate retention of shellstock tag – 90 days**
  - **Consumer Advisory**
- **Country of Origin Labeling (USDA)**
  - **Provide name of country product originated from**

## **FD&C Act**

**Shellfish are adulterated under FD&C Act if they contain poisonous or deleterious substances such as pathogenic bacteria, viruses, marine biotoxins, or chemical contaminants, or if manufactured under insanitary conditions - 402(a)(1) & (3) and 801(a)(1) & (3).**

3500036702014  
中国特产海蛎  
3500036702014



# 连江海蛎王

## SPECIES CRAB



制造商：（福州宏利食品有限公司）  
FUZHOU HONGLI FOOD CO., LTD.  
HACCP 注册号：3500/0013 IT 注册号：3500/02087

**Mislabeled product**





**Multiple raw fish products**



# **Molluscan Shellfish Import Bulletins**

**Short duration – internal to FDA**

**Directions to inspect and sample**

**Following Import Bulletins are expired and are shown simply to demonstrate prior problems with molluscan shellfish**

- **Import Bulletin #16-B12, “Whole Cleaned Clams From Vietnam”**
- **Import Bulletin #16-B15, “Clams From Fuzhou Haiding Aquatic Product Co., Ltd., China”**





# **Molluscan Shellfish Import Alerts**

**Long duration – open to public**

**Directions to detain**

**Import Alert #16-50: "Detention Without Physical Examination  
Of Molluscan Shellfish" - 12/19/13**

- **Examination found pathogens; or**
- **Epidemiologically linked to food-borne illness outb; or**
- **Labeled as "cooked" when not**



# **Action Regarding Imported Shellfish**

## **Uncertified Shellfish and Shellfish Shippers**

- **Contact the ORA Regional Shellfish Specialist**
- **Work with the State Shellfish Control Authority to embargo/destroy (state contacts listed in ICSSL)**
- **Importer should be advised of State embargo if FDA releases shipment into commerce**
- **If State chooses not to take action, CFSAN, Shellfish and Aquaculture Policy Branch and Product Adulteration Branch**

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