

## Molluscan Shellfish Guidance Document

### Definitions

**Molluscan shellfish** - An edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

**Shellstock** - Raw, in shell molluscan shellfish.

**Shucked shellfish** - Molluscan shellfish that have one or both shells removed.

**Commingle** means:

- To combine **SHELLSTOCK** harvested on different days or from different growing areas as identified on the tag or label, or
- To combine **SHUCKED SHELLFISH** from containers with different container codes or different shucking dates.

**Interstate Certified Shellfish Shippers List (ICSSL)** - published monthly for the information and use by food control officials, seafood industry and other interested persons. The shippers listed have been certified by regulatory authorities in the United States, Canada, Korea, New Zealand and Mexico under the uniform sanitation requirements of the National Shellfish Program.

### Health Risks

**Shellfish Poisoning** (Marine Biotoxins) - Diarrhetic Shellfish Poisoning, Paralytic Shellfish Poisoning, Amnesic Shellfish Poisoning. Cooking **DOES NOT** destroy marine Biotoxins. Shellfish must always come from an approved source (ICSSL). Recreational harvested shellfish is prohibited.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

**Vibriosis** (Vibrio spp.) - An intestinal disease caused by the bacteria called Vibrio. Vibrio are found in fish and shellfish living in saltwater and in rivers and streams where freshwater meets saltwater. Symptoms usually appear about 15 hours after consumption but can take as long as four days. Vibrio is destroyed by cooking shellfish to an internal temperature of 145° F for 15 seconds.

### Regulatory Requirements

#### **Shucked Shellfish, Packaging and Identification**

Raw **shucked shellfish** shall be obtained in nonreturnable packages which bear a legible label that identifies the

- Name, address, and certification number of the shucker, packer or repacker of the molluscan shellfish; and
- The "sell by" or "best if used by" date for packages with a capacity of less than 1.89 L (one-half gallon) or the date shucked for packages with a capacity of 1.89 L (one-half gallon) or more.

A package of raw **shucked shellfish** that does not bear a label or which bears a label which does not contain all the information shall be subject to a **HOLD ORDER**, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding

### **Shellstock Identification**

**Shellstock** shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester or dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list;

- The harvester's identification or the dealer's name assigned by the shellfish authority
- The date of harvesting
- The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested
- The type and quantity of shellfish
- The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"

A container of **shellstock** that does not bear a tag or label or that bears a tag or label that does not contain all the information shall be subject to a **HOLD ORDER**, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

### **Shellstock, Condition**

When received by a food establishment, **shellstock** shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or shellstock with badly broken shells shall be discarded.

### **Molluscan shellfish, original container**

**Molluscan shellfish** may not be removed from the container in which they are received other than immediately before sale, preparation for service or under the following conditions;

For display purposes, **shellstock** may be removed from the original container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:

- The source of the shellstock on display is identified and recorded; and

- The labeling information for the shellfish on display is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and
- The **shellstock** are protected from contamination.

**Shucked shellfish** may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a CONSUMER'S request if:

- The labeling information for the shellfish on display is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and
- The shellfish are protected from contamination.

**Shucked shellfish** may be removed from the container in which they were received and repacked in consumer self-service containers where allowed by law if:

- The labeling information for the shellfish is on each CONSUMER self service container
- The labeling information is retained and correlated with the date when, or dates during which, the shellfish are sold or served;
- The labeling information and dates are maintained for 90 days; and
- The shellfish are protected from contamination.

### **Shellstock, Maintaining Identification**

**Shellstock** tags or labels shall remain attached to the container in which the shellstock are received until the container is empty.

The date when the last **shellstock** from the container is sold or served shall be recorded on the tag or label.

The identity of the source of **shellstock** that are sold or served shall be maintained by retaining **shellstock** tags or labels for 90 calendar days from the date that is recorded on the tag or label

All operators must use a record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label

If **shellstock** are removed from its tagged or labeled container the source identification must be preserved by using an approved record keeping system and ensuring that **shellstock** from one tagged or labeled container are not **commingled** with **shellstock** from another container with different certification numbers; different harvest dates; or different growing areas as identified on the tag or label before being ordered by the consumer.

### **Molluscan Shellfish Tanks**

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern. If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

### **Inspections**

When evaluating approved sources for shellfish, such as clams, oysters, and mussels, inspectors should ask whether shellfish are served at any time during the year. If so, inspectors should review the tags or labels to verify that the supplier of the shellfish is certified and on the most current Interstate Certified

Shellfish Shippers List found at

(<http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006753.htm>)

Inspectors should note whether all required information is provided on the tags or label (harvester's certification number, harvest waters and date, type and quantity of shellfish and similar information for each dealer that handles the shellfish after the harvester). **Shellstock** tags should also be retained for 90 days in chronological order.

Shellfish in the food establishment should be labeled at all times.

Recreation harvested shellfish is prohibited.

### **Consumer Advisory**

All food establishments serving raw or undercooked shellfish must inform consumers about the increased risk of foodborne illness when eating these foods.

Raw and undercooked shellfish are never allowed to be served to highly susceptible populations.