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**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Washington DC 20204**



**POLICY STATEMENT**

**CONSUMPTION OF RAW MOLLUSCAN SHELLFISH**

Molluscan shellfish are animal-derived protein foods that are widely consumed and play an important role in the diets of some consumers. Most animal-derived protein foods are cooked prior to consumption. Cooking can reduce a number of potentially pathogenic organisms and the risk of illness. However, molluscan shellfish are often consumed raw or partially cooked. Therefore, some cases of illness are inevitable from consuming them in this way.

The majority of illnesses that occur from the consumption of raw molluscan shellfish are the result of pollution. They are not life threatening to the general population and commonly range from mild intestinal disorders of short duration to acute gastroenteritis. More serious illnesses can occur, but are rare.

Certain medically compromised individuals are at increased risk from common marine *Vibrio* bacteria that are unrelated to pollution. Therefore, it may not be possible to address this risk through environmental controls. Although the reported number of illnesses and fatalities from these bacteria in the United States each year is small in comparison with other food borne illnesses, the best advice for medically compromised individuals is not to eat raw molluscan shellfish. At most risk are those affected by: AIDS; chronic alcohol abuse; liver, stomach or blood disorders; cancer; diabetes; and kidney disease. Those uncertain of their health should seek the advice of their physician.

To reduce the risk of illnesses associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite cooperative program of Federal and State public health officials and the shellfish industry working together to improve shellfish safety. FDA is committed to the NSSP partnership as providing the best means of making molluscan shellfish as safe as possible. States annually spend millions of dollars to monitor waters to assure that they are safe before harvesting is permitted. FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. FDA has also increased its cooperative efforts with State and Federal law enforcement officers to prevent illegal harvesting from closed waters, a practice that probably leads to most shellfish illnesses. Adhering to NSSP controls will help to keep risks to a minimum.

## **ISSC POLICY STATEMENT**

### **CONSUMPTION OF RAW MOLLUSCAN SHELLFISH**

#### **Introduction**

The Interstate Shellfish Sanitation Conference (ISSC) was organized in 1982 to address the safety and sanitation of molluscan shellfish (oysters, mussels, clams, and whole and roe-on scallops). The ISSC has a formal Memorandum of Understanding with the U.S. Food and Drug Administration (FDA) to promote shellfish sanitation through the National Shellfish Sanitation Program (NSSP), a tripartite cooperative program of Federal and State public health officials and the shellfish industry working together to improve shellfish safety. The ISSC recognizes the success of this Program, which is founded on the premise that through appropriate controls, molluscan shellfish can be consumed raw by most people with reasonable risk. The ISSC remains committed to that premise.

#### **Policy Statement**

Molluscan shellfish are animal-derived protein foods that are widely consumed and play an important role in the diets of some consumers. Most animal-derived protein foods are cooked prior to consumption. Cooking can reduce a number of potentially pathogenic organisms and the risk of illness. Consumption of raw shellfish, as with consumption of other types of raw animal-derived protein foods, increases the risk of illness. The majority of illnesses related to the consumption of raw molluscan shellfish are a result of pollution. These illnesses are not life threatening to the general population and commonly range from mild intestinal disorders of short duration to acute gastroenteritis. More serious illnesses can occur, but are rare.

To reduce the potential risk associated with consumption of raw molluscan shellfish, the FDA in cooperation with the States administers the National Shellfish Sanitation Program. States monitor shellfish growing waters to determine that they are safe before harvesting is permitted. The FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. The FDA has also increased its cooperative efforts with State and Federal law enforcement officers to prevent illegal harvesting from closed waters and ensures that all shellfish in interstate commerce are properly labeled or has a tag identifying the harvest area and shipper. The tagging and labeling requirement of the NSSP is designed to ensure that only shellfish from approved growing waters reach interstate commerce. Adherence to NSSP controls minimizes risks. Recognizing the NSSP partnership provides the best possible means of ensuring that molluscan shellfish are safe, the FDA, the States, and the ISSC are committed to continued support of the Program.

Certain medically compromised individuals are at increased risk from common marine bacteria that are unrelated to pollution. Therefore, it may not be possible to address this risk through environmental

controls. Although the reported number of illnesses and fatalities from these bacteria in the United States each year is small in comparison with other food borne illnesses, total abstinence from raw molluscan shellfish is the best advice for medically compromised individuals. Those at greatest risk include, but are not restricted to those affected by: AIDS; chronic alcohol abuse; liver, stomach or blood disorders; cancer, diabetes and kidney disease. Those uncertain of their health status should seek the advice of their physician.

## INTERSTATE SHELLFISH SANITATION CONFERENCE

### RESOLUTION 97 - 01

**SUBJECT:** Post-Harvest Treatment Processing

**TEXT OF RESOLUTION:**

**WHEREAS**, the effect of naturally occurring *Vibrio vulnificus* in raw shellstock oysters has been a problem that has caused considerable concern for the Interstate Shellfish Sanitation Conference (ISSC), the FDA, State public health regulators, the molluscan shellfish industry and the general public; and

**WHEREAS**, the ISSC had previously adopted a position (stated in a resolution by the 1991 conference) that "in absence of definitive information regarding *Vibrio vulnificus*, the only realistic approach is education of the high risk groups"; and

**WHEREAS**, the ISSC also had recommended that "states and industry take immediate steps to institute harvesting, processing and handling procedures which will eliminate illnesses attributable to *Vibrio vulnificus*"; and

**WHEREAS**, the State public health regulators and shellfish control agencies are awaiting guidance from the ISSC and FDA regarding Post-Harvest Treatment (PHT) processes; therefore

**BE IT RESOLVED**, that the ISSC encourages the development and SSCA approval of PHT processes which are able to consistently and reliably reduce *Vibrio vulnificus* to non-detectable levels in raw molluscan shellfish.

## INTERSTATE SHELLFISH SANITATION CONFERENCE

### RESOLUTION 09-001

**SUBJECT:** Educational Outreach Common Carrier Associations

**TEXT OF RESOLUTION:**

**WHEREAS**, the National Shellfish Sanitation Program, (NSSP), was developed in 1925 when the U. S. Public Health Service responded to a request for assistance from local and state public health officials in controlling disease associated with the consumption of raw shellfish, and

**WHEREAS**, each shellfish shipping state has adopted adequate laws and regulations for sanitary control of the shellfish industry, completed sanitary surveys of harvest areas, delineated and patrolled restricted areas, inspected shellfish plants, and conducted such additional inspections, laboratory investigations, and control measures as were necessary to insure that the shellfish reaching the consumer had been grown, harvested and processed in a sanitary manner, and

**WHEREAS**, the shellfish industry has cooperated by obtaining shellfish from safe sources, by providing plants which met the agreed upon sanitary standards, by maintaining sanitary operating conditions, by placing the proper certificate number on each package of shellfish, and by keeping and making available to the control authorities records which showed the origin and disposition of all shellfish, and

**WHEREAS**, in 1982, a delegation of state officials met in Annapolis, Maryland and formed the Interstate Shellfish Sanitation Conference (ISSC), that is composed of state shellfish regulatory officials, industry officials, FDA, and other federal agencies, and

**WHEREAS**, the ISSC has provided a forum for state shellfish regulatory officials, industry officials, FDA, and other federal agencies, to establish uniform national guidelines and to exchange information regarding sources of safe shellfish, and

**WHEREAS**, under the guidance of the ISSC, the NSSP has lead the United States in the prevention of food-borne illnesses by requiring the States, to monitor bacteriological water quality of shellfish growing areas, to label shellfish with exact growing area information for trace-back purposes, to inspect and certify shellfish processing facilities, to require refrigeration of shellfish to reduce the growth of food-borne pathogens, and

**WHEREAS**, shellfish dealers are required by the NSSP to ensure that shellfish is shipped under proper temperature control to prevent possible pathogen growth, especially natural marine pathogens such as *Vibrio vulnificus* and *Vibrio parahaemolyticus* that have substantial growth based on temperature, and

**WHEREAS**, common carriers are exempt from the time-temperature control requirements of the Model Ordinance, causing most dealers to be concerned if the shellfish products shipped via these carriers are maintained at proper temperatures and

**BE IT RESOLVED**, that the ISSC acknowledge that managing pathogen growth comes from proper temperature control and maintaining this proper temperature control is of concern for dealers who ship shellfish including shipping via common carriers,

**BE IT FURTHER RESOLVED**, that the ISSC will extend an educational outreach to Common Carrier Associations to express these concerns in a letter to Common Carrier Associations detailing the need for proper temperature control for shipping shellfish,

**BE IT FURTHER RESOLVED**, that the ISSC will extend an educational outreach to Common Carrier Associations to express these concerns by promoting the attendance of an Executive Board member to attend Common Carrier Association Conferences as they may occur and as executive board budget allows.