



DATE: May 15, 2012

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: 
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Director, Food Protection Program

SUBJECT: Korean Shellfish Advisory

SUGGESTED ACTION: Information provided in case of consumer inquiry. Undeclared Allergens.

Korean Shellfish Advisory

FDA has removed all Korean certified shippers from the Interstate Certified Seafood Shippers List (ICSSL) effective May 1, 2012. All fresh and fresh frozen molluscan shellfish from Korea should be considered from an unapproved source. In addition, FDA considers all fresh and fresh frozen molluscan shellfish and all products subsequently derived from fresh and fresh frozen molluscan shellfish from the Republic of Korea to be adulterated. Accordingly, the sale, service, further processing or further distribution of these products is prohibited. There are no details regarding disposition at this time. Updates will be issued as more information is received. Questions regarding this matter may be directed to this office at 317-650-2880.

Background Information

1. The safety of molluscan shellfish - oysters, clams, and mussels, whole and roe-on scallops either shucked or in the shell, fresh or frozen, whole or in part - entered into interstate commerce is ensured through the National Shellfish Sanitation Program (NSSP). The NSSP is a cooperative program overseen by the Food and Drug Administration (FDA), State regulatory agencies, and the shellfish industry; these entities work together with the Interstate Shellfish Shippers Conference (ISSC) to set, require, and monitor strict controls on the growing, harvesting, processing, packaging, and transport of molluscan shellfish. Under international agreements with FDA, foreign governments also participate in the NSSP.
2. As listed, the cooperative program has four components to help keep contaminated molluscan shellfish out of the marketplace:

- a. Classifying growing areas based on pollution source identification and assessment, water quality monitoring, and other factors that indicate suitability for harvest;
 - b. Inspecting facilities that handle shellfish to ensure the use of proper sanitary measures;
 - c. Patrolling to deter illegal harvesting from prohibited waters; and
 - d. Conducting laboratory testing and analysis of shellfish and water samples.
3. Each month, a list of certified shippers who meet the requirements of the NSSP is published. The list is called the Interstate Certified Shellfish Shippers List (ICSSL) and only those entities identified on the list can enter shellfish into interstate commerce.
 4. All South Korean shellfish shippers were removed from the ICSSL on May 1, 2012, following an FDA evaluation that determined the Korean Shellfish Sanitation Program no longer meets the sanitation controls spelled out under the NSSP. The removal of South Korean shellfish shippers from the list is intended to stop the import of molluscan shellfish harvested from polluted waters.
 5. Korean molluscan shellfish that entered the U.S. prior to May 1st and any product derived from Korean molluscan shellfish, i.e., breaded shellfish, are considered adulterated under the Federal Food, Drug, and Cosmetic Act. FDA is deliberating the need to recall suspect product entered into the U.S. prior to May 1st, including the scope of such a recall; more information will be provided on these deliberations in the next few days.
 6. Under the Food Code, such product would be considered an unapproved source.

What led to FDA De-listing Korean Shellfish Shippers?

1. From March 19 - 30, 2012, FDA conducted a comprehensive evaluation of the Korean Shellfish Sanitation Program and performed pollution source assessments. During the evaluation and pollution source assessments, FDA identified significant shellfish growing area deficiencies. Specifically, FDA noted:
 - a. Ineffective management of land-based pollution sources that can impact shellfish growing areas;
 - b. Inadequate sanitary controls to prevent the discharge of human fecal waste from fish farms and commercial fishing and aquaculture vessels operating in and adjacent to shellfish growing areas; and
 - c. Detection of norovirus in shellfish growing areas analyzed by FDA during the evaluation.
2. Korea's National Fisheries Research and Development Institute (NFRDI) testing has found norovirus periodically in the growing areas between 2008 and 2012.
3. There have been norovirus illnesses in the U.S. from the consumption of Korean oysters as recently as 2011.

Link to Interstate Certified Shellfish Shippers List on FDA.gov website:

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/InterstateShellfishShippersList/default.htm>.