

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

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Commissioner



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Environmental Health Section

EHS Circular Letter # 2012-72

Date: December 21, 2012

To: Directors of Health
Certified Food Inspectors
Chief Sanitarians
Interested Parties

From: Tracey Weeks, MS, RS 
Food Protection Program

Re: Update Regarding Removal of all Korean Shellfish Shippers from the Interstate Certified Shellfish Shippers List

This notice provides an update to EHS Circular Letter #2012-25 dated May 3, 2012, concerning a notice from the Federal Food and Drug Administration (FDA) that the country of Korea was removed from the Interstate Certified Shellfish Shippers List, as of Tuesday, May 1, 2012. The notice stated that all fresh and fresh/frozen shellfish from Korea, regardless of the production date, shall be considered to be an **unapproved source until further notice**. Subsequently, all **canned** molluscan shellfish from Korea were added to the ban.

This current update issued today by FDA restates that the Korean molluscan shellfish import restriction includes canned molluscan shellfish harvested from Areas 1 or 2 during 2012. Not included in the import restriction are canned molluscan shellfish from Korea harvested from Areas 1 or 2 prior to 2012 and canned product from Chilcheondo during any year.

The removal of Korea from the Shellfish Shippers list was a result of FDA's investigation that determined the program did not meet the sanitation requirements of the National Shellfish Sanitation program. The investigation uncovered deficiencies including detection of fecal material and norovirus in the shellfish growing areas. The FDA is currently working with the Korean government to resolve the water quality deficiencies that prompted their removal from the list.

Local health departments that inspect foodservice establishments that currently serve shellfish or have dishes on their menu containing shellfish ingredients should verify the source of such shellfish on site by utilizing the most current Interstate Certified Shellfish Shippers List, which can be found at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/InterstateShellfishShippersList/default.htm>.

The CT Department of Agriculture, Bureau of Aquaculture (DOAG/BA) has requested that local inspectors witness the destruction of any shellfish originating from Korea if found during routine



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inspections or site visits. The DOAG/BA also requests to be notified of the specific product(s) found and destroyed on-site. Please send destruction notifications directly to Kristin DeRosia-Banick by email at kristin.frank@snet.net. See attached notices from FDA.

Questions regarding this notification may be directed to the FPP at (860) 509-7297.

c: Suzanne Blancaflor, M.S., M.P.H., Chief, Environmental Health Section, DPH
Ellen Blaschinski, R.S., M.B.A., Chief, Regulatory Services Branch, DPH
David Carey, Bureau Director, Bureau of Aquaculture, Dept. of Agriculture
Kristin Frank, Environmental Analyst II, Bureau of Aquaculture, Dept. of Agriculture

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Food

Important Information for Food Distributors, Retailers, and Food Service Operators Regarding the Sourcing of Molluscan Shellfish from Korea



Center for Food Safety and Applied Nutrition • Food and Drug Administration

May 18, 2012; Updated May 25, 2012; Updated December 21, 2012

December 21, 2012 Update:

After reviewing new information and data that the Ministry of Food, Agriculture, Forestry and Fisheries of the Republic of Korea provided regarding the conditions of the Korean molluscan shellfish growing areas, in addition to the results of FDA's on-site evaluation earlier this year, the Agency maintains its view that canned molluscan shellfish harvested from growing Areas 1 or 2 during 2012 is not fit for human food and should be removed from the market. FDA may take action to restrict the import and/or distribution of canned and processed products harvested from Areas 1 or 2 during 2012.

FDA does not intend to restrict the import and/or distribution of canned molluscan shellfish harvested from Areas 1 or 2 prior to 2012 and canned product harvested from Chilcheondo or other areas during any year. Importers and distributors are responsible for ensuring that products in commerce have not originated from Areas 1 or 2 during 2012.

This Constituent Update was amended on May 25, 2012 to clarify that canned products are considered adulterated and to offer more detailed advice to consumers.

Oysters, clams, mussels, and scallops from Korea should be removed from the market

On May 1, 2012, the Food and Drug Administration (FDA) removed all Korean certified shippers of molluscan shellfish (oysters, clams, mussels, and scallops) from the Interstate Certified Shellfish Shippers List (ICSSL), following a comprehensive FDA evaluation that determined that the Korean Shellfish Sanitation Program (KSSP) no longer meets the sanitation controls spelled out under the National Shellfish Sanitation Program. FDA's evaluation of the KSSP found significant shellfish growing area deficiencies including:

- 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

Because of inadequate sanitation controls, the molluscan shellfish harvested from Korean waters may have been exposed to human fecal waste and have the potential to be contaminated with norovirus.

Noroviruses are a group of viruses that cause gastroenteritis. Symptoms of illness associated with norovirus include nausea, vomiting, diarrhea, and stomach cramping. Affected individuals often experience low-grade fever, chills, headache, muscle aches and a general sense of tiredness. Most people show symptoms within 48 hours of exposure to the virus. The illness typically lasts one to two days. Norovirus is usually not life-threatening and does not generally cause long-term effects.

The removal of Korean shellfish shippers from the ICSSL is intended to stop the import of molluscan shellfish harvested from polluted waters. Korean molluscan shellfish that entered the United States prior to May 1 and any product made with Korean molluscan shellfish are considered adulterated under the Federal Food, Drug, and Cosmetic Act.

FDA recommends that food distributors, retailers, and food service operators remove from sale or service, all fresh, frozen, and processed (including canned) Korean molluscan shellfish and any product subsequently made with them. Korean molluscan shellfish represents only a small fraction of the oysters, clams, mussels, and scallops sold in the United States. FDA is currently working to determine the distribution of the product.

Distributors, retailers, and food service operators can continue to receive molluscan shellfish from any of the other shellfish shippers listed in the [ICSSL](#)¹.

Advice for Consumers:

Consumers who have recently bought molluscan shellfish and are concerned that it may have come from Korea, should contact the store from which it was purchased and ask where the shellfish were harvested. Consumers can check the label on packaged (bagged, boxed, canned, etc.) seafood to see if it is from Korea. If it is not clear where the product is from, consumers can call the manufacturer to find out. Molluscan shellfish from Korea and products made with molluscan shellfish from Korea should be thrown out.

FDA will post on its website any recall notices it receives from companies identifying specific products that contain molluscan shellfish harvested from Korea.

No U.S. illnesses from the consumption of Korean shellfish have been reported in 2012.

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

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December 21, 2012 Update:

After reviewing new information and data that the Ministry of Food, Agriculture, Forestry and Fisheries of the Republic of Korea provided regarding the conditions of the Korean molluscan shellfish growing areas, in addition to the results of FDA's on-site evaluation earlier this year, the Agency maintains its view that canned molluscan shellfish harvested from growing Areas 1 or 2 during 2012 is not fit for human food and should be removed from the market. FDA may take action to restrict the import and/or distribution of canned and processed products harvested from Areas 1 or 2 during 2012.

FDA does not intend to restrict the import and/or distribution of canned molluscan shellfish harvested from Areas 1 or 2 prior to 2012 and canned product harvested from Chilcheondo or other areas during any year. Importers and distributors are responsible for ensuring that products in commerce have not originated from Areas 1 or 2 during 2012.

FDA NEWS RELEASE

For Immediate Release: June 14, 2012

Media Inquiries: Curtis Allen, 301-796-0393, Curtis.Allen@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA urges that oysters, clams, mussels, and some scallops products from Korea should be removed from the market

The U.S. Food and Drug Administration is urging food distributors, retailers, and food service operators to remove from sale or service all fresh, frozen, canned, and processed oysters, clams, mussels, and whole and roe-on scallops (molluscan shellfish) from Korea that have entered the United States. This includes molluscan shellfish from Korea that entered the United States prior to May 1, 2012, when the FDA removed such products from the Interstate Certified Shellfish Shippers List (ICSSL), and that which may have inadvertently entered the country after that date. These products and any products made with them may have been exposed to human fecal waste and are potentially contaminated with norovirus.

Molluscan shellfish contaminated with fecal waste and/or norovirus are considered adulterated under the Federal Food, Drug, and Cosmetic Act. Following initial notifications last month, a number of food companies have begun to remove these products from their distribution chain. However, many others have yet to take action.

A comprehensive FDA evaluation determined that the Korean Shellfish Sanitation Program (KSSP) no longer meets the sanitation controls specified under the United States' [National Shellfish Sanitation Program](#)¹. The FDA's evaluation found significant deficiencies with the KSSP including inadequate sanitary controls, ineffective management of land-based pollution sources and detection of norovirus in shellfish growing areas.

The deficiencies in the KSSP prompted the FDA to remove all Korean certified shippers of molluscan shellfish from the ICSSL on May 1, 2012. Although Korean molluscan shellfish represent only a small fraction of the oysters, clams, mussels, and scallops sold in the United States, the removal of Korean shellfish shippers from the ICSSL is an important step in stopping the importation of molluscan shellfish harvested from polluted waters.

Consumers who have recently bought molluscan shellfish and are concerned that it may have come from Korea, should contact the store where it was purchased and ask about its origin. Consumers can check the label on packaged seafood to see if it is from Korea. If it is not clear where the product is from, consumers can call the manufacturer to find out. Consumers should dispose of molluscan shellfish from Korea and any products made with molluscan shellfish from Korea.

These actions only affect molluscan shellfish harvested from Korean waters. They do not affect the receipt of fresh and frozen molluscan shellfish by distributors, retailers, and food service operators from any of the other shellfish shippers listed in the [ICSSL](#)². Further, these actions do not affect the importation of canned and other processed product made with molluscan shellfish harvested from non-Korean waters. The FDA is in ongoing discussions with Korean authorities to resolve the issue.

Although the heat treatment that canned products undergo should eliminate the risk of norovirus, the contents of the cans of molluscan shellfish from Korea are still considered not fit for human food because the products were harvested from

waters subject to human fecal contamination. For fresh, frozen, or products processed by methods other than canning, the products should also be considered food not for human consumption and may also carry a risk of norovirus.

Noroviruses cause gastroenteritis. Symptoms of illness associated with norovirus include nausea, vomiting, diarrhea, and stomach cramping. Affected individuals often experience low-grade fever, chills, headache, muscle aches and a general sense of tiredness. Most people show symptoms 12 to 48 hours after exposure to the virus. The illness typically lasts one to three days. Dehydration is the most common complication, especially in young children and older adults, which may require medical care. While there have been norovirus illnesses in the United States from the consumption of Korean oysters as recently as 2011, there have been no U.S. illnesses from the consumption of Korean shellfish reported in 2012.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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