

December 18, 2015

FDA provided the following information to ISSC:

Korean oysters shipped to the U.S. from Dai One Food Company LTD (NSSP certification number KR8SP) have been linked to the occurrence of eleven illnesses in Hawaii. Testing of oysters by FDA's Gulf Coast Seafood Lab demonstrated the oysters to be positive for norovirus. The lab results are attached. Implicated product includes block frozen oysters and IQF half shell oysters that were harvested from Korean lease number 290 and 382 on February 10, 11 and 12, 2015. A recall is currently underway and includes oysters that were shipped to the attached list of U.S. companies. While the U.S. companies that initially received shipment from Dai One Food Company have been notified and have held all remaining product for destruction, FDA has requested that Korea notify the initial receiving state control authorities in order for state officials to work with the initial receiving dealers to ensure that the recall is extended to their customers.

At this point it appears that an effective recall is being conducted. In Hawaii where the illnesses occurred, the Department of Health has issued a recall notice (attached).

Addresses and ICSSL No. of Customers received oysters from Dai One

Company Name (ICSSL NO.)	Address	Contact
SUNNY SEAFOODS INC. (NJ-55-RS)	197 WEST SPRING VALLEY AVE. MAYWOOD, NJ 07607 U.S.A.	TEL. 201-880-9780
GRAND BK CORP.(H- MART) (NY-459-RS)	4708 GRAND AVENUE MASPETH, NY 11378 U.S.A.	TEL. 718-417-5607
KHEE TRADING, INC. (CA-911-RS)	1150 S. VAIL AVE, MONTEBELLO, CA 90640	TEL. 323-583-8114
PACIFIC AMERICAN FISH CO., INC. (CA-650-RP)	5255 SOUTH SANTA FE AVENUE VERNON, CA 90058 U.S.A.	TEL. 323-319-1515
HONG CHANG CORP. (CA-689-RS)	10135 PAINTER AV. SANTA FE SPRING, CA 90670 U.S.A.	TEL. 562-309-0068



DEPARTMENT OF HEALTH

DAVID IGE
GOVERNOR

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DIRECTOR

FOR IMMEDIATE RELEASE

Dec. 10, 2015

15-58

DEPARTMENT OF HEALTH RECALLS FROZEN RAW IMPORTED OYSTERS ASSOCIATED WITH NOROVIRUS ILLNESS

HONOLULU - The Hawaii State Department of Health (DOH) is issuing a recall notice for frozen, raw oysters imported from Korea and sold in bulk to distributors and food establishments in Hawaii. The individually quick frozen (IQF) raw oysters on the half shell are packaged under the Dai One Food Company label. The shellfish harvest dates are Feb. 10, 11, 12, and 13, 2015 and are listed on the required shellfish identification tags for all bulk shellfish cases.

“The department has already conducted product trace-backs and embargoed all of the suspect product on Nov. 24 at various local shellfish distributors and restaurants,” said Peter Oshiro, “Although this product is not sold directly to the public, a recall has been issued as an additional safeguard to further notify anyone who may possess the product that it is unsafe and should be destroyed.”

A product embargo prohibits businesses from using a product suspected of causing illness until a determination is made on the safety of the product. The department received reports of sporadic illnesses (11 total) in September, October, and November of this year that appeared to be linked to the consumption of raw oysters. Samples of the suspect oysters were sent to U.S. Food and Drug Administration Gulf Coast Seafood Laboratory in Alabama for testing, and the samples tested positive for Norovirus. With the positive lab results, DOH has ordered all of the embargoed product held by distributors and restaurants to be destroyed.

Norovirus symptoms include nausea, vomiting, abdominal cramps, diarrhea, fever, and headaches with onset usually within 12-48 hrs after consuming contaminated food. Anyone experiencing these symptoms should consult a physician and if foodborne illness is suspected, report it to the DOH Disease Investigation Branch at (808) 586-4586.

Department of Health food rules effective February 2014 require a consumer advisory at the point of sale for any restaurant or eatery serving raw or undercooked foods. The advisory states, "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness." Pregnant or immunocompromised individuals are also advised not to consume any raw or undercooked foods.

For more information on the department's new restaurant rules and food safety program go to <http://health.hawaii.gov/san/>

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Food and Drug Administration
 Gulf Coast Seafood Laboratory
 P.O. Box 158, 1 Iberville Drive
 Dauphin Island, AL 36528-0158
 (251) 406-8106

From: FDA Gulf Coast Seafood Laboratory
 Microbiological Hazards Science Branch

To: Jessie Deloach
 Regional Shellfish Specialist
 Tacoma Resident Post
 U.S. Food and Drug Administration, Pacific Region
 949 Market Street, Suite 602
 Tacoma, WA. 98402

Date: December 8, 2015

<p>Organization Requesting Analysis:</p> <p>FDA Regional Shellfish Specialist</p>	<p>Organization Point of Contact:</p> <p>Jessie Deloach Regional Shellfish Specialist Tacoma Resident Post (206) 455-4712</p>	<p>Type of Analysis Requested:</p> <p>Molecular detection of norovirus and enumeration of male-specific bacteriophage in shellfish</p>
<p>Date Samples Collected: November 30, 2015</p> <p>Dealer- Dai One Food Co. 31, Nonaraetgae-Gil, Sanyang-Eup, Tongyeong-City Gyeongsangnam-Do Republic of Korea</p> <p>Harvest Dates: <i>Sample001</i>—February 10, 2015 <i>Sample 002</i>—February 11, 2015 <i>Sample003</i>—February 12, 2015</p> <p>Shippers no.: KR-8-SP</p>	<p>Lot codes: <i>Sample 001</i>—DO50411 <i>Sample 002</i>— DO50421 <i>Sample 003</i>—DO50431</p> <p>Distributed by: Khee Trading, Inc Certificate: CA 911 RS Montebello, CA 90640</p>	<p>Date Samples Received by FDA/GCSL: December 2, 2015</p> <p>Date Samples Analyzed: December 3, 2015</p>
<p>Description of Samples: Sample 001, 002, and 003 consisted of 48 IQF oysters on half shell received in Whirl Pak bags. Samples were shipped and received under frozen conditions.</p>		
<p>Reason for submission of report: Request by FDA regional shellfish specialist - Possible norovirus related illnesses.</p>		

REPORT OF RESULTS

Sample 001 sub-sample A

Norovirus GI	positive
Norovirus GII	positive
Male specific bacteriophage	< 10 pfu/100g

Sample 001 sub-sample B

Norovirus GI	none detected
Norovirus GII	positive
Male specific bacteriophage	not done

Sample 002 sub-sample A

Norovirus GI	positive
Norovirus GII	positive
Male specific bacteriophage	<10 pfu/100g

Sample 002 sub-sample B

Norovirus GI	positive
Norovirus GII	positive
Male specific bacteriophage	not done

Sample 003 sub-sample A

Norovirus GI	positive
Norovirus GII	positive
Male specific bacteriophage	<10 pfu/100g

Sample 003 sub-sample B

Norovirus GI	none detected
Norovirus GII	positive
Male specific bacteriophage	not done

Virus Extraction Efficiency: **77%**

Samples were spiked with an aliquot of the murine norovirus. This virus was added to assess viral extraction efficiency from shellfish tissue.

References

Extraction

Woods, J. K. R. Calci, J. G. Marchant, W. Burkhardt III. 2015. *Food Microbiology* Concentration, detection, and characterization of norovirus from oysters implicated in outbreaks. Accepted Nov 2015.

Mullendore, J. L., M. D. Sobsey, and Y. C. Shieh. 2001. Improved method for the recovery of hepatitis A virus from oysters. *J Virol Methods*. 94: 25-35.

Detection

Kageyama T, Kojima S, Shinohara M, Uchida K, Fukushi S, Hoshino FB, Takeda N, Katayama K. 2003. *J Clin Microbiol*. Broadly reactive and highly sensitive assay for Norwalk-like viruses based on real-time quantitative reverse transcription-PCR. 41:1548-57

Burkhardt III, W., J. W. Woods, J. Nordstrom, and G. Hartman. 2006. A Real-Time RT-PCR protocol for the Simultaneous Detection of Norovirus and Enteroviruses. *U.S. Food and Drug Administration Laboratory Information Bulletin #4369*.

2011 NSSP Guide- Section IV- Chapter II Growing Areas.
Modified Double Agar Overlay Method for Determining Male-specific Coliphage In Soft Shelled Clams and American Oysters. ISSC Summary of Actions 2009. Proposal 05-114, Page 50

Analysts: K. Calci, R. Rodriguez, J. Woods

Signature/s:	Title:	Date:
Jacqueline W. Woods, Ph.D.	Research Microbiologist	December 8, 2015
Kevin R. Calci, MS, REHS	Environmental Health Spec V	December 8, 2015
Rachel Rodriguez, BS	GCSL Contractor	December 8, 2015