CORE Network Report for September 13 - 15, 2016

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All information found in this report is available on the FDA CORE intranet site on the "CORE Incident Status Board" (http://inside.fda.gov:9003/CFSAN/CORE/ucm273650.htm).
Click on the EON URL to receive the latest and most detailed information on specific incidents.
***The new information presented in this report has been included below in BOLD, red text.**

The CORE Report can also be found at the CORE Daily Report SharePoint site.

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HIGH PROFILE- OUTBREAK

1. *Salmonella* Reading & Abony/Alfalfa sprouts/ML/Jul 2016 (EON-271094)

Background

CORE Signals was notified by CDC on 7/12/16 about a cluster of 7 human cases of Salmonella Reading in 4 states [CO (3), KS (2), NE, and NYC]. Cases range in age from 12-51 years, with a median of 24 years, and 57% of cases are female. Isolation dates range from May 25, 2016 to July 2, 2016. The cluster so far includes two S. Reading PFGE pattern combinations, JLGX01.0036 and JLGX01.0139. Pattern JLGX01.0036 is very rare and pattern JLGX01.0139 is new. CO has several additional cases pending PFGE, including one case that is co-infected with S. Reading and S. Abony, and one S. Abony case, for a total of 8 potentially linked cases in CO. Given the co-infected case, it is possible this cluster investigation will be expanded to include both serotypes. CO has identified exposure to a common sandwich chain for five of their cases (three separate locations). This chain is local to CO and also included locations in AZ, WY and WI. CO has identified produce (lettuce, tomatoes and sprouts) as a food of interest, but is also still considering turkey deli meat and cheese. A 6th CO case ate at a different sandwich shop but reported similar food items. CO is planning to collect food invoices and possibly conduct a case-control study as well.

The NYC case also reported exposure at a sandwich shop and NYC may collect invoices in case there is a common exposure with the CO cases. Two new cases (one in KS and one in NE) have been identified, bringing the potential total number of cases to 14 [CO (8), KS (3), NE (2), and NYC].

KS and NE are gathering additional exposure information. CO is planning to collect samples of turkey, cheese and sprouts at all the sandwich stores identified by cases. CDC added two new *Salmonella* Abony ABOX01.0030 cases to this cluster. Lettuce, tomato and deli turkey were common exposures noted during a states call on 7/18/16.

CDC will issue a focused questionnaire specific to deli-style exposures for cases to interview/re-interview cases moving forward. There are now 3 restaurant subclusters as follows: 2 separate restaurant chain clusters in CO (Silver Mine Subs has 6 cases at 4 locations and Cheba Hut has 2 cases at the same location); and 1 restaurant subcluster in KS (Planet Sub, 3 cases, 3 locations). CO and KS are collecting records for a variety of meal ingredients from the various chain restaurants identified in the subclusters and sharing with FDA district offices. CO conducted a case-control study at Silver Mine Subs and determined sprouts as significant. Based on additional epidemiologic exposure information; CDC has identified alfalfa sprouts as the suspect vehicle for this cluster.

This incident transferred to CORE Response Team 3 on 7/26/16.

- Investigation partners: DAL-DO, MIN-DO, DEN-DO, KAN-DO, NYK-DO, CIN-DO, NOL-DO
- Initial monitoring/involvement by FDA/CORE: 7/12/16
- CORE Response Team: COREResponseTeam3@fda.hhs.gov

- Emergency Operations Network URL: EON-21094

Epidemiology:

As of 8/31/16, CDC Reports*

- Total Cases: 33
- Case Distribution: CO (16), KS (8), MN, MO, NE (2), NYC, OR, TX, and WY (2)
- Hospitalizations: 6
- Deaths: 0
- Estimated Illness Onset Date Range: 5/21/16 – 8/7/16

* Information is preliminary and all cases may not be related. The numbers are subject to change pending further information and analysis. Cases identified may be secondary cases.

Laboratory:

- Total Samples: 24
- Positive Samples: 0
- Negative Samples: 24
- Pending Samples:

Completed Actions:

- Tactics Meeting: 7/26/16, 8/2/16, 8/9/16
- Kansas City District Office (KAN-DO) provided invoice records from multiple Planet Sub locations and Bison Witches.
- On 7/22/16, a DEN-DO and Colorado-DPHE (CDPHE) team collected samples of sprouts and irrigation water at Sprouts Extraordinaire in Denver, CO. No outstanding conditions were noted during the walk-through; no official inspection was performed.
- On 7/30/16, CDPHE contacted Sprouts Extraordinaire (Denver, CO) to discuss the outbreak in Colorado. The firm agreed to hold distribution of their 5 lb living alfalfa sprouts produced from any seed lot.
- FDA and CDC participated on a firm call with Sprouts Extraordinaire (Denver, CO) on 8/4/16. The firm will determine action based on epidemiologic and traceback information shared on the call.
- CDPHE is followed up at Food Service of America and US Food Service for additional record collection.
- On 8/5/16, FDA and CDC participated on a firm call with Sprouts Extraordinaire. The firm recalled all 5lb. living alfalfa sprouts harvested during 7/4/16 – 7/26/16. No press was issued by the firm.
- DEN-DO closed out the inspection (FACTS assignment # 11659427) at sprouter Sprout Extraordinaire (Denver, CO). A 483 was issued noting water on the floor underneath boxed used for packing product.
- On 8/12/16, CIN-DO provided records and information regarding the origin of seeds implicated in the outbreak that were distributed by Caudill Seed & Warehouse (Louisville,

KY). NOL-DO followed up at the seed distributor International Specialty Supply (Cookeville, TN) to determine origin of seeds implicated in the outbreak. The implicated seeds were sourced from different suppliers; two Italian and one Australian.

Ongoing Actions:

- WGS is being performed on *Salmonella* Reading and Abony clinicals to determine relation to ongoing outbreak. Thirteen *Salmonella* Reading isolates (NY, CO (8), KS (2), NE, and WY) included in the analysis (representing three different PFGE patterns: JLGX01.0139, JLGX01.0036, JLGX01.0141) were indistinguishable or highly similar by hqSNP analysis (0-2 SNPs difference) and two isolates of *Salmonella* Abony (CO, WY) are considered highly related within 0-2 snps.

Pending Actions:

Recent Media Coverage:

- FDA web posting: http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm515300.htm
- CDC web posting: http://www.cdc.gov/salmonella/reading-08-16/index.html

2. Hepatitis A/Scallops/HI/Jul 2016 (EON-271074)

Background

CORE Signals was notified by the San Francisco District Office on 7/8/16 of an outbreak of 31 cases of Hepatitis A virus (HAV) infections in Hawaii, with additional cases under investigation by the Hawaii Department of Health. These cases are not associated with international travel or any common restaurant or grocery store location. Onset dates for the cases range from 6/12/16 to 7/1/16, suggesting an exposure period beginning in May through early to mid-June. Ahi poke (marinated, uncooked tuna) has been identified as a potential food exposure of interest for at least half of the cases interviewed, but there are also some cases who specifically denied eating poke. On 7/13/16, CORE Signals participated in a conference call with CDC and HI to discuss this investigation. No suspect vehicle has been identified. HI will be requesting shopper card records for several grocery store chains to see if there are any common foods. HI posted an Epi-X update on their investigation, identifying at least 52 cases and requested information on any cases of HAV in tourists from other states who traveled to Hawaii within 50 days of their onset. CDC completed genotyping on HI case patient isolates and determined that they are genotype 1A. This is a common HAV genotype in the US. There are at least 74 confirmed cases of Hep A in HI. The onset range for the illnesses is June 12 through July 14. All exposures occurred on Oahu. There will be a call with CDC and HI on Thursday, 7/28/16, to discuss the HI

investigation and potential next steps. During the call on 7/28/16, HI updated the case count to 107 total cases (primarily on Oahu) with onset dates ranging from 6/12/16 to 7/23/16. Of these 107, 85 cases have been interviewed and 65% of those reported dining at various locations of a specific sushi restaurant chain. The only common food identified amongst cases dining at locations of this chain restaurant was scallops (tuna was also mentioned by a majority of cases). HI will be conducting a case-control study among cases who dined at locations of this chain restaurant. CORE Signals and CDC have requested more specific meal date, location and meal information from HI.

- Investigation partners: SAN-DO, CDC, Hawaii Department of Health
- Initial monitoring/involvement by FDA CORE: 7/8/16
- Transferred to CORE Response Team 1: 8/3/2016
- CORE Response Team: COREResponseTeam1@fda.hhs.gov
- Emergency Operations Network URL: https://eon.fda.gov/eon/browse/EON-271074

Surveillance Information/Epidemiology:

As of 9/**14**/16, Hawaii Department of Health reports:

Total Cases: **271**
Illness onset dates: 6/12/16 – **9/04/16**
Age distribution: 18-79 years
Hospitalizations: **68**
Deaths: **Unknown**

Laboratory:

- On 8/12/16, GCSL reported that they had developed the Hepatitis A scallops, tuna, and masago matrix extension method.
- On 8/17/16, ORA ORS reported that scallop sample #s 826782 and 971929 collected by SAN-DO from Koha Oriental distributor in Hawaii, tested positive for Hepatitis A virus at GCSL.
- On 8/22/23, ORA ORS reported that sample #s 971930 (tuna), and 623284 (masago) collected by SAN-DO from Koha Oriental distributor in Hawaii tested negative for Hepatitis A at Pacific Regional Laboratory-Northwest.
- On 8/26/2016, ORA ORS reported that scallop samples #973694 and #973695, collected at True World identified as lot 6455 (different from implicated lot of scallops), tested negative for Hepatitis A. These findings were reported to Sea Port Products by SEA-DO.

Sample #	Lab of Analysis	Date Collected	Product	Hepatitis A
971930	PRL-NW	8/8/2016	Tuna cubes	Negative
826782	GCSL	8/8/2016	Scallops	**Positive**
971929	GCSL	8/8/2016	Scallops	**Positive**
623284	PRL-NW	8/8/2016	Masago	Negative
972699	PRL-NW	8/8/2016	Tobiko	Negative
972698	PRL-NW	8/8/2016	Tobiko	Negative
931841	PRL-NW	8/8/2016	Tobiko	Negative
971932	PRL-NW	8/8/2016	Tuna cubes	Negative

971934	PRL-NW	8/8/2016	Tuna cubes	Negative
971936	PRL-NW	8/8/2016	Tuna cubes	Negative
971940	PRL-NW	8/8/2016	Tuna cubes	Negative
971942	PRL-NW	8/8/2016	Tuna cubes	Negative
971944	PRL-NW	8/8/2016	Tuna cubes	Negative
971946	PRL-NW	8/8/2016	Tuna cubes	Negative
971938	PRL-NW	8/8/2016	Tuna cubes	Negative
971928	PRL-NW	8/8/2016	Scallops	Lab class 5
826781	PRL-NW	8/8/2016	Scallops	Lab class 5
973694	PRL-NW	8/18/2016	Scallops	Negative
973695	PRL-NW	8/18/2016	Scallops	Negative

- On 8/30/16, CDC reported that Hepatitis A virus DNA sequence from scallops, FDA sample # 826782 (sub 1 and sub 5) collected at Koha Oriental Foods in Hawaii, matched the clinical isolates.

Completed Actions:

- Tactics Calls: 8/4; 8/12; 8/22; 8/31; 9/9
- Special Purpose Tactics Call: 8/4; 9/2
- Firm Call: 8/18
- CORE issued a records and sample (scallops, masago, and tuna) collection assignment (MARCS Operation ID # 31314) at Koha Oriental Foods (Honolulu, HI).
- On 8/5/16, CORE issued a samples, and records collection assignment (MARCS Operation ID# 31387) at Y. Hata & Co. (Honolulu, HI); a samples, and records collection assignment. (MARCS Operation ID# 31388) at Wismettac/Nishimoto Trading Company (Honolulu, HI).
- On 8/8/16, HI Resident Post collected one masago sample, two scallop samples, and nine Poke Ahi samples from Koha (MARCS Operation ID # 31314). Also collected nine tuna samples from Nishimoto.
- Samples collected by SAN-DO HI resident post were shipped to GCSL and SRL on 8/10/16.
- On 8/10/16, CORE issued a traceback records assignment (FACTS Assignment #11661860, Operations ID #8751493) from Showa Marine Inc., of Los Angeles, California. Koha supplied Genki restaurants with scallops during the period of interest. Koha was supplied with scallops by Sea Port. Sea Port's consignee for scallops in the past two years is recorded as Showa Marine Inc., of Los Angeles, California.
- On 8/15/16, ORA DIO drafted a 180 days (as resources allow) increased surveillance criteria for scallops imported/manufactured by De Oro Resources Inc. of Philippines
- On 8/16/16, Hawaii Department of Health embargoed Sea Port scallops at True World (Honolulu, HI).
- On 8/18/16, Sea Port Products Corporation initiated a voluntary recall of frozen Bay Scallops produced on November 23, 2015 and 24, 2015. The products were distributed to California, Hawaii, and Nevada.
- On 8/25/16, ORA ORS finalized the hepatitis A laboratory worksheets for ORS DIO to proceed with the import alert. The worksheets were also shared with the Sea Port Products.
- On 8/29/16 ORA/ORS reported that sample analyses are complete for all samples of tuna, masago, tobiko, and scallops collected in Hawaii (see table in Laboratory section).

- On 8/29/16, GCSL provided sequencing analysis of the positive scallop sample #826762. The sequences were shared with CDC for comparison to the sequences of the clinical isolates.
- On 9/7/16, CORE issued assignments for sampling and record collection for De Oro Resources scallops at Showa Marine FEI# 2026439 (Los Angeles, CA), Atlantic Capes Fisheries FEI# 3005229667 (Fall River, MA) and Atlantic Capes Fisheries FEI# 2245692 (Cape May, NJ). Sample analysis will be done by PRL-NW, and composite.
- ORA ORS and GCSL completed the scallops sample analysis worksheets and collection reports for #s 973964 and 973695 and sent them to SEA-DO district, to be shared with Sea Port.
- On 9/9/16, LOS-DO collected and sent 12 frozen scallops samples from Showa Marine Cold Storage in Los Angeles. The samples will be analyzed at PRL-NW.
- **On 9/9/16 per HI DOH, Genki restaurants received approval to reopen all locations.**
- **On 9/15/16, De Oro Resources was placed on Import Alert #16-50, "Detention Without Physical Examination of Molluscan Shellfish"**
- **On 9/15/16, a Special Purpose Tactics call was held to discuss De Oro Resources scallops currently in the US. Sea Port Products FEI# 3000210511 (Kirkland, WA) and Atlantic Capes Fisheries FEI# 3005229667 (Fall River, MA), the two firms with De Oro Resources scallops in the US, are holding all scallops in their cold storages until more information is provide on ongoing testing of scallops from Showa Marine Cold Storage (CA) or information is received on the root cause of the contamination event at De Oro Resources.**

Ongoing Actions:

- On 8/23/16, Massachusetts Department of Public Health verified that the 207 cases of scallops are "on hold" at Cold Storage Solutions (CSS), Lakeville, MA. CSS is working with DiCarlo and Sea Port to dispose the products. The state of Massachusetts will witness the disposal and forward relevant paperwork to New England District.
- Hawaii Department of Agriculture was contacted by the Philippines Bureau of Fisheries requesting for FDA's Hepatitis A sampling and testing protocol. Philippines is looking into testing other seafood products. CFSAN IAS was given a heads up to look out for the request.
- On 9/13/16, NWE-DO investigation branch is collecting samples at Atlantic Capes Fisheries in MA.

Pending Actions:

- Tactics call to be held on Monday 9/19/16 at 3:00 PM EST.
- California Department of Public Health to collect restaurant traceback information for the California case matching the Hawaii Hepatitis A virus outbreak strain
- LOS-DO to provide the Sea Port recall audit records
- Sea Port will follow up with De Oro in Philippines for more information about the scallops harvest water

Recent Media Coverage:

- On 8/16/16, Hawaii issued a press release, implicating Genki restaurant chain and embargoing scallops
- On 8/18/16, Hawaii issued a web posting mentioning Sea Port Bay scallops sourced from De Oro Resources Incorporated in Philippines. Sea Port Products did not issue press, but promised to recall the suspect scallops
- On 8/19/16, CDC and FDA issued web postings

3. Hepatitis A (1b) / Frozen Strawberries (suspect) / ML / August 2016 (EON- 274950)

Background

CORE Signals began evaluating a cluster of acute hepatitis A infections on 8/5/16, after receiving a CDC Epi-X notification stating that the Virginia Department of Health (VDH) was investigating a newly identified illness cluster. At that time, seven cases of non-travel associated acute hepatitis A have been identified in multiple regions of the Commonwealth. Four clinical isolates has been genotyped as 1b; additional isolates were pending analysis. This characterization differs from the illness cluster in Hawaii. Illness onset dates ranged from 7/11/16 to 7/24/16 and all cases reported consuming Tropical Smoothie Café smoothie products. VDH did not believe illnesses were caused by an ill food handler and there were no known ill employees. Cases did not report any additional common food or restaurant exposures. VDH contacted the restaurant representatives and determined that strawberries and bananas were two ingredients that are included in most smoothie types; however, blenders were rinsed, but not sanitized between orders, therefore, there was a chance of cross-contamination. Based on informational traceback, the strawberry (sourced from Egypt) and mango (sourced from Guatemala) suppliers were unique to Virginia stores. Neighboring states had not reported a recent increase in hepatitis A cases. Retail stores in VA changed suppliers of strawberries.

On 8/12/16, CORE Signals was notified by the FDA liaison to CDC about a single WI Hepatitis A illness in a 12 year child. Serology was positive for Hepatitis A Virus IgM and IgG; however, as of 8/12/16, Hepatitis A had not been confirmed. This child had an onset on 8/10/16. On 8/15/16, NYC, MI, and WI illnesses were also mentioned as recent Hepatitis A illnesses for evaluation for this cluster.

This incident transferred to Response Team 3 for continued coordination on 8/16/16.

- Investigation partners: BLT-DO, ATL-DO, MIN-DO, LOS-DO, DET-DO, DAL-DO, CHI-DO
- Initial monitoring/involvement by FDA/CORE: 8/5/16
- CORE Response Team: CREResponseTeam3@fda.hhs.gov
- Emergency Operations Network URL: EON-274950

Epidemiology:

As of 9/14/16, CDC Reports*

- Total Cases: 114
- Case Distribution: MD (10), NC (1), NYC (1), OR (1 with travel to VA), VA (94), WI (1), WV (6)
- Hospitalizations: 32
- Deaths: 0
- Estimated Illness Onset Date Range: 5/2/16– 9/7/16
- 100% of cases interviewed report consuming strawberries.
- 54 out of 56 report exposure to Tropical Smoothie Café locations in the Virginia area (VA, MD, WV, part of NC). The WI and NYC cases are the outliers.

* Information is preliminary and all cases may not be related. The numbers are subject to change pending further information and analysis. Cases identified may be secondary cases.

Laboratory:

- On 8/18/16, Baltimore District Office collected six samples from the Preferred Freezers storage facility in Chesapeake, VA for analysis at San Francisco Lab (SFL).
- On 8/19/16, VA collected 4 samples from various Tropical Smoothie Café locations to be sent to SFL.
- On 8/30/16, SAN-Lab received two samples collected of frozen strawberries collected as a result of the increased imports screening.
- On 9/1/16, Sample #959446 was reported as CRO from SFL
- On 9/8/16, Sample #959447 and #974807 were reported as CRO from SFL and WEAC, respectively.
- On 9/8/16, BLT-DO collected an import sample #976332, of Egyptian Strawberries for analysis at PRL-SW.
- On 9/8/16, sample 959449, was reported as negative for Hepatitis A Virus.
- On 9/12/16, Sample #959448 was reported as CRO from SFL.
- On 9/12/16, sample #973575, #974269 and #974558 were reported as CRO from WEAC.
- **On 9/13/16, SAN-Lab received two** samples (976879 and #976896), c**ollected of frozen strawberries collected as a result of the increased imports screening.**
- **On 9/14/16, sample 974900 and 974899 were reported as negative for Hepatitis A Virus.**

Completed Actions:

- Tactics Meeting: 8/17/16, 8/22/16, 8/25/16, 9/2/16, 9/8/16, **9/15/16**
- Targeted Tactics Meeting: 8/16/16, 8/19/16, 9/2/16, 9/13/16
- CDC States Calls: 8/18/16, 8/29/16, 9/6/16, 9/13/16

- Baltimore District Office (BLT-DO) provided smoothie ingredient list from Tropical Smoothie Café and invoice records, from Sysco, a supplier of strawberries for Tropical Smoothie Café.
- VA Rapid Response Team was activated on 8/16/16
- On 8/17/16 CORE issued a sampling assignment to the BLT-DO to collect product from the storage facility in Chesapeake, VA.
- On 8/18/16 the WI isolate was found to match the VA cases by sequencing.) The case reports consuming strawberries but did not eat at Tropical Smoothie Café or at McDonalds (which was previously reported and is not involved in this investigation at this time). BLT-DO held a call with Virginia lab and health department on 8/19/16 to discuss the sampling collection to be conducted by VDH at the Tropical Smoothie Café locations.
- CORE issued an assignment on 8/18/16 to LOS-DO to initiate an investigation at Patagonia Foods in California.
- CORE notified the Canadian Food Inspection Agency on 8/19/16 of the current incident, due to information suggesting that a Canadian importer may be importing implicated product to the firms of interest.
- CORE issued an assignment on 8/19/16 to DAL-DO to initiate an investigation at Sysco Corporation (Houston, TX).
- Virginia Department of Health issued press release implicating Tropical Smoothie Cafes and Egyptian frozen strawberries in the VA cases on 8/19/16.
- On 8/21/16, Tropical Smoothie Café released a public statement.
- BLT-DO and the Virginia Rapid Response Team reported that Tropical Smoothie Café ceased the use of the Egyptian frozen strawberries at VA locations on 8/6/16 and nationwide around 8/16/16.
- On 8/22/16, CORE issued an assignment to NYK-DO to conduct investigation at Restaurant Depot in College Point, NY.
- On 8/22/16**,** Virginia partners placed Egyptian strawberries of interest under state seizure until further notice.
- FDA, CDC, and VA RRT held a Firm Call with Patagonia Foods to provide an incident update.
- On 8/23/16, FDA responded to a Request for Information regarding investigational updates from the Egyptian International Health Regulations National Focal Point.
- On 8/25/16, CORE responded to a Congressional Inquiry regarding the outbreak investigation.
- On 8/26/16, FDA and CDC held a call with Tropical Smoothie Café Headquarters to share epi and an update on the investigation.
- On 8/30/16, CDC updated their media talking points with the current case count.

- On 8/31/16, CORE issued an assignment to BLT-DO to collect an additional frozen strawberry sample from Preferred Freezer Services from an un-sampled lot originating from United Co. for Food Industries/Montana (Cairo, Egypt).
- On 9/1/16, Tropical Smoothie Café issued a statement and FDA and CDC issued web postings.
- On 9/2/16, CORE held a Special Purpose Tactics call to discuss potential product actions (voluntary recall) associated with Patagonia Foods.
- On 9/6/16, FDA and CDC held a call with Patagonia Foods, to discuss epi and traceback updates on the investigation.
- On 9/8/16 FDA and CDC held a call with ASPR to discuss the information requests from the Egyptian Government regarding the incident.
- On 9/9/16, FDA and CDC held a call with Restaurant Depot to discuss the investigation and product that is currently on hold at their facilities.
- On 9/13/16 FDA held a Special Purpose Tactics call to discuss potential product action (voluntary recall) associated with VLM Foods, Inc.
- On 9/13/16, FDA held a Special Purpose Tactics call to discuss the hepatitis A in scallops and frozen strawberries and the issue of continuing to sample product.
- **On 9/14/16, FDA held a firm call with VLM Foods, Inc. to discuss the incident and potential product actions. VLM Foods, Inc., stated that they will be moving forward with issuing a recall and press. The scope of the recall is still underway.**
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***Ongoing Actions*:**

- WGS analysis for clinical isolates is ongoing.
- Virginia Department of Health collected samples from various Tropical Smoothie Café's on 8/19/16, to be delivered to San Francisco Lab (SFL) for analysis, and is determining if additional lots of interest are available for sampling.

***Pending Actions*:**

- **On 9/15/16, FDA and CDC will be holding a call requested by VLM Foods, Inc., to further discuss the incident thus far, and their product action decisions.**

Recent Media Coverage:

- Virginia Department of Health: http://www.vdh.virginia.gov/news/public-relations-contacts/news-releases/2016-statewide-news-releases/health-officials-warn-of-increased-hepatitis-a-risk/.
- CDC: http://www.cdc.gov/hepatitis/outbreaks/2016/hav-strawberries.htm
- FDA: http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm518775.htm

4. Lead/Dietary supplement/IL/Aug 2016- EON 277302

Background

On 8/24/2016, CORE Signals was notified by FDA's Chicago District Office (CHI-DO) of a cluster of four adverse event reports (including two fatalities) possibly associated with a dietary supplement called DHZC-2 and sold under the brand name "Life Rising" by Ton Shen Health/Life Rising (Retail Location; Chicago, IL FEI: 3003606135). Investigation of this incident began when CHI-DO initiated follow-up to a consumer complaint/MedWatch report by Cook County (IL) Health Department for Patient A, a five year old child diagnosed with high lead levels who was reported to have consumed the DHZC-2 supplement. The event date for the MedWatch report for patient A was listed as 8/29/2015, but the report itself was not received by the district until April 2016. CHI-DO visited the distributor/retailer and collected a sample of the DHZC-2 product. Analysis of this sample revealed high lead levels (86-102 mg/kg). A Health Hazard Evaluation (HHE) was completed by FDA/CFSAN based on the levels identified in the product and determined that it was of concern and should result in a class I recall. CHI-DO notified the firm of the sample results and Ton Shen Health/Life Rising agreed to voluntarily recall all lots of the DHZC-2 product on 8/11/2016.

During the recall audit checks, CHI-DO learned of a reported death that may have been caused by the product (Patient B). The caregiver for Patient B reported that the deceased patient had already consumed half of the bottle of supplement at the time her reaction occurred. An hour after she took a dose of the supplement she began vomiting blood and was admitted to the emergency room; Patient B expired three days later on 5/21/2016. After learning of Patient B, CHI-DO contacted the firm and learned that the firm was aware of another possibly associated death (Patient C) in July 2016, and an additional ten year old child with high lead levels (Patient D) that might be associated with the product. On 8/28/2016, CHI-DO reported that recall audit checks revealed two additional adverse event reports (including 1 child); additional details for these cases are pending. Medical records have been requested, however, toxicology/blood lead level information is currently unavailable for each of the patients.

The 'Life Rising' product DHZC-2 is produced by Life Rising (Tianjon) Natural Product R & D Center, LTD located in Tianjon, China (FEI: 3004001932). Initial reports indicated that the foreign manufacturer supplied product only to Ton Shen Health/Life Rising (Warehouse/Distributor; Willowbrook, IL; FEI: 1000139959) during the time period 1/1/2015 to 8/23/2016.

- Investigation partners: CHI-DO, NYK-DO, and state/local investigators from IL
- Initial monitoring/involvement by FDA/CORE: 8/24/2016
- CORE Response Team: COREResponseTeam2@fda.hhs.gov
- Emergency Operations Network URL: EON-277302

Surveillance Information/Epidemiology:

- Total Cases: 5

- Location of Cases: IL (5)
- Hospitalizations: 0
    - Deaths: 0
    - On 9/9/2016, the assigned CFSAN Medical Officer provided a memo outlining review of the clinical findings associated with two reported deaths that were being investigated, noting that based on medical information received the reported deaths do not appear to be associated with the recalled product (DHZC-2).

Laboratory:

- Total Samples: 33
    - CHI-DO sampled 20 'Life Rising' products from Ton Shen/Life Rising locations in IL, including DHZC-2 (lot # 2163-844 and 2163-864) and items sharing common ingredients with DHZC-2.; raw ingredients used in Brain ECM from the Willowbrook, IL location of Ton Shen/Life Rising were also sampled.
    - NYK-DO sampled a product (Long Dan Xie Gan Wan) that had been imported from the Chinese firm of interest Tianjin Medicines & Health Products Imports and Exports Corp.
    - FDA investigators sampled 5 products from Life Rising Natural Product R & D Center, LTD (Tianjon, China), including DHZC-2 and a premix component ingredient; samples are at the embassy being prepped for shipping to an FDA laboratory.
- Positive Samples: 3
    - Sample #965959 of DHZC-2 (lot# 2163-844) collected by CHI-DO on 6/28/2016, which confirmed high lead levels (86-102 mg/kg lead).
    - Sample #298384 of DHZC-2 (lot# 2163-864) collected by CHI-DO on 8/24/2016, was confirmed to contain 3.57 ppm lead, which is a health concern for children (lead exposure is 12.85 ug/day which is greater than the FDA PTTDI of 6 ug/day).
    - Sample #308225 of Brain ECM collected by CHI-DO on 8/26/2016 were found to contain 8.0 ppm lead, which is a health concern for children and women of childbearing age (47 ug/day based on the FDA measured average capsule weight, which is above FDA's PTTDI for lead of 6 ug/day for children and 25 ug/day for women of childbearing age). The product is a capsule formulation that was likely manufactured domestically and is currently in distribution.
- Pending Samples: 15
- Negative Samples: 15

Completed Actions:

- On 8/25/2016, Ton Shen Health/Life Rising agreed to temporarily hold additional dietary supplement product sourced from the manufacturer of interest until 3rd party analytical results are available (approximately 9/1/2016).
- On 8/25/2016, Life Rising Corporation (Tianjin, China) was added to Import Alert 54-17 "Detention Without Physical Examination Of Dietary Supplements Due To Lead, Arsenic, Mercury, And/Or Cadmium Contamination" for DHZC-2.
- Tactics Meeting held on 8/26/2016, 9/1/2016, 9/8/2016

- 3rd party laboratory results for samples collected by Ton Shen Health/Life Rising were shared with CHI-DO on 8/31/2016 and 9/1/2016; FDA's review of analytical results for new batches of DHZC-2 indicated a calculated total exposure of 12.348 ug/day, which is over the FDA Provisional Total Tolerable Daily Intake (PTTDI) for children of 6 ug/day; 3rd party results reviewed for other products analyzed (Brain Des, GMD, HB, TRCHQ, Clean Tea) were found not be a health concern.
- On 8/31/2016, CHI-DO reported that 22 finished Life Rising products Cook County Department of Health collected from the household of the cases that had elevated lead levels were reported to have less than 10 ug/g lead.
- Ton Shen Health/Life Rising agreed to extend their temporary hold of dietary supplement product inventory until 3rd party and FDA analytical results have been received and reviewed; agreement received in writing on 9/2/2016.
- On 9/2/2016, CFSAN issued an assignment for inspection at Life Rising Natural Product R & D Center, LTD and Tianjin Medicines & Health Products Imports and Exports Corp (foreign firms of interest); earliest assignment may be initiated is 9/7/2016.
- On 9/12/2016, CHI-DO reported that communications were received from the firm indicating they will resume distribution of BZYQ, Brain-DES, BYT, B-HXT and DACH products (FDA analysis of samples of these products indicated no health risk). The firm has reported they will be holding remaining products from the same manufacturer until FDA sample results are shared.
- **On 9/13/2016, CHI-DO presented preliminary results of Sample 308225 to the firm owner, who verbally agreed to hold the Brain ECM product; analytical worksheets were provided for this sample on 9/14/2016.**

***Ongoing Actions*:**

- CHI-DO's investigation/inspection and sample collection is ongoing at Ton Shen Health/Life Rising; on 9/6/2016, CHI-DO reported their investigation involves five locations associated with Ton Shen Health/Life Rising Corporation in Illinois (Chicago, Northbrook, Willowbrook, and Westmont).
- CHI-DO's 100% recall audit check related to DHZC-2 is ongoing.
- FDA's China Office reported that the foreign inspection at Life Rising (Tianjin) Natural Product R & D Center was initiated on 9/8/2016.
    - The firm had reportedly ceased operations as of 9/2/2016. FDA investigators collected samples of several products including DHZC-2. It was reported that DHZC-2 contains additional ingredients not listed on the label: maltodextrin, starch, lubricant and four different types of insects. The firm does not have the capacity to test for heavy metals but on occasion may send product out for testing and they don't have raw material specifications.
    - On 9/12/2016 FDA's China Office reported that translation of documents collected during the inspection at the Chinese manufacturer are in progress and that the inspectional team will likely return to the firm on 9/14/2016 to request additional information and records. It was noted that the firm is not being cooperative and limited invoices are available. It was reported that the firm receives raw ingredients through two brokers and is not aware of the actual manufacturer/source of these

products. It was also noted that some finished product may be hand carried to the US for distribution by the firm's General Manager.

Pending Actions:

- Additional information, including medical records and autopsy results if applicable, for adverse event reports have been requested by CHI-DO for all patients.

Recent Media Coverage:

- Ton Shen Health/Life Rising recall announcement issued on 8/11/2016.
  - http://www.fda.gov/Safety/Recalls/ucm516439.htm
- FDA web post issued on 8/26/2016; updated on 8/29/2016.
  - http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm518288.htm
- IDPH web post issued on 8/26/2016.
  - http://www.dph.illinois.gov/news/health-risks-associated-herbal-supplement
- Ton Shen Health/Life Rising revised recall announcement issued on 8/30/2016.
  - http://www.fda.gov/Safety/Recalls/ucm518608.htm

5. *Salmonella* Oranienburg/ Shell eggs (suspected) / MO / August 2016 (1505MOJJX-1)

Background

CORE Signals received notification from CDC on 8/17/2016 that Missouri had identified recent *Salmonella* Oranienburg cases with isolates matching PFGE JJXX01.0027 (the previous outbreak pattern linked to an egg firm in Bonne Terre, MO; cluster code 1505MOJJX-1). There are five cases under investigation in MO. Isolation dates for these cases range from 3/26/16 to 8/19/16. A few other recent clinical isolates are being evaluated in other states but the link to the MO illnesses is still being evaluated. Missouri Department of Agriculture (MDA) collected egg samples at the restaurant identified by two MO case patients, and the exterior shell of one of the eggs tested positive for *Salmonella* Oranienburg matching the outbreak PFGE pattern. The inside of the egg was not positive for *Salmonella*. KAN-DO has been working with MDA and Missouri Department of Health & Senior Services on this investigation and determined that another St. Genevieve egg farm is involved and is identified as Cedar Creek.
KAN-DO conducted an inspection at Cedar Creek Egg Farm Environmental samples collected inside the laying houses were negative for both *Salmonella* Oranienburg and *Salmonella* Enteritidis. Cedar Creek sells eggs laid on their farm to Good Earth Egg and Good Earth sells them to their customers. Cedar Creek is currently not registered as an Egg Facility with the FDA. KAN-DO conducted an inspection (inspection concluded on 8/25/16) including collection of environmental samples inside the laying houses (some of which were originally reported as CRO for *Salmonella* Oranienburg; however, has since been determined to be negative for both *Salmonella* Oranienburg and *Salmonella* Enteritidis). A multi-observation FDA 483 was issued to the firm last week.

KAN-DO initiated an inspection at Good Earth Egg Company LLC on 9/1/16. The facility is supplying brown cage-free eggs to one location of Dierberg's Markets, some or all of which are repackaged. The facility is working on producing a list of suppliers which may or may not include breakers. Of note, Good Earth Egg sold their egg grading equipment to Cedar Creek Egg Farm prior to the outbreak investigation. The equipment was sold to Cedar Creek in June 2015. This incident transferred to Response Team 1 for continued coordination on 9/2/16. Investigation partners: KAN-DO, CDC, Missouri Department of Agriculture, and Missouri Department of Health.

- Initial monitoring/involvement by FDA CORE: 8/17/16
- Transferred to CORE Response Team 1: 9/2/2016
- CORE Response Team: COREResponseTeam1@fda.hhs.gov
- Emergency Operations Network URL: https://eon.fda.gov/eon/browse/EON-278401

Surveillance Information/Epidemiology:

- As of 9/12/16, the total case count is 59 with 6 cases in 2016.
- Location of cases: IL (2), IN, KS (2), MO (50), TN (3), and TX.
- Illness onset dates: 4/1/15 to 8/21/2016
- Age distribution: 1-87 years (median 37)
- Hospitalizations: 13
- Gender: 67% female

**CDC has reopened the cluster to include the 52 cases from last year's incident, and 5 new cases in 2016 beginning with an illness onset date of 3/26/16.*

Laboratory:

- On 8/17/16 MO identified three recent *Salmonella* Oranienburg cases with isolates matching PFGE JJXX01.0027 (the previous outbreak pattern linked to Good Earth Egg Farm in Bonne Terre; cluster code 1505MOJJX-1; EON-241321.
- On 8/25/16, KAN-DO took environmental swabs (#911751 and #911752) inside the chicken houses at Cedar Creek, salmonella was present but did not match the outbreak; no egg samples were taken.
- MODHSS took environmental swabs of the processing facility and those samples were negative for *Salmonella*.
- WGS results for two environmental isolates collected at Good Earth Egg Company during the 2015 Salmonella Oranienburg incident and 2 recent clinical isolates are highly related (2-9 SNPs apart).
- The environmental swabs collected at Cedar Creek processing facility were further characterized by PFGE and the results show that two of the isolates match recent clinical cases:
    - FCF__0911751-001-001 – S. Senftenberg JMPX01.0010; No clinical matches in 2016 in SEDRIC.
    - FCF__0911751-007-021 – S. Thompson JJPX01.0884; Associated with current cluster code 1609MLJJP-1 – 12 cases from IN, KY (5), MA, MI, MO (3), WI.

  - FCF__0911752-003-002 – S. Newport JP6X01.0227; 5 clinical matches in July and August (CA, IA, MO, NE, OK), 3 are included in closed cluster 1607MLJP6-1 (no vehicle identified).
- **KAN-DO reports preliminary results from samples taken at Good Earth Egg Company are PCR positive.**

Completed Actions:

- Tactics Calls: 9/06/16, 9/12/16
- On August 25, 2016, KAN-DO closed the inspection at Cedar Creek Egg Farm, the inspection /EIR will be endorsed.
- On September 8, 2016, KAN-DO and the Missouri Department of Health and Senior Services conducted an investigation at Good Earth Egg Company. CORE continues to work with KAN-DO evaluating records upon receipt. Missouri Department of Health and Senior Services issued a close order (the company must close and cannot distribute or process eggs), during the investigation. However, the owner has decided to continue operations because the company only acts as a broker of eggs. Missouri Department of Health and Senior Services is continuing internal discussions regarding next step of action on the firm.
- **KAN-DO initiated an inspection at Cedar Creek Egg Co. in St. Genevieve, MO on 9/13/16. The inspection will include environmental sampling of the processing area (Zone 1 areas), feed, and water samples. The water samples will be taken from the outlet of the wells.**

Pending Actions:

- CFSAN/OAO is working to perform complete laboratory characterization for environmental samples collected at Cedar Creek.

Recent Media Coverage:

CORE SIGNALS ACTIVITIES – ON THE RADAR

(Items reported in the "On the Radar" section are currently under evaluation by the CORE Signals Team. If these incidents progress to the point that a CORE Response is warranted, these will be transferred to a Response Team and reported in the "Outbreak" section of the Daily Report. If an incident is not transferred, and no further evaluation by Signals is needed/possible, reporting will cease.)

6. *Salmonella* Minnesota (0009) / Unknown / ML / August 2016

CORE Signals is evaluating a cluster of *Salmonella* Minnesota (serotype; not location) illnesses that includes a recent FDA cantaloupe import sample. The illness cluster, 1608MLJIG-1, consists of ten cases in nine states: GA, LA, MA, MS(2), NJ, NY, PA, RI, and TX. Patients range in age from <1-81 years (median: 30), and 78% are female. Isolation dates are from June 29 to August 10, 2016. All cases have the same rare PFGE pattern, JIGX01.0009. CDC is

working with states to collect exposure information, with preliminary reports indicating that two cases consumed cantaloupe and an additional consumed a fruit sample. The Public Health Agency of Canada reported that they are investigating 12 illnesses with this PFGE pattern; all 12 reported raw fruits, including 6/6 who reported melons in a pre-cut fruit tray mix that included cantaloupe, honeydew melon and watermelon. On June 29, 2016 a cantaloupe import sample was collected by FDA and tested positive for the same *Salmonella* PFGE pattern as the illness cluster. The cantaloupe sample originated from a firm in Zaragoza, Coahuila, Mexico. In July, this firm was placed on Import Alert 22-01 "Detention without physical examination of Cantaloupes from Mexico". This PFGE pattern has been identified in one additional non-clinical isolate, a 2008 water sample from Navolato (outside Culiacán), Sinaloa, Mexico. On August 29, CORE Signals participated in a multi-state conference call to discuss the investigation.

CORE POST RESPONSE ACTIVITIES