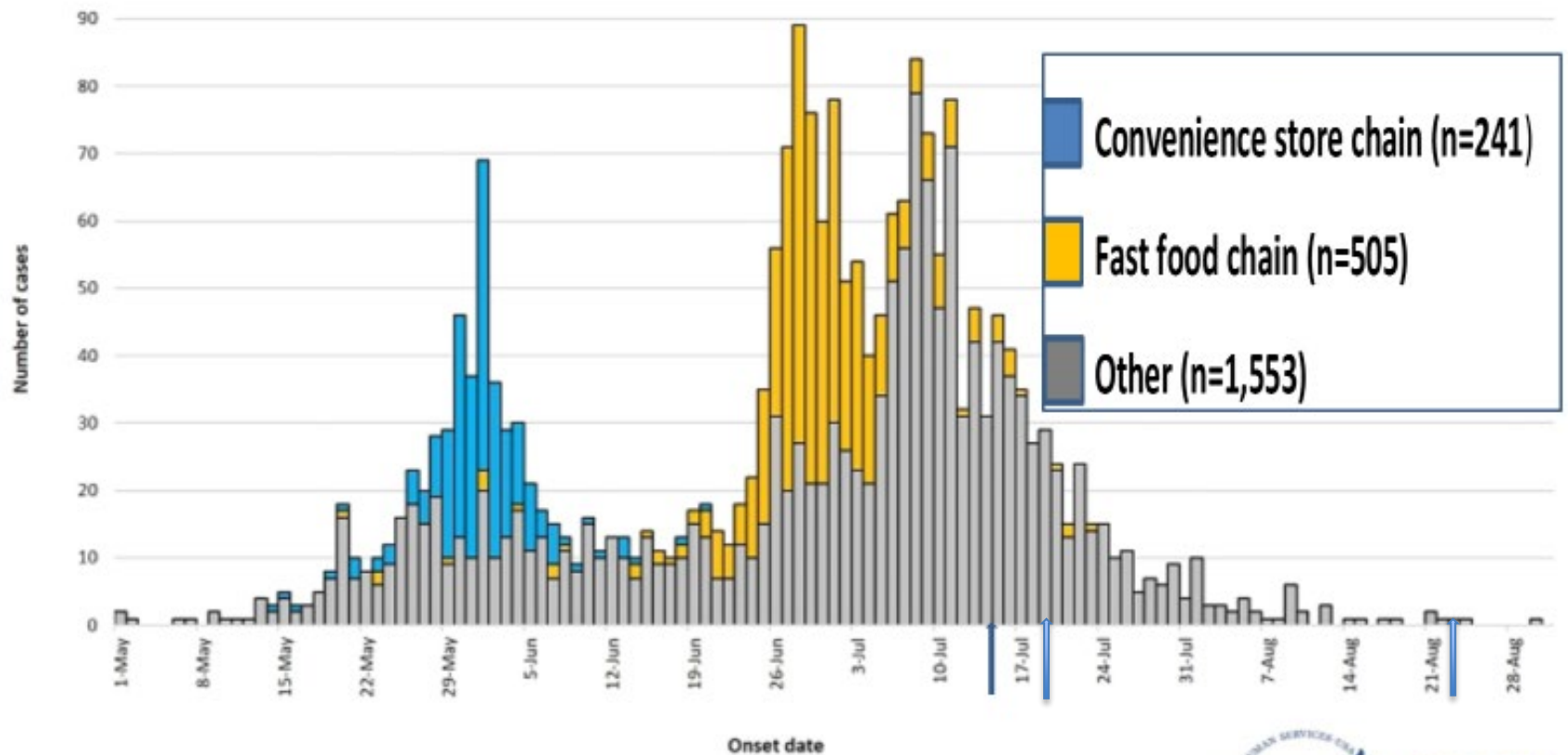


CYCLOSPORA WEBINAR PART 2: REGULATORY APPROACH

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Cases of domestically acquired cyclosporiasis 2018



Investigation related to detection of *Cyclospora cayetanensis* in salad mix

- Traceback on each of the components for the salad mix FDA sampled and the salad mix corresponding to case individuals
 - No common farm or supplier of any component
 - Four crews from one contract harvester
- Investigate four crews

Samples from a single California romaine field

- 4 product harvested by each crew
 - 2 of 4 yielded *Cyclospora cayetanensis*
- 2 unharvested romaine were negative for *Cyclospora cayetanensis*

Disposition of affected product

- Because salads were discontinued on July 13, there was no additional response needed by the fast food company or its supplier
- The farm associated with the findings voluntarily destroyed harvested and unharvested product



Potential Sources of Contamination

Potential routes

- Agricultural water
- Worker hands and worker clothing such as boots, smocks and gloves
- Harvest tools

Sampling Cilantro, Basil and Parsley (FY 18-20)

- 708 total samples analyzed as of May 26, 2020
 - 4/409 domestic samples yielded *C. cayetanensis* (Oregon (1), California (1), Hawaii (2))
 - 13/299 samples of imported herbs yielded *C. cayetanensis* (Colombia (5), Costa Rica (1), Ecuador (1), Mexico (6))
- Future sampling will be based, in part, on recommendations of the FDA *Cyclospora* task force in response to findings and outbreaks

Sample findings of *C. cayetanensis* in domestically grown produce



- Produce is adulterated within the meaning of FD&C Act 402(a)(4)
- FDA has access to all the enforcement tools that hinge on adulteration charges

Response to positive finding

- Remove adulterated product from the market
- Prevent the introduction of adulterated product onto the market
- Prevent future adulteration of product
 - Root cause investigation
 - Corrective action

Remove adulterated product from the market

- Notify corresponding State
- Voluntary recall
- Press

Preventing the introduction of adulterated product onto the market

As appropriate, based on findings:

- Work with State and farm to effect voluntary hold
- State embargo (or equivalent)
- Administrative Detention Order/ Seizure**

** seizure requires documentation of interstate commerce

Prevent future contamination

Root cause investigation

- FDA and State counterparts discuss the most appropriate way to cooperate on the investigation
- Evaluate relevant evidence
- Investigate potential sources and routes of contamination
- Begin investigation where the evidence leads
- Continue to follow evidence as it develops

On-farm investigation

Review of worker health and hygiene

- Policies and practices (compliance with PSR)
- Training records (required by PSR)
- Workers and worker clothing (PSR—must use hygienic practices)
- Harvest tools (PSR—maintained such that they are not a source of contamination)



Prevent future contamination

Implement produce safety rule

- PSR requires farms to exclude persons from work that may result in contamination of covered produce or food contact surfaces when the person is shown to have, or appears to have, an applicable health condition.
- Cyclosporiasis is an applicable condition.

Prevent future contamination

Investigate agricultural water

- Investigate the source of agricultural water (grower, State, FDA)
- Look for point sources of contamination (grower, State)
- May take samples of agricultural water



At the end of the inspection

- Significant violations will be noted on the 4056 and discussed
- FDA will ask for voluntary correction, may include:
 - Recall adulterated produce
 - Voluntary hold of potentially adulterated produce
 - Eliminate sources and routes of contamination

Compliance strategy for preventing future contamination

- Voluntary, documented corrective action
- Regulatory meeting
- Reinspection

Follow-up process for domestic positive findings



- Initially based on herb sampling assignment
- Similar framework for state-initiated sampling, simply more coordination between FDA and the involved states
 - Phases
 - Tasks
 - Objectives
 - Entities involved and to engage
 - Reminder about regulatory tools
 - Communication with state partners

Phase 1: Pre-farm investigation

Phase 1: Traceback (Pre-Farm) Investigation

Sample (1) positive Cc (warehouse/distributor), collected by HAF-Div. (CSO)

Task A: Notify food safety partner

Invite participation & follow-up.

Sampling location, and produce origin, if possible.

-Who: HAF Div. (DCB/ DIB/ DRC/ ERC/ state liaison); state contact, state PSN, or other; CFSAN-OC; ORA-PSN; notify CORE signals

Task B: Discuss recall with warehouse/distributor

Adulterated 402(a)(4), class 2 hazard

Scope: product represented by the sample (by lot, date, etc.)

Traceback/forward to CORE signals

-Who: state, as appropriate; HAF Div.; notify CORE signals

If **YES** to voluntary recall:

Follow [RPM chapter 7](#)

If **NO** to voluntary recall:

Discuss state tools with state partner

FDA: Public notification of positive & sample source

-Who: HAF Div.; state; CFSAN-OC; Comms

Task C: Evaluate handling practices

Standard: 21 CFR Part 117 or 21 CFR Part 112, as applicable.

Determine if contamination likely occurred at sampling location or a previous handler.

-Who: HAF Div. or state (notify CFSAN-OC/DPS)

If likely route of contamination **IS** identified

Sampling to confirm, as appropriate

Document deficiency

Trace forward, as appropriate

Firm's voluntary mitigation and corrective action plan

-Who: HAF Div. (DIB/ DCB) or state follow-up, as appropriate; CFSAN-DPS to consult; CORE signals,

If likely route of contamination **NOT** identified

Use traceback to identify previous firm.

Evaluate new location for likely routes of contamination

Outcomes

Determine likely route and/or identify a farm for further investigation (**Move to Phase 2**)

Phase 2: On-Farm investigation

Phase 2: On-Farm Investigation

Traceback investigation from positive sample event OR farm identified through outbreak traceback
ORA-PSN (HAF Div., as necessary) and state; Standard: Part 112 and FD&C Act 402

Task A: Notify farm & trace forward

Determine if farm is operational & subject to PSR.

Request documents related to original sample (1).

As appropriate, determine what sample (1) represented.

-Who: HAF Div., ORA-PSN, or state as appropriate; notify-CORE signals

Task B: Follow-Up Sampling

Additional product sampling (2)

Water sampling

Determine which laboratory will analyze

-Who: ORA-PSN or state to sample

If no positive sample results

Share results with state and firm

(Move to Task C)

If positive product samples

Voluntary recall and hold discussion with firm

Alternatively, utilize state tools or public notification

-Who: state, ORA-PSN, CFSAN-OC, CFSAN-DPS, ORA-ORS; HAF Div.

Expand sampling to similarly situated commodities (3)

-Who: ORA-PSN; state; CFSAN-DPS; TBD

If positive water samples

Implement controls to address water, as appropriate

Determine action on existing and produce on the market

-Who: CFSAN-OC; CFSAN-DPS; state; ORA-PSN; HAF-Div.

Task C: Observational investigation

Interview/observe/evaluate personnel health and hygiene, equipment, tools and sanitation, and agricultural water for potential sources/routes of contamination.

-Who: ORA-PSN; state; CFSAN-DPS; CFSAN-OC; state PSN

If no significant issues

No additional action (except as warranted by Task B)

If significant routes of contamination

Document possible sources/routes of contamination.

Farm's voluntary action to develop mitigation strategy

Farm's voluntary action to evaluate on-farm and produce on the market

Tools: voluntary corrective action, public notification, state tools, ADO/ seizure

-Who: state PSN; ORA-PSN; CFSAN-OC; HAF-Div.; CFSAN-DPS

(Move to Phase 3)

Phase 3: investigational outcome

Phase 3: Investigational Outcomes

Yes, likely sources and routes identified

Assess corrective action for adequacy and determine next steps.

-*Who*: state, CFSAN-OC, ORA-PSN, CFSAN-DPS; state

Tools: Accelerated follow-up inspection, advisory action, injunction, state tools

No, likely sources and routes not identified.

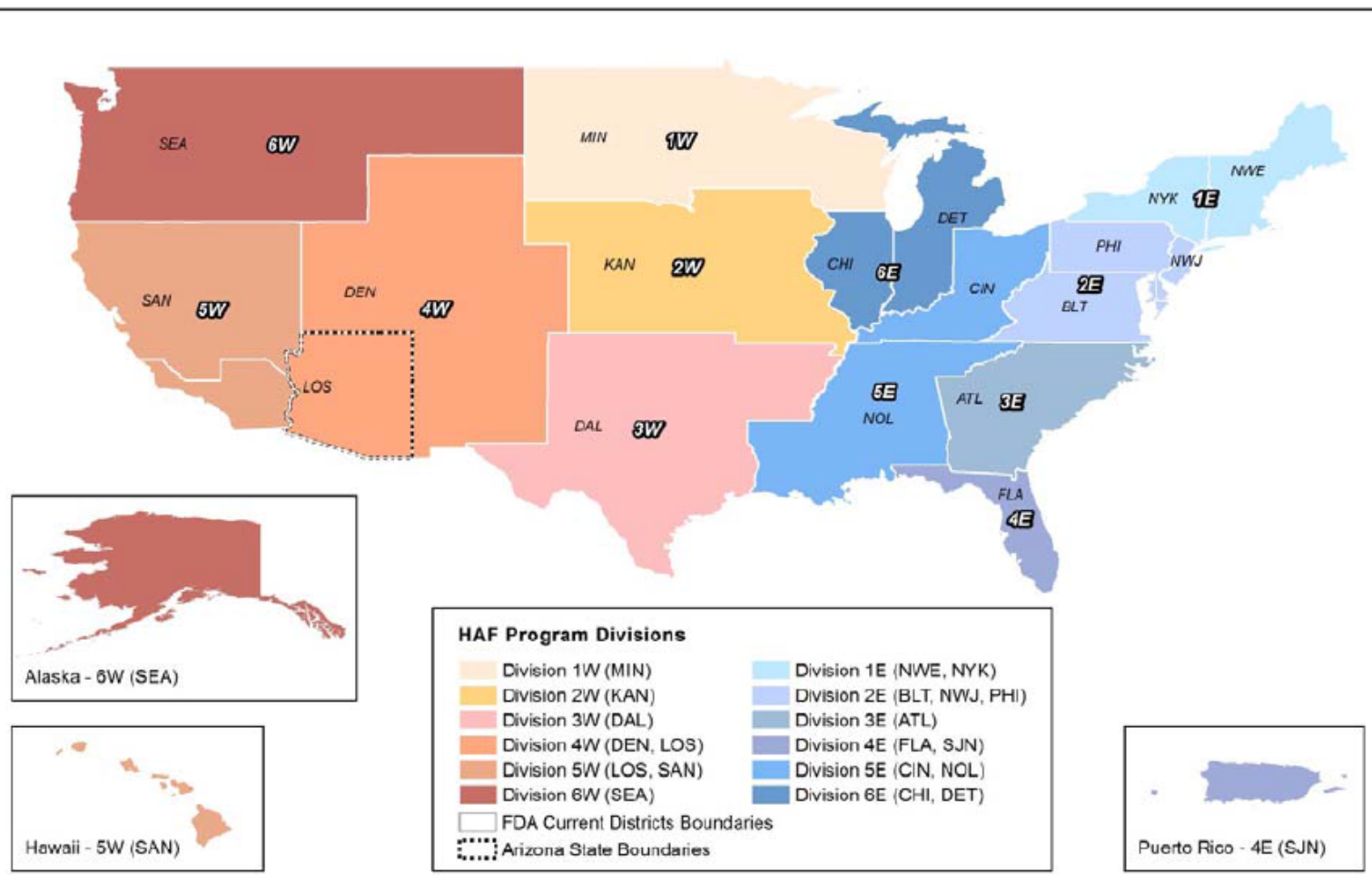
Close investigation or continue outbreak investigation elsewhere.

Coordinating with state partners

- Maintain routine communication to the division POCs
- Traceback documentation during sample collection
- Laboratory / analytical documents for FDA review
- Coordinated on-site response (domestic finding)
- Communication is two-way
 - Feedback loop with states regarding outcomes

Office of Human and Animal Food Operations (OHAFO)

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS



U.S. FOOD & DRUG ADMINISTRATION (FDA) DIRECTORY – HUMAN AND ANIMAL FOOD (HAF)

Updated: February 26, 2020

Division	District Office	States	Program Division Director/District Director (PDD/DD)	State Liaison	Emergency Response Coordinator (ERC)	Director Investigations Branch (DIB)	Director Compliance Branch (DCB)	Recall Coordinator*
HAF East 1	NWE-DO NYK-DO	CT, MA, ME, NH, NY, RI, VT	Ronald Pace	Jeanette McGinnis (NH, NY, RI) Robert Veitch (CT, MA, ME, VT)	Kimberly Langello (CT, MA, ME, NH, RI, VT) Nicole Vaught - HAF (NY)	Lori Holmquist	CDR Catherine Beer	Randi-Lynn Bodah Melissa Henaghan
HAF East 2	BLT-DO NWJ-DO PHI-DO	DC, DE, MD, NJ, PA, VA, WV	acting Randy Pack Evelyn Bonnin (retired 12/31/2019)	JoAnn DeClement (NJ) Natasha DeZinna (VA) Margaret DiGennaro (DE, PA) William Murray (MD, WV)	Valeria Moore - HAF (DC, MD, VA, WV) William Muszynski (DE, NJ) Judith Paterson (PA)	CDR Martin Guardia	Randy Pack	Ruark Lanham
HAF East 3	ATL-DO	GA, NC, SC	Ingrid Zambrana	Michele Howard (NC) Vacant (GA, SC)	Wilbur Higgins - HAF (GA, NC, SC)	Ivy Sweeney	Derek Price	Emma Nesbit
HAF East 4	FLA-DO SJN-DO	PR, VI, FL	Ramon Hernandez	Leslie Mendoza	Marianela Aponte Cruz – HAF (FL, PR, VI)	Sonia Monges	Edwin Ramos	Wanda Torres
HAF East 5	CIN-DO NOL-DO	OH, KY, LA, MS, AL, TN	Steven Barber Deputy: Kimberly McMillan	Diane McDaniel (KY, OH) Scott Watson (AL, LA, MI, TN)	Brenda Zimmer - HAF (OH, KY) Lindsay Bertling (AL, LA, MS, TN)	Thomas Clarida Heather McCauley	Toniette Williams	Chris Dedeaux
HAF East 6	CHI-DO DET-DO	IL, IN, MI	William Weissinger	Kathryn Blackshear (IN, MI) Maria Diaz (IL)	Joseph Cooper - HAF (IL) Lisa Joseph (IN, MI)	Tamara Qtami	LCDR Kelli Wilkinson	Michael Larson

Division	District Office	States	Program Division Director/District Director (PDD/DD)	State Liaison	Emergency Response Coordinator (ERC)	Director Investigations Branch (DIB)	Director Compliance Branch (DCB)	Recall Coordinator*
HAF West 1	MIN-DO	MN, ND, SD, WI	Michael Dutcher, DVM	Eric Breselow (ND, WI) Jennifer Guttuso (MN, SD)	Heidi Debeck - HAF (MN, ND, SD, WI)	CAPT Greg Smith	CDR Chris vanTwuyver	Kristine Zuroski
HAF West 2	KAN-DO	IA, KS, MO, NE	Cheryl Bigham	Samuel Gibbons (KA) Julie Vosilus (NE) Steven Allen (MO)	Erin Dugan - HAF (IA, KS, MO, NE)	Jeffery Moody Deputy: Dina West	Miguel Hernandez-Sanchez	Matthew Sleeter
HAF West 3	DAL-DO	AR, OK, TX,	Edmundo Garcia	Lourdes Genera (AR, OK, TX)	Jane Broussard - HAF (AR, OK, TX)	Karen Daugherty	CDR Jessica Havranek	Casey Hamblin
HAF West 4	DEN-DO	AZ, CO, NM, WY, UT	LaTonya Mitchell, PhD	Elisa Beard (AZ, CO, NM, WY) Nathan Moon (CO, NM, UT)	Holly Miller - HAF (AZ, CO, NM, WY, UT)	Mark Harris	Kimetha King	Vacant
HAF West 5	LOS-DO SAN-DO	AS, CA, HI, NV, Guam	Darla Bracy	Jessica Kimbrough (CA, HI); Jennifer King (AS, CA, CNMI, Guam, HI, NV); Maxyne Lam (CA)	Nicole Yuen - HAF (AS, No. CA, NV, HI, Guam, CNMI) Herminio Francisco (So. CA)	Darlene Almogela CDR Matthew Walburger	Sergio Chavez	Marjorie Schultz
HAF West 6	SEA-DO	AK, ID, MT, OR, WA	Miriam Burbach	Dawn Barkans (MT (feed), WA); Ian Thomson (AK, ID, MT (food)); LCDR Steven Galvez (OR)	LCDR Kelsey Volkman - HAF (AK, ID, MT, OR, WA)	Katie Alford	Lisa Althar	Anh Trinh Nguyen

Follow-up process for imported samples



- State-initiated samples: coordinating potential compliance action with FDA and state partners
- Information needs
 - Traceback to foreign farm / packing house
 - Understanding of handling (packing/repacking) process
- Potential outcomes
 - Recall of production lot
 - Import alert 99-35
 - Additional screening and sampling
- Communicate with state partners

2020 Activities

- Ultra filtration water analysis at ORA laboratories
- Import alert 24-23, seasonal cilantro
- Import alert 99-35
- Recalls
- CORE: outbreak signals monitoring & response team
- CORE: Import bulletin with targeted screening and sampling
- Status: herb sampling assignment
- Status: import bulletin alternate criteria from select countries
- Coordination with states on any signals or domestic positives
- Coordination on compliance action for import sample findings

QUESTIONS

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