CYCLOSPORA WEBINAR PART 2: REGULATORY APPROACH

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Crystal McKenna
Maria S. Knirk
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

**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

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

<table>
<thead>
<tr>
<th>Task A: Notify farm &amp; trace forward</th>
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<tbody>
<tr>
<td>Determine if farm is operational &amp; subject to PSR. Request documents related to original sample (1). As appropriate, determine what sample (1) represented.</td>
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<tr>
<td><strong>Who:</strong> HAF Div., ORA-PSN, or state as appropriate; notify CORE signals</td>
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<thead>
<tr>
<th>Task B: Follow-Up Sampling</th>
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<tr>
<td>Additional product sampling (2)</td>
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<td>Water sampling</td>
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<tr>
<td>Determine which laboratory will analyze</td>
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<tr>
<td><strong>Who:</strong> ORA-PSN or state to sample</td>
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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.

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<thead>
<tr>
<th>Task C: Observational investigation</th>
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<tbody>
<tr>
<td>Interview/observe/evaluate personnel health and hygiene, equipment, tools and sanitation, and agricultural water for potential sources/routes of contamination. <strong>Who:</strong> ORA-PSN; state; CFSAN-DPS; CFSAN-OC; state PSN</td>
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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 outcomes

**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)

HAF Program Divisions
- Division 1W (MIN)
- Division 2W (KAN)
- Division 3W (DAL)
- Division 4W (DEN, LOS)
- Division 5W (LOS, SAN)
- Division 6W (SEA)
- Division 1E (NWE, NVK)
- Division 2E (BLT, NWJ, PHI)
- Division 3E (ATL)
- Division 4E (FLA, SJN)
- Division 5E (CIN, NCL)
- Division 6E (CHI, DET)

Source: ORA

Prepared by Office of Regulatory Affairs (ORA) Division of Planning, Evaluation & Management (OPEM), Program Evaluation Branch, 2017
## U.S. FOOD & DRUG ADMINISTRATION (FDA)
### DIRECTORY – HUMAN AND ANIMAL FOOD (HAF)
*Updated: February 26, 2020*

<table>
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<tr>
<th>Division</th>
<th>District Office</th>
<th>States</th>
<th>Program Division Director/District Director (PDD/DD)</th>
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<th>Director Investigations Branch (DIB)</th>
<th>Director Compliance Branch (DCB)</th>
<th>Recall Coordinator*</th>
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<tbody>
<tr>
<td>HAF East 1</td>
<td>NWE-DO NYK-DO</td>
<td>CT, MA, ME, NH, NY, RI, VT</td>
<td>Ronald Pace</td>
<td>Jeanette Mcginnis (NH, NY, RI)</td>
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<td>Randi-Lynn Bodah, Melissa Henaghan</td>
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<td>HAF East 2</td>
<td>BLT-DO NWJ-DO PHI-DO</td>
<td>DC, DE, MD, NJ, PA, VA, WV</td>
<td>acting Randy Pack, Evelyn Bonnin (retired 12/31/2019)</td>
<td>JoAnn DeClement (NJ), Natasha DeZinna (VA), Margaret DiGennaro (DE, PA), William Murray (MD, WV)</td>
<td>Valeria Moore - HAF (DC, MD, VA, WV), William Muszynski (DE, NJ), Judith Paterson (PA)</td>
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<td>Ruark Lanham</td>
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<td>HAF East 3</td>
<td>ATL-DO</td>
<td>GA, NC, SC</td>
<td>Ingrid Zambrana</td>
<td>Michele Howard (NC), Vacant (GA, SC)</td>
<td>Wilbur Higgins - HAF (GA, NC, SC)</td>
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<td>Ivy Sweeney, Derek Price, Emma Nesbit</td>
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<td>HAF East 4</td>
<td>FLA-DO SIN-DO</td>
<td>PR, VI, FL</td>
<td>Ramon Hernandez</td>
<td>Leslie Mendoza</td>
<td>Marianela Aponte Cruz - HAF (FL, PR, VI)</td>
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<td>Sonia Monges, Edwin Ramos, Wanda Torres</td>
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<td>HAF East 5</td>
<td>CIN-DO NOL-DO</td>
<td>OH, KY, LA, MS, AL, TN</td>
<td>Deputy: Kimberly McMillan, Steven Barber</td>
<td>Diane McDaniel (KY, OH), Scott Watson (AL, LA, MI, TN)</td>
<td>Brenda Zimmer - HAF (OH, KY), Lindsay Bertling (AL, LA, MS, TN)</td>
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<td>Chris Dedeaux</td>
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<td>HAF East 6</td>
<td>CHI-DO DET-DO</td>
<td>IL, IN, MI</td>
<td>William Weissinger</td>
<td>Kathryn Blackshear (IN, Mi), Maria Diaz (IL), Joseph Cooper - HAF (IL), Lisa Joseph (IN, MI)</td>
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<td>Tamara Qtami, LCDR Kelli Wilkinson, Michael Larson</td>
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<td>HAF West 1</td>
<td>MIN-DO</td>
<td>MN, ND, SD, WI</td>
<td>Michael Dutcher, DVM</td>
<td>Eric Breslow (ND, WI)</td>
<td>Heidi Debeck - HAF (MN, ND, SD, WI)</td>
<td>CAPT Greg Smith</td>
<td>CDR Chris van Twuyver</td>
<td>Kristine Zuroski</td>
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</tbody>
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| 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 |
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Nathan Moon (CO, NM, UT) | Holly Miller - HAF (AZ, CO, NM, WY, UT) | Mark Harris | Kimetha King | Vacant |
| HAF West 5 | LOS-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));  
LCSR 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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