

***Cyclospora cayetanensis*/Parsley/Jul 2024**

CARA # 1237

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EXECUTIVE SUMMARY

Initial Notification and Vehicle Identification

On 7/2/2024, CORE Signals was notified by Office of Regulatory Affairs (ORA) Human and Animal Foods (HAF) East 1 (New York District) about a Cyclospora illness cluster (2406NYCYCLO-1) associated with a catered event in (b)(4), NY, with a signal for parsley with 26 confirmed cases in 2 states (NY(25), TX(1)) and 195 probable cases. On 7/12/2024, CORE Signals was notified by CDC of (b)(4) restaurant-associated Cyclospora illness clusters (2406NCCYCLO-1, 2406NCCYCLO-2) with a signal for parsley with 12 confirmed cases and 4 probable cases in NC. On 8/9/2024, these cluster investigations were combined into a single investigation.

Epidemiology Overview & Genomic Analysis

As of 11/7/2024, a total of 47 laboratory confirmed cases were associated with this outbreak, with three hospitalizations and no deaths. Cases resided in five states: CT (1), NJ (1), NY (25), NC (19), TX (1). Reported illness onset dates ranged from 6/13/2024-7/19/2024. Cases ranged in age from 27-77 (median 56) and 54% of the cases were female. Cases were epidemiologically linked by reporting dining at one of (b)(4) locations at the NC restaurant (b)(4) or at an event in (b)(4), NY that took place on 6/15/2024 prior to illness onset. Meals at all (b)(4) locations were reported to commonly include parsley as an ingredient or garnish. Genetic fingerprinting was done on 20 clinical specimens; temporogenetic cluster (TGC) analysis grouped 19/20 samples into TGC 2024-003 and one sample into TGS 2024-002. The two TGCs were not closely related genetically. On 10/16/2024, CDC informed FDA that it closed its investigation for the outbreak.

Traceback Abbreviated Summary

The FDA initiated traceback at (b)(4) points of service (POS), all POSs were multiple case clusters. One POS in NY served a catered meal on 6/15/2024, resulting in 26 lab confirmed cases of cyclosporiasis, and the other (b)(4) POS in NC were (b)(4) restaurants where a total of nine lab confirmed cases of cyclosporiasis reported eating prior to illness onset. All cases traced reported consuming meal items containing fresh parsley. Traceback records for all (b)(4) POS's converged at (b)(4), the common importer of fresh parsley. The implicated fresh parsley was sourced from (b)(4), Mexico and grown by (b)(4), Mexico. For all the POSs included in the traceback investigation, (b)(4) harvest dates could explain the illnesses: (b)(4). The fresh parsley was delivered to (b)(4) on 5/28/2024. (b)(4) point of service ((b)(4) in NY) received fresh parsley from (b)(4) distribution centers (DC) and a (b)(4) firm in Mexico (b)(4), Mexico). The other (b)(4) POSs ((b)(4) restaurants in NC) received fresh parsley from a (b)(4) farmers' market that sourced parsley from (b)(4) DCs, the parsley source for the NC traceback leg was only (b)(4).

Field Investigations & Findings

Two inspections were performed as part of this investigation. One was a joint unannounced inspection performed by the FDA, COFEPRIS, and SENASICA at (b)(4).

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(b)(4) (FEI: (b)(4), Mexico); the other was a farm inspection performed by the FDA at (b)(4) (FEI: (b)(4), Mexico).

(b)(4)

On 9/9-11/2024, the FDA performed a joint unannounced inspection at this firm along with Mexican counterparts from COFEPRIS and SENASICA. During this inspection, the firm indicated it does not engage in farm activities. As such, the FDA inspection was under 117 CGMP and not the Produce Safety Rule. At the end of the inspection, the firm was issued a Form 483 with three observations:

1. You did not store or transport a food under conditions that protect against contamination and deterioration.
2. You did not clean and sanitize your utensils or equipment as frequently as necessary to protect against contamination of food.
3. You did not clean and sanitize your utensils or equipment as frequently as necessary to protect against contamination of food.

During the subsequent inspection at the grower, (b)(4), inspectors learned that (b)(4) was responsible for harvesting the parsley of interest. Attempts to observe harvesting and inspect harvesting equipment while an FDA inspector was in the area were unsuccessful.

(b)(4)

This firm was a (b)(4) grower in (b)(4), Mexico with (b)(4). This grower was not enrolled in SENASICA's System for Risk Reduction from Contamination (SRRC) program; therefore, no Mexican partners had the authority to inspect this grower. The FDA conducted an announced inspection on 9/18-19/2024. After the inspection, the firm was issued an FDA Form 4056 with one written observation relating to the lack of bathroom facilities near the growing fields.

Laboratory Sample Overview

The FDA collected samples at import for the Mexican firms identified in traceback. In total, 18 samples were collected at import: four samples from (b)(4) (FEI: (b)(4), MX) and 14 samples were collected from (b)(4) (FEI: (b)(4), MX). Samples from (b)(4) were not from the same farm as the product of interest. All samples tested negative for *Cyclospora cayetanensis*.

Samples were also collected by Mexican counterparts during the joint inspection at (b)(4). SENASICA collected 3 water samples and 3 parsley samples and reported all samples were negative for *Cyclospora cayetanensis*. COFEPRIS collected 5 parsley samples and 2 water samples during the joint inspection at (b)(4) and reported all samples as negative.

Product & Firm Actions

No product or firm actions were taken as a result of this investigation.

Communications Overview

This incident first appeared on the CORE investigation table on 7/31/2024, and parsley will be named as the vehicle at close out if the incident.

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Conclusions

Parsley was confirmed as the vehicle for this outbreak which combined multiple clusters of cyclosporiasis illnesses, one centered on an event in NY and the other focused on (b)(4) restaurants in NC.— Parsley was identified as a food item of interest for both clusters and traceback identified a common shipment of parsley to (b)(4) from (b)(4), Mexico), of parsley grown by (b)(4), Mexico). This is supported by the available TGC data available for 20 cases, 19 of which fell into the same TGC (2024-003). Inspections in Mexico did not indicate a route of contamination.

Acknowledgements

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