

***Cyclospora* Infections Associated with Pre-packaged Salads**

May – June

Multiple counties/Multiple states

Routine surveillance interviews of three cyclosporiasis cases conducted by Minnesota Department of Health (MDH) staff in mid-June 2020 revealed that all three cases had eaten a pre-packaged salad mix named Garden Salad purchased from Grocery Chain A stores in the 2 weeks prior to illness onset. The salad mix contained iceberg lettuce, red cabbage, and carrots. On June 15, MDH epidemiologists notified the Minnesota Department of Agriculture (MDA) and the Centers for Disease Control and Prevention (CDC) about the cases. On June 16, CDC reported receiving reports of several cyclosporiasis cases reporting prepackaged salad from Grocery Chain A in at least two other states. A multi-state investigation was initiated on June 16.

A case was defined as a person with a laboratory-confirmed *Cyclospora* infection who reported consumption of a Brand X bagged salad mix containing lettuce, carrots, and red cabbage in the 2 weeks prior to illness onset. Cases were interviewed using both a broad-based exposure questionnaire and an outbreak-focused questionnaire.

MDA and United States Food and Drug Administration (FDA) staff conducted tracebacks on salad ingredients.

A total of 701 people with laboratory-confirmed *Cyclospora* infections associated with the outbreak were reported from 14 states: GA, IL, IA, KS, MA, MI, MN, MO, NE, ND, OH, PA, SD, WI. Reported onset dates were May 11, 2020 to July 24, 2020. Fifty-one percent of cases were female, and the median age was 57 years (range, 11 to 92 years). Thirty-eight (5%) cases were hospitalized; no deaths were reported.

The 87 cases from Minnesota reported a median onset date of June 8, 2020 (range, May 29 to June 21, 2020). Forty-two (48%) Minnesota cases were female, and the median age was 60 years (range, 23 to 80 years). One (1%) Minnesota case was hospitalized; no deaths were reported. Cases were residents of 38 counties throughout Minnesota.

The CDC Laboratory was able to successfully perform next-generation sequencing on 42 Minnesota case specimens; 30 were identified to be part of group 2020_001 and 12 were identified to be part of the similar group 2020_003.

On June 20, 2020, Grocery Chains B and C recalled their 12-ounce bagged and labeled “Garden Salad” products. Brand X was the manufacturer of these products. On June 22, 2020, Grocery Chain A, in association with Brand X, recalled Grocery Chain A’s 12-ounce Brand Y Garden Salads from stores in 10 states, including Minnesota. On June 25, 2020, Brand X recalled 12- and 24-ounce bagged Brand Z Classic Iceberg Salad, sold in Grocery Chain D stores in seven states, including Minnesota. On June 27, 2020, Brand X recalled products containing either iceberg lettuce, red cabbage, or carrots and displaying the product code Z178 or a lower number. The “best by” date on the products ran through July 14, 2020. The recalled products were made in the Brand X production facility in Streamwood, Illinois.

FDA's traceback investigation identified several farms in the U.S. that could have provided product used in the Brand X salads that were recalled. FDA investigated multiple farms. In Florida, FDA analyzed water samples from two public access points along a regional water management canal located west of Port St. Lucie, Florida. These samples tested positive for *Cyclospora* using FDA's validated testing method. Given the emerging nature of genetic typing methodologies for *Cyclospora*, FDA was unable to determine if the *Cyclospora* detected in the canal was a genetic match to the clinical cases.

Based on traceback, carrots were ruled out as a potential source of the outbreak. However, red cabbage and iceberg lettuce continued to be items of interest.

This was a foodborne outbreak of cyclosporiasis associated with garden salad products made by Brand X. The outbreak resulted in a recall of Brand X branded products as well as products made by Brand X for retail store brands. FDA conducted a traceback investigation, but the specific vehicle and source of the outbreak were not determined.