



June 17, 2021

Mike Joyner, President
Mike Aerts, Science & Regulatory Affairs
Florida Fruit & Vegetable Association

This letter is being sent with the request that the Florida Fruit & Vegetable Association serve as the conduit to the produce growers, harvesters, packers and distributors of the St. Lucie area in delivering the message of the public health risk of *Cyclospora cayetanensis*.

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have noted that the number of reported cases of cyclosporiasis have increased significantly in recent years. While this increase may be partially attributed to better diagnostic and detection methods, we also know that many cases likely go unreported. Cyclosporiasis is an illness caused by the parasite *Cyclospora cayetanensis* that is most often caused by consumption of contaminated food or water. In [2018](#), [2019](#), and [2020](#), CDC reported that there have been respectively 2,299, 2,408, and 1,241 domestically acquired cases of cyclosporiasis. Outbreaks of cyclosporiasis have been reported in the United States since the mid-1990s and have been linked to various types of imported fresh produce, including raspberries, basil, snow peas, mesclun, and cilantro. Importantly, 2018 marked the first year FDA found the first confirmed evidence of the presence of *Cyclospora cayetanensis* in [domestically grown produce](#).

In 2020, a [multistate outbreak of 701 *Cyclospora* infections was linked to bagged salad mix](#) containing carrots, red cabbage, and iceberg lettuce. FDA investigated multiple farms identified in the traceback, and FDA sampled and conducted an investigation around a farm in south Florida. In response to these events and as part of FDA's investigation, FDA sampled and found *Cyclospora cayetanensis* in canal water used for irrigation. Following its investigation, FDA was unable to conclusively determine the source of this outbreak. FDA continues to work with the state of Florida and the local water district to try to determine the source and impact of *Cyclospora cayetanensis* that was found in the regional water management canal (C-23), located west of Port St. Lucie.

Given the emerging nature of genetic typing methodologies for this parasite in foods and in environmental samples, the FDA has been unable to determine if the *Cyclospora cayetanensis* detected in the canal can be definitively linked to the clinical cases. However, the presence of *Cyclospora cayetanensis* in a water management canal that had previously supplied water to produce farms in the region, and specifically to a farm identified in the traceback, suggests the need for a collaborative effort by state, federal and industry partners to better define the scope and sources of contamination and identify appropriate risk mitigation measures.

The detected presence of *Cyclospora cayetanensis* in the water management canal system may constitute a known or reasonably foreseeable hazard that has the potential to serve as a source of contamination when growing, harvesting, packing, and holding produce. FDA urges produce growers in the St. Lucie produce growing region that use water from the water management canals to consider *Cyclospora cayetanensis* when assessing the risks associated with their operations and take risk mitigation measures, where appropriate.

In an effort to increase awareness about the public health risks associated with *Cyclospora cayetanensis* and inform produce growers, shippers and handlers about potential ways to reduce the risk of produce contamination with this hazard, the FDA, in collaboration with the Florida Fruit and Vegetable Association and the University of Florida Institute of Food and Agricultural Sciences, held a virtual workshop on May 13, 2021, for all interested stakeholders in the St. Lucie produce growing region. This workshop covered the unique aspects of *Cyclospora cayetanensis* compared to other pathogens and provided insights on how it may be controlled, reduced, or eliminated. Detailed information regarding *Cyclospora cayetanensis*, including some requirements for farms covered by the Produce Safety Rule may be found on the FDA website page entitled: [Cyclosporiasis and Fresh Produce](#).

FDA has a duty to help protect consumers from contaminated food, a commitment at the heart of our public health mission and one that we take very seriously. In pursuit of this goal FDA, in 2015, established standards for the safe growing, harvesting, packing, processing and holding of produce sold, imported, or offered for import in the United States, no matter where it is grown.

Industry stakeholders have a responsibility to ensure that foods they bring to market are safe for consumers to eat and serve their families. We urge all segments of the St. Lucie produce industry to review their operations and make all necessary changes to strengthen

Call to Action for the St. Lucie area produce industry
Below are a combination of potentially applicable food safety requirements and best practices for produce:

- be aware that FDA detected the presence of *Cyclospora cayetanensis* in this water management canal system, which may be considered a known or reasonably foreseeable hazard that has the potential to be a source of contamination.
- assess practices that may lead to *Cyclospora cayetanensis* contamination of produce, so as to identify and minimize risks from this and other human pathogen(s). Specific consideration should be given to evaluating the microbial quality of water for the potential presence of *Cyclospora cayetanensis*, especially if water is used in a manner where it is intended or likely to directly contact covered produce during growing, harvest, or post-harvest activities (including water used for irrigation, crop protection sprays (e.g., pesticides, fungicides), or to move, rinse, and/or wax crops).
- use water of adequate quality for its intended use and follow [good agricultural practices](#) to minimize hazards and prevent adulteration under section 402 of the Federal Food, Drug, and Cosmetic Act.
- to evaluate level of risk, consider the use of environmental and/or product testing for the presence of *Cyclospora cayetanensis* rather than merely relying on visual observations.
- to evaluate if preventive measures for *Cyclospora cayetanensis* are effective, consider the use of product testing for the presence of *Cyclospora cayetanensis*.
- when *Cyclospora cayetanensis* is identified through microbiological surveys, consider pre-harvest or post-harvest testing of the product or the environment, implement root cause analysis, working with relevant partners, to determine the potential source(s) and route(s) of contamination and then implement appropriate prevention and verification measures for risk management purposes.
- consider collectively funding and actively engaging with state officials and academia in research (including microbiological surveys) to identify the potential sources and routes of *Cyclospora cayetanensis* contamination of produce and further enhance data-driven, risk-based preventive measures.

public health safeguards against the risk of *Cyclospora cayetanensis* contaminating fresh produce.

Working together, we can help prevent these outbreaks.

Rest assured the FDA intends to further strengthen safeguards and prevent produce contaminated with *Cyclospora cayetanensis* from being sold, imported, or offered for import in the U.S. We conduct compliance and enforcement activities, as appropriate, and are actively engaging in education, outreach, training, and research activities designed to support growers' efforts to keep their food safe for consumers.

However, we can't do this alone and believe that more must be done by industry to further safeguard public health. We look forward to working with you to reach our shared goal of helping to ensure a safe food supply for consumers.

Sincerely,



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Director, Office of Food Safety
Center for Food Safety & Applied Nutrition

CC:

Produce Marketing Association
United Fresh Produce Association
Food Industry Association
Associated Wholesale Grocers
International Foodservice Distributors Association
National Grocers Association
National Restaurant Association
Consumer Brands Association
National Customs Brokers and Forwarders Association