U.S. FOOD & DRUG ADMINISTRATION

FDA FACT SHEET

Produce Safety Rule (21 CFR 112) July 2022

Cyclosporiasis and Fresh Produce: An Overview of *Cyclospora cayetanensis* for Farmers

Fast Facts for Farmers:

- Cyclosporiasis is an intestinal illness caused by the parasite *Cyclospora cayetanensis* (*C. cayetanensis*).
- Cyclosporiasis outbreaks have been associated with the consumption of fresh fruits and vegetables around the world, including in the U.S.
- Cyclosporiasis occurs only in humans, the only known host for *C. cayetanensis*.
- The most common symptom is diarrhea.
- Infected people shed the parasite in their feces -- good hygiene and other sanitary protections such as those described in the Produce Safety Rule (e.g., evaluating worker health and hygiene practices, or assessing septic systems and water sources) are key to preventing the spread of *C. cayetanensis* to fresh produce.
- Chlorine and other common anti-microbial chemical treatments are not effective against *C. cayetanensis.*
- As a parasite, *C. cayetanensis* behaves differently than other gastrointestinal pathogens that commonly cause foodborne illness.
    - The parasite must be shed by an infected person and remain in the environment for 1-2 weeks before becoming infective to other humans. Once infective, people can become sick by ingesting contaminated food or water and continue the cycle.
    - The host may not be ill or show symptoms.

What is *Cyclospora cayetanensis*?

C. cayetanensis is a parasite that must live inside a human host for part of its life cycle, as well as living outside the host during an environmental phase. Although there are many species of *Cyclospora*, only *C. cayetanensis* has been known to cause illness in humans, an infection called cyclosporiasis. A person can become infected after ingesting food or water contaminated with the parasite. Infected people (including those who are asymptomatic or show no symptoms of illness) can shed the parasite in their feces. Without good hygiene practices, among other protections, this can result in the contamination of food, water and the environment and lead to the infection of other people. Cyclosporiasis outbreaks have been associated with the consumption of fresh fruits and vegetables around the world, including the United States.

What are the symptoms of cyclosporiasis?

Most people infected with *C. cayetanensis* who develop symptoms have diarrhea, with frequent, sometimes explosive, bowel movements. Other symptoms may include vomiting, body aches, headache, fever, other flu-like symptoms, loss of appetite, weight loss, stomach cramps/pain, bloating, increased gas, nausea, and fatigue.

Symptoms may seem to go away and then return one or more times (relapse). If not treated, the illness may last from a few days to a month or longer. Some people who are infected with *C. cayetanensis* do not show any symptoms. The infection is treated with antibiotics, and most infected people respond quickly to treatment.

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
College Park, MD, 20740
https://www.fda.gov

Where is this parasite found?

- Cyclosporiasis occurs only in humans, and the parasite originates from the feces of infected people. The parasite is transmitted when feces of infected people contaminate food or water. While there are species of *Cyclospora* that infect animals, *C. cayetanensis* only infects humans.
- Cyclosporiasis is endemic, or commonly found, among certain populations around the world[1], and was previously thought to occur only in produce grown in those regions. However, recent sample findings and outbreak investigations indicate domestic sources of *C. cayetanensis*. In July 2019, FDA found the first confirmed evidence of the presence of *C. cayetanensis* in two samples of domestically grown cilantro also related to outbreak cases.

What else do we know about this parasite?

- *C. cayetanensis* needs to spend some time in specific environmental conditions to become infectious and later cause cyclosporiasis; therefore, this parasite is unlikely to be transmitted directly from person-to-person.
- Under experimental conditions, a combination of time and temperature (temperatures from 73° to 77°F for 7 – 15 days) were required for *C. cayetanensis* to become infectious. Although clinical testing for the parasite in human feces has been available since the 1970s, FDA recently improved the method for the detection of this parasite on some fresh fruits and vegetables. Traditional microbial testing (such as for fecal indicators like generic *E. coli* or fecal coliforms) will not identify the presence of *C. cayetanensis* but may help identify poor water quality, which may also be an indicator of human fecal contamination.
- It is possible that municipal wastewater treatments may render *C. cayetanensis* inactive, however, some conflicting evidence also suggests that *C. cayetanensis* may remain viable even after wastewater is treated. Currently, little conclusive data exists on whether municipal water treatments are effective against *C. cayetanensis*.
- Although chlorine and other antimicrobial chemical treatments are effective at reducing harmful populations of bacteria and viruses, they are not considered effective on *C. cayetanensis*. In countries/regions where Cyclosporiasis is endemic, microfiltration, ozone, or UV treatments may be necessary to effectively decrease populations of *C. cayetanensis* in irrigation waters.

What can I do to reduce the likelihood of contaminating fresh produce with *C. cayetanensis*?

Controlling sources of contamination in the field, in the packinghouse, and from farm workers is key to preventing outbreaks. Since infected humans are the only source of *C. cayetanensis*, practices that ensure proper worker hygiene, workplace sanitation, and monitoring of inputs that may be contaminated by human feces (e.g., surface waters that may be impacted by sewage leaks) are critical to reducing the likelihood of contamination.

To minimize the chance of contaminating fresh produce with *C. cayetanensis*:

- Educate farm personnel on good health and hygienic practices:
    - Train employees on food safety practices, including those required under the Produce Safety Rule.
    - Train farm personnel on the availability and proper use of toilet facilities provided by the farm, including the sanitary disposal of toilet paper.
    - Train personnel on proper handwashing technique and frequency.
    - Include information about symptoms of cyclosporiasis during training.

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
College Park, MD, 20740
https://www.fda.gov

- Assess the potential for conditions on the farm that could introduce or contribute to contamination:
    - Consider environmental conditions and sources of human waste.
    - Consider potential for contamination by farm employees or visitors.
    - Consider whether contamination can occur early in the growing season. *C. cayetanensis* oocysts can persist in the environment after a contamination event and later transfer to produce or food contact surfaces.

For example, it is possible that the contamination may be introduced to the environment or to covered produce via contaminated water during early season irrigation.

- Manage septic systems and portable toilets on the farm so that they do not serve as a source of contamination.
    - Consider where and how toilet facilities are cleaned and maintained, to ensure these activities do not serve as a source of contamination.
- Identify steps to address sewage spills or leaks and consider contacting your local public health or waste management authorities for assistance.
- Assess water systems and adjacent land for potential for contamination sources (e.g., landfills, sewage or septic systems, and land application of wastewater), including the likelihood of run-off.
- Review conditions and practices on the farm with a food safety team to identify and mitigate potential sources or routes of contamination.

What are some steps that farms are required to take according to the FSMA Produce Safety Rule?

Farms covered by the Produce Safety Rule must do the following:

- Train personnel who handle covered produce or food contact surfaces on the importance of health and personal hygiene, including recognizing symptoms of a health condition likely to result in contamination of covered produce or food contact surfaces.
- Instruct personnel to notify a responsible party of applicable symptoms and illnesses and exclude ill employees from tasks that could contaminate produce or food contact surfaces.
- Personnel who work on tasks that could contaminate covered produce or food contact surfaces must use hygienic practices to protect against contamination. These hygienic practices include:
    - maintaining adequate personal cleanliness;
    - washing their hands thoroughly by scrubbing with soap and running water and drying hands thoroughly.
- Ensure toilet facilities and handwashing stations are designed, located, and maintained in a manner that prevents contamination of produce, food contact surfaces, areas where covered activities occur, water sources and water systems.
    - Maintenance activities include cleaning and sanitizing activities, sanitary disposal of toilet paper, and storage of human waste and gray water.
- Dispose of sewage into an adequate sewage or septic system or other adequate means, according to federal, state and local regulations.

What should a farm do if an employee has symptoms of Cyclosporiasis?

Personnel infected with *C. cayetanensis* can shed the parasite into the environment and/or directly onto produce. As a result, people who consume the contaminated produce after the necessary incubation period can become sick. Therefore, it is essential that employees who have or appear to have *C. cayetanensis* infection be excluded from any tasks where produce or food contact surfaces could become contaminated. If a *C. cayetanensis* infection is confirmed, consider working with your public health agency and other relevant partners to identify corrective measures and support any follow-up investigations. Identifying and reducing risk from active infection is essential to reducing transmission through contaminated food and water and preventing new infections amongst consumers or farm personnel.

---

[1] Bangladesh, Brazil, Chile, China, Cuba, Dominican Republic, Egypt, Guatemala, Haiti, India, Indonesia, Jordan, Mexico, Morocco, Nepal, Nigeria, Pakistan, Peru, Puerto Rico, Romania, Saudi Arabia, Tanzania, Thailand, Turkey, Venezuela, Viet Nam, and Zimbabwe; (Ortega, et al. Clinical Microbiology Reviews, 2010 Jan; 23(1):218-234.)

[2] Ortega, et al. Clinical Microbiology Reviews, 2010 Jan; 23(1):218-234.

Additional Information

- FSMA Final Rule on Produce Safety: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm
- Produce Safety Network: ProduceSafetyNetwork@fda.hhs.gov
- *Cyclospora*: https://www.fda.gov/Food/FoodborneIllnessContaminants/Pathogens/ucm610936.htm
- Cyclosporiasis: https://www.cdc.gov/parasites/cyclosporiasis/index.html

---

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
College Park, MD, 20740
https://www.fda.gov