

# FDA FACT SHEET

## Produce Safety Rule (21 CFR 112)

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### Cyclosporiasis and Fresh Produce

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#### Fast Facts for Farmers:

- Cyclosporiasis is an intestinal illness caused by the parasite *Cyclospora cayetanensis* (*C. cayetanensis*), which only occurs in humans, and the most common symptom is diarrhea.
- Infected people shed the parasite in their feces.
- When the parasite is found in water or food, it means that the water or food has been contaminated with human feces.
- Other people may become sick by ingesting water or food contaminated with the parasite.
- Good hygiene (including proper handwashing) is a critical component of ensuring the safety of fresh produce, but by itself it may not be enough to prevent infected employees from contaminating fresh produce.
- The FSMA Produce Safety Rule requires that personnel on farms use hygienic practices (§ 112.32) and that ill employees are excluded from handling fresh produce and food contact surfaces (§ 112.31).

#### What is *Cyclospora cayetanensis*?

*C. cayetanensis* is a human parasite, which means it must live inside a human host to survive and multiply. The parasite can cause an infection, called cyclosporiasis. A person may become infected after ingesting food or water contaminated with the parasite. Infected people, even if showing no symptoms of infection, may shed the parasite in their feces, which can contaminate food and water, leading to the infection of other people. Cyclosporiasis outbreaks have been associated with the consumption of fresh fruits and vegetables around the world, including in the U.S.

#### What are the symptoms of cyclosporiasis?

Most people infected with *C. cayetanensis* develop 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.

#### Where is this parasite found?

- Cyclosporiasis is endemic or commonly found among the population in certain countries/regions.<sup>1</sup>
- Since the infection occurs only in humans, the parasite originates from the feces of ill people.
- The parasite may also be found in water and food, if it has been contaminated by human feces.

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<sup>1</sup> 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.)

- No non-human host (animals) for this parasite has been identified.
- *C. cayetanensis* is not limited to imported foods. In July, FDA found the first confirmed evidence of the presence of *C. cayetanensis* in domestic produce when two cilantro samples tested positive for the parasite.

## What else do we know about this parasite?

- 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.
- The parasite needs to spend some time in the environment to later cause cyclosporiasis, therefore, *C. cayetanensis* is unlikely to be transmitted directly from person-to-person and still cause illness.
- The parasite needs specific environmental conditions to become infectious. Under experimental conditions, a combination of time and temperature (temperatures from 73° to 77°F during 7 – 15 days)<sup>2</sup> were required for *C. cayetanensis* to become infectious.
- Although chlorine and other antimicrobial washes are effective at reducing harmful populations of bacteria and viruses, they are not as effective on *C. cayetanensis*. In countries/regions where cyclosporiasis is endemic, microfiltration, ozone, or UV treatments may be effective at decreasing 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 illnesses. Farms can do the following to minimize the chance of contaminating fresh produce with *C. cayetanensis*:

- Train farm workers on how to properly use toilet facilities provided by the farm, including the sanitary disposal of toilet paper.
- Consider the varying cultural practices of farm workers when providing training on produce safety.
- If utilizing a contractor for cleaning and sanitizing the portable toilets, consider using reputable companies that dispose of human waste into an adequate sewage system or through other adequate means. Municipal wastewater treatment incorporates disinfection processes designed to kill or inactivate *C. cayetanensis*.

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

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

- Train farm workers who handle produce or food contact surfaces on how to properly wash their hands with soap and running water, properly dry hands, and properly dispose of the paper towels. Free videos and training materials exist in multiple languages online<sup>3</sup>.
- Make sure toilets and handwashing stations are maintained, cleaned, and emptied in a way that prevents human waste and/or gray water from contaminating fresh produce, food contact surfaces, and adjacent areas.
- Train farm workers to self-report applicable symptoms and illnesses to the appropriate responsible person, and don't allow ill farm workers to handle fresh produce or touch food contact surfaces.

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<sup>2</sup> Ortega, et al. Clinical Microbiology Reviews, 2010 Jan; 23(1):218-234.

<sup>3</sup> For example, see <https://www.cdc.gov/cdctv/spanish/healthyliving/acabe-con-los-microbios.html>

## What happens if infected farm workers handle produce?

Workers infected with *C. cayetanensis* can transmit the parasite to fresh produce, which can cause people to get sick if the contaminated produce is consumed. Therefore, it is essential that ill employees be excluded from handling fresh produce and food contact surfaces. If you have reason to suspect a cyclosporiasis infection, consider working with your public health agency. Identifying and treating the infection is essential to preventing new infections, amongst consumers or farm workers, through contaminated food and water.

### For more information:

- FSMA Final Rule on Produce Safety:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

- Produce Safety Network:

[ProduceSafetyNetwork@fda.hhs.gov](mailto:ProduceSafetyNetwork@fda.hhs.gov)

- *Cyclospora*:

<https://www.fda.gov/Food/FoodborneIllnessContaminants/Pathogens/ucm610936.htm>

- Cyclosporiasis:

<https://www.cdc.gov/parasites/cyclosporiasis/index.html>

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