Cyclospora cayetanensis Fact Sheet

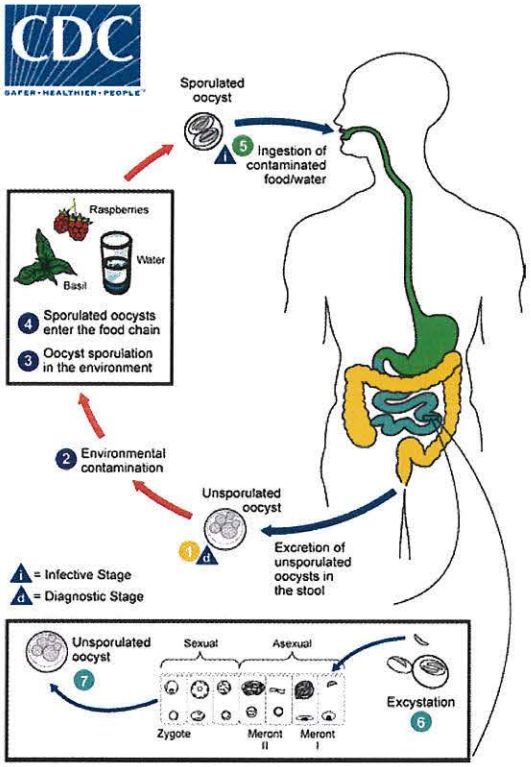
OVERVIEW

Cyclospora is a single-celled, sporulating coccidian protozoan parasite *(12, 19)*. Of 16 *Cyclospora* species currently identified, *Cyclospora cayetanensis* is the only known to infect humans *(33)*, and is believed to infect humans exclusively *(13, 22)*. *C. cayetanensis* is an environmentally-mediated fecal-oral parasite and the causative agent of human cyclosporiasis.

LIFECYLE

The lifecycle of *C. cayetanensis* begins when a person ingests sporulated (active, infectious) oocysts *(12)*. Oocysts travel to the small intestine, where they excyst and invade gut epithelial cells *(33)*. There, they undergo asexual division followed by sexual development to produce oocysts, which are shed in the stool. Oocysts that enter the environment through stool are initially unsporulated (inactive, noninfectious) *(28)*.

The course of sporulation depends on environmental factors, including temperature. At 25ºC (77ºF), oocysts can become infectious in 7-12 days *(33)*. In warmer climates (26-30ºC; 78.8-86 ºF), the viability of oocysts increases *(34)*. Consequently, *C. cayetanensis* is believed to exhibit geographic and seasonal distribution, with peak infection occurring between May and August (Guatemala *(3)*, Nepal *(20)*, and the United States (US) *(17)*; January-March in Haiti *(13)*; December-May in Peru *(4)*).



Source: CDC 2018 *(9)*

Once sporulated, infectious oocysts can be transmitted by food and water *(16)*. In the US and Canada, outbreaks of *C. cayetanensis* have been associated with raspberries (imported from Guatemala), blackberries (Guatemala/unknown), mesclun (Peru/US), basil (Mexico/US), salad mix (Mexico/US) *(33)*, cilantro (Mexico) *(30)* and tap water, in the case of a physicians' dormitory in Chicago (US) *(18)*. *C. cayetanensis* has been isolated from wastewater in Arizona *(21)* and farm samples in California.

EPIDEMIOLOGY

According to the US Centers for Disease Control and Prevention (CDC) National Outbreak Reporting System (NORS) database, there were 40 foodborne outbreaks associated with *C. cayetanensis* in the US between 1998 and 2017 *(6)*. Of these outbreaks, 36 (90%) had etiology confirmed by the CDC. Of the 23 outbreaks with identified food sources, none were traced

definitively to domestic produce. Seven outbreaks (7/23; 30%) were attributable to berries, 4 (17%) were attributable to fresh herbs, 3 (13%) were attributable to green salads and leafy greens, and 9 (39%) were attributable to other or multiple commodities (see appendix for commodity details) *(6)*. States with the greatest number of confirmed foodborne *C. cayetanensis* outbreaks were Florida (6), Texas (5), and Georgia (5). The majority of outbreaks (34/36, 94%) were contained to a single state *(6)*.

The CDC NORS database indicates that foodborne *C. cayetanensis* outbreaks resulted in 1,823 illnesses between 1998 and 2017. This equates to an expected 46 illnesses per outbreak, well above the national average across commodities of 26 illnesses per outbreak *(6)*. However, outbreak statistics understate the total number of incident cyclosporiasis cases, estimated at over 16,000 per year in the US *(23)*.

In 2014, the US Food and Drug Administration (FDA) began sampling food commodities for *C. cayetanensis*. On September 4, 2018, the FDA reported its first confirmed positive finding in US-grown produce, which originated from a sample of fresh cilantro collected at a domestic distribution facility in July 2018 *(2)*. While the positive sample was not linked to human disease, it coincided with the heaviest season of cyclosporiasis observed in the US to date *(37)*. Between May 1 and September 1 2018, 2,173 cases of cyclosporiasis were reported to the CDC. Of these, 250 were attributable to Del Monte veggie trays, and 511 were attributable to McDonald's salads containing a romaine and carrot mix supplied by Fresh Express *(36)*. In addition to large retail outbreaks, CDC and FDA have identified two basil- and three cilantro-associated outbreaks.

Studies from endemic countries reveal *C. cayetanensis* prevalence as high as 15% during spring and summer months, with the majority of infections resulting in asymptomatic disease *(27, 33, 35)*. Of infected individuals in a Venezuelan study, 85% reported no symptoms *(10)*. Adults are less frequently affected than children—likely due to acquired immunity *(15)*—but their potential for asymptomatic presentation puts them at risk of becoming parasite carriers *(33)*. Unlike *Giardia lamblia* and *Entamoeba histolytica,* with their irregular shedding patterns *(12)*, *C. cayetanensis* is believed to be released at continuous low levels in stool *(33)*.

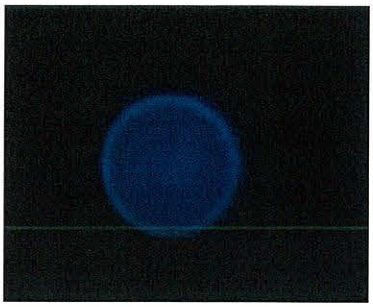
SIGNS AND SYMPTOMS

Symptoms of cyclosporiasis include watery diarrhea, fatigue, anorexia, nausea and abdominal pain, roughly 7 days (range of 2 days to 2 weeks) after exposure to infectious *C. cayetanensis* oocysts *(12, 19)*. Diarrhea can last weeks to a month if not treated *(33)* and longer in immunocompromised patients, who may present with a relapsing-remitting profile *(19)*. Potential complications include reactive arthritis, Guillain-Barré syndrome, and acalculous cholecystitis *(11, 33)*.

DETECTION AND DIAGNOSIS

Clinical

Human cyclosporiasis can be diagnosed by stool microscopy or genetic amplification techniques. *C. cayetanensis* is not tested in standard Ova and Parasite (O&P) clinical diagnostic panels *(33)*. Therefore, clinicians must request a *C. cayetanensis*-specific investigation, such as targeted microscopy, antibody assays or Polymerase Chain Reaction (PCR) for diagnosis.



Source: CDC 2018 *(9)*

Oocysts are 8-10um in diameter and autofluorescent, reflecting blue light when viewed under ultraviolet (UV) fluorescence microscopy. UV-fluorescence can be used as to identity *C. cayetanensis* oocysts in stool samples. Modified acid-fast and safranin stains may also be used to improve detection *(19)*. *C. cayetanensis* oocysts found in stool samples from patients with cyclosporiasis will be unsporutaled. However, the microscopic diagnostic method used in the laboratories are not designed to differentiate unsporulated from sporulated oocysts.

The most sensitive method for clinical *Cyclospora* detection is based on quantitative real-time PCR (qPCR). This format is employed by the BioFire® FilmArray® Gastrointestinal (GI) Panel, which allows clinicians to test for *C. cayetanensis* as part of a routine syndromic workup *(5)*. By automatically testing for the parasite, providers who employ this assay are now able to efficiently identify *C. cayetanensis* among their patients. Advances in clinical diagnosis, such as expanded adoption of the Biofire® GI panel, may have contributed to the increase in reported cyclosporiasis cases during summer 2018 *(37)*.

Cyclosporiasis has been a nationally-notifiable disease since 1999 *(7)*. In the State of California, reporting to the Department of Public Health (CDPH) is required within one week *(1)*.

Environmental

Cyclospora oocysts in fresh human stool will be unsporualted and belong to the *cayetanensis* species. In contrast, oocysts recovered from environmental samples may exist in any stage of sporulation and can belong to a variety of non-human *Cyclospora* species or closely related genera (e.g., *Neospora, Isopera* and *Eimeria*).

Determining sporulation, and therefore infectiousness, would aid in environmental investigation; however, morphological assessment via microscopy is unreliable and requires recovery and isolation of intact oocysts for visualization. Because *C. cayetanensis* cannot replicate outside of a human host, culturing oocysts from environmental samples is not possible.

The detection of *C. cayetanensis* in fresh produce can be achieved by methods described in the FDA's Bacteriological Analytical Manual (BAM) Part 19b *(25)*. This test replaces FDA's previous nested PCR assay, BAM Part 19a *(26)*. The new method has been fully validated for cilantro and raspberries, and matrix extended to shredded carrots, parsley, romaine lettuce and basil fresh produce commodities.

Table: Capabilities of Available Clinical and Environmental Tests for *Cyclosopra*

Capability	Standard Ova & Parasite Test *Clinical*	Targeted Microscopy *Clinical*	BioFire FilmArray GI Panel *Clinical*	FDA BAM 19a (2004-2016) *Environmental*	FDA BAM 19b (2016-present)* *Environmental*
Detect *Cyclospora*	+/-	+	+	+	+
Detect *C. cayetanensis*	-	-	+	+	+
Sensitive (> 80%)	-	-	+	-	+
Specific (> 80%)	-	-	+	-	+
Rapid (< 2 hours)	-	-	+	-	-
Determine infectiousness	-	+	-	-	-

*Multi-laboratory validation: cilantro and raspberries. Matrix extension : shredded carrots, parsley, romaine lettuce and basil *(24)*

TREATMENT

C. cayetanensis is treated with combination Trimethoprim-Sulamethoxazole (TMP-SMZ) *(38)*. A 7- to 10-day course of oral TMP-SMZ has demonstrated a 90% cure rate for immunocompetent people *(19)*; however, effectiveness is lower in immunocompromised patients *(29)*. Ciprofloxicin may be an option for patients unable to tolerate TMP-SMZ *(38)*. While treatment may hasten recovery and prevent complications, cyclosporiasis is generally self-limited and is not associated with death *(25)*.

CONTROL

Because *C. cayetanensis* requires time in the environment to sporulate and become infectious *(12)*, direct human-to-human transmission is unlikely. Control emphasis should therefore be placed on limiting introduction of oocysts into the environment and onto produce, where they can sporulate. Growers and food handlers should wash hands regularly, wear gloves when possible, and abstain from work if suffering from diarrhea *(19)*.

C. cayetanensis oocysts are robust to temperature fluctuation and commercial pesticides. They can survive for at least one week in 37°C (98.6°F) water and two months in 4°C (39.2 °F) water *(33, 34)*. Heating to 60°C (140°F) for one hour or freezing at -20°C (-4°F) for four days *(32)* will prevent sporulation; however, such treatments are rarely appropriate for fresh produce. Pesticides used during the growing process (Captan 50% WP, benomyl 50% WP, zineb 57% WP, malathion 25% WP, diaszinon 4E 47.5%) show no effect on sporulation *(31, 33)*. *C. cayetanensis* is additionally resistant to chlorination *(19)*.

According to the CDC, consumers can reduce their risk of *C. cayetanensis* infection by washing cooking equipment "between the preparation of raw meat, poultry, and seafood products and the preparation of fruits and vegetables that will not be cooked." While good food hygiene practice, it is unclear how this will reduce *C. cayetanensis* exposure, given no known association between the human parasite and animal products. The CDC further recommends washing and refrigerating all produce. Washing is not expected to substantially reduce *C. cayetanensis* oocysts *(16)*, which can withstand fluctuating water temperature and avoid expulsion by adhering to produce. Refrigeration at standard 0-4°C (32-39°F) does not inactivate oocysts, which have been shown to

survive for two months at this temperature *(24)*. Given the lack of evidence to support consumer-oriented recommendations, infection control efforts should focus on preventing *C. cayetanensis* from entering the food system, including treating infectious farm workers and food handlers.

OTHER CONSIDERATIONS

The required infectious dose for *Cyclospora* has not been determined; however, it is likely low. According to Medscape, "The disease rate after a presumed exposure has been reported to vary from 32.5-100%, with a median of 91.7%, suggesting that a small inoculum of organisms is sufficient to infect" *(33)*. As few as one sporulated oocyst may be required for infection, compared to an infectious dose of 10^8 organisms for enterotoxigenic *Escherichia coli* (ETEC) *(14)*.

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APPENDIX: US Centers for Disease Control and Prevention (CDC) National Outbreak Reporting System (NORS) Data on Cyclosporiasis 1998-2017

Year	Month	State	Primary Mode	Etiology	Etiology Status	Setting	Illnesses	Hospitalizations	Deaths	Food Vehicle
1998	5	Georgia	Food	Cyclospora cayetanensis	Confirmed		17			
1999	5	Florida	Food	Cyclospora cayetanensis	Confirmed	Restaurant - other or unknown type; Other	94	1		blackberries; raspberries; strawberries
1999	7	Missouri	Food	Cyclospora cayetanensis	Confirmed	Caterer (food prepared off-site from where served)	62	1	0	basil, unspecified
2000	5	Georgia	Food	Cyclospora cayetanensis	Confirmed	Restaurant - other or unknown type	19	0	0	blackberries; raspberries
2000	6	Pennsylvania	Food	Cyclospora cayetanensis	Confirmed	Caterer (food prepared off-site from where served)	54	3	0	raspberries
2001	1	Florida	Food	Cyclospora cayetanensis	Confirmed	Restaurant - other or unknown type; Private home/residence	39	6		
2001	1	New York	Food	Cyclospora cayetanensis	Confirmed	Private home/residence	3			arugula, unspecified
2002	1	Vermont	Food	Cyclospora cayetanensis	Confirmed	Other	26	0	0	raspberries
2002	4	Massachusetts	Food	Cyclospora cayetanensis	Suspected	Other	8	0	0	mesclun mix, unspecified
2002	6	New York	Food	Cyclospora cayetanensis	Confirmed	Caterer (food prepared off-site from where served); Hospital	14			gravy, unspecified
2004	2	Illinois	Food	Cyclospora cayetanensis	Confirmed	Restaurant - other or unknown type	56	0	0	pasta salad; vegetable-based salads unspecified; tuna salad
2004	5	Tennessee	Food	Cyclospora cayetanensis	Suspected	Private home/residence; Caterer (food prepared off-site from where served)	13	0	0	condiment, unspecified; bean salad
2004	6	Pennsylvania	Food	Cyclospora cayetanensis	Confirmed	Long-term care/nursing home/assisted living facility	116		0	pasta salad; green beans, unspecified
2005	3	Florida	Food	Cyclospora cayetanensis	Confirmed	Restaurant - other or unknown type	592			basil, unspecified
2005	4	Massachusetts	Food	Cyclospora cayetanensis	Confirmed	Banquet Facility (food prepared and served on-site)	58	0	0	
2005	5	South Carolina	Food	Cyclospora cayetanensis	Confirmed	Restaurant - other or unknown type	6	0	0	
2005	6	Connecticut	Food	Cyclospora cayetanensis	Confirmed	Restaurant - other or unknown type	30	1	0	bruschetta; house salad
2005	6	Massachusetts	Food	Cyclospora cayetanensis	Suspected	Restaurant - other or unknown type; Banquet Facility (food prepared and served on-site)	16	0	0	
2006	6	Minnesota	Food	Cyclospora cayetanensis	Confirmed	Restaurant - other or unknown type	14	0	0	fruit salad
2006	6	New York	Food	Cyclospora cayetanensis	Confirmed	Restaurant - other or unknown type	20	1	0	
2006	7	Georgia	Food	Cyclospora cayetanensis	Confirmed	Grocery store	3	0	0	
2008	3	Wisconsin	Food	Cyclospora cayetanensis	Confirmed	Private home/residence	4	0	0	peas, green
2009	6	Connecticut	Food	Cyclospora cayetanensis	Confirmed	Private home/residence	8	0	0	blackberries; raspberries
2011	6	Florida	Food	Cyclospora cayetanensis	Confirmed	Restaurant - Sit-down dining	12	0	0	cilantro and onions
2011	7	Georgia	Food	Cyclospora cayetanensis	Confirmed		99	3	0	lettuce based salads
2013	6	Multistate	Food	Cyclospora cayetanensis	Confirmed	Restaurant - Sit-down dining	161	10	0	salad mix, bagged
2013	6	Texas	Food	Cyclospora cayetanensis	Confirmed		38		0	cilantro, unspecified
2013	7	Wisconsin	Food	Cyclospora cayetanensis	Confirmed	Private home/residence	8	0	0	blackberries
2014	6	Texas	Food	Cyclospora cayetanensis	Confirmed	Restaurant - Sit-down dining	2	0	0	
2014	6	Michigan	Food	Cyclospora cayetanensis	Confirmed	Restaurant - Sit-down dining; Restaurant - other or unknown type; Banquet Facility (food prepared and served on-site)	14	1	0	
2014	7	South Carolina	Food	Cyclospora cayetanensis	Confirmed	Unknown	13	3	0	
2015	5	Multistate	Food	Cyclospora cayetanensis	Confirmed	Restaurant - Sit-down dining; Restaurant - other or unknown type	90	3	0	cilantro, unspecified
2016	7	Texas	Food	Cyclospora cayetanensis	Confirmed	Restaurant - Sit-down dining	15	0	0	
2017	3	Florida	Food	Cyclospora cayetanensis	Suspected	Other	10	1	0	
2017	5	Florida	Food	Cyclospora cayetanensis	Confirmed	Caterer (food prepared off-site from where served)	6	0	0	blackberries
2017	5	Texas	Food	Cyclospora cayetanensis	Confirmed	Restaurant - Sit-down dining; Restaurant - other or unknown type	41	2	0	green onion/scallion
2017	6	Ohio	Food	Cyclospora cayetanensis	Confirmed	Unknown	6	0	0	
2017	6	Michigan	Food	Cyclospora cayetanensis	Confirmed	Banquet Facility (food prepared and served on-site); Caterer (food prepared off-site from where served)	29	1	0	
2017	7	Connecticut	Food	Cyclospora cayetanensis	Confirmed	Caterer (food prepared off-site from where served); Other	3	0	0	
2017	7	Florida	Food	Cyclospora cayetanensis	Confirmed	Restaurant - Sit-down dining	4	0	0	salsa; guacamole