

CYCLOSPORA OUTBREAK

Operational actions for food and beverage manufacturers

The Cyclospora outbreak continues to pose challenges to those working hard to keep the food supply safe. Cyclospora is a microscopic parasite that causes cyclosporiasis. Contaminated workers, food or water can transmit the parasite, and fresh produce has been the primary vehicle in U.S. outbreaks. Currently, there are no registered products with efficacy claims for the organism and the FDA continues to provide updated guidance as the outbreak evolves. Despite these challenges, there are some actions you can take today in your processing facility.

Start with the ingredients in your facility

Since ingredients themselves become infected with Cyclospora, effective response to this outbreak requires supplier controls, product disposition decisions, traceability and diligent sanitation practices. Here are a few ways to evaluate and reduce your supply risk.

1 Map your produce exposure

Identify every raw and processed produce ingredient in current production. Ensure you have easy-to-access documentation that can link each ingredient to its supplier, growing region, packing location, receiving dates, lot codes and finished-product uses.

2 Reconfirm supplier controls

Engage suppliers on agricultural water management, worker hygiene, restroom and handwashing access, septic management, harvest practices and traceability. Ask suppliers to communicate changes in source, packing location, water events or product disposition as they arise.

3 Put traceability to a response test

Run a targeted traceback exercise. Confirm that your team can connect an incoming ingredient lot to production runs, finished goods, customers and distribution locations. Record gaps and assign owners to close them.

Manage hygiene and flow of product

As you work with your team to ensure proper cleaning and sanitation protocols, clarify that the goal is to prevent cross-contamination and restore sanitary conditions after handling potentially affected materials. Cleaning and sanitation does not eliminate Cyclospora from an affected ingredient.

1 Separate raw-produce handling from finished-product risk

Review traffic patterns, equipment, utensils, employee movement and staging areas around raw produce. Identify routes that could transfer contamination to food-contact surfaces, adjacent operations or ready-to-eat product areas.

2 Strengthen hygiene controls during receiving and handling

Confirm handwashing access, requirements and compliance; employee illness self-ID allowance; illness reporting procedures; and direct food contact mitigation efforts in areas where employees handle raw produce or food-contact equipment. These controls reduce opportunities for contamination to move through the plant.

3 Execute sanitation procedures and verify the results

At a minimum, utilize a general-purpose rapid residue detection system such as ATP swabs. Although these swabs are not able to identify specific residues, they will indicate that an organic residue is present, which may include infectious material, and the area should be re-cleaned and re-tested. Consider expanding sampling zones and high-touchpoint locations to include areas leading to or from breakrooms and restroom facilities.

Stress test your response plan

- 1 Confirm records are complete and accessible**
Maintain current supplier approval records, receiving records, lot documentation, sanitation records, production records and distribution records. An investigation moves quickly once an ingredient or supplier becomes implicated.
- 2 Define escalation triggers**
Set a documented process for supplier notifications, regulatory alerts, product holds, customer communication, additional sanitation, investigation support and release decisions. Confirm decision authority across food safety, quality, operations, procurement and commercial teams.
- 3 Check execution on the floor**
Use observation, record review and corrective-action follow-up to verify that procedures operate consistently across shifts and facilities. A written program only protects the operation when employees routinely execute it without exceptions under normal production conditions.

Control boundaries to keep in view

Cyclospora controls begin upstream. Agricultural water quality, worker hygiene, restroom access and sanitation at the growing and packing stages shape the risk profile of fresh produce before it enters a manufacturing facility.

Produce washing can reduce contamination. It cannot guarantee removal of Cyclospora. The FDA states that chlorine and other common antimicrobial chemical treatments are not currently considered effective against the Cyclospora parasite.

Action list for this week

- ✓ Complete a produce-ingredient and supplier map.
- ✓ Conduct one traceability exercise from ingredient receipt through customer distribution.
- ✓ Reconfirm supplier escalation contacts and documentation requirements.
- ✓ Inspect raw-produce handling routes for cross-contamination pathways.
- ✓ Review sanitation verification and pre-operational inspection records.
- ✓ Confirm who can place product on hold and approve release.

For additional information, please refer to the food safety practices required under the [FSMA Final Rule on Produce Safety | FDA](#) and consult the FDA for new guidance as it is released.
