Current Issues in Produce Safety

Inputs and Practices

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Produce Safety is Complex

- Today's Update
  - Inputs
    - Water quality
    - Soil & Soil amendments
  - Practices
    - Cleaning and Sanitation
    - Worker health and hygiene (*Cyclospora*)

25 FDA investigated outbreaks in 2022

Ongoing Outbreaks

- *Salmonella* outbreak linked to alfalfa sprouts: >15 illnesses, 2 hospitalizations in 3 states (12/10/2022- present in SD, OK, NE)
- *Listeria monocytogenes* in enoki mushrooms (2 illness and 2 hospitalizations in NV and MI) from 11/17/2022- present

Closed Outbreak Investigations

- Strawberries and hepatitis A virus (outbreak investigation ended 8/14, 19 cases, 13 hospitalizations, 4 states)
- Lettuce and *E. coli* O157:H7: Wendy's Romaine lettuce on sandwiches, but not confirmed by the CDC, 109 illnesses, 52 hospitalizations, across 6 states (MI, IN, OH, KY, PA, NY)
- *Cyclospora* and unknown commodities resulted in >127 illness in July and August
- 4 outbreaks associated with packaged salads and spinach in 2021

NEWS > QUICK SERVICE

E. coli outbreak linked to Wendy's leaves lawsuits in wake

The E. coli outbreak linked to Wendy's involved 109 reported cases and 52 hospitalizations.

CDC, investigators could not confirm source of infections reported in 6 states

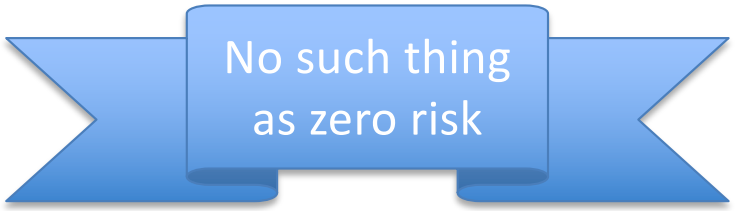
Ron Ruggless | Oct 24, 2022

Agricultural inputs

- Almost any input into the fresh produce production environment (pre- and post-harvest) can be a source of contamination
- To reduce the risk of contamination, must identify potential hazards that may be associated with these inputs

- Seeds, Plants, Irrigation Water, Soil Amendments, Crop Treatments, Wash Water, Packaging, Cleaning and Sanitation Chemicals
- Animal Intrusion

Hazard vs Risk



- Hazard: A biological, chemical, or physical agent in, or condition of, food with the **potential** to cause and adverse health effect.[1]

- Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.[1]
  - The **likelihood** of the occurrence and the magnitude of the consequences of exposure to a hazard on human health.[2]

[1]CodexAlimentarius Commission. Procedural Manual, 24th edition at http://www.codexalimentarius.org/
[2]Initiation and Conduct of All "Major" Risk Assessments within a Risk Analysis Framework. A Report by the CFSAN Risk Analysis Working Group. 2002.

Hazard vs. Risk

Hammer
"Hazard"

Toolbox
"Controls/Manages/Influences
Hazard"

Act of Hammering
"Risk"

Slide curtesy of Channah Rock, UA 2022

Hazard vs. Risk

E.coli Bacteria
"Hazard"

Method of Irrigation
"Controls/Manages/Influences Hazard"

Eating a Salad
"Risk"

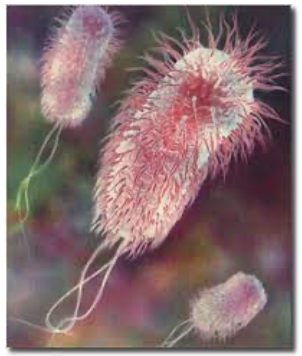
Slide curtesy of Channah Rock, UA 2022

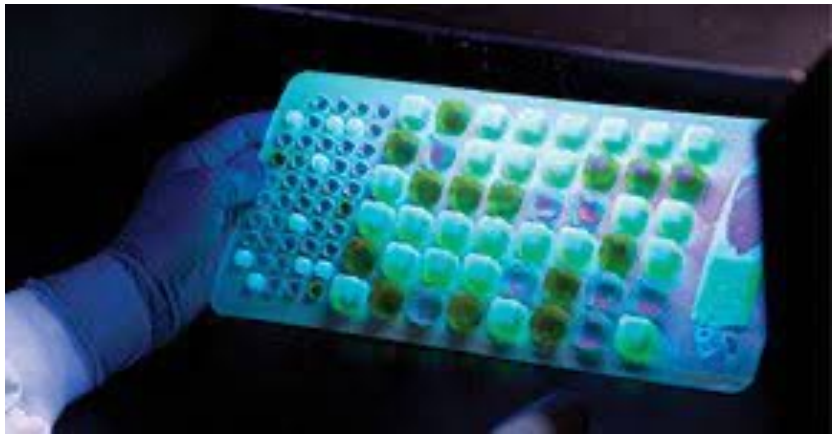
Water and Water Quality

- Contamination risk is higher if water is applied to the edible portion of the crop and immediately before harvest (e.g. overhead irrigation)
- Risk is reduced is irrigation water does not contact the edible portion of the crop (e.g. trickle irrigation)
- Risk is greater for water that is recycled or not adequately treated or stored

Water Testing for *E. coli*

- Presence of generic *E. coli* in water usually indicates recent fecal contamination
  - *E. coli* is an indicator organism
  - Risk of presence of pathogens
- While testing may not be prescribed under the Produce Safety Rule, it is still useful to understand the microbiological quality of your water





Applied and Environmental Microbiology

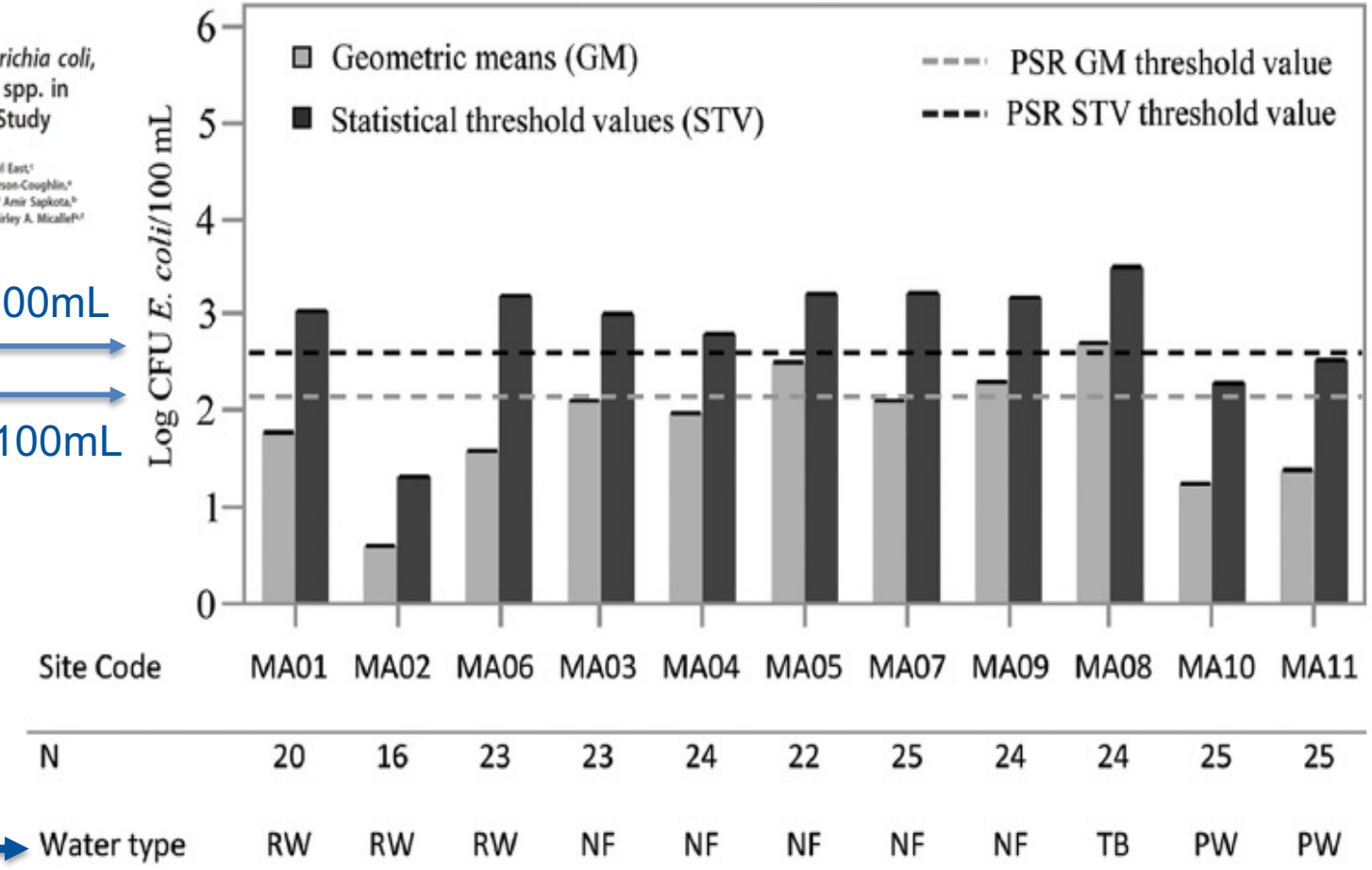
FOOD MICROBIOLOGY

Longitudinal Assessment of the Dynamics of *Escherichia coli*, Total Coliforms, *Enterococcus* spp., and *Aeromonas* spp. in Alternative Irrigation Water Sources: a CONSERVE Study

Sultana Solaiman,[a] Sarah M. Allard,[b#] Mary Theresa Callahan,[a] Chengsheng Jiang,[b] Eric Handy,[c] Cheryl East,[c] Joseph Haymaker,[d] Anthony Bui,[b] Hillary Craddock,[b] Rianna Murray,[b] Prachi Kulkarni,[b] Brienna Anderson-Coughlin,[a] Shani Craighead,[a] Samantha Gartley,[a] Adam Vanore,[a] Rico Duncan,[d] Derek Foust,[d] Maryam Taabodi,[d] Amir Sapkota,[b] Eric May,[d] Fawzy Hashem,[d] Salina Parveen,[d] Kalmia Kniel,[a] Manan Sharma,[c] Amy R. Sapkota,[b] Shirley A. Micallef[a,c]

410 cful/100mL

126 cful/100mL



Agricultural Water Assessment

https://agwaterassessment.fda.gov/

Factor	Description
Agricultural water system(s)	The location and nature of the water source; The type of water distribution system; The degree to which the system is protected from possible sources of contamination
Agricultural water practices	The type of application method; The time interval between the last direct application of agricultural water and harvest of the covered produce
Crop characteristics	Susceptibility of the produce to surface adhesion or internalization of hazards
Environmental conditions	Frequency of heavy rain or extreme weather events that may impact the agricultural water system – such as by stirring sediments that may contain human pathogens - or that may impact or damage produce. Damage can increase the susceptibility of produce to contamination. Air temperatures Sun (UV) exposure
Other relevant factors	Including, if applicable, results of testing that could inform the assessment

Agricultural Water Assessment

Thank you for using the Agricultural Water Assessment Builder. The Agricultural Water Assessment Builder v. 1.1 is a user-friendly tool designed to help farms understand the proposed requirements for an agricultural water assessment in the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water" proposed rule (agricultural water proposed rule). If finalized, the rule would replace the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) in the 2015 Produce Safety Final Rule with provisions for systems-based agricultural water assessments. In the proposed rule, an agricultural water assessment means an evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) related to growing activities for covered produce (other than sprouts) to: (1) identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; and (2) determine whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with such known or reasonably foreseeable hazards.

Included in the builder are two options for exporting data. One is this PDF, which is intended to be an offline copy of the assessment, and the other is a JSON file that can be used for continuing an unfinished assessment or conducting a re-assessment. The JSON file is only to be used for importing information into the builder and should not be modified. This PDF is available for you to use however you choose.

Use of the Agricultural Water Assessment Builder v. 1.1 does not constitute FDA approval of an agricultural water assessment or guarantee compliance with FDA's requirements, if finalized.

FDA has taken all reasonable precautions in creating the Agricultural Water Assessment Builder v. 1.1. However, FDA is not responsible for errors, omissions or deficiencies regarding the tool. The Agricultural Water Assessment Builder v. 1.1 is available "as is" and without warranties of any kind, either expressed or implied, including, but not limited to, warranties of performance, merchantability, and fitness for a particular purpose. FDA is not making a commitment in any way to regularly update the tool.

What about post-harvest water?

Postharvest Wash Water

Water must have no detectable generic *E. coli* per 100 mL sample.

Farms may choose to include a sanitizer in wash water.

Before we leave water…

Hydroponic Lettuce Was Seen as Safe From Salmonella, Until an Outbreak

The F.D.A. criticized measures at a hydroponics greenhouse linked to an outbreak last summer, and offered guidelines that have ramifications for the popular industry.

Give this article 20

Hydroponic growers advertise their produce as singularly fresh, typically raised close to customers' homes rather than in far-off farm fields. Robert Franklin/South Bend Tribune, via Associated Press

By Deborah Schoch
May 3, 2022

Before we leave water…

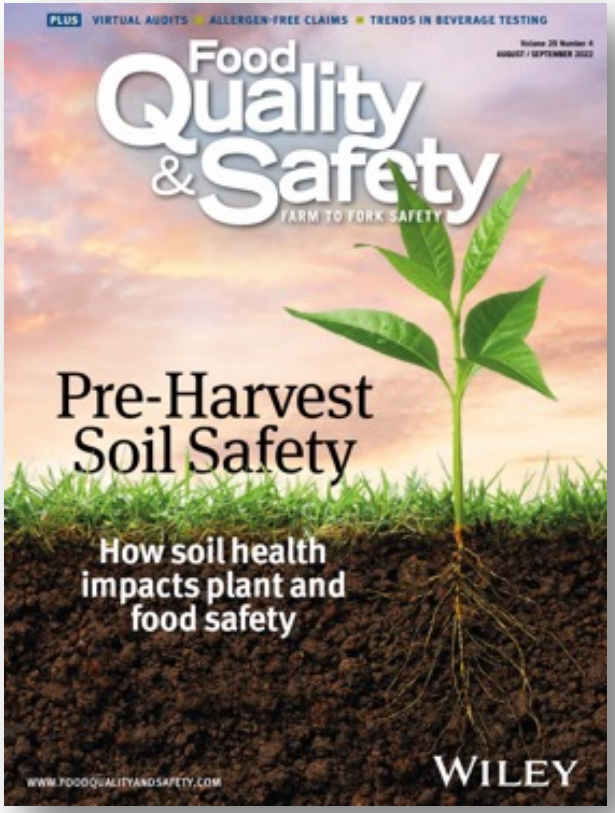
Investigation Report:
Factors Potentially Contributing to the Contamination of Packaged Leafy Greens Implicated in the Outbreak of *Salmonella* Typhimurium During the Summer of 2021

U.S. FOOD & DRUG ADMINISTRATION

The FDA investigators' observations and the analysis of approximately 300 product, water, and environmental subsamples collected during the investigation provide insights on how the pathogen may have first been introduced into the operation and factors that may have allowed the movement and growth of the pathogen within the establishment.

- Protection of Raw Materials: media stored outside without adequate protection
- Growing Pond Water: active production pond was positive for *Salmonella*; no method to ensure adequate water treatment (peroxyacetic acid)
- Design and Maintenance of Operation: did not exclude leaves in contact with pond water; condensate on overhead chiller
- Cooling and Cold Holding of Post-harvest Product: no temperature detection or way to verify cooling
- Nearby Stormwater Retention Pond: 25 ft from CEA structure positive for *Salmonella* outbreak strain
- Sanitary Pre- and Post-harvest Environments: did not adequately document cleaning and sanitizing of equipment, tools, etc.

Soil Amendments



It's important that growers use soil amendments appropriately to grow healthy efficient crops as well as avoid the excessive use of soil amendments that could affect agricultural water if contamination occurs by run-off into produce fields.

—Kali Kniel, PhD

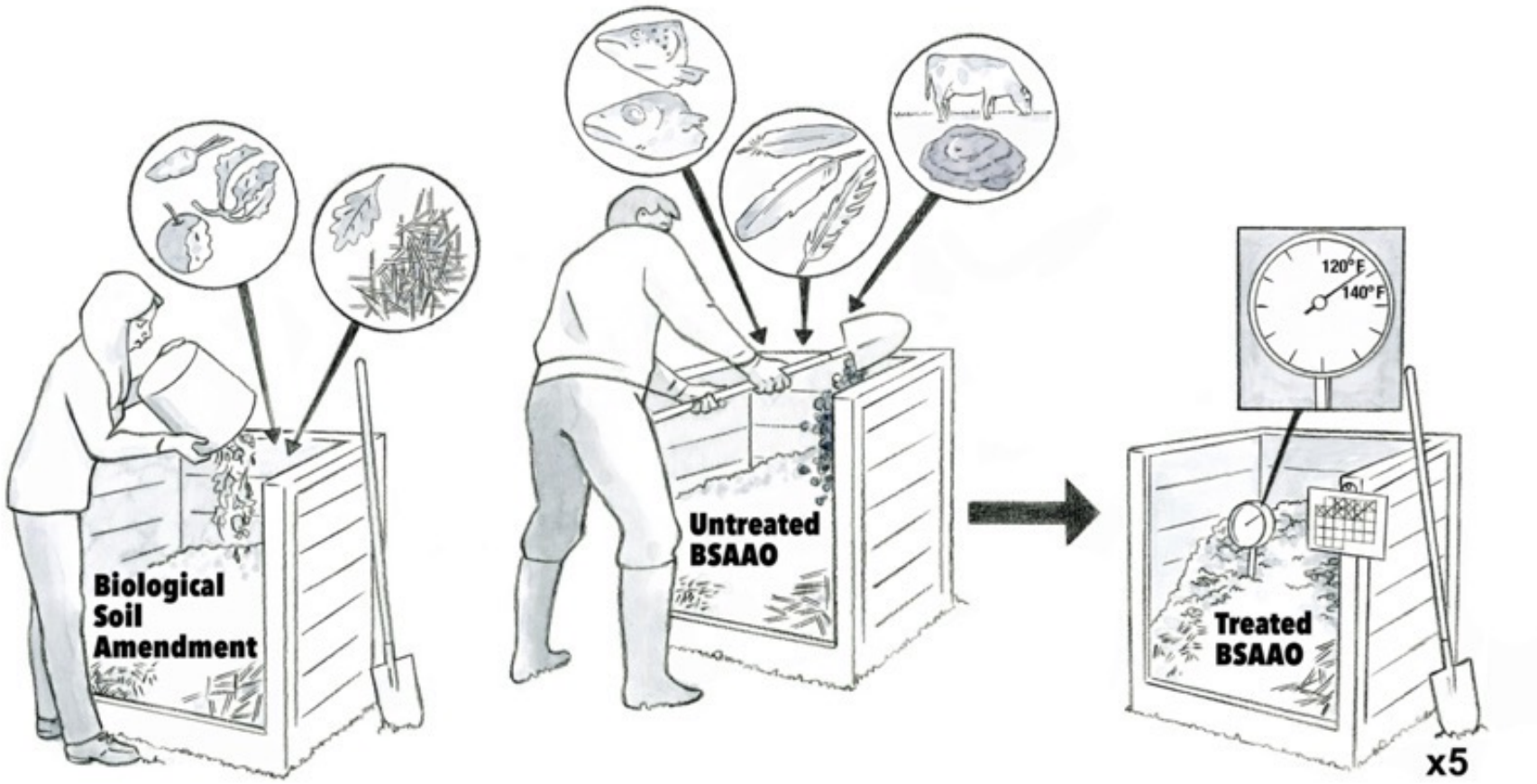


Illustration by Anni Matsick | © 2022 Cornell University

Examine the influence of extrinsic and intrinsic factors of soil on *E. coli* survival and transfer to cucumbers

Year	Total Rainfall (in.)	Mean duration (days) to observe a 4 log CFU decline in soils	% of cucumbers where *E. coli* was recovered
2018	24.9	77 $\pm$ 30	98% (n=160)
2019	12.6	56 + 21	35% (n=180)

E. coli survival in soils is affected by a combination of amendment type, rainfall pattern, and soil moisture content.

Adjacent Land Use?!

Adjacent Land Use?
What about near by animals?

- Location, Location, Location

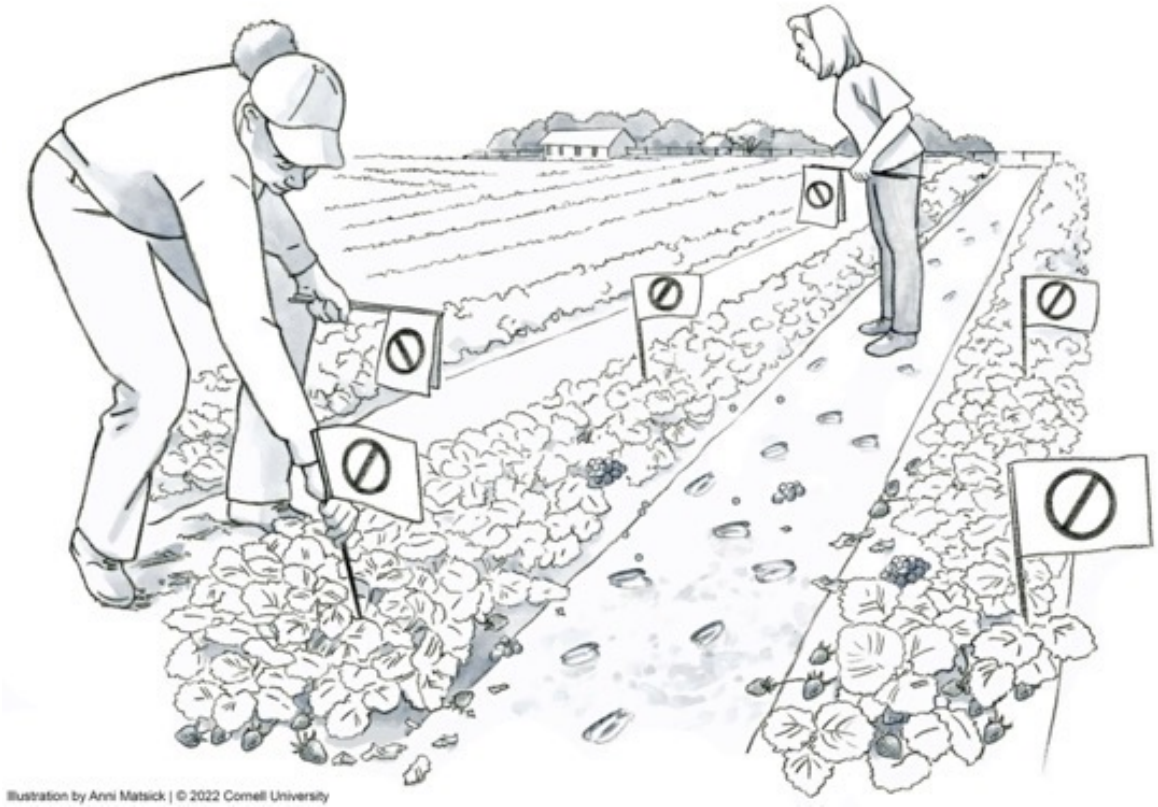
- Pathogen transport during rain or irrigation
  - Complex interactions: rainfall intensity, droplet size, soil type, splash range, plant height and canopy architecture
  - Splash transfer of soil particles and *Salmonella* from soil onto crops(Lee et al., 2019)

    - Salmonella detected for 8-10 days after inoculation in soil and on produce
    - Salmonella detected in splash water at heights of up to 80 cm
    - Soil moisture conditions may affect the transfer potential of *Salmonella*

Establishing No Harvest Buffer Zones

Mature ‘Magenta’ lettuce

Results indicate that, following rain, for both fresh and stale fecal deposits, *E. coli* dispersed to lettuce at high levels up to 30 cm, dropped off after 60 cm and tapered off at at about the 1 m mark.



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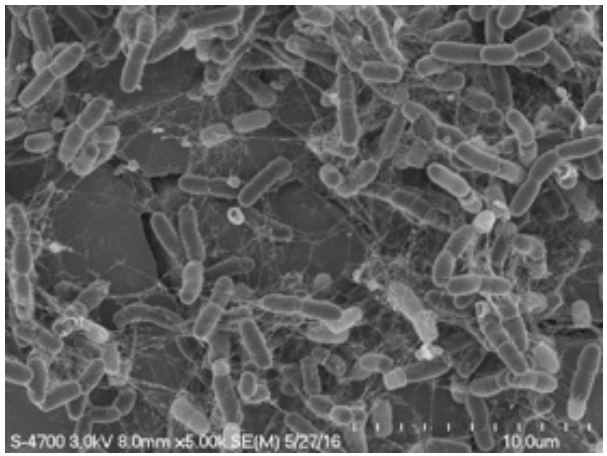
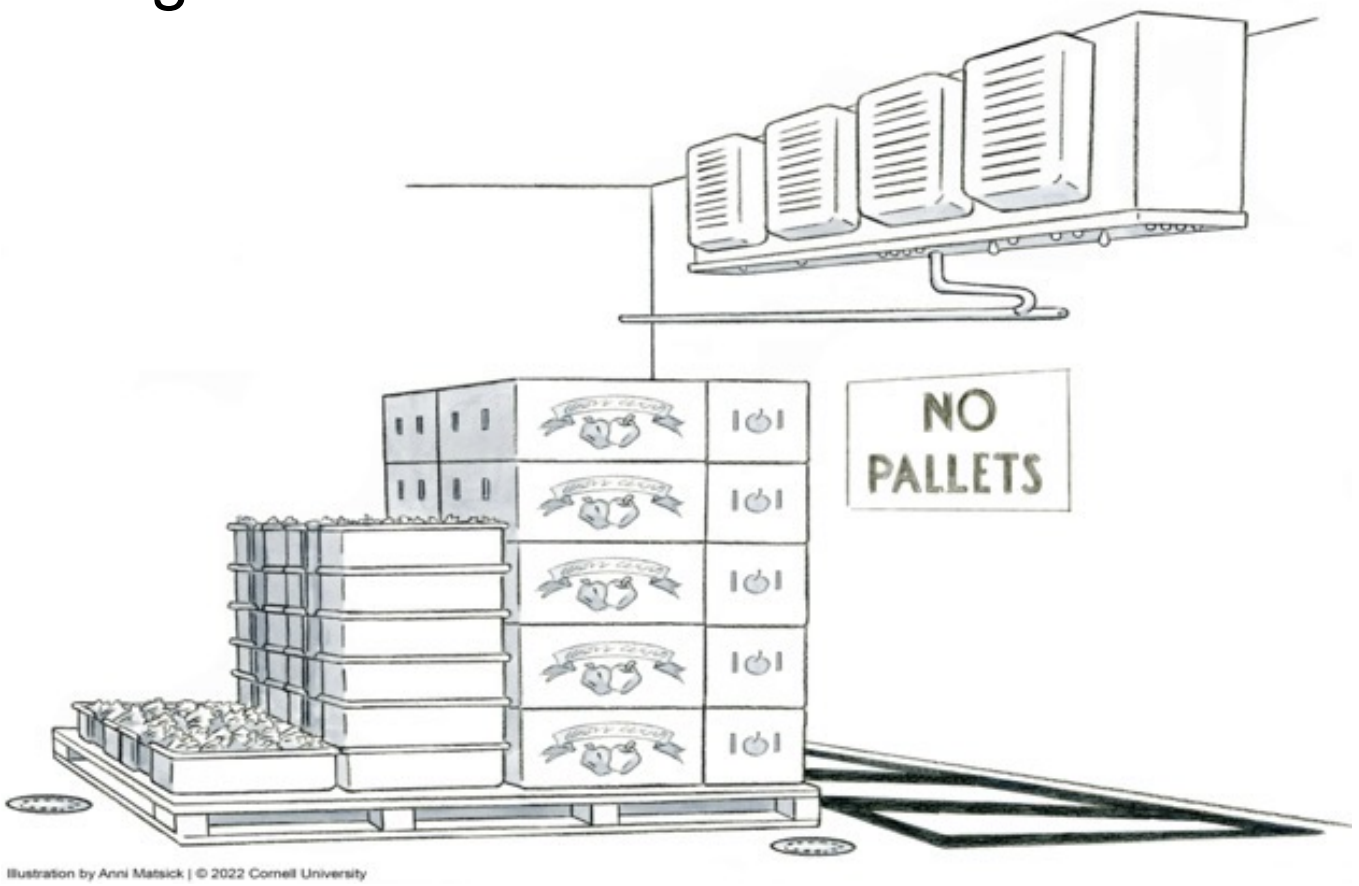
PRACTICES
(SANITATION & WORKER HEALTH)

Food Safety in a Packinghouse Cooler

Listeria monocytogenes





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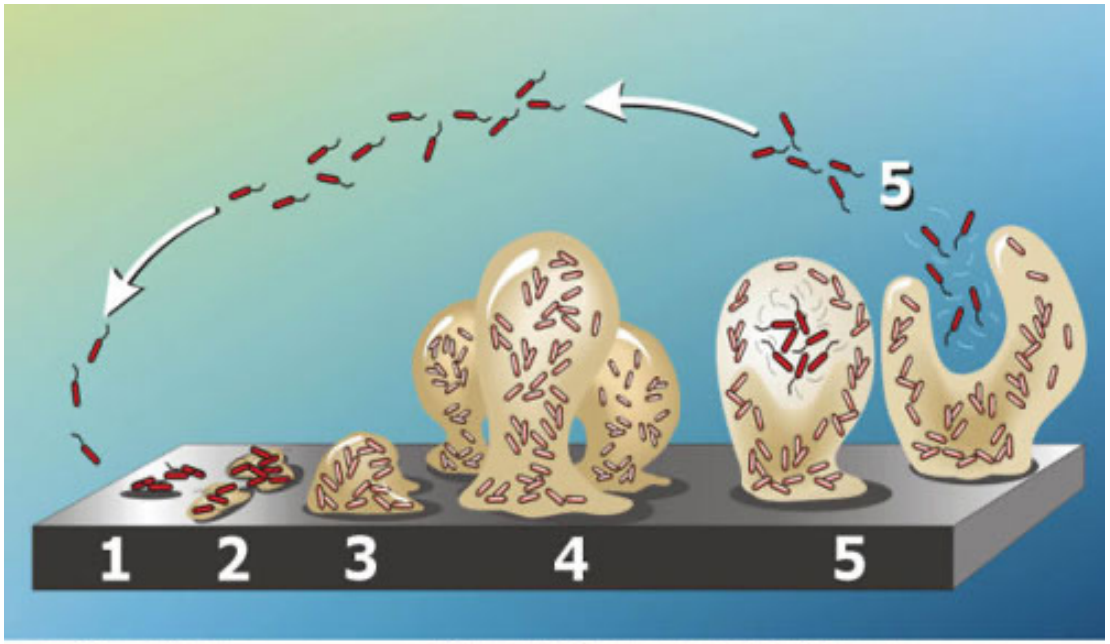
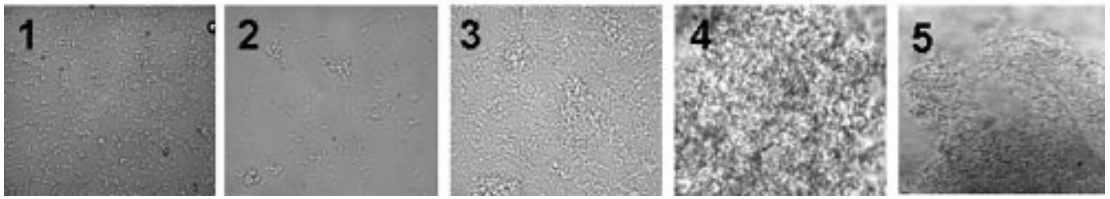
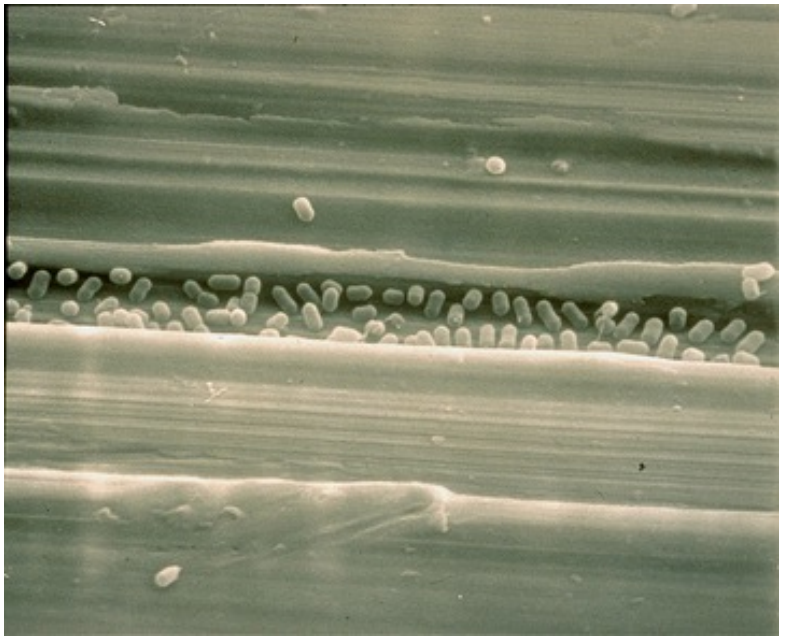
Clean First and Then Sanitize





biology.binghamton.edu/davies/research.htm

You don't want Bacterial Biofilms



Cleaning and Sanitizing

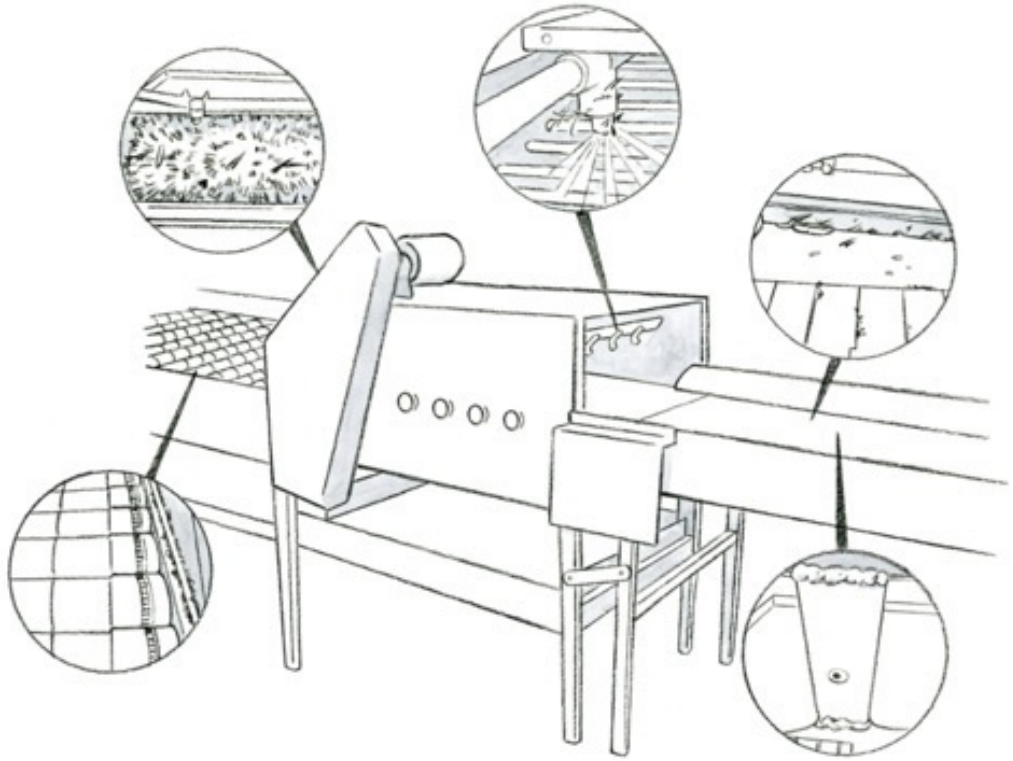
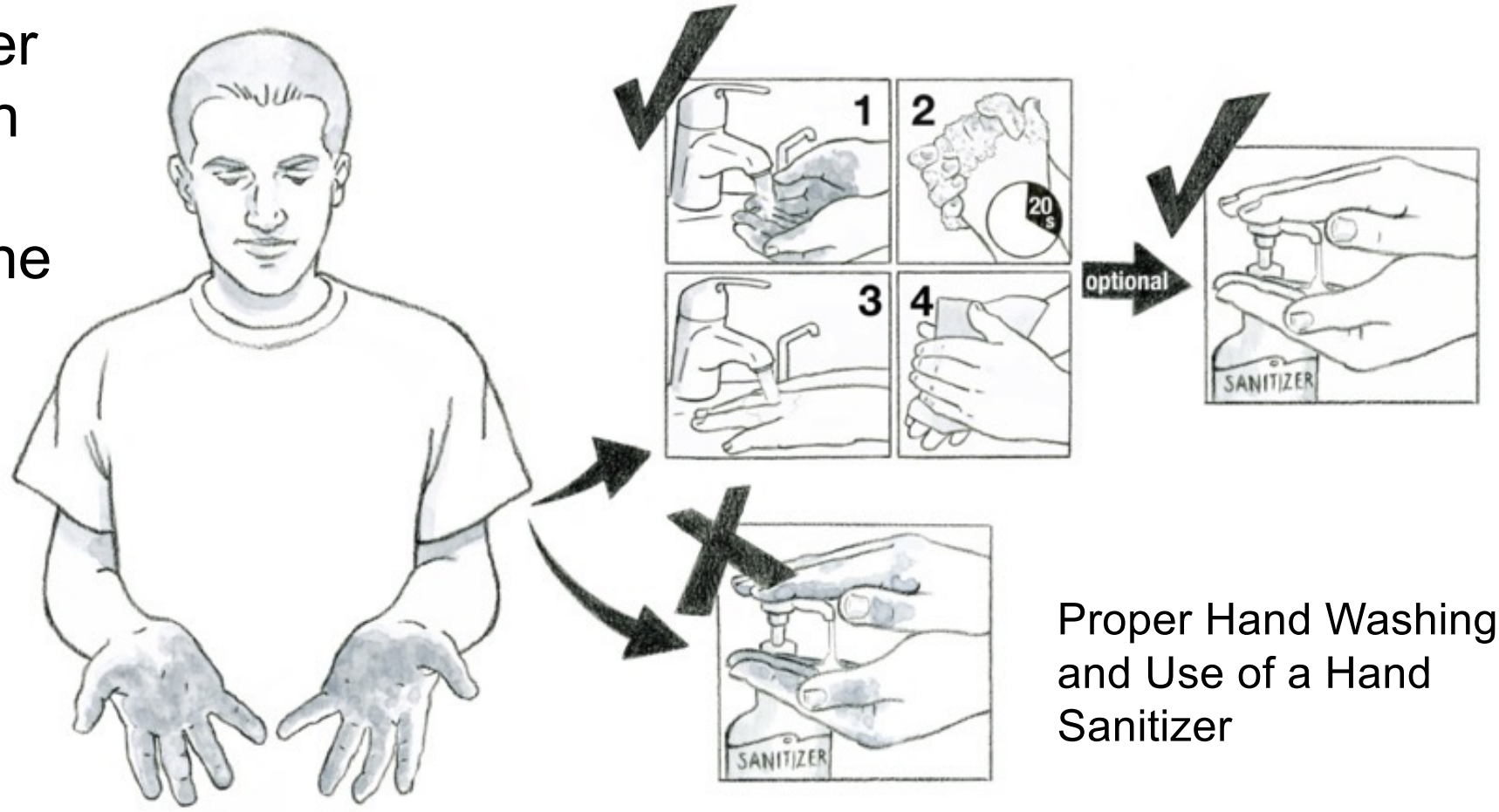


Illustration by Anni Matsick | © 2022 Cornell University

Dry Cleaning

Illustration by Anni Matsick | © 2022 Cornell University

Worker Health And Hygiene



Proper Hand Washing and Use of a Hand Sanitizer

Cyclospora is not a bacterium

- It is a protozoan parasite
- Unlike bacteria, protozoa can **not** grow outside a host
- Transmitted by **mature** oocysts

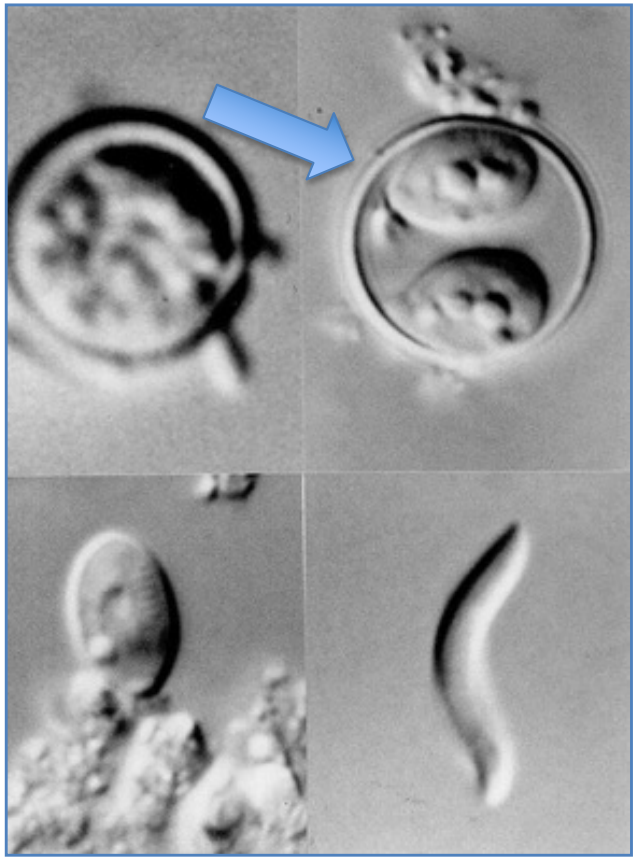
There are still numerous remaining questions, challenges, and work needed to better understand and manage this pathogen.

Difficult to study without an animal or cell-culture laboratory model.

Cyclospora cayetanensis oocyst (8-10 µm)

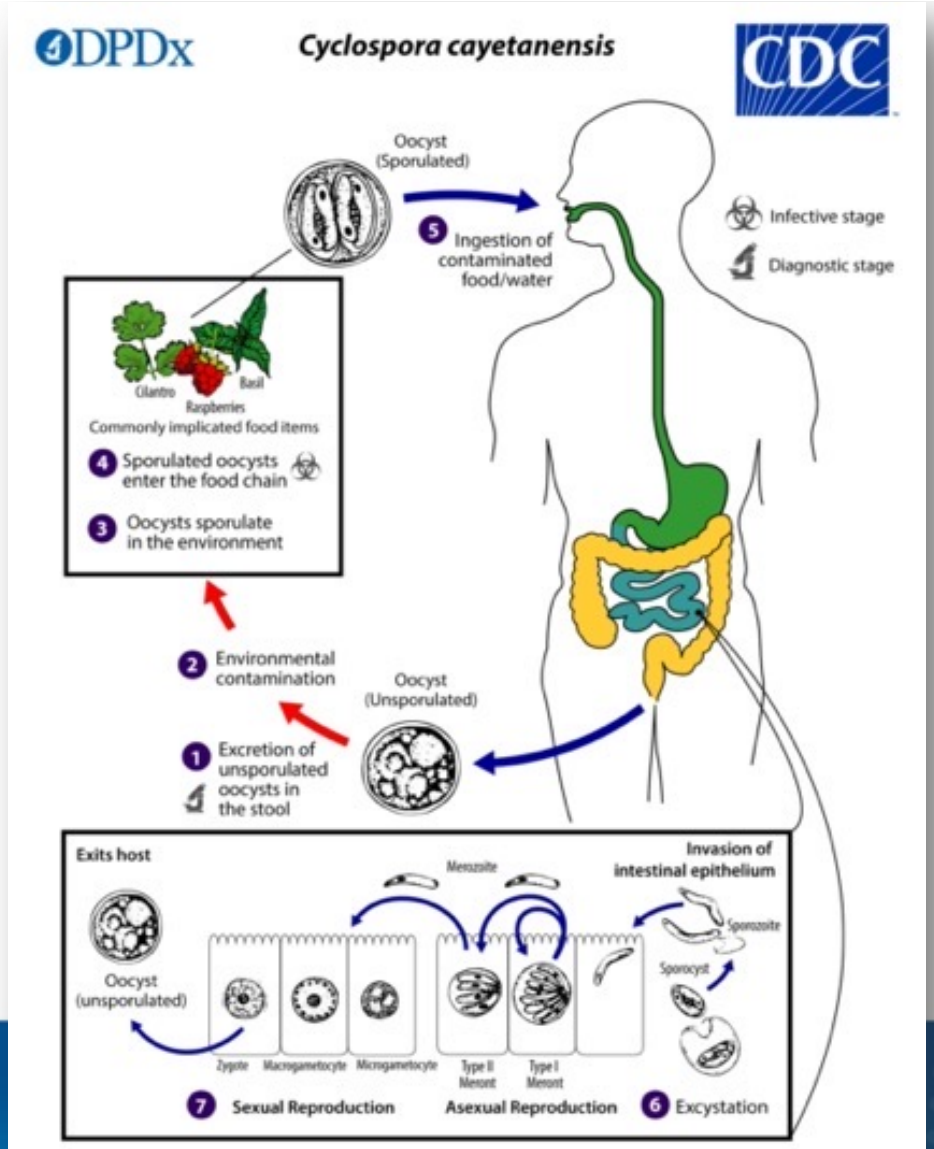
Cyclosporiasis

- *Cyclospora cayetanensis* infects the human intestine
- Spread by people ingesting contaminated produce or water
- *Cyclospora* needs time (typically at least 1-2 weeks) after being passed in feces to become infectious for another person
  - Sporulated oocysts are infectious
  - So it is unlikely that *Cyclospora* is passed directly from one person to another
- Time from ingestion to illness ranges ~2-14 days



Cyclospora cayetanensis oocyst
(8-10 µm)

Life Cycle


DPDx
Cyclospora cayetanensis
CDC
Oocyst (Sporulated)
5 Ingestion of contaminated food/water
Infective stage
Diagnostic stage
Cilantro
Basil
Raspberries
Commonly implicated food items
4 Sporulated oocysts enter the food chain
3 Oocysts sporulate in the environment
2 Environmental contamination
Oocyst (Unsporulated)
1 Excretion of unsporulated oocysts in the stool
Exits host
Oocyst (unsporulated)
Merozoite
Invasion of intestinal epithelium
Sporozoite
Sporocyst
Zygote
Macrogametocyte
Microgametocyte
Type II Meront
Type I Meront
7 Sexual Reproduction
Asexual Reproduction
6 Excystation

Clinical Detection

Cyclosporiasis – Provider Fact Sheet

How is cyclosporiasis treated?

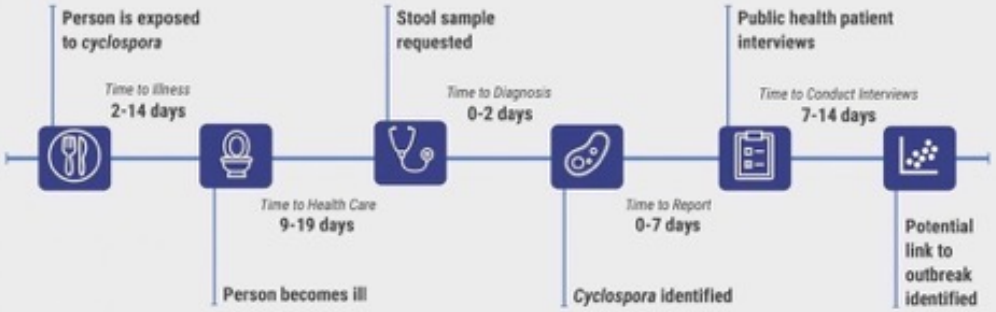
- Trimethoprim-sulfamethoxazole (TMP-SMX) is the treatment of choice.
- The typical regimen for immunocompetent adults is TMP 160 mg plus SMX 800 mg (one double-strength tablet), orally, twice a day, for 7–10 days. HIV-infected patients may need longer courses of therapy.
- No highly effective alternatives have been identified for persons who are allergic to (or are intolerant of) TMP-SMX.

CDC

OUTBREAK INVESTIGATION TIMELINE

Cyclospora Infection

The time from when a person is exposed to *Cyclospora* from contaminated food or water to the confirmation that he or she is part of an outbreak is typically about three to six weeks.



IDPH

Average Time: 3-6 weeks

The BioFire® FilmArray® Gastrointestinal (GI) Panel

THE BIOFIRE GI PANEL MENU

Overall 98.5% Sensitivity and 99.2% Specificity[A]
Sample Type: Stool in Cary Blair medium

BIOFIRE BY BIOMÉRIEUX

BACTERIA:

- *Campylobacter (jejuni, coli, and upsaliensis)*
- *Clostridium difficile* (toxin A/B)
- *Plesiomonas shigelloides*
- *Salmonella*
- *Yersinia enterocolitica*
- *Vibrio (parahaemolyticus, vulnificus, and cholerae)*
- *Vibrio cholerae*

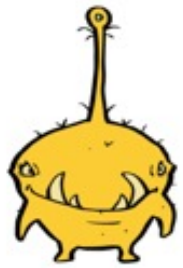
DIARRHEAGENIC E. COLI/SHIGELLA:

- *Enteroaggregative E. coli* (EAEC)
- *Enteropathogenic E. coli* (EPEC)
- *Enterotoxigenic E. coli* (ETEC) *lt/st*
- *Shiga-like toxin-producing E. coli* (STEC) *stx1/stx2*
  E. coli O157
- *Shigella/Enteroinvasive E. coli* (EIEC)

PARASITES:

- *Cryptosporidium*
- *Cyclospora cayetanensis*
- *Entamoeba histolytica*
- *Giardia lamblia*

- Astrovirus
- Norovirus GI/GII
- Rotavirus A
- Sapovirus (I, II, IV, and V)

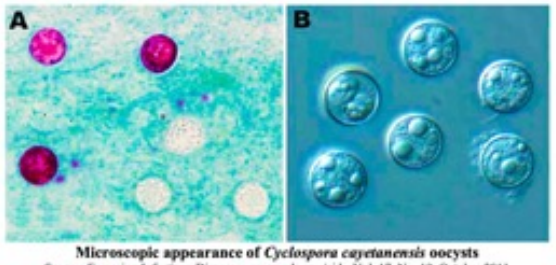


The future of testing and detection?

Not yet feasible or widely available

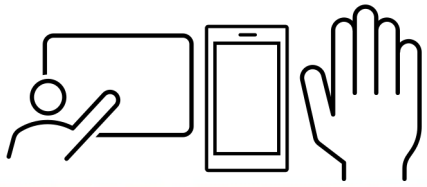
Many tests are under development

Focus on molecular diagnostics and testing platforms



Microscopic appearance of *Cyclospora cayetanensis* oocysts
Source: Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 17, No. 10, October 2011

Focus on People!



- Train employees in their native language.
- Train farm workers on how to properly use only toilet facilities provided by the farm, including the sanitary disposal of toilet paper inside the toilet.
- Train farm workers on the importance of proper handwashing.
- Train farm workers on the criticality of not working with specific symptoms which could indicate an illness.
- Ensure there is supervisory oversight for farm worker health/hygiene/sanitation.
- Ensure field workers' own tools are properly cleaned and sanitized before and after the workday.
- Cleaning and maintenance of portable toilets should be done away from the growing environment.
- Develop a plan to manage and dispose of leakages or spills of human waste to prevent contamination as well as for flooding events.

Thank You

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