Starting Soon: Biologicals CEC

- ITRC Resource: https://cec-bio.itrcweb.org
- CLU-IN Training Page (slides available): https://www.clu-in.org/conf/itrc/CECBio

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Biological Contaminants of Emerging Concern (BioCEC)

Sponsored by: Interstate Technology & Regulatory Council

Hosted by: US EPA Clean Up Information Network (Clu-In)

Meet the ITRC Trainers

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Learning Objectives

1. Define a **biological contaminant of emerging concern (BioCEC)**
2. Understand that the **key variables** that influence BioCEC transmission necessitate a holistic approach
3. Gain an understanding of reactive and proactive approaches to assess **transmission or risk**
4. Provide **case studies** that highlight the importance of the One Health Framework
5. Understand **how to use the ITRC BioCEC Guidance**

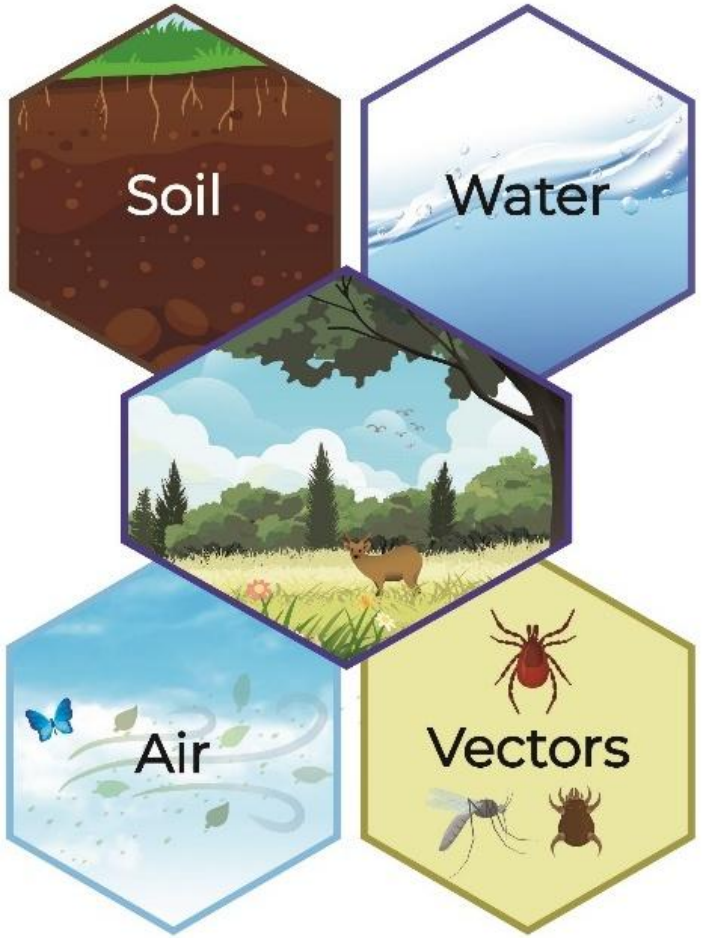
How this relates to the ITRC Guidance

Phase 1. Characterize the BioCEC

- **Identification**
  - Introduction
  - Analytical Methods
- **Evaluation**
  - Conceptual Exposure Model (CEM)
  - Key Variables

Phase 2. Taking Action

- Process Guide
- Monitoring Programs



Analytical Methods Figure 1. Graphical depiction of environmental matrices.

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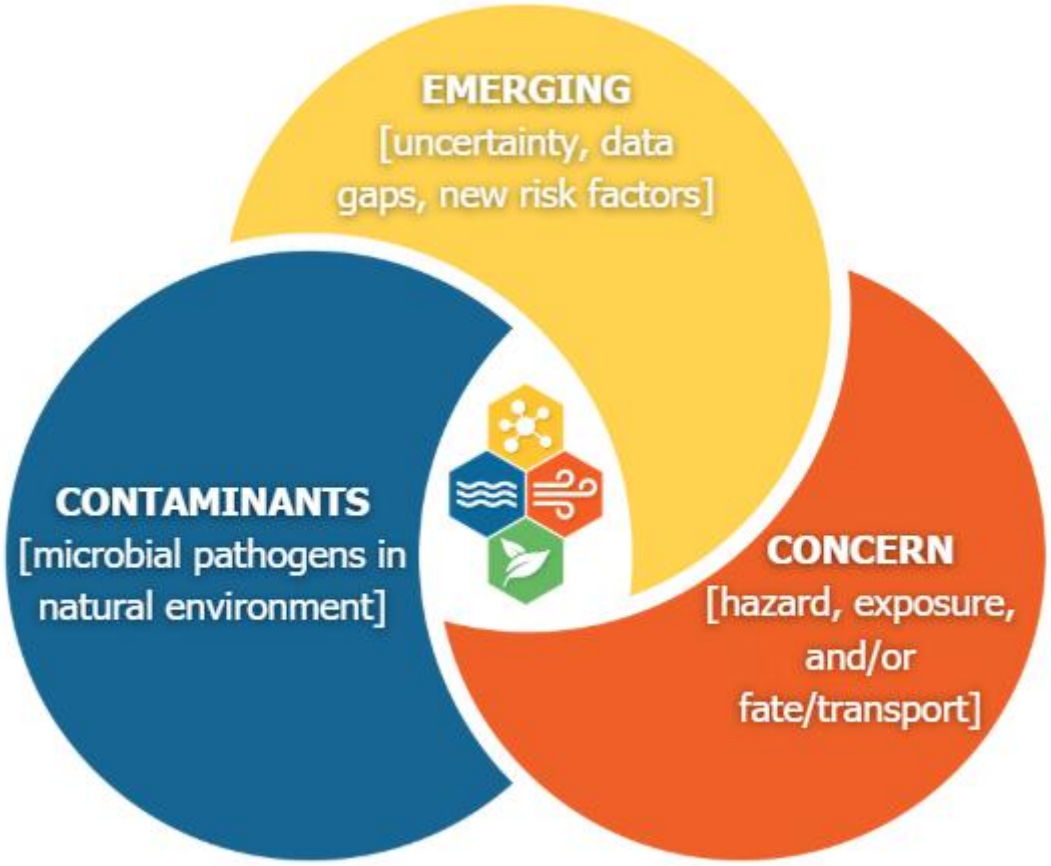
CEC Include Microorganisms But...



CEC refers to...

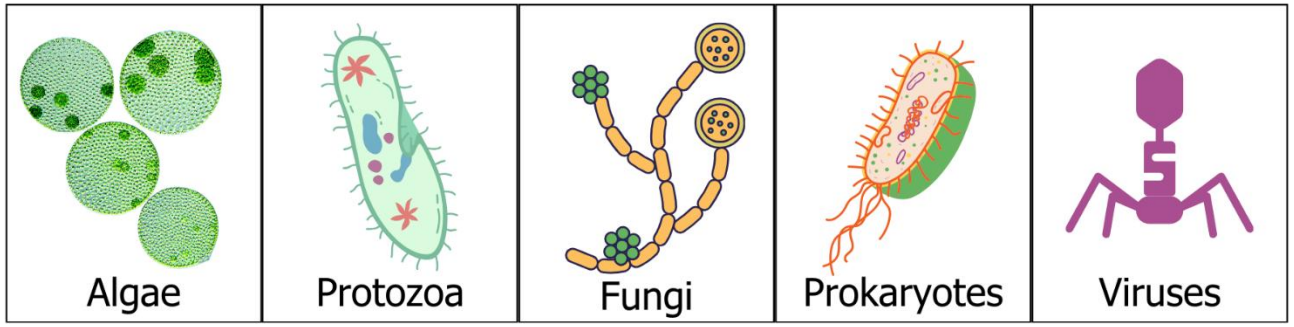
Substances or **microorganisms** including physical, chemical, **biological**, or radiological materials, known or **anticipated in the environment** that may pose **newly identified** **risks** to human health or the environment

https://cec-bio.itrcweb.org/introduction

Defining Biological CEC (BioCEC)

A microbial pathogenic agent that may pose newly identified risks to humans through the environment and is found in water, soil, waste, air, or a vector.

Types of Pathogens (BioCEC)



Created for ITRC. Used with Permission

BioCEC Versus Chemical CEC

- Less familiarity with BioCEC
- Analytical methods (culture based vs. molecular)
- Viability, growth, and transmission in environment
- Mass balances do not work on BioCEC
- A large number of key variable influence BioCEC transmission and disease

Anywhere US News Headline

XYZ company recalls nearly 245,000 pounds of ABC Product tied to listeria outbreak

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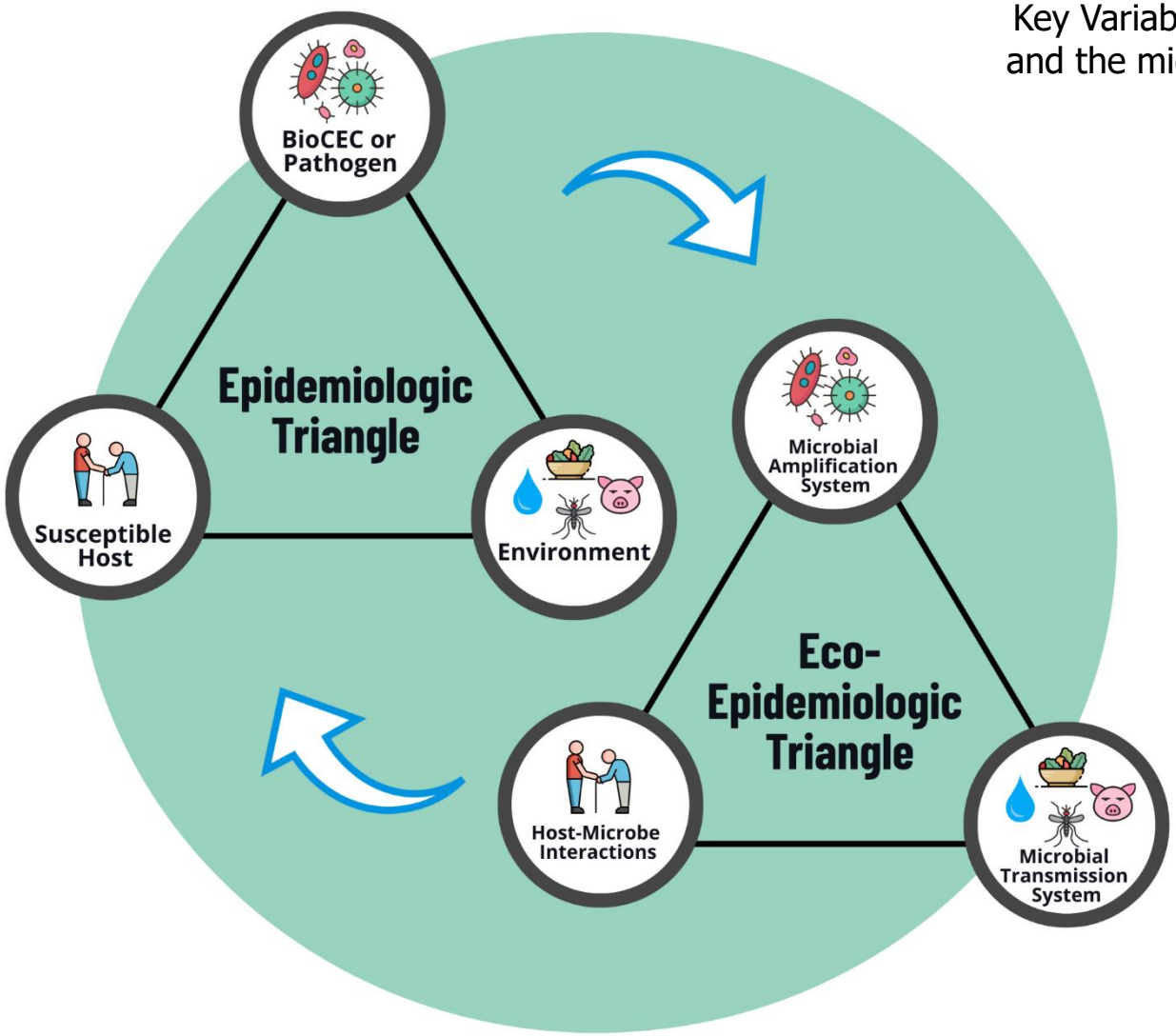
Variables that Influence Transmission



Key Variables Figure 2. The epidemiologic triangle and the microbiological eco-epidemiologic triangle.

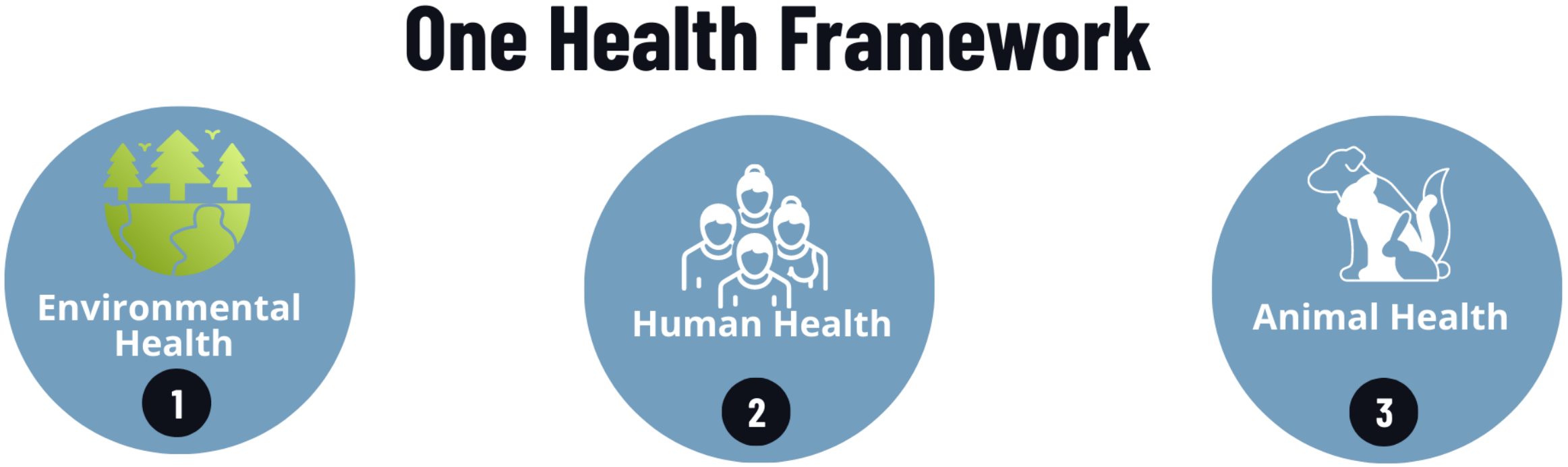
Why You Need to Understand Key Variables

- There are many potential BioCEC, but not all BioCEC present the same risk to human health or the environment

- We want to use key variables to help assess risk from BioCEC
  - **Outcome:** Severity from mild infection to death
  - **Scale:** Single infection versus outbreak
  - **Prediction:** Empirical vs. Theoretical Risk

- Key variables help develop targeted strategies for monitoring, controlling, and preventing outbreaks

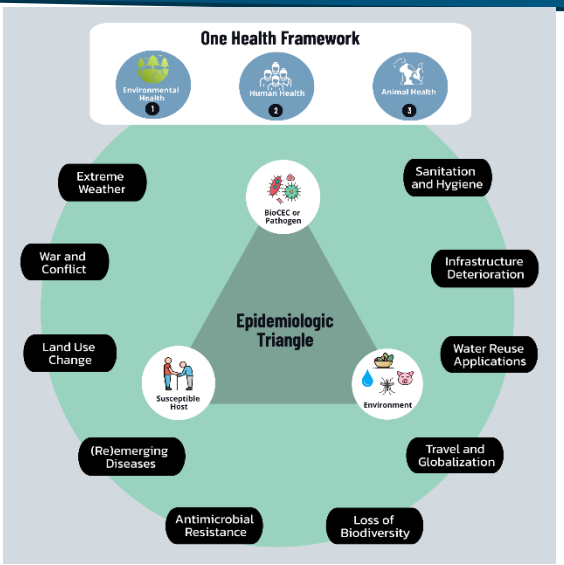
One Health Framework



One Health links human, animal, and environmental health to understand disease transmission comprehensively.

Key Variables Figure 1. Variables that influence the transmission of biological contaminants of emerging concern in the One Health framework. (Reference: https://www.cdc.gov/one-health/about/index.html)

Understanding the Epidemiologic Triangle



Key Variables Figure 1. Variables that influence the transmission of biological contaminants of emerging concern in the One Health framework.

(Reference: https://www.cdc.gov/one-health/about/index.html)

https://cec-bio.itrcweb.org/key-variables

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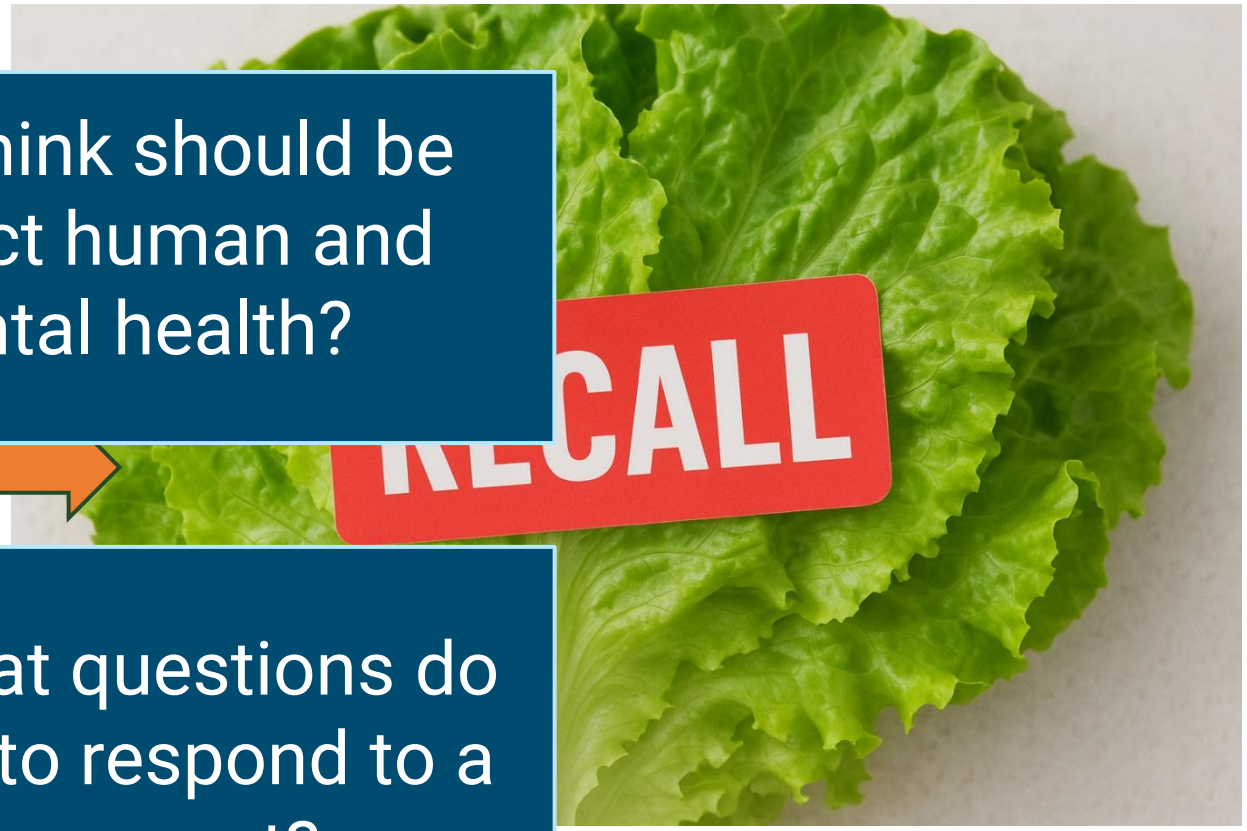
Approaches to managing and controlling risk from BioCEC

CAFO image: OpenAI. Response to "cattle farm with lagoon next to lettuce field." ChatGPT-4.

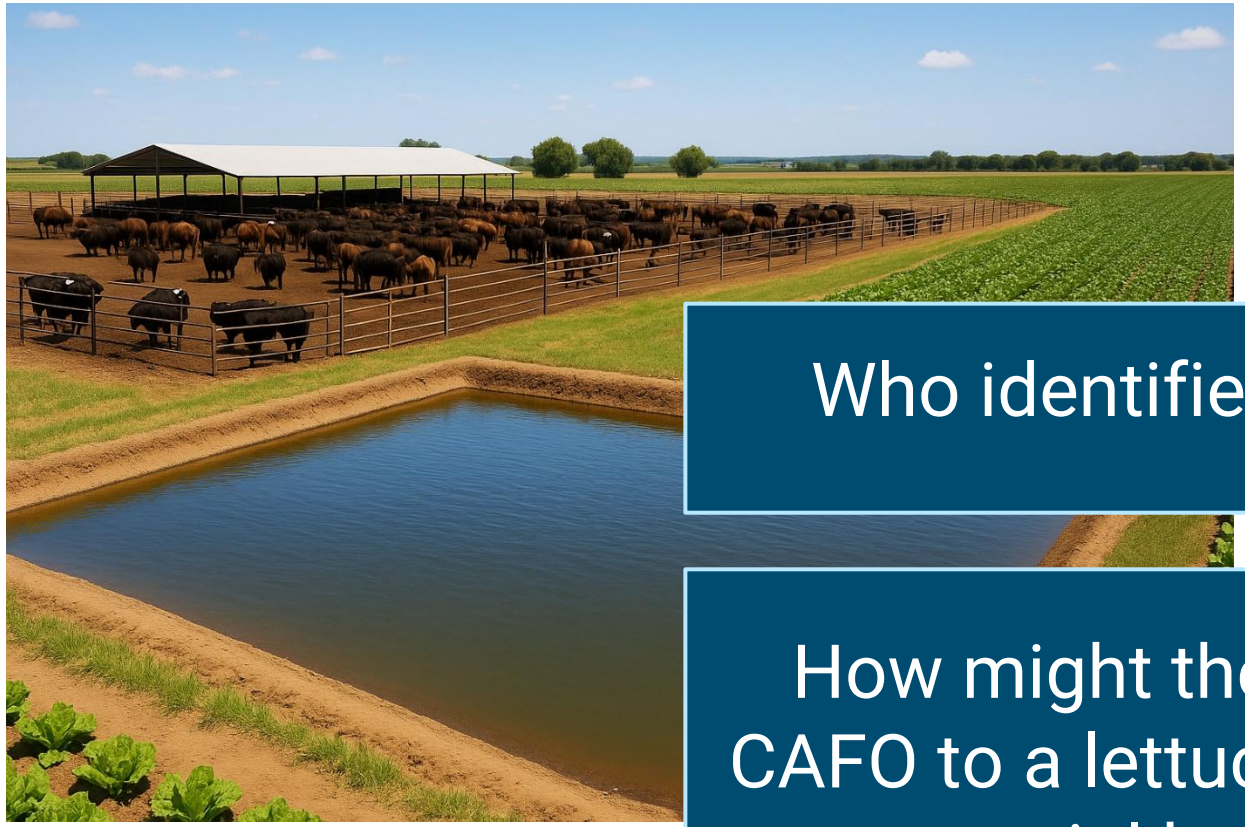
What do you think should be done to protect human and environmental health?

Brainstorm: What questions do we need to ask to respond to a transmission event?



Lettuce image: OpenAI. Response to "lettuce with recall label." Copilot.

Approaches to managing and controlling risk from BioCEC



CAFO image: OpenAI. Response to "cattle farm with lagoon next to lettuce field." ChatGPT-4.

Who identifies the concern?

How might the proximity of a CAFO to a lettuce farm present a potential health concern?

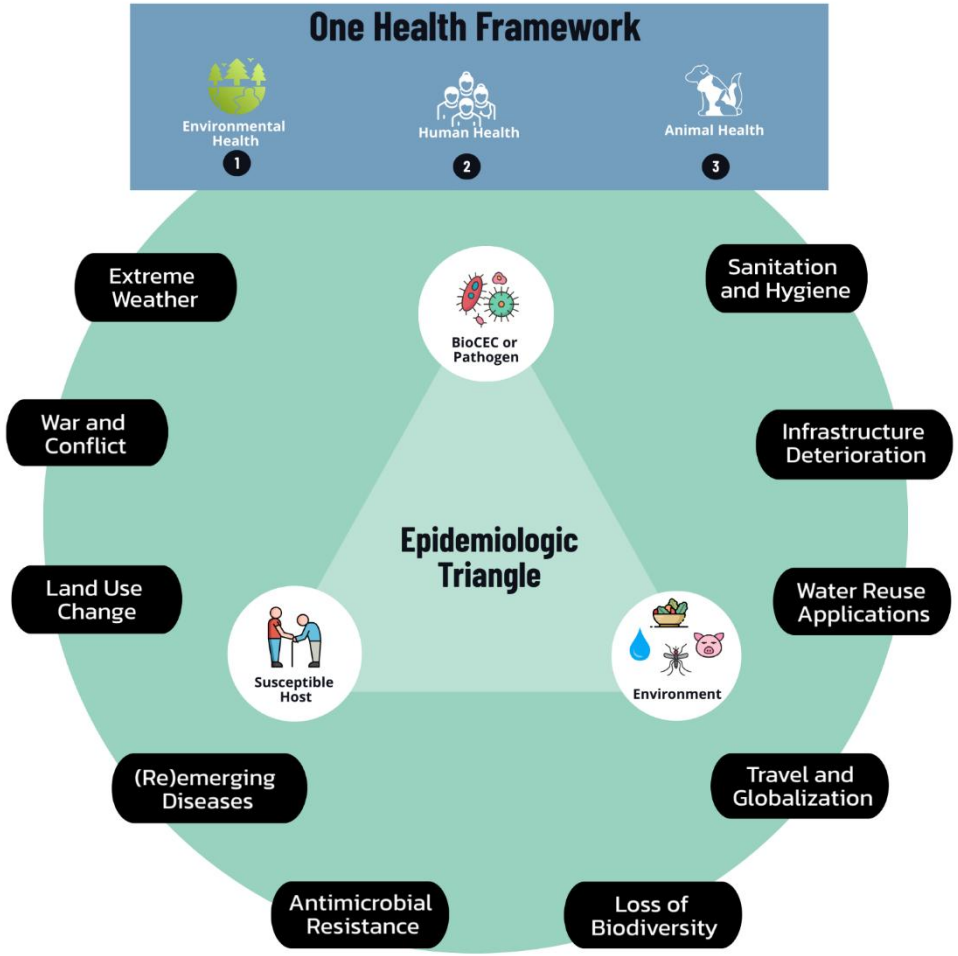
Lettuce image: OpenAI. Response to "lettuce with recall label." Copilot.

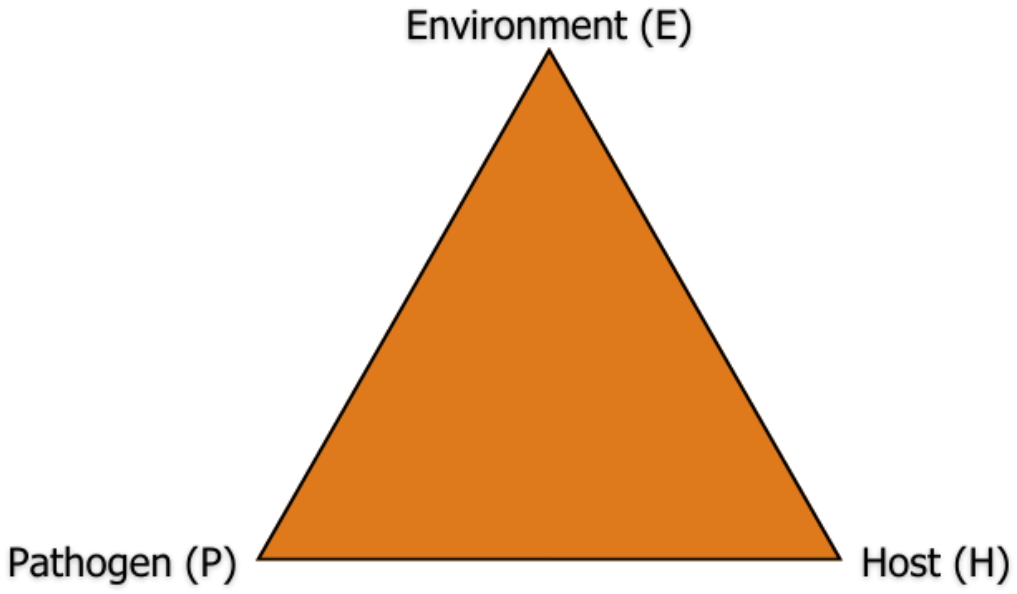
Conceptual Exposure Models (CEMs)

- A CEM can be a proactive or reactive approach to controlling and mitigating risk from a BioCEC
- Identifies potential pathways of BioCEC transmission in the environment using the **Epidemiologic Triangle**
- It uses **One Health data** (i.e., the public health and environmental) to identify the likelihood of BioCEC transmission from a source to a host
- A **CEM** is the equivalent of a CEC Mass Balance

Health Framework to CEM

Introduction Figure 1. Variables that influence the transmission of biological contaminants of emerging concern in the One Health framework.

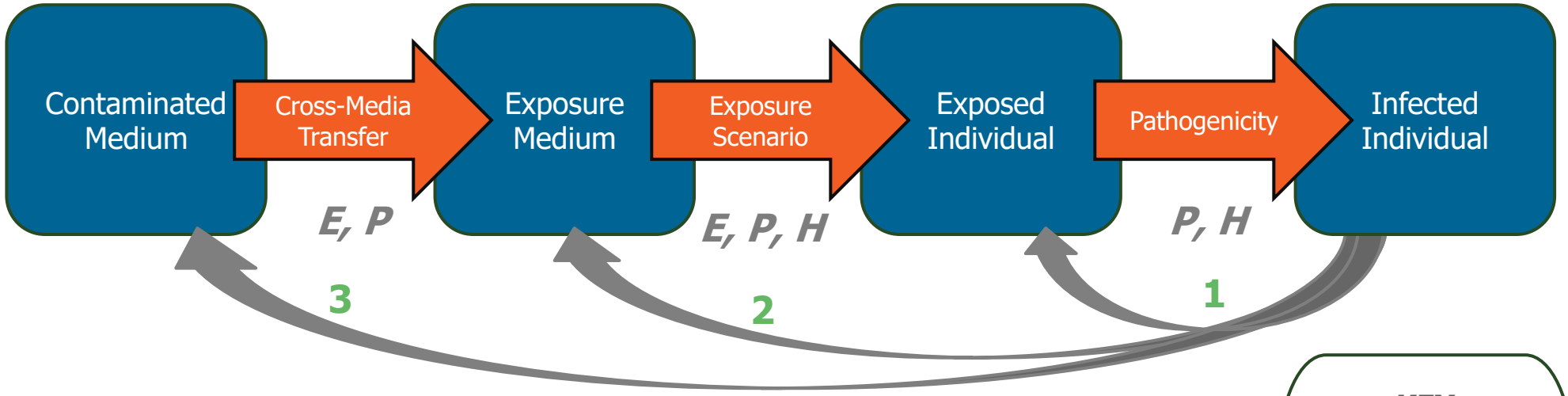




CEM Figure 1. The epidemiologic triangle

General Conceptual Exposure Model

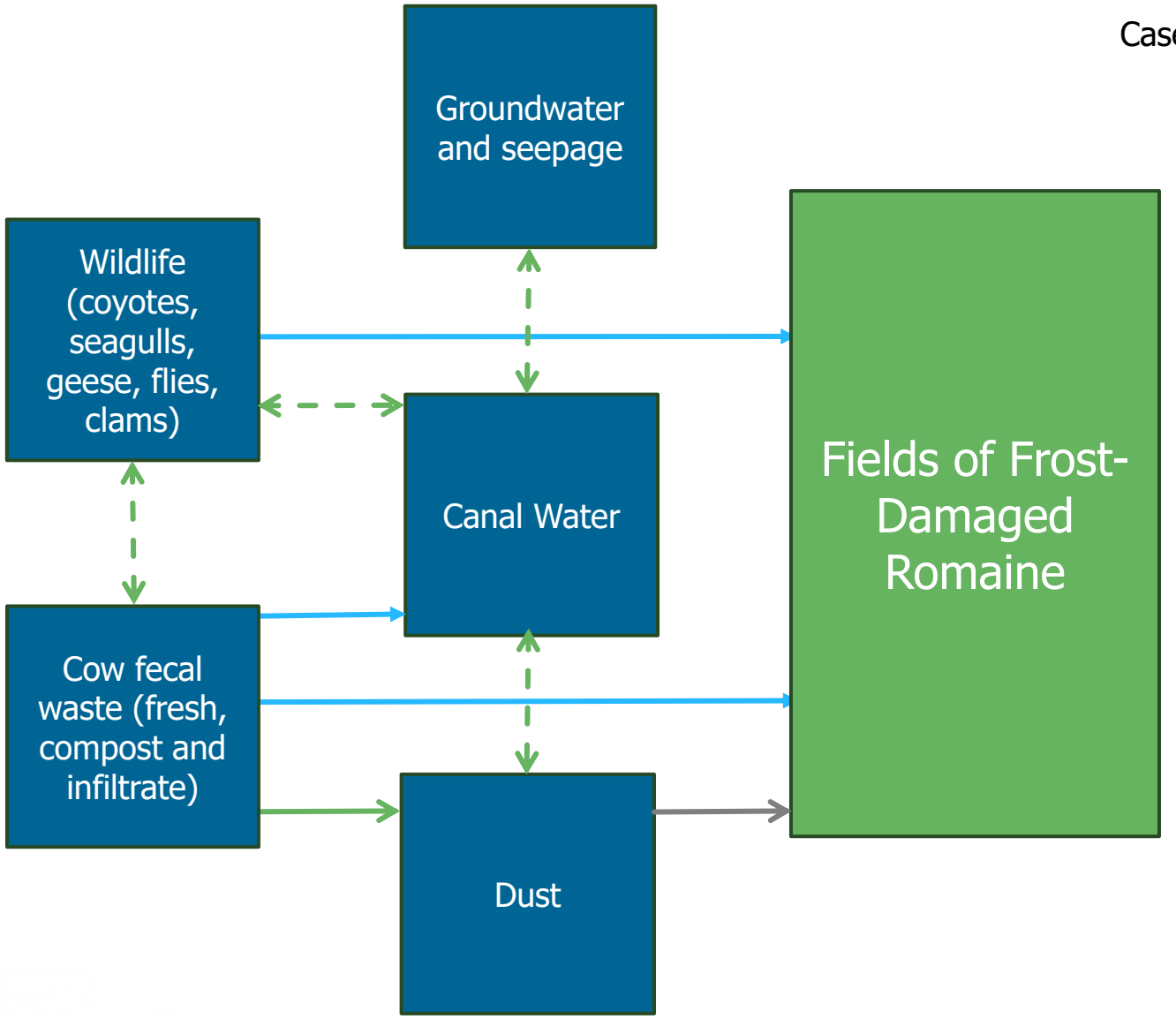
CEM Figure 2. General conceptual exposure model.



CONTROLS:

1. ***Pre-/Post-Exposure Control (e.g., immunization)***
2. ***Exposure Control (e.g., access controls, mitigation)***
3. ***Source Control (e.g., treatment, removal)***

CAFO – AZ DEQ Investigation



Case Studies Figure 8. Potential transmission pathways. *(reworked)*

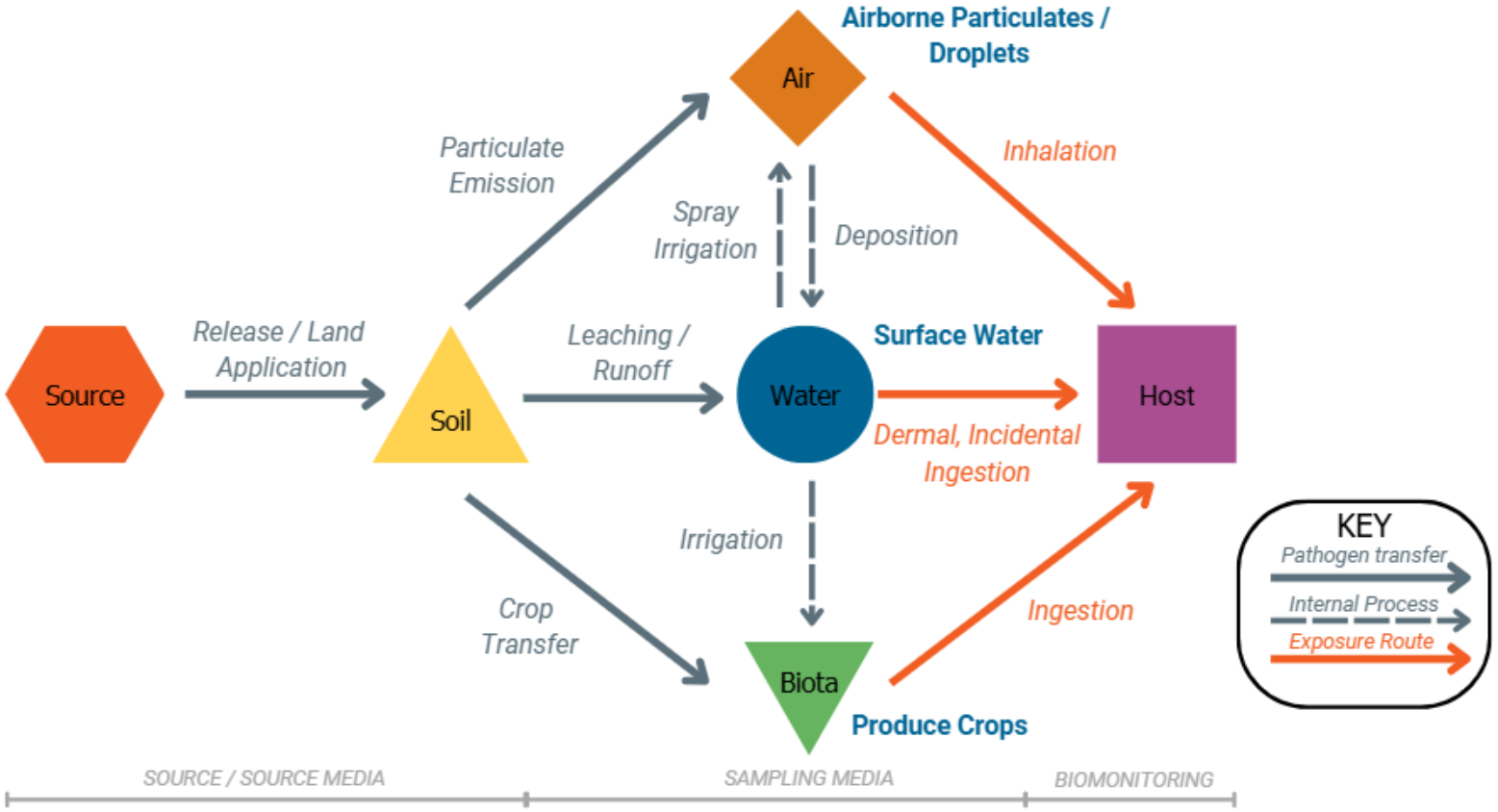
Arrow Key
Blue = Confirmed Pathway
Gray = Rejected Pathway
Green = Potential Pathway

Solid = Data and/or Observations
Dashed = No Data and/or Observations

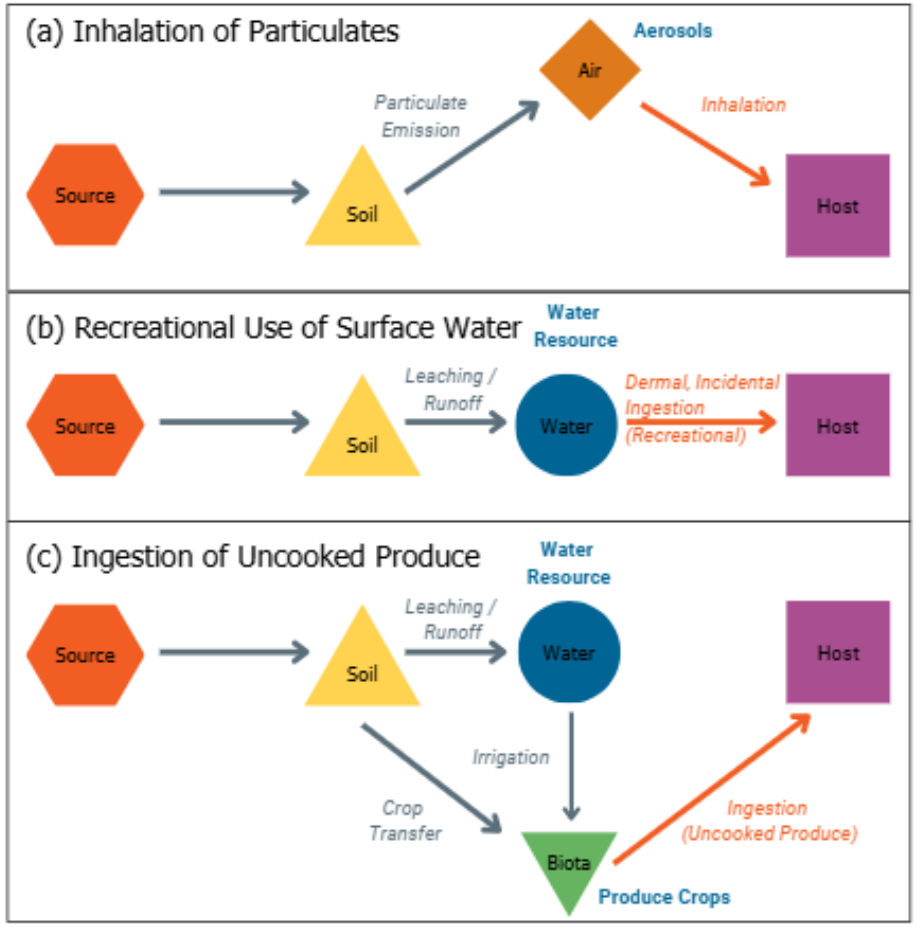
https://cec-bio.itrcweb.org/case-studies/#2

General CEM: Biosolid Application

CEM Figure 3. Biowaste release to soil / land application of Class B biosolids (Example 1).



CEM Figure 4. Individual exposure pathways within a conceptual exposure model (Example 1).



https://cec-bio.itrcweb.org/conceptual-exposure-model/#4

E. coli outbreak linked to lettuce

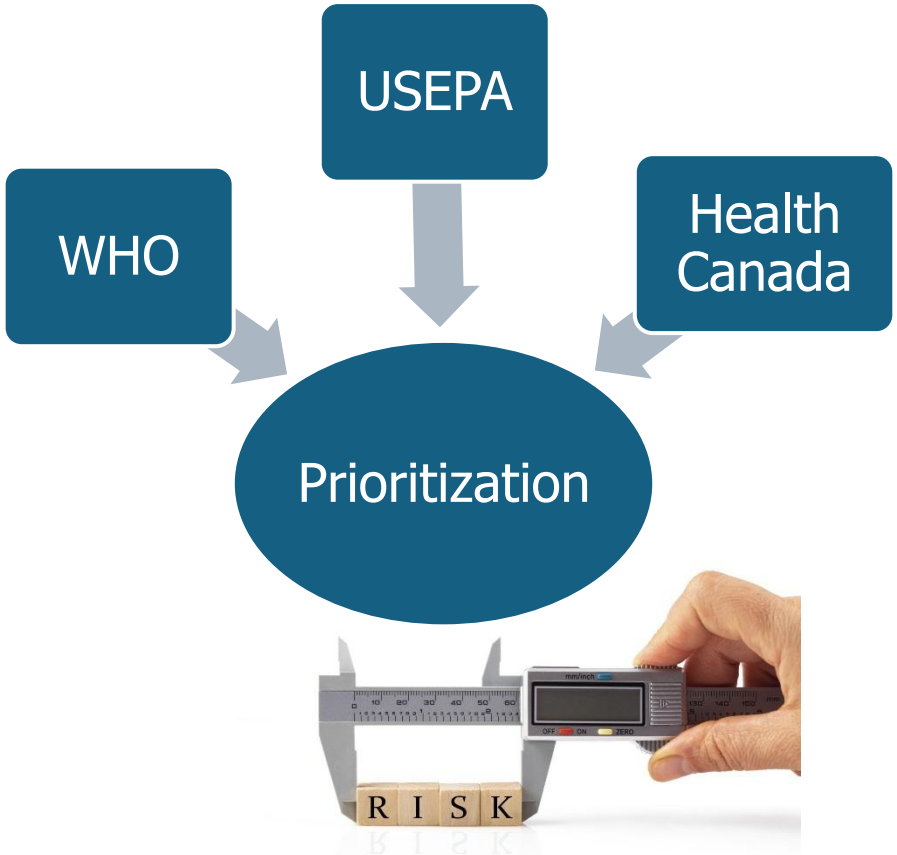
How do we prioritize control strategies?

CAFO image: OpenAI. Response to "cattle farm with lagoon next to lettuce field." ChatGPT-4.

Lettuce image: OpenAI. Response to "lettuce with recall label." Copilot.

Prioritization Tools to Control Risk

- Use the identified key variables to characterize risk from BioCEC
- Three main prioritization approaches discussed in the BioCEC Guidance
- Choice of tool depends on expertise and data availability



Sanitary Inspection or Survey

- On-site visual evaluation of observable features, conditions, or documents
- Includes using standardized forms, checklists
- Identify causes and pathways of contamination and control options
- Helpful in rural and small communities
- Useful to inform regional or national priorities for improving small supplies

Risk Matrix

- Qualitative or semi-quantitative risk approach
- Likelihood that a hazardous event will occur and the severity or consequence of the hazard
- Combines them into a risk score or risk rating
- Heavily relies on expert judgement
- Adaptable to different levels of detail, matrices or impacts of interest

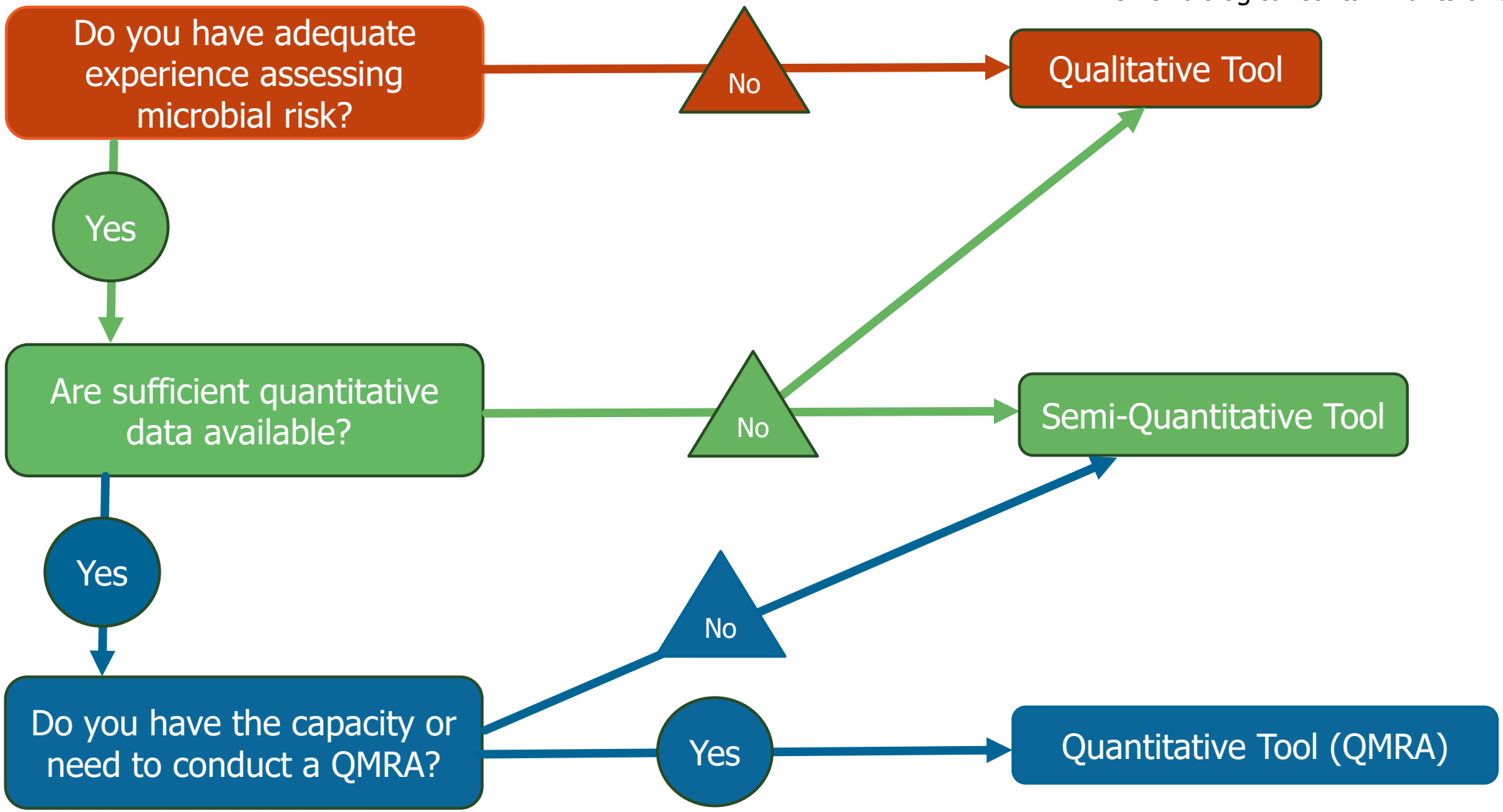
Quantitative Microbial Risk Assessment (QMRA)

- Highly specialized approach with four steps
- Relies on significant amounts of expertise and data
- Uses sensitivity analyses to account for variability and uncertainty
- Uses regulatory agencies, scientists, and others
  - Quantifies the health risks from exposure to microorganisms in environmental matrices
  - Compares the calculated probability against a benchmark acceptable level

Key Variables Figure 6. The World Health Organization quantitative microbial risk assessment framework.

How to Select the Right Tool for Your Scenario

Key Variables Figure 9. Approaches applied to assess the risk of biological contaminants of emerging concern.



https://cec-bio.itrcweb.org/key-variables/#1

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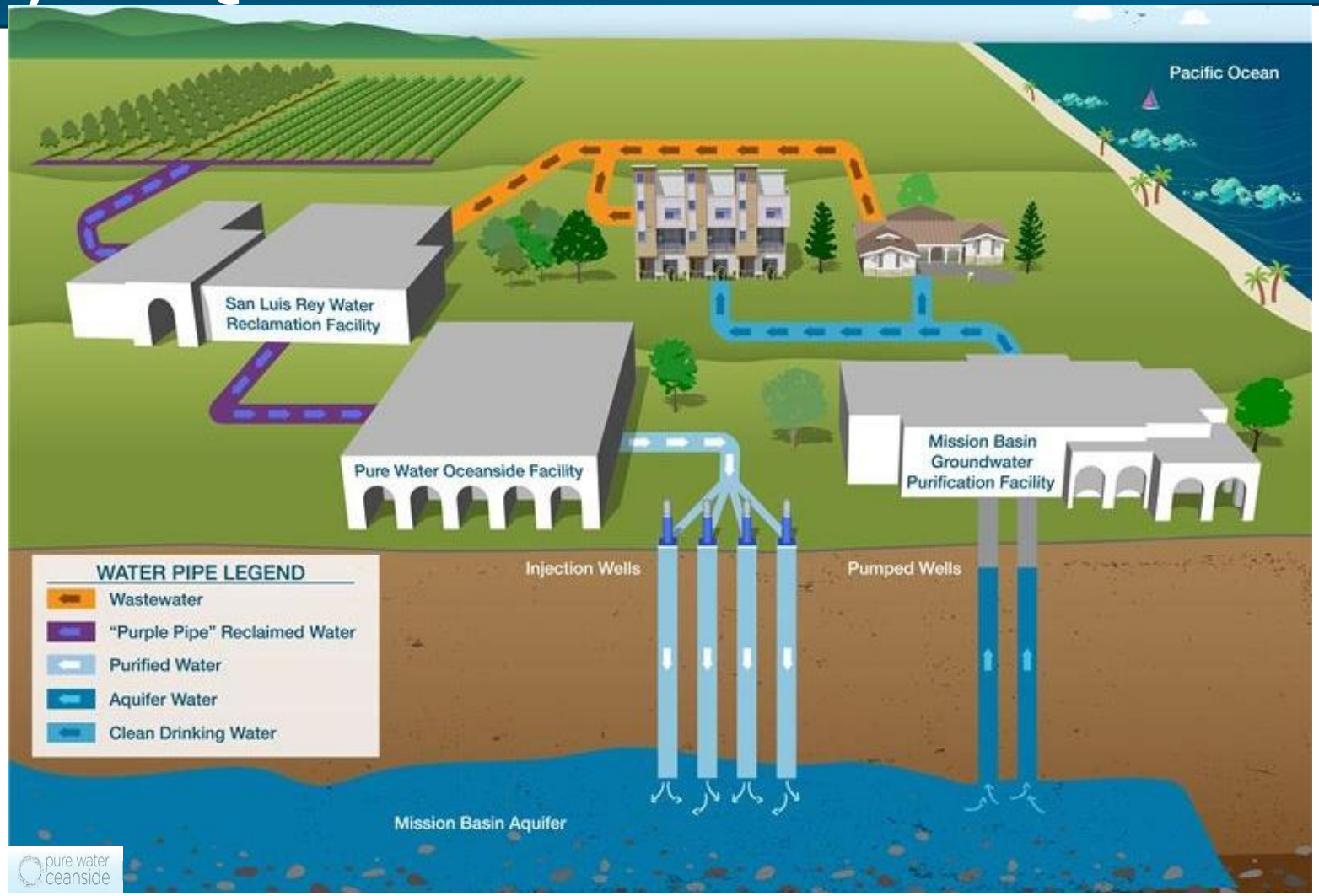
Case Study 1: Extreme flooding after Hurricane Helene

- Extreme weather events increase risk of exposure to biological contaminants
- Federal, state, and local agencies critical for recovery and public health protection.

ntroduction Figure 2. Aerial photo of floodwater inundating the Asheville River Arts District along Foundy Street on September 27, 2024
Source: Tim Reaves Photography 2024 used with permission.

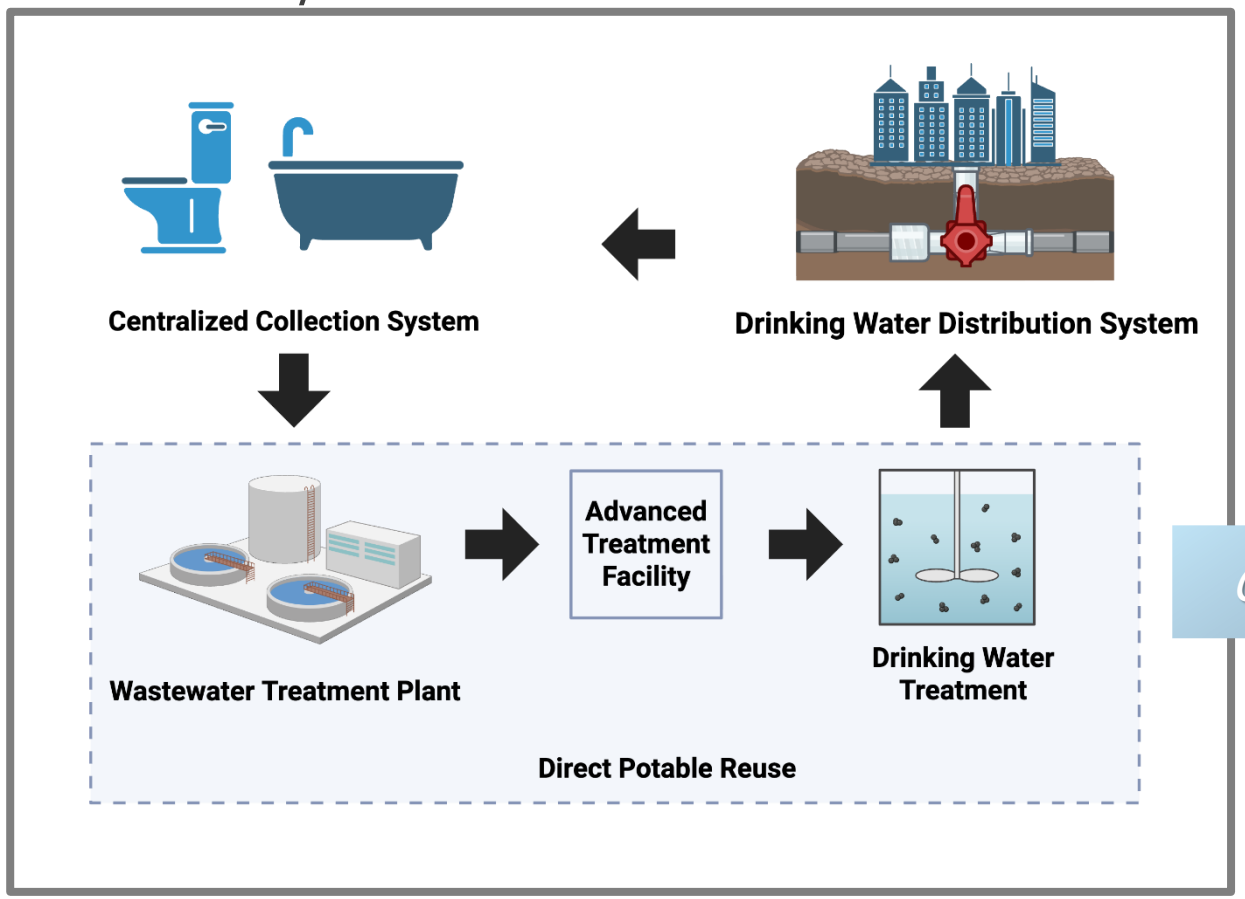
Case Study 2: QMRA for Indirect Potable Reuse (IPR)



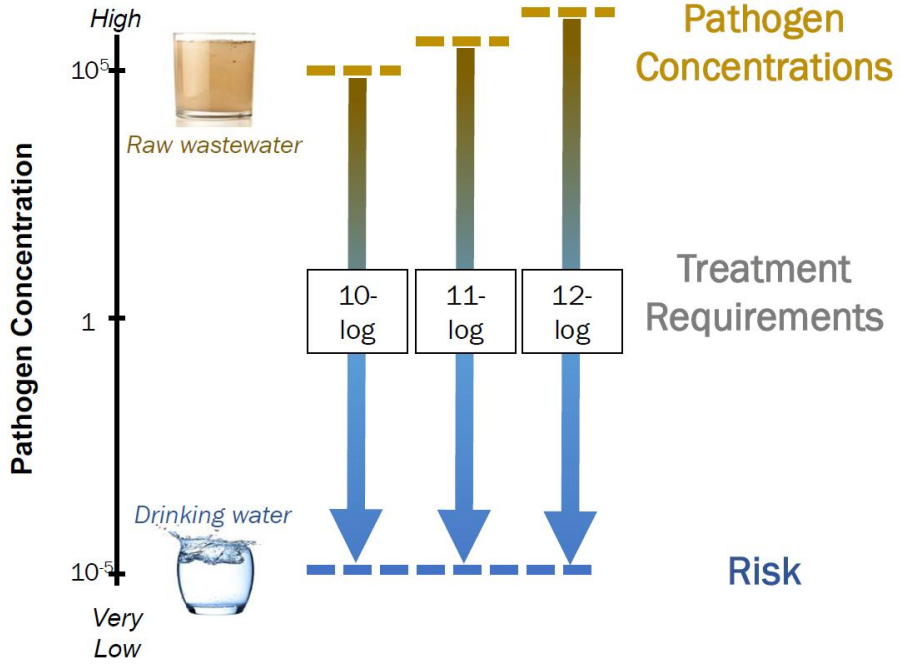
Source Image: https://www.cwea.org/news/pure-water-oceanside-makes-history-as-first-water-reuse-project-in-san-diego-county/

Case Study 3: QMRA in Direct Potable Reuse (DPR)

"Toilet to Tap"



QMRA*



Case Studies Figure 11: Direct potable reuse pathogen risk. Source: Pecson et al. 2021 The Water Research Foundation Pecson et al. 2021

** Quantitative Microbial Risk Assessment*

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  - Key Variables

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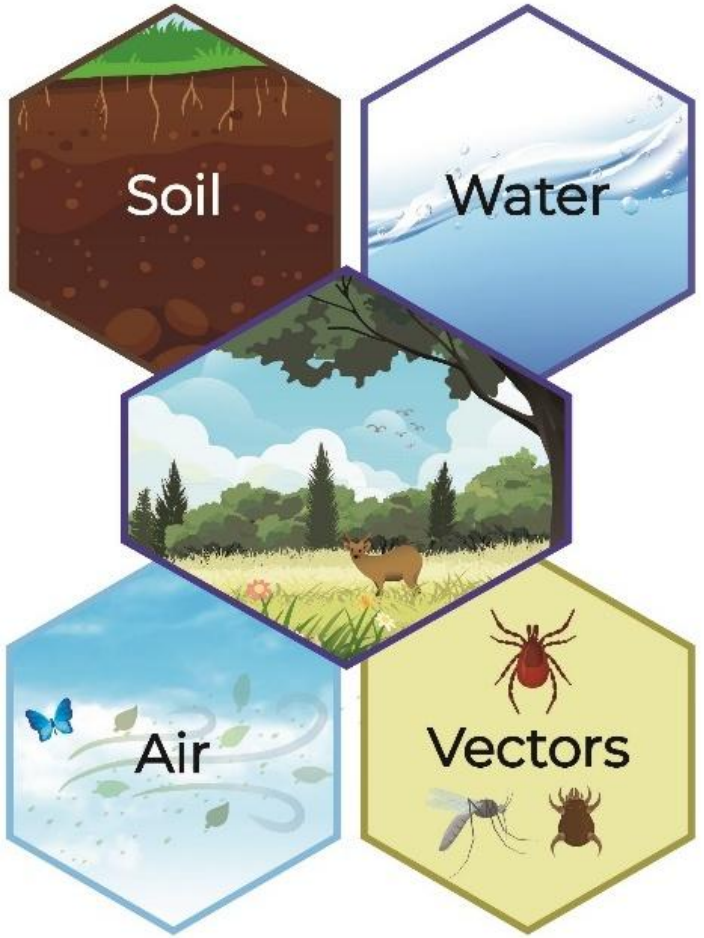
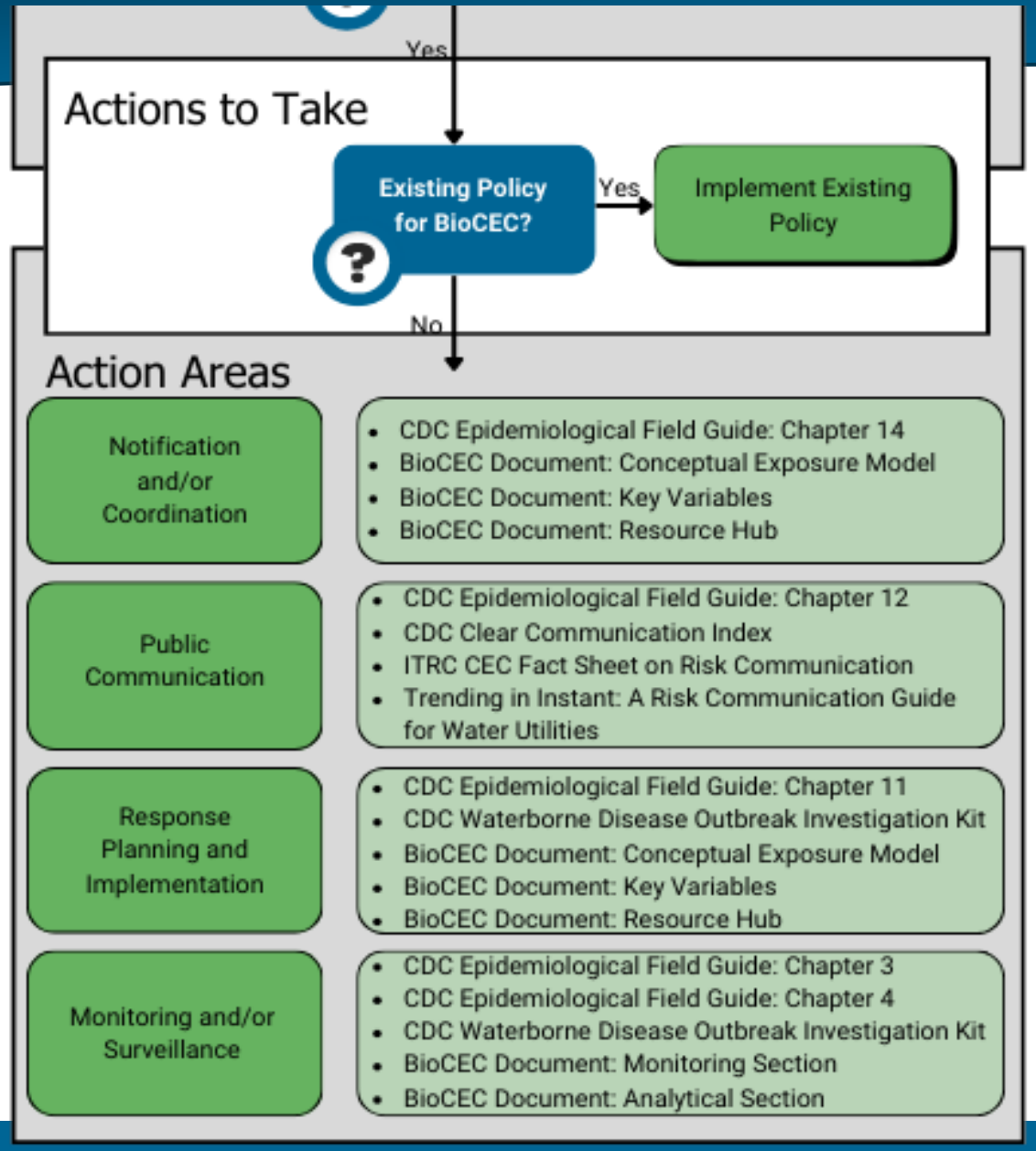
- Process Guide
- Monitoring Programs



Analytical Methods Figure 1. Graphical depiction of environmental matrices.

The Process Guide

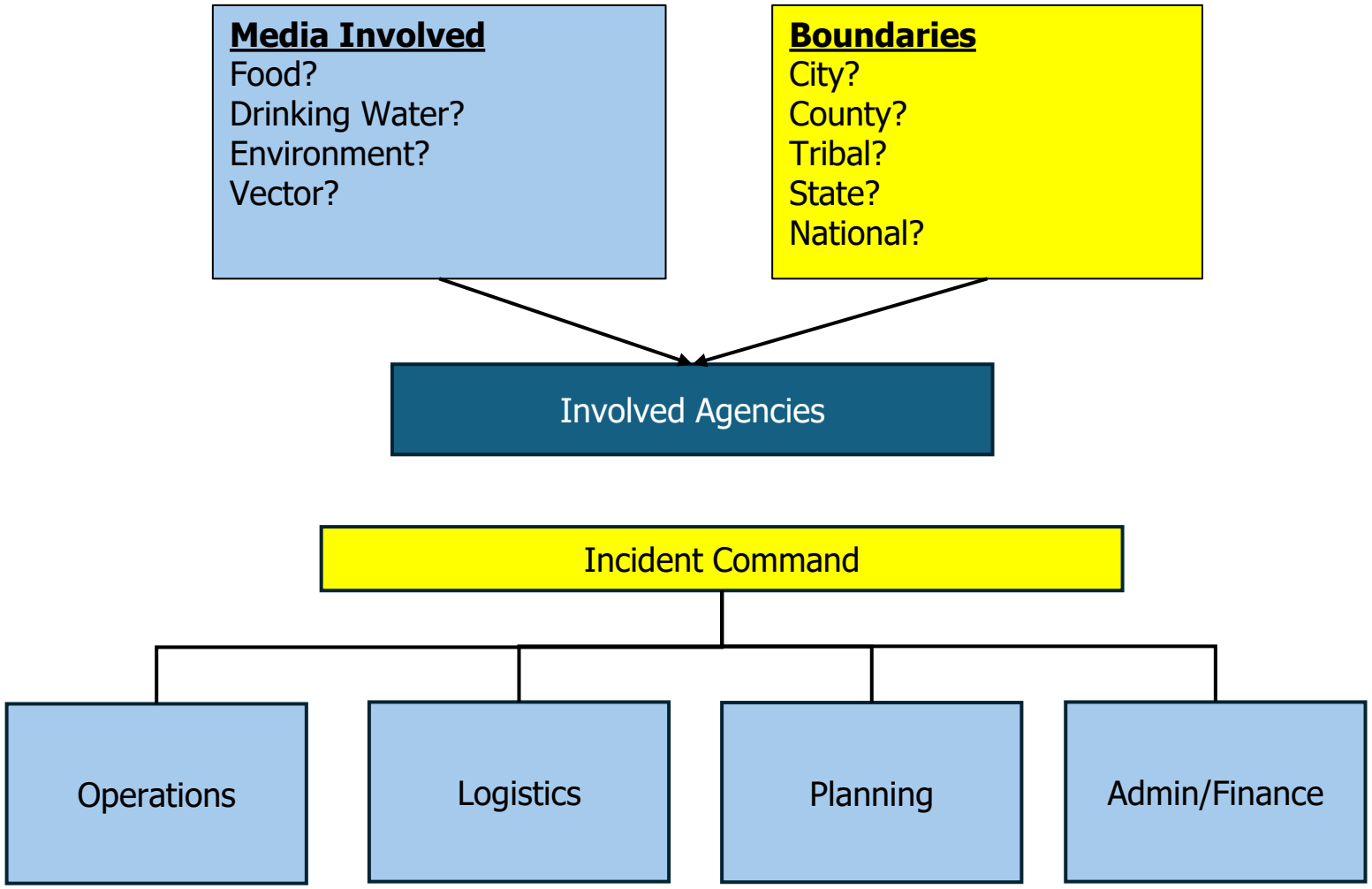
1. Identification and Evaluation (complete)
2. Taking Action
   - Notification and Coordination
   - Public Communication
   - Response Planning and Implementation
   - Monitoring and Surveillance



Process Guide Figure 1. Process Guide components, flow, and key references.

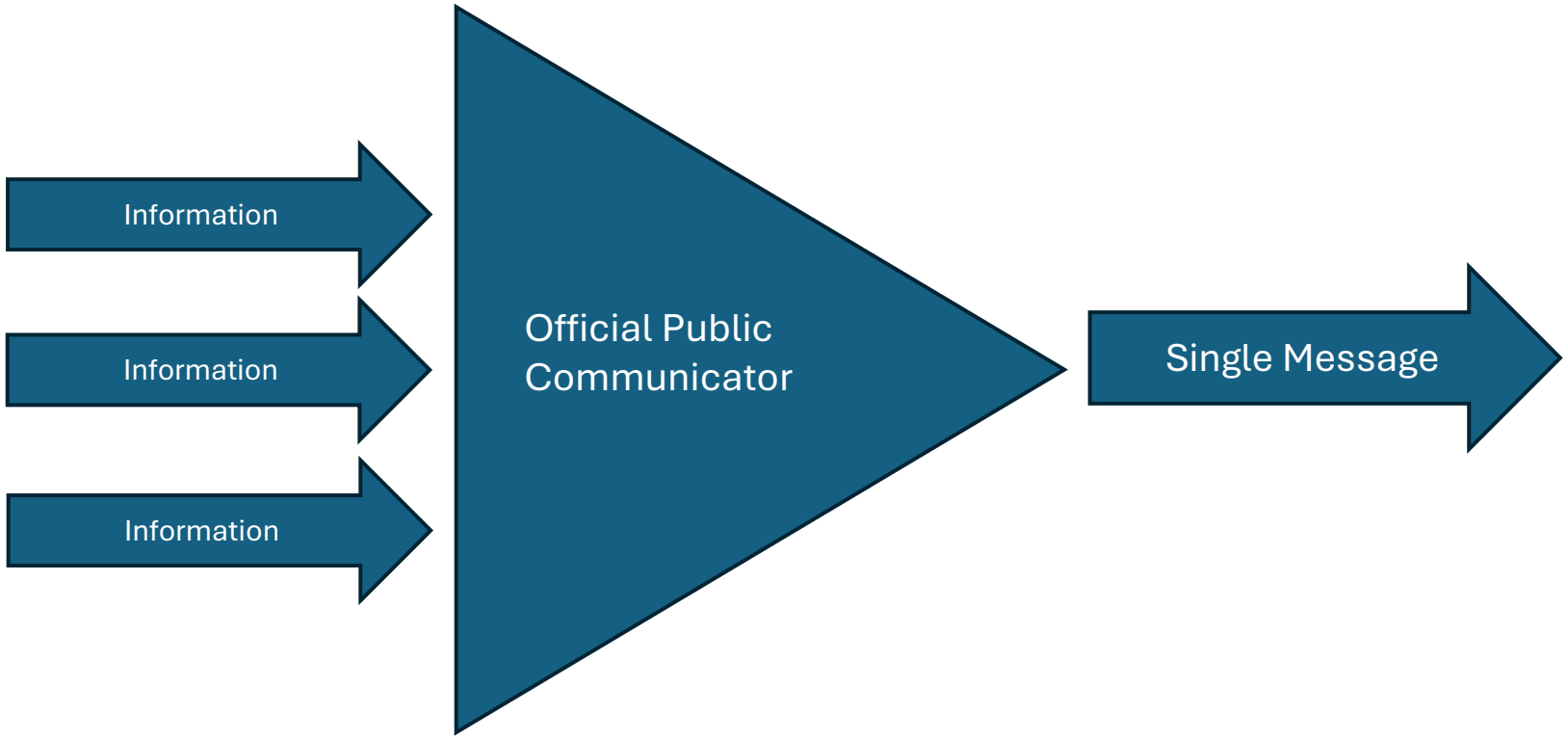
Notification and Coordination

- ✓ Get smart
- ✓ Determine jurisdiction
- ✓ Get connected



Public Communication

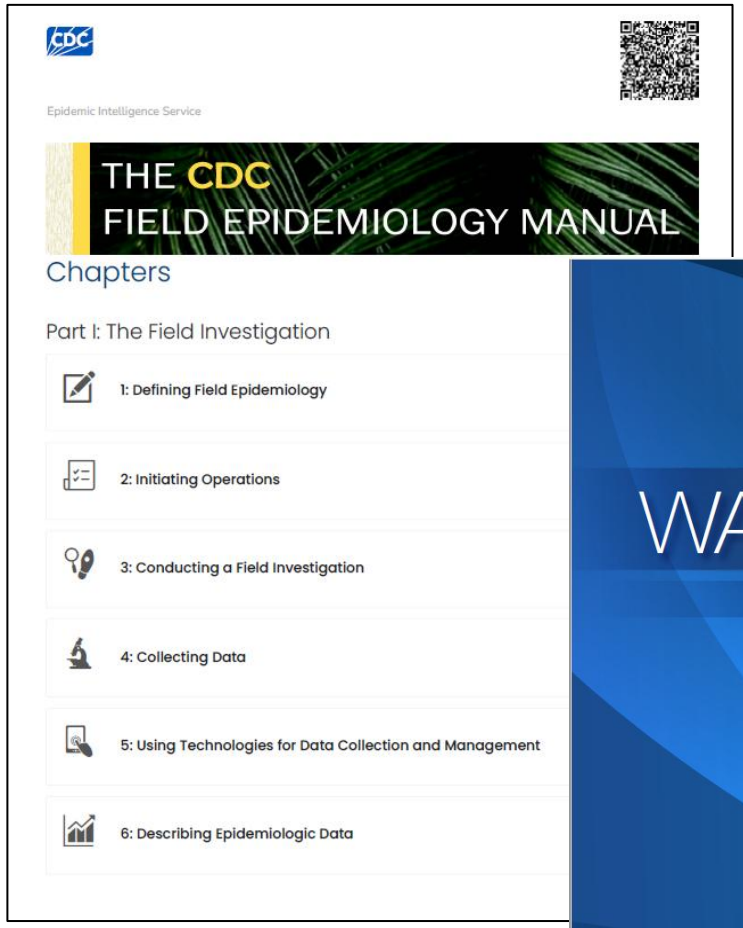
- ✓ Clear agency roles
- ✓ Effective message
- ✓ Build trust through consistency

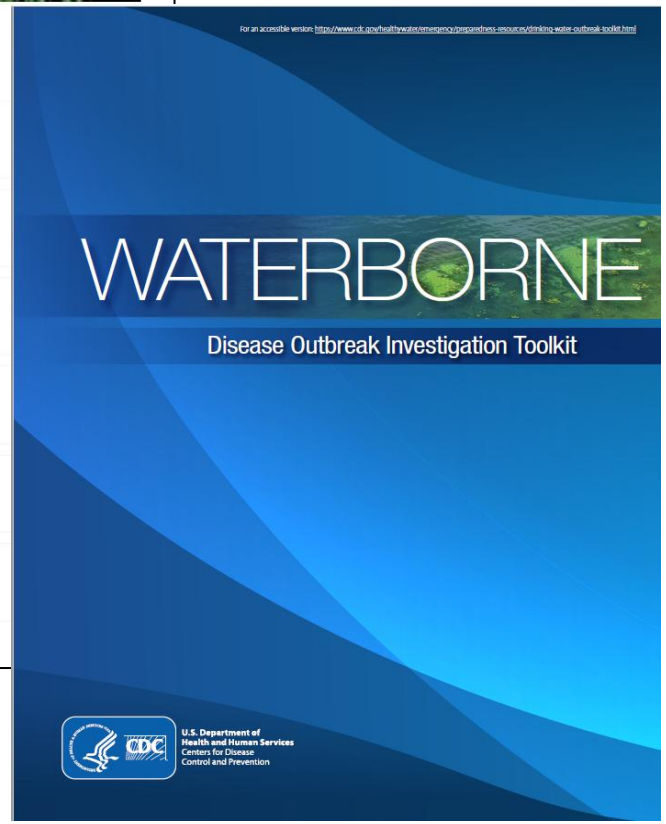


Planning and Implementing a Response

Comprehensive response plan

- ✓ Science-driven and adaptive
- ✓ Plans agency coordination, jurisdiction, and communication
- ✓ Considers potential severity
- ✓ Accounts for existing guidance
  - CDC Field Epidemiology Manual and CDC Waterborne Disease Outbreak Toolkit





Monitoring Programs and Resources

	A	B	C	D	E	F	G	H
1	Monitoring Program Name	Organization Name	State Location/ Federal	Pathogen/ Toxin Monitored	Media (As per BioCEC Definition)	Media (broad)	Program Description	Link
2	Ambient Monitoring System	North Carolina Department of Environmental Quality	NC	Fecal coliform	Water	Water	Since the 1960s, the Ambient Monitoring System has collected water quality data in North Carolina's 2.2 million acres of estuarine waters and ~38,000 miles of freshwater creeks, streams, and rivers. The Ambient Monitoring System consists of a relatively static network of more than 300 stations located in all 17 major river basins. These stations provide site-specific, long-term water quality information on significant rivers, streams, and estuaries. Stations are visited at least quarterly year-round for collection of chemical, physical, and bacterial pathogen characteristics of the water column.	https://www.deq.nc.gov/about/divisions/water-resources/water-sciences/ecosystems-branch/ambient-monitoring-system-ams
3	Arizona's Wastewater Surveillance Program	Arizona Department of Health Services	AZ	Multiple	Water	Wastewater	Monitoring wastewater allows for early detection of a pathogen that may be circulating within a community. We can detect pathogens in feces shortly after a person has been infected, even when they are asymptomatic (not experiencing any symptoms). Samples are collected from wastewater treatment sites and sent to a laboratory for testing. Current targets being tested for are adenovirus, *Candida auris* , coronavirus, enteroviruses, hepatitis A, influenza A, influenza B, respiratory syncytial virus, mpox, and norovirus. The targets may vary by who is performing the testing and where they are located.	https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-services/wastewater-surveillance/index.php
4	Association of Public Health Laboratories	Association of Public Health Laboratories (APHL)	Federal/ international	Multiple	Multiple	Wastewater, water, human and animal tissue, and blood serum	APHL builds public health lab capability to detect, identify and respond to infectious disease threats including Cyanotoxins, SARS COVID-2, antimicrobial resistance genes, influenza, mpox, Norovirus, polio, vector-borne diseases, oropouche, dengue, Lyme, Colorado tick fever, Eastern equine encephalitis virus, Jamestown Canyon Virus, LaCrosse, Powassan, St. Louis encephalitis, West Nile, etc.	https://www.aphl.org/programs/infectious_disease/Pages/default.aspx
5	Automated Disease Surveillance Section	Los Angeles County (LAC), California	CA	All pathogens	Vector	Human health	Syndromic surveillance is a population-based early detection and monitoring system that uses data collected in near real time from emergency departments and other clinical and non-clinical sources. Since 2002, the LAC Department of Public Health (DPH's) Syndromic Surveillance Project has provided timely awareness of disease trends, aided traditional surveillance in monitoring outbreaks, and added to LAC DPH's emerging event detection capabilities. Visit the syndromic surveillance web page for LAC.	http://publichealth.lacounty.gov/acd/adss.htm#:~:text=Automated%20Disease%20Surveillance%20Section&text=ADSS%20monitors%20these%20systems%20daily,health%20in%20Los%20Angeles%20County.
6	BEACH Act Implementation	Wisconsin Department of Natural Resources	WI	*E.coli.* enterococci, others	Water	Surface waters	The Wisconsin Department of Natural Resources works closely with approximately 16 local health departments, university researchers, the State Lab of Hygiene, and the US Geological Survey to regularly monitor and provide online notification of advisories for approximately 107 sites along the shorelines of Lake Michigan and Lake Superior under the BEACH Act, which is implemented by Great Lakes states and coastal state governments.	https://dnr.wisconsin.gov/topic/SurfaceWater/Monitoring.html

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Thank You!

https://cec-bio.itrcweb.org/

Additional ITRC Resources

Contaminants of Emerging Concern Framework: https://cec-1.itrcweb.org/

Managed Aquifer Recharge: https://mar-1.itrcweb.org/

Strategies for Preventing and Managing Harmful Cyanobacterial Blooms (HCB-1): https://hcb-1.itrcweb.org/