From Outbreak to Prevention
Learning from failures and near misses

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Regulator - Outbreak / adverse event inputs

- Interstate outbreaks
- Intrastate outbreaks
- Surveillance sampling programs
- Consumer complaints
- Other adverse event / risk drivers:
  - International outbreaks
  - Compliance data
  - Import sampling
  - Recalls
  - Emerging issues
  - Risk assessments

Photo: www.steamit.com

Food producer - Origin of incident or “near miss” information

- Information from internal programs:
  - Finished product verification data
  - Environmental monitoring data
  - Hygiene audit finding
  - Evidence of control measure deviation or failure
- External contacts:
  - Consumer and customer complaints
    - Call center
    - Social media
    - Regulatory agencies
  - Supply chain
    - Food Service or retail customer
    - Warehouse observation
    - Ingredient supplier
  - Regulatory agencies
    - Enforcement action from manufacturing site or suppler audits
    - Import verification of products upon import
    - Outbreak investigation

Root cause investigation

Collecting information during outbreak / incident response

What is root cause investigation?

- Investigation to determine factors that could have contributed to the introduction, proliferation and transmission of pathogens and other hazards.

What data inform the root cause investigation?

- Investigation of firms / farms, products and all aspects of the manufacturing process, including environment
- Traceback information
- Firm inspections
- Firm records and verification data
- Analysis of products, ingredients and the environment

Photos: Natalie Brasilli UAX; 155675038 | Inspection © Lacheev | Dreamstime.com

Root cause analysis

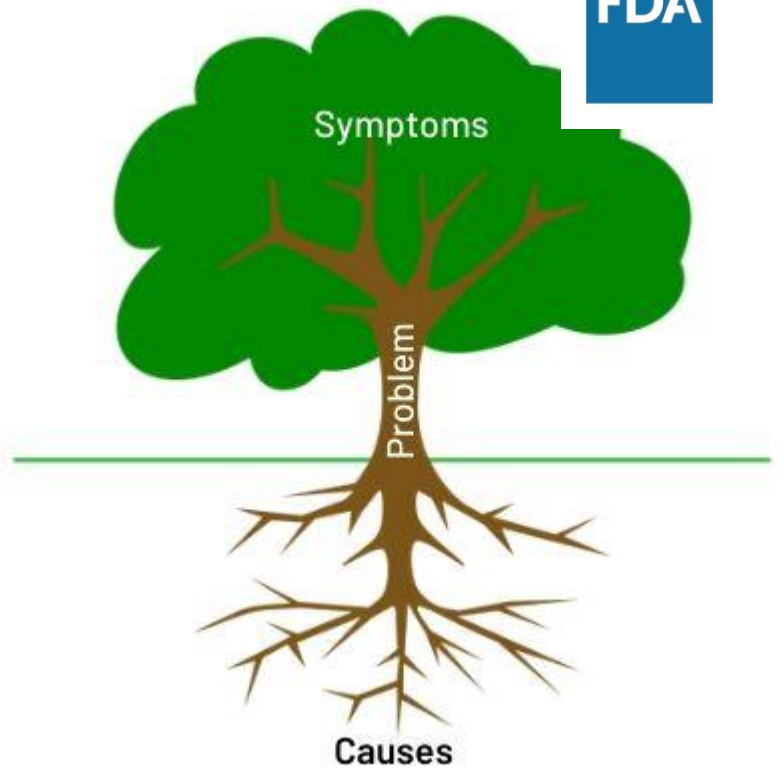
Digging for more after an outbreak

What is root cause analysis?

- Retrospective investigative method;
- Used to determine how the root cause/s of a trigger event occurred and provide information for determining what actions can be taken to eliminate the root cause and preventing a recurrence of the trigger event.

What data inform the root cause analysis?

- Information collected during the outbreak / root cause investigation;
- Scientific literature;
- Expert elicitation.



Photos: www.zentools.com; www.gitmind.com

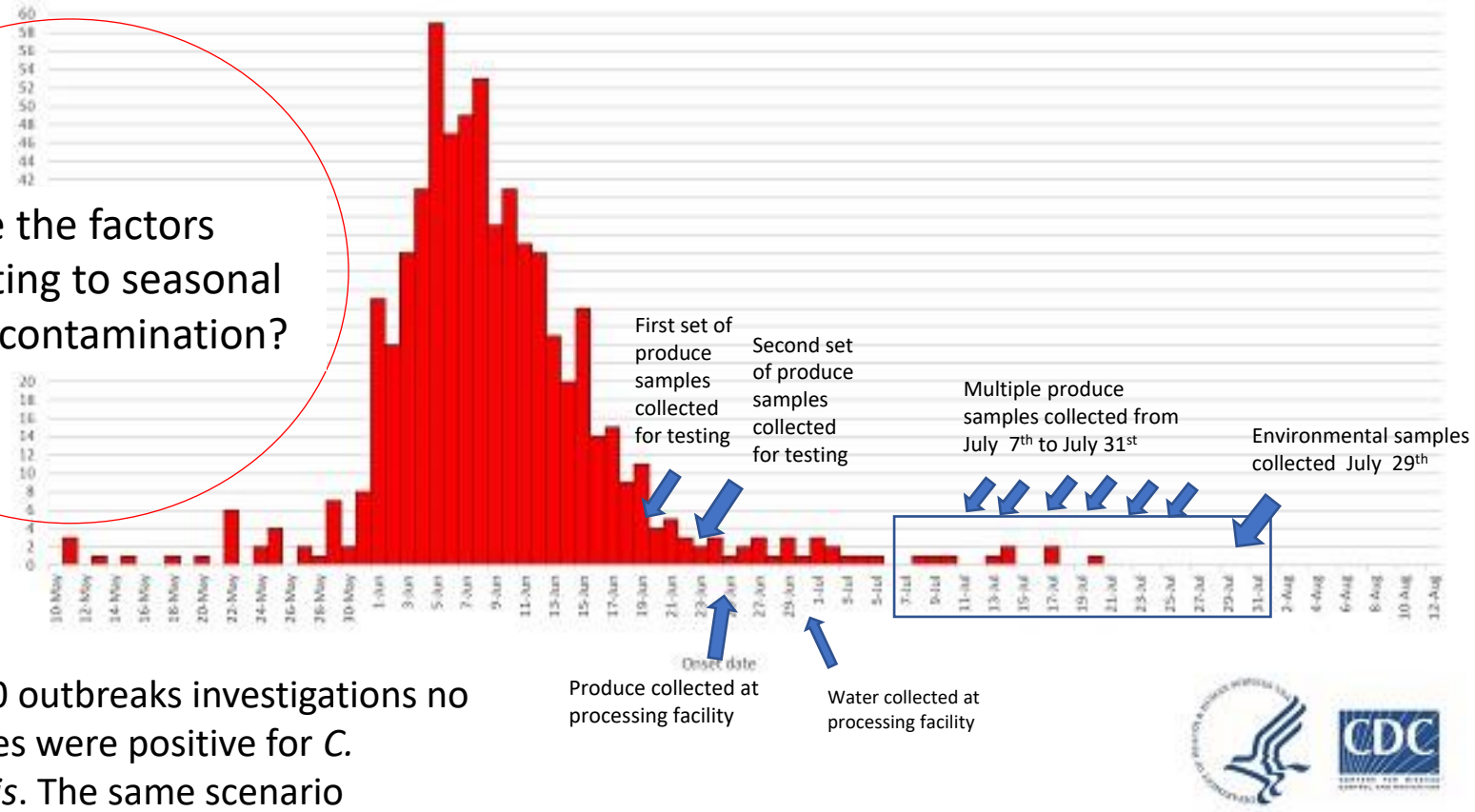
Challenges to RCI and RCA

- Often outbreak / issue investigations are conducted after the outbreak / issue is over
- Issue investigations are usually retrospective
- Analytical testing is statistically limited and often inconclusive
- Fresh produce has short shelf lives and may not be available for analysis
- In multi-component or assembled products, supply chain is often complex
  - Relationship sophistication of others in the supply chain
  - Manufacturers, retailers, distributers may source from a variety of growers / suppliers
  - Importance of traceability scope, accuracy and precision
- Many processes are complex
  - Swiss cheese model
- Limited tools for analysis of some agents
- Insufficient evaluation of underlying causes

Outbreak of *Cyclospora* Infections Linked to Bagged Salad Mix

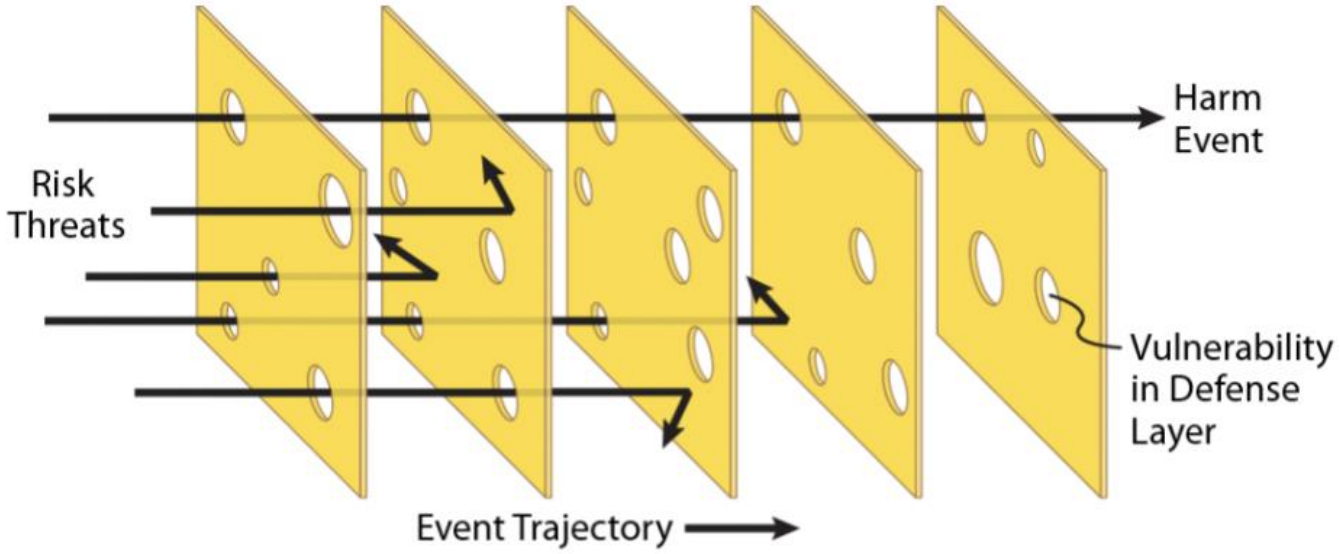
Domestically Acquired Cyclosporiasis 2020 – sampling challenges

What are the factors contributing to seasonal produce contamination?



During 2020 outbreaks investigations no food samples were positive for *C. cayetanensis*. The same scenario repeated during the investigations conducted in 2021 and 2022

Accident causation – “Swiss Cheese Model”



PHILOSOPHICAL TRANSACTIONS OF THE ROYAL SOCIETY B
BIOLOGICAL SCIENCES

Volume 327, Issue 1241

Article

The contribution of latent human failures to the breakdown of complex systems

J. Reason

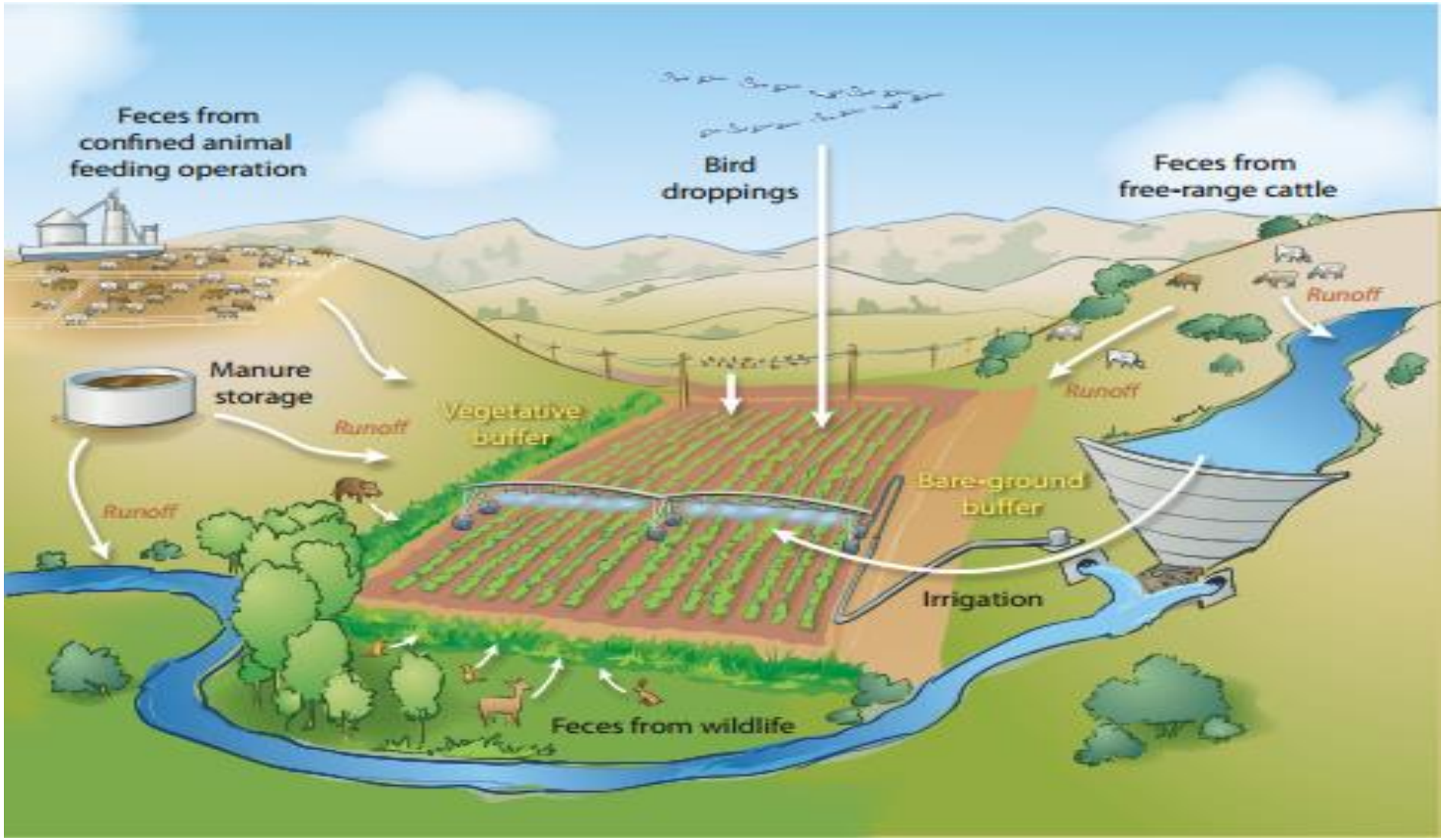
Published: 12 April 1990
https://doi.org/10.1098/rstb.1990.0090

Image: Vanderbuilt University Medical Center
Graphic & Interaction Design Services | Center for Research and Innovation in Systems Science (vumc.org)

Control measures – nursery, growing

- Site risk evaluation and management
- Safety and application of pesticides
- Condition and treatment of irrigation water
- Safety of soil amendments
- Hygienic design and cleanliness of farm equipment
- Proximity to animal production
- Exclusion of wild and domestic animals
- Cleanliness of transport equipment

Factors impacting water risk



Control measures - harvesting

- Protection and handling of primary and secondary packaging
- Hygienic design and cleanliness of harvesting equipment and tools
- Cleanliness and access to bathrooms, hand washing facilities
- Worker cleanliness (clothing, hand-washing)
- Hygienic handling of fruit during inspection, sorting, repacking
- Cleanliness of transport equipment

Control measures – cooling and packing

- Protection and handling of primary and secondary packaging
- Hygienic design and cleanliness of cooling tunnels and storage areas
- Movement of people and materials
- Cleanliness of transport equipment
- Facility pest control

Hygienic design, cleaning and sanitation of equipment

Control measures – storage and distribution

- Hygienic design and cleanliness of product and packaging facilities
- Movement of people and materials
- Cleanliness of equipment
- Hygienic practices of workers
- Inspection and cleanliness of incoming and outgoing transport
- Facility pest control

Control measures – retail and food service

- Cleanliness of transport vehicles
- Hygiene, zoning, and GHP at wholesale markets
- Hygiene, zoning and GHP at customer facilities
- Segregation and management of in store storage and display
- Sanitation and hygiene in food preparation
- Hygiene in re-packing

Challenges and limitations of testing

- Analytical methods for viruses and parasites require specialized equipment and expertise
- Testing of fruit in the field or cooler is statistically limited
  - Only provides information on the sample evaluated.
  - Can only detect a significant contamination event; not low level, sporadic contamination.
  - A “robust” sampling plan (n=60) can only detect contamination in a lot in which >= 10% contam

Statistical power of representative sampling plans (assumes homogeneous distribution)

Samples taken from lot	Proportion of units defective in lot	Probability of detecting that lot is defective	Probability of not detecting that lot is defective
15	0.001 (1 in 1000)	1.5 %	98.5 %
	0.01 (1 in 100)	14 %	86.0 %
	0.1 (1 in 10)	79.4 %	20.6%
30	0.001 (1 in 1000)	3.0 %	97.0 %
	0.01 (1 in 100)	26.0 %	74.0 %
	0.1 (1 in 10)	95.8 %	4.2 %
60	0.001 (1 in 1000)	5.8 %	94.2 %
	0.01 (1 in 100)	45.3 %	54.7%
	0.1 (1 in 10)	99.8 %	0.2 %

Limitations of water testing

- Presence of hygiene indicators does not necessarily correlate with the presence of pathogens
  - Generic *E. coli* in water associated with the Yuma leafy green outbreak ranged from 4 - 53 MPN / 100 mL, even thought the pathogenic strain was present.
- Pathogens present in sediment may not be recovered by water testing
- The microbiological profile of water will change based upon a variety of factors (rainfall, agitation, wild and domestic animals)

U.S. FOOD & DRUG ADMINISTRATION

The FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Rule)

April 4, 2023







RCA tools to assist with evaluation of ambiguity

- Go-See-Think-Do
- Brainstorming / hypothesis generation
- Fishbone diagram
- Is / Is not
- 5-why

Brainstorming to find possible causes of the problem

1. **Explain the problem**

   Coordinator explains the problem to the group

   If possible, shares relevant historical data

2. **Identify possible causes**

   Participants brainstorm / brainwrite the possible causes of the problem

3. **Team decides which causes should be further considered**

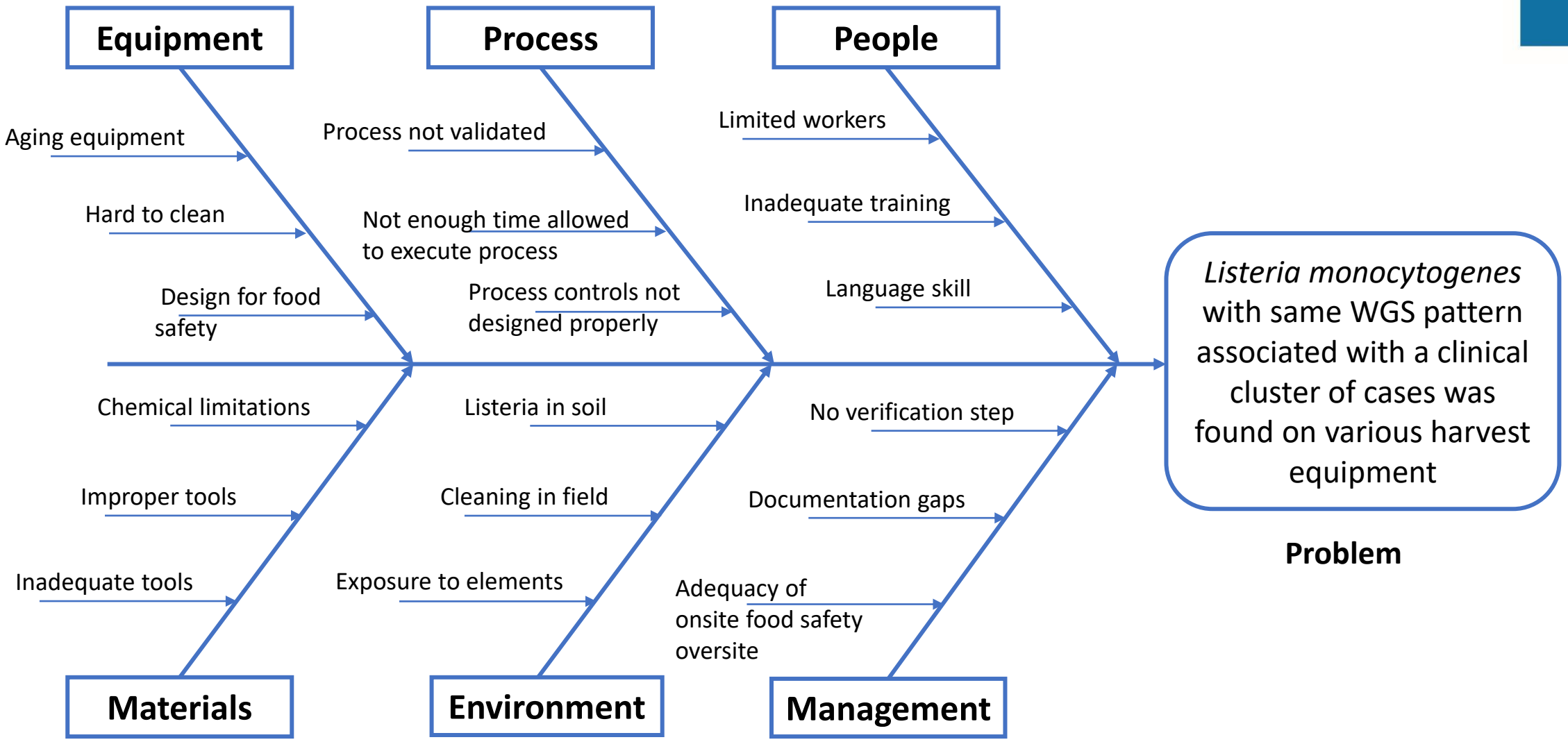
4. **Group similar causes together and organise them in the Cause and Effect diagram (Fishbone)**

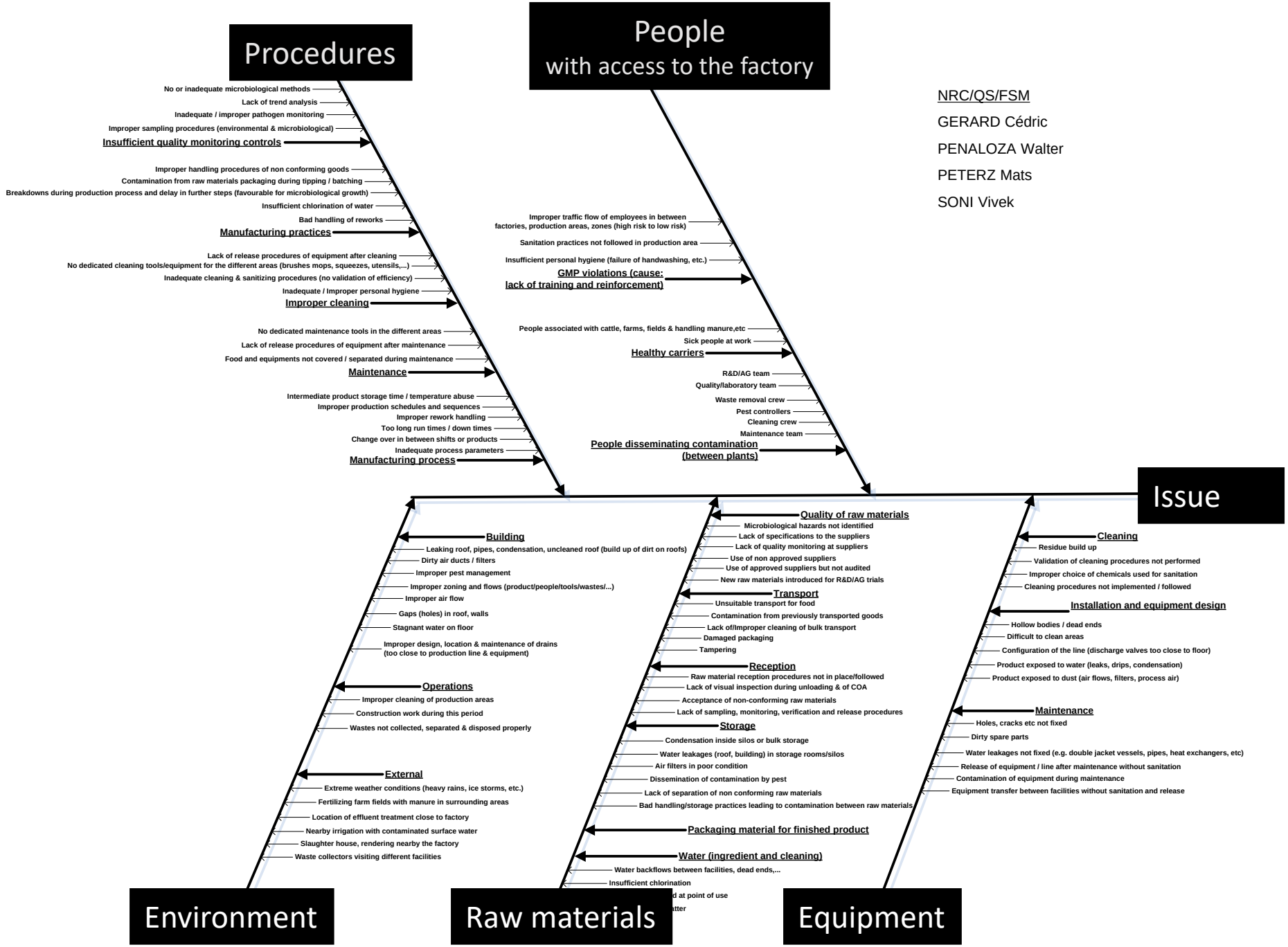
5. **All participants should have an opportunity to contribute**

Investigation - Hypotheses

- Contamination from air / water / soil / soil amendment
- Contaminated raw material
- Contamination from employee
- Harborage in the factory / equipment
- Cross contamination from adjacent production

Fishbone Diagram – Ag operations





NRC/QS/FSM

GERARD Cédric

PENALOZA Walter

PETERZ Mats

SONI Vivek

* Factory people, contractors, temporary people, visitors

5-why in root cause analysis

Problem: *Salmonella* was recovered from lettuce mix

Why?

Salmonella originated from lettuce used to manufacture mix

Why?

Salmonella was present in water used for overhead irrigation

Why?

Water treatment was not sufficient to inactivate pathogens from animals in / adjacent to open water source

Why?

Chemical treatment delivery was not sufficient for pathogen inactivation

Why?

Chemical delivery system was not validated or verified

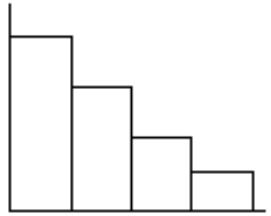
Photo 83540022 © Yuri_arcurs | Dreamstime.com

Corrective actions:

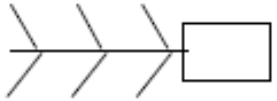
- Work with chemical provider to validate delivery system
- Implement process to verify chemical delivery

Tools used in root cause analysis

BRAINSTORMING

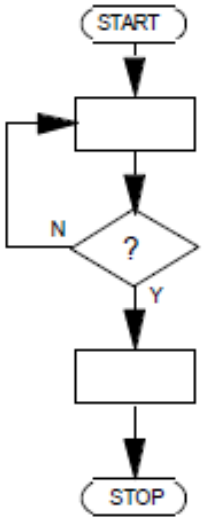


PARETO CHART

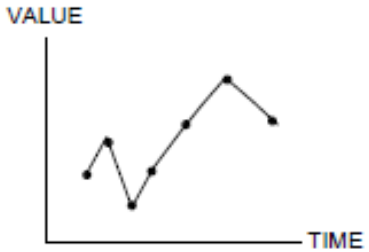


FISHBONE DIAGRAM

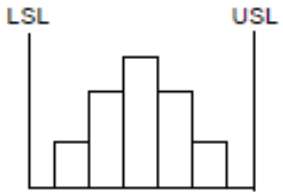
SCATTER DIAGRAM



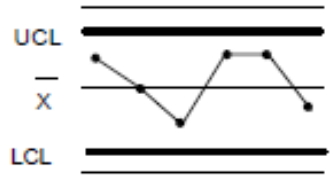
FLOWCHART



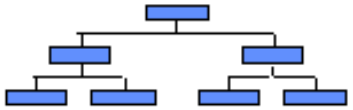
RUN CHART



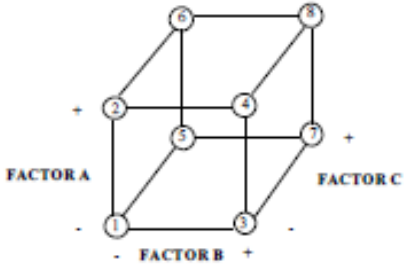
HISTOGRAM



CONTROL CHARTS



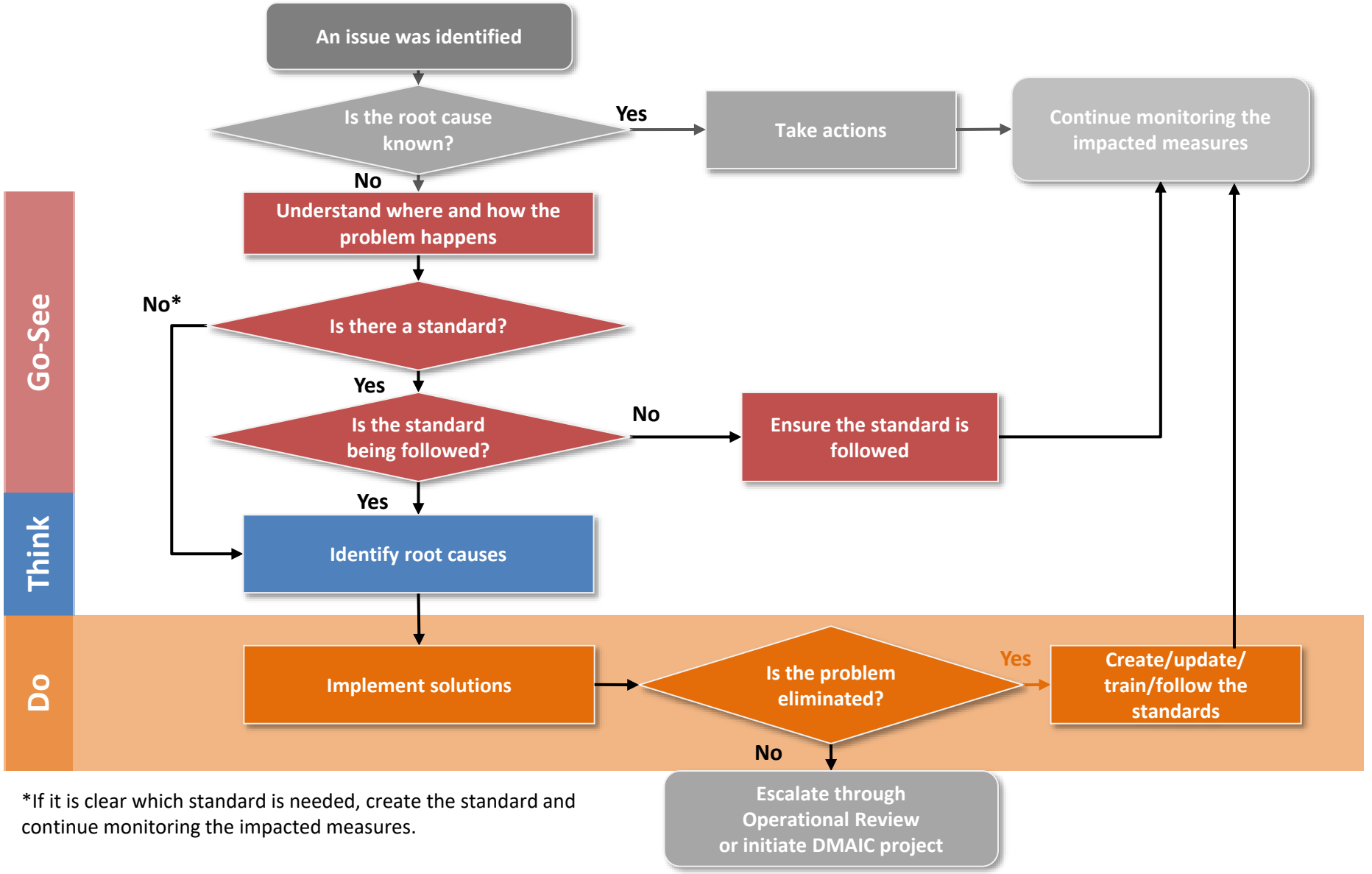
TREE DIAGRAM



DESIGN OF EXPERIMENTS

US Military (http://www.au.af.mil/au/awc/awcgate/nasa/root_cause_analysis.pdf)

Go-See Think Do Process



*If it is clear which standard is needed, create the standard and continue monitoring the impacted measures.

Nestle USA GSTD Generic November 2013

Outcome of RCI and RCA

- Identification of failure (s) that led to issue
- Identification of underlying factors that led to failure
- Information to characterize and determine scope of underlying factors
  - Inform needed corrective / preventive actions
- Often there is no “smoking gun” found
  - Need to identify all potential root causes and likely causal factors and implement corrective / preventive actions
  - In many cases research or ongoing verification needed to identify, confirm or characterize root cause

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FDA – Route to prevention

Where we are going……..

Prevention

How and why

Analysis of outbreak
- Category challenge?
- Levers of prevention?

Prevention Strategy?

yes

Project Management

Stakeholder Engagement

- Research
- Publications/communications
- **Industry influence**
- **Industry training**
- Compliance activities (inspections and sampling assignments)
- Regulator training
- Rule-making
- Guidance development

Observations

Root Cause Analysis

Signals

Outbreak

Investigation

Outbreak: What and the where
Root Cause Analysis: How and the why

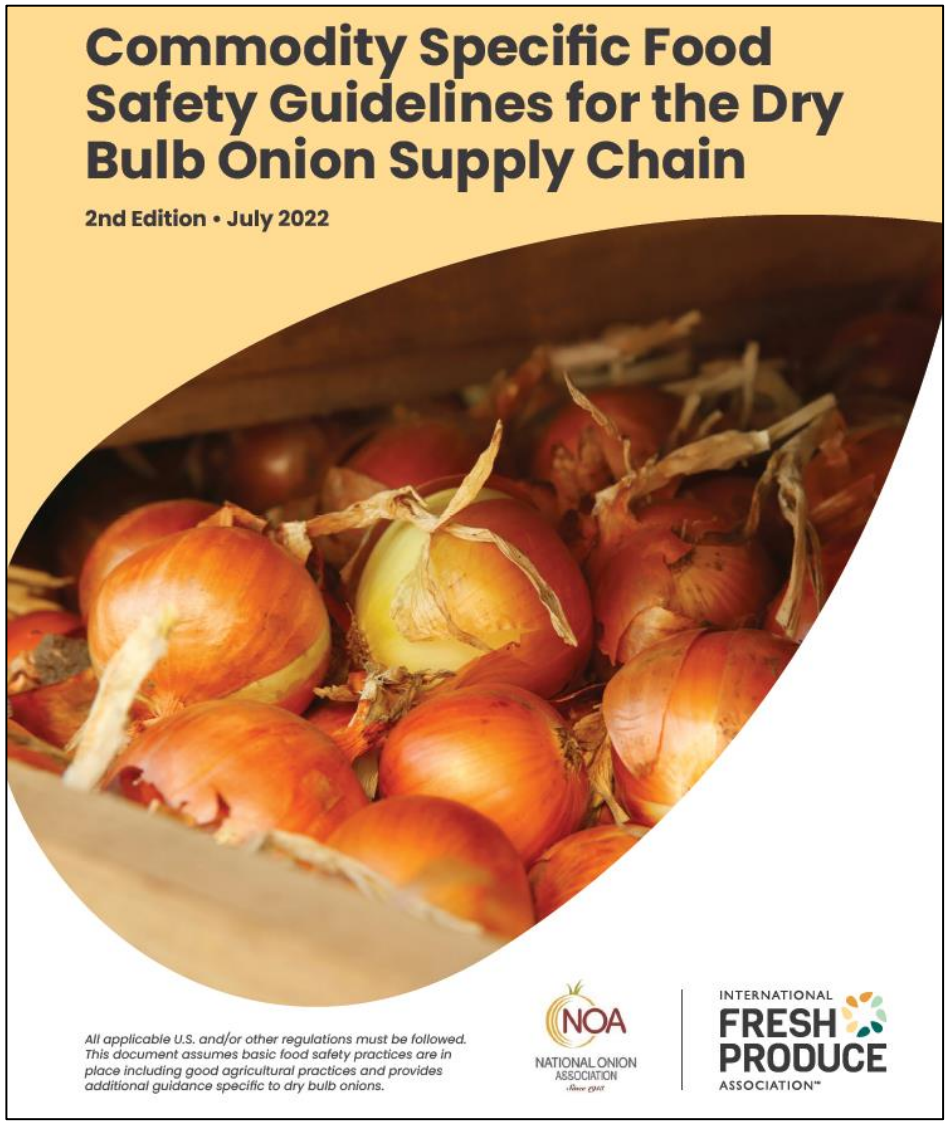
Prevention Strategies

Current Prevention Strategies

Listeria monocytogenes in imported Enoki and Wood Ear Mushroom
Salmonella in Bulb Onions
Enteric viruses in Berries
Cronobacter sakazakii in Powdered Infant Formula
Listeria monocytogenes in Queso Fresco Cheese
Enteric pathogens in Sprouts (in development)
Salmonella in flour (frozen pizza, cookie dough) (in development)
Listeria monocytogenes in Ice Cream (in development)

Development and Implementation of Best Management Practices

Industry Stakeholder Engagement: Providing Technical Assistance



An activity from the prevention strategy involving bulb onions:

- The FDA provided technical support in updating and implementing the IFPA/National Onion Association led - 2010 Food Safety, Bulb Onion Best Management and Practices Guidance Document for domestic and international bulb onion growers and shippers
- The FDA continues to contribute to the socialization, promotion of the updated Bulb Onion Best Management and Practices Guidance across the domestic and international bulb onion industry to encourage adoption and implementation by industry members.

Areas of focus for prevention

Enteric viruses in berries

- Communicate learnings from recent enteric virus outbreaks
- Identification of best practices and development of commodity-specific guidance
  - Design and management of sanitary facilities
  - Practices for handling and transfer of berries
  - Worker health, including vaccination
- Research to understand the transfer, distribution and viability of hepatitis A in the farm and processing environment
- Research to identify relevant treatments for control of enteric virus in agricultural and process water, and sanitation processes.

Outbreak Investigation of Hepatitis A Virus: Strawberries (May 2022)

FDA's investigation is complete; CDC declares outbreak over.

Outbreak Investigation of Hepatitis A Virus Infections: Frozen Strawberries (February 2023)

Additional recall initiated for DayBreak Blend. Do not eat recalled Frozen Organic Strawberries. FDA's investigation is ongoing.

Government of Canada | Gouvernement du Canada

Search website

Canada.ca > Health > Recalls and safety alerts

Recalls and safety alerts

Food recall warning

Alasko brand IQF Whole Raspberries and IQF Antioxidant Blend recalled due to norovirus

▸ Brand(s)

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