



GOT ROOT CAUSE?

CELEBRATING
25 YEARS
Produced by **FoodSafety**
MAGAZINE



Polling Questions

CELEBRATING
25 YEARS
Produced by FoodSafety
MAGAZINE

Moderators:
Brendan Niemira & Robert Prevendar

What is your sector (choose the one that fits best)?

1. Manufacturing / food processor
2. Fresh produce industry
3. Distribution
4. Food service
5. Retail
6. Academic
7. Service/equipment provider/consultant
8. Government (non-regulatory)
9. Government (regulator)
10. Other



What is your level of experience with root cause analysis?

1. Beginner
2. Knowledgeable
3. Formally trained



What would you like to take away from this session?

1. Learn new tools
2. Learn from others
3. Regulations around root cause analysis
4. Understand validation/verification
5. All the above



What is your biggest obstacle to proper root cause analysis?

1. Time, competing priorities
2. Lack of top management support
3. Cooperation
4. Lack of risk-based thinking
5. Lack of training/expertise
6. All the above



Session Overview

- **Why Root Cause Analysis is Important: Deb Kane & Tim Jackson**
- **Root Cause Analysis Tools to Use: Tim King & Natalie Dyenson**
- **Considerations for Success: Angie Siemens**
- **Break**
- **Interactive Session (live): Brendan Niemira, Robert Prevendar & Team**
- **Interactive session (virtual): Tim Jackson & Natalie Dyenson**
- **Validation & Verification: John Butts & Natalie Dyenson**
- **Wrap-up, closing, lessons learned: Tim Jackson & Tim King**





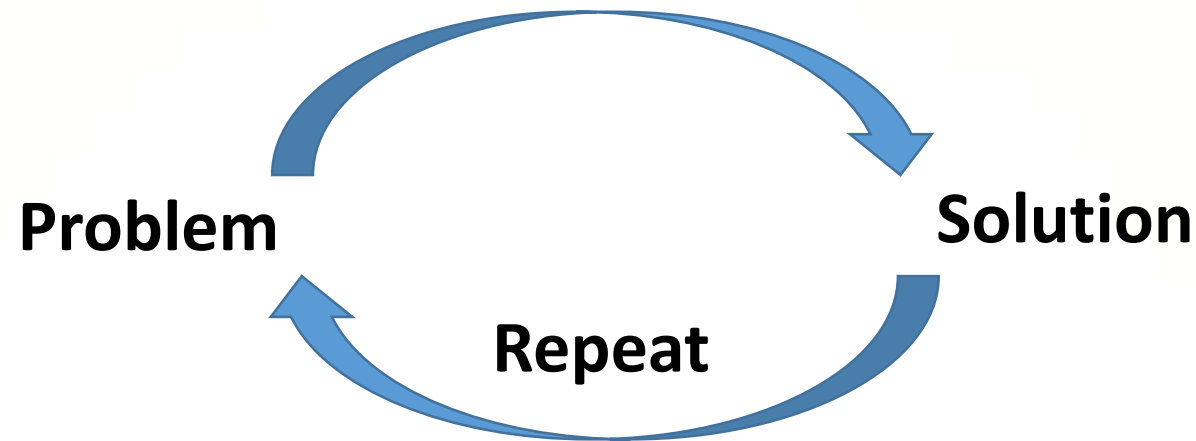
Why Root Cause Analysis is Important

CELEBRATING
25 YEARS
Produced by FoodSafety
MAGAZINE

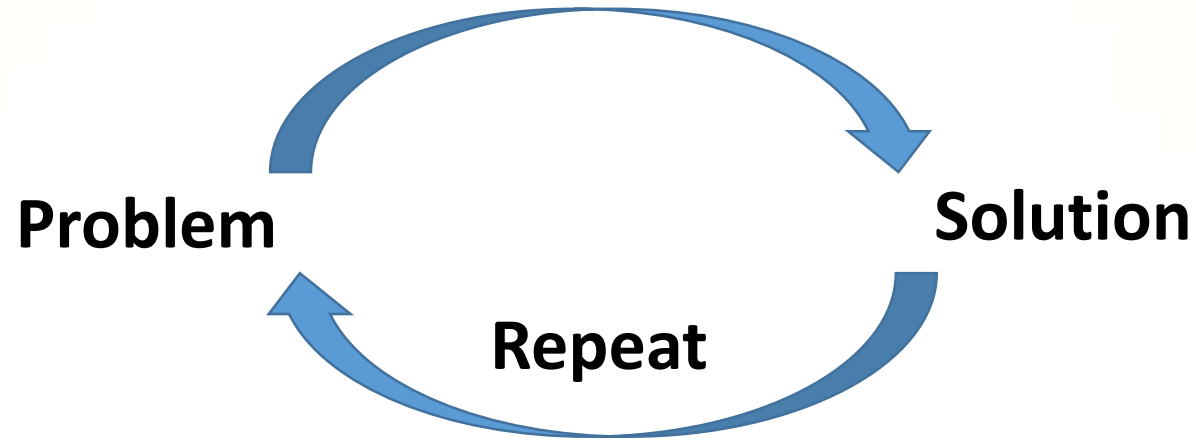
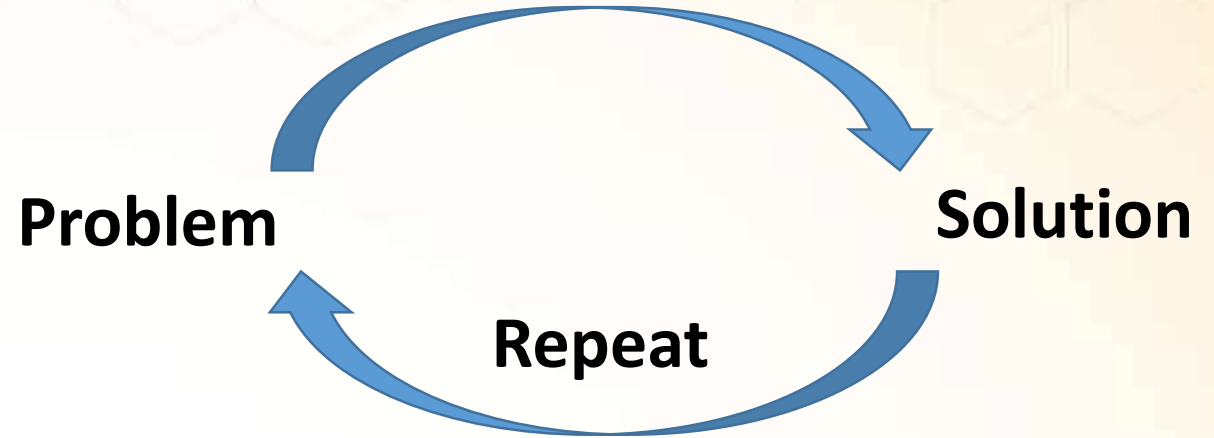
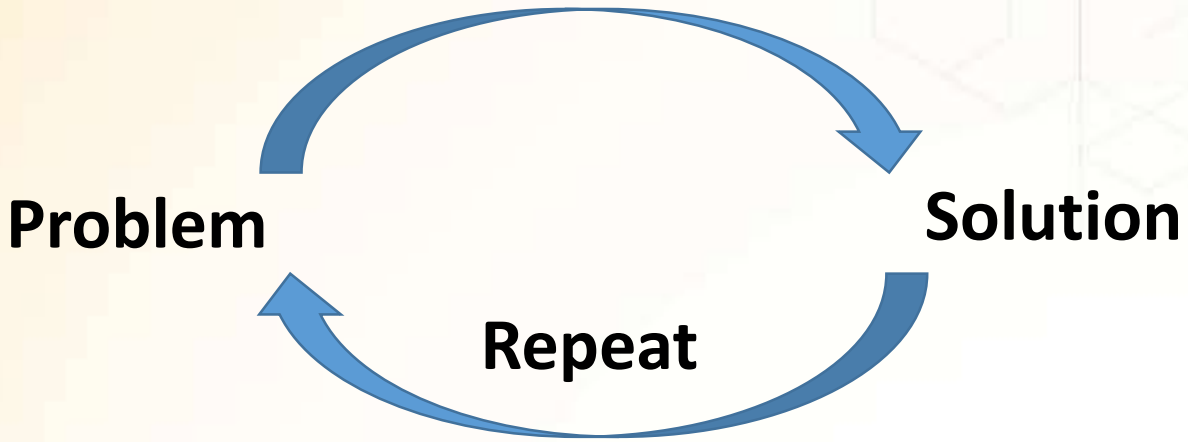
Speakers:
Deb Kane & Tim Jackson

Has this ever happened to you?

Have you ever worked on a problem, determined what you deemed to be an acceptable solution and then had the problem reoccur?



And repeat?



True Root Cause?

- **Why did the problem repeat again and again?**
- **We did not get to the true root cause for the problem!**
- **If the true root cause for a problem is not identified, ineffective solutions will be implemented, and the problem will likely reoccur**



Basic Definitions

Root cause (RC)

- the underlying reason(s) or cause(s) for a problem (nonconformance)

Nonconformance (NC)

- a process, product, or outcome that does not meet the specifications or acceptance standards (i.e., requirements)

Root cause analysis (RCA)

- collective term that describes a wide range of [approaches, tools, and techniques](#) used to uncover causes of problems (nonconformances)



Basic Definitions

Correction and Containment Actions

- actions to contain a problem and keep it from occurring again while the root cause is being investigated
- any action to eliminate a nonconformity
 - also includes the correction of nonconforming parts, documents, tools, and re-training as appropriate
 - may include reprocessing/destroying of potentially unsafe products



Basic Definitions

Corrective Actions (CA)

- after root cause is identified, the steps or actions taken to eliminate the causes of nonconformities to prevent recurrence

Preventive Actions (PA)

- any actions and/or controls taken that prevents occurrence of a problem



Correction or Corrective Action?

- **If we performed a plant audit, and observed dirty overheads, would cleaning the overheads get rid of our problem?**
- **Is cleaning the overheads an immediate correction or an effective corrective action?**
- **What would be a corrective action to prevent recurrence?**
- **What would be an action to prevent future occurrences of the same problem?**



True Root Cause

If the true root cause for a problem is not identified, ineffective corrective actions will be implemented, and the nonconformance will likely reoccur

If we do not get to the reason for why we had dirty overheads, there will be a repeat nonconformances on future audits (and we will be cleaning them over again)



Impact on Efficiencies

Plant, process and people efficiencies are all impacted if we do not get to the true root cause for a nonconformance

We may:

- **Define a process change and change a process**
- **Then – Train, untrain, and retrain**
- **Monitor to determine effectiveness (more to come in validation section)**



Impact on Brand

Brands may be impacted if the true root cause is not identified

Example: metal found in finished product

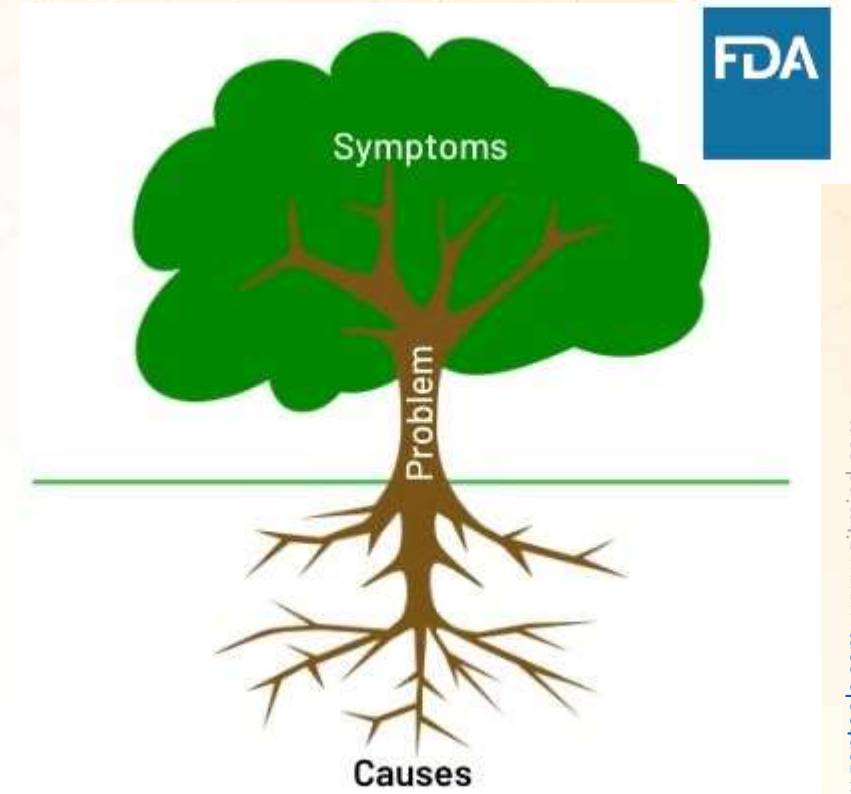
- **Root cause originally identified as a training issue on operator led metal detector challenges**
- **Repeat metal hits in subsequent lots demonstrate true root cause was not identified (could lead to product recalls)**
- **True root cause was a faulty rejection mechanism when product accumulated at the metal detector**
 - **Or was the true root cause an “unvalidated process?”**



FDA's Expectations of Industry

Corrective actions must ensure (117.150 (a), (b)):

- Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;
- Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;
- All affected food is evaluated for safety; and
- All affected food is prevented from entering into commerce

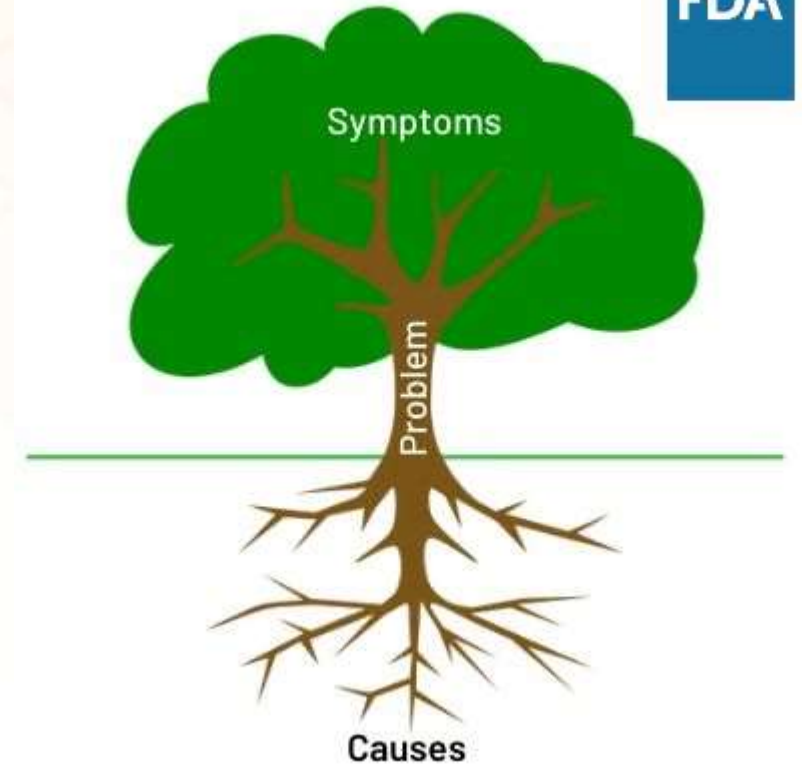


FDA's Expectations of industry

Use of Root Cause Analysis (RCA) methodology could help:

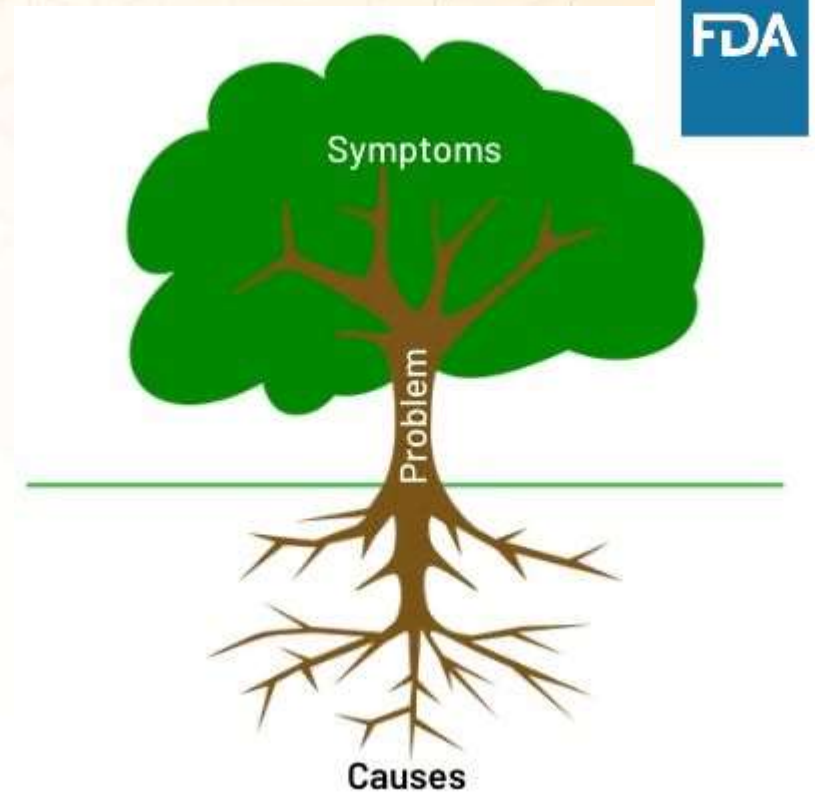
- Correctly identify the root causes of food safety problems
- Determine the origin and scope of a problem
- Determine appropriate corrective actions to prevent recurrence

Methodology could be useful for certain trigger events (outbreaks, recurrent issues)



FDA's Use of RCA

- Firm or FDA RCA following outbreak
- Analysis of recurring outbreaks
- Evaluation of information on adverse issues
 - Recalls
 - Information from surveillance or import analyses
 - Information from firm inspections
 - New and emerging issues
- Outcome will inform follow up actions
 - Compliance actions
 - Stakeholder communications
 - Prevention activities



Any Questions or Comments?



**Next session: Root Cause Analysis Tools to Use
Tim King & Natalie Dyenson**



**CELEBRATING
25 YEARS**
Produced by Food Safety



CELEBRATING
25 YEARS
Produced by **FoodSafety**
Magazine

MAY 8 – 11 | 2023

Donald E. Stephens Convention Center | Rosemont, IL

COMMUNITY · EDUCATION · SOLUTIONS

Deb Kane

Vice President

Food Safety, Quality & Regulatory

J&J Snack Foods Corp.

dkane@jjsnack.com

Tim Jackson

Regulatory, Sr. Science Advisor

FDA

Timothy.Jackson@fda.hhs.gov

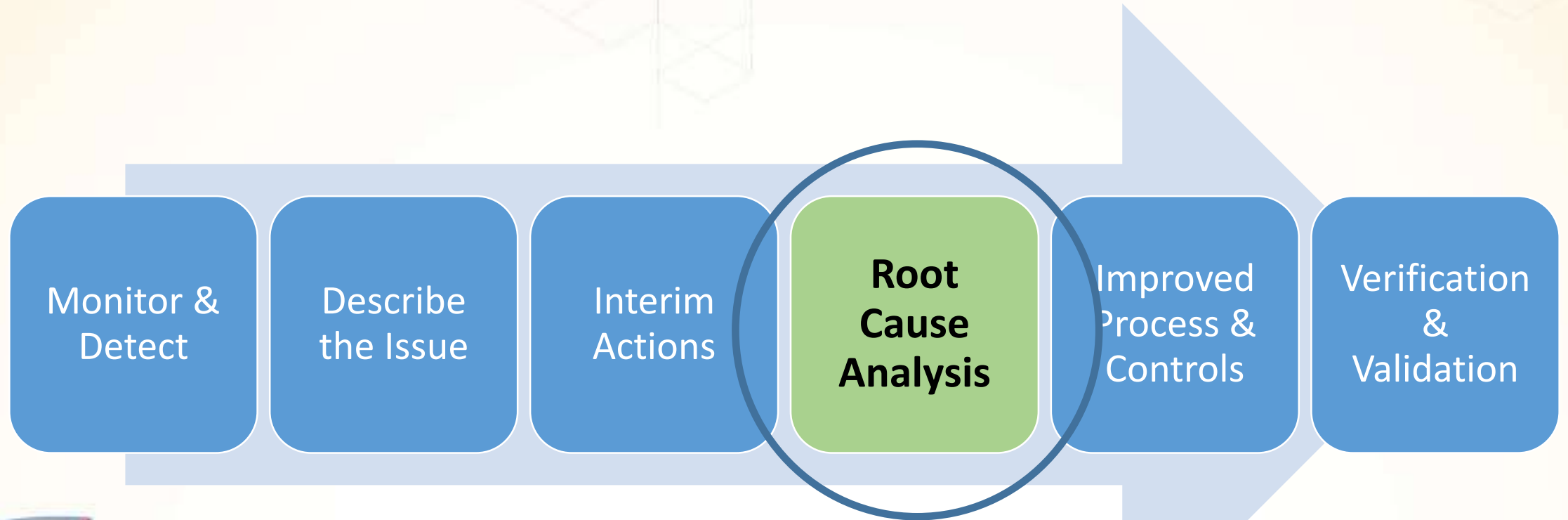


Root Cause Analysis Tools to Use

CELEBRATING
25 YEARS
Produced by FoodSafety
MAGAZINE

Speakers:
Tim King & Natalie Dyenson

RCA- The Gateway to Improvement



Process Approach- Six Sources of Process Conditions That Can Cause Quality Issues

(these are used on the “fishbone” diagram)

1. **Manpower** (employee competency; aptitude)
2. **Method** (process steps; layout; sequencing)
3. **Materials** (chemicals, supplies, bins)
4. **Machines** (equipment, tools, devices)
5. **Measurement** (accuracy, lack of; type; use of)
6. **Environment** (ergonomics; distraction; complacency; temperature, humidity, lighting...)



Root-Cause Standard at ASQ

“An underlying condition of the process or system that directly results in non-conformance in a product or service” (correlation is evident)

- it can be identified in terms of inadequate aspects of the 6 process elements
- it can be an aspect of design (FF&F)
- Escapes: inadequate aspect of controls: inspection; self-checks; testing; metrology, personnel aptitude for QC

If the inadequacies are removed, that will result in indisputable improvement in quality.”

It is not: operator error, rushing, forgot, needs re-training, etc.



The 3 Levels of Root Cause Identification

- 1. Why the process created the issue (process elements)**
- 2. Why the issue went undetected- passed through the established controls and inspections (ability to escape)**
- 3. Where the organization's food safety quality system is not preventing this type of issue systemically**
 - example: systemic competency problems; inadequate process and/or product change control**



Factors Behind Human Error

- Skill aptitude
- Knowledge access
- Memory/recall lapse
- Cognitive decision making
- Personal discipline “stamina”
- Tools, equipment
- Ergonomics- stress/strain/fatigue
- Information, communications
- “Environment” issues
- Sensory challenges (seeing, hearing, touch, etc.)



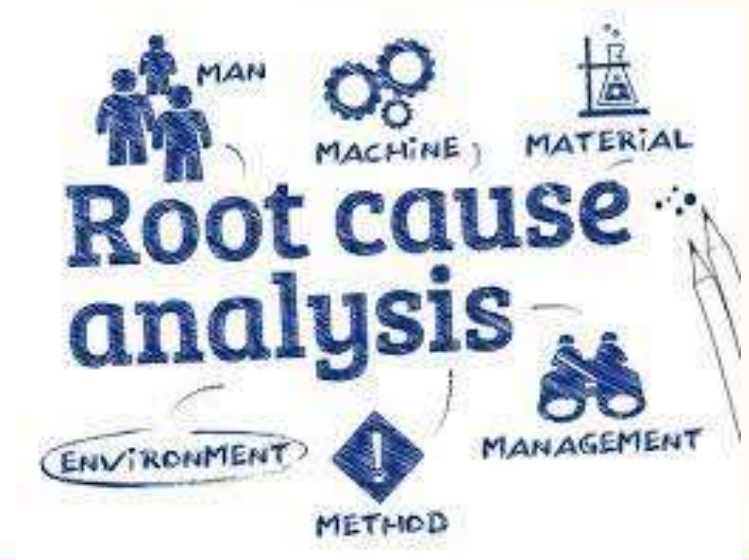
RCA Analysis- It Takes a Tool!

Common ones:

- Human Factors Checklist (email Tim for one)
- 5-Why *
- Cause-Effect Diagram (a.k.a. fishbone) *
- Hybrid: Cause-Effect Matrix **

* Will review & give tips

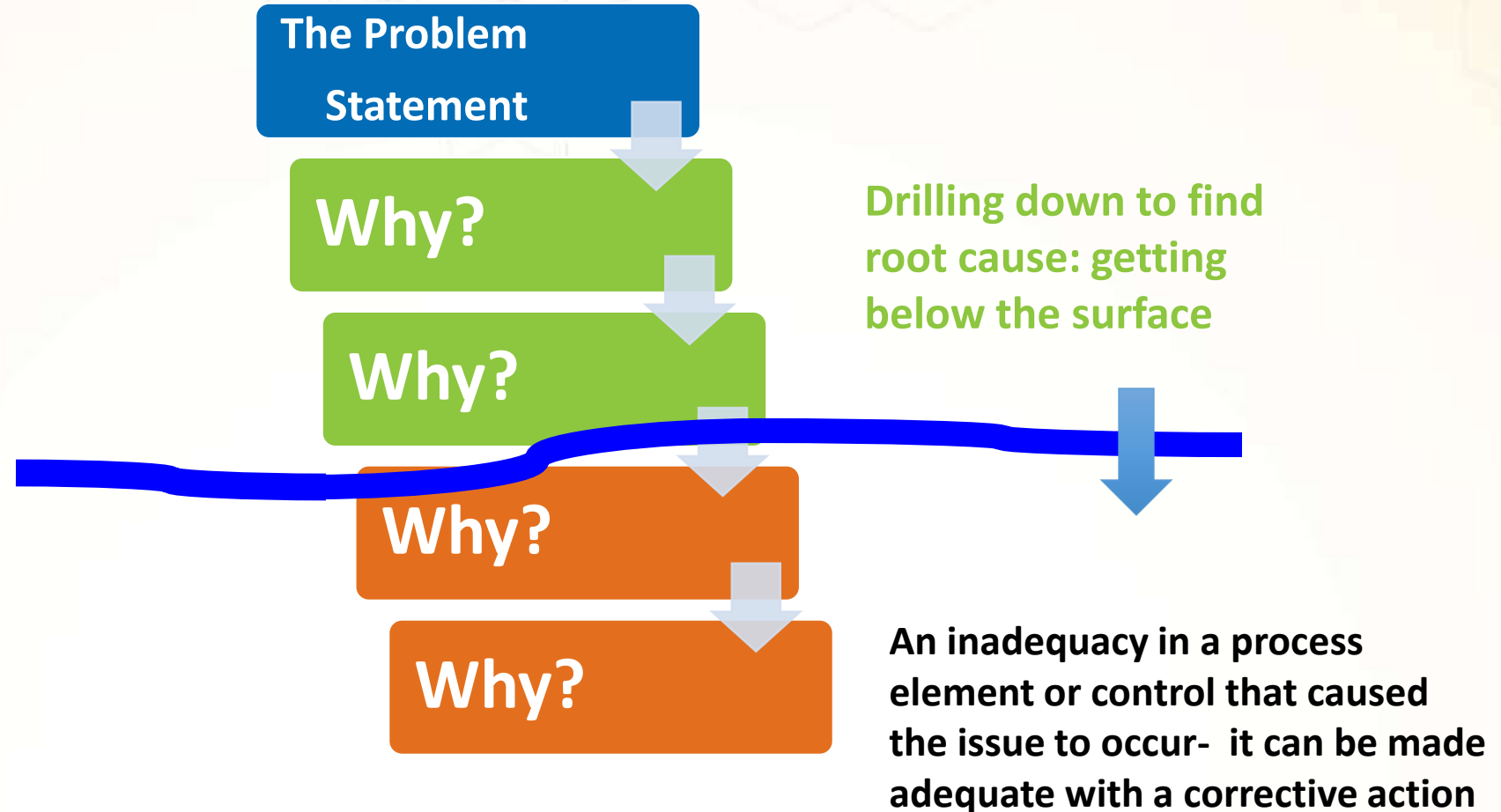
** Will teach and use in today's case study



Using Five Why Cause Analysis

Tips

1. Put a proper problem statement at top
2. Identify the most immediate action that made that happen
3. Then ask why that immediate action happened
4. And so on...
5. Stay in process or controls "language"



A 5-Why Example

Problem: Patient in Room 101 rolled out of bed and fell last night

- 1. Why did the patient fall out of bed?**
 - **Because the bed restraints opened.**
- 2. Why did the bed restraints open?**
 - **Because the fasteners weren't closed correctly.**
- 3. Why weren't the fasteners closed correctly?**
 - **Because the technique used by the floor nurse was incorrect for the type of restraints being used.**
- 4. Why did the nurse use an incorrect technique?**
 - **Root Cause: Because training was not provided to the nurse (new to the floor) prior to independently performing this task.**



5 Why Example

Problem Statement: *Listeria monocytogenes* (LM) was found in two bags of iceberg containing salads from two plants

Why did the *Listeria monocytogenes* get into these different packages of finished product?

- *The Listeria monocytogenes was introduced from the processing facilities and/ or raw material.*
 - A) Why #2a- Why would the LM have been introduced from the processing facilities?
 - *LM is an environmental contaminant and was present in cool, wet environments at the salad plant.*
 - B) Why #2b – Why would the LM have been introduced from the raw material?
 - *LM is naturally occurring in soil in growing regions from which iceberg was sourced.*



#2b: Why would the LM have been introduced from the raw material?

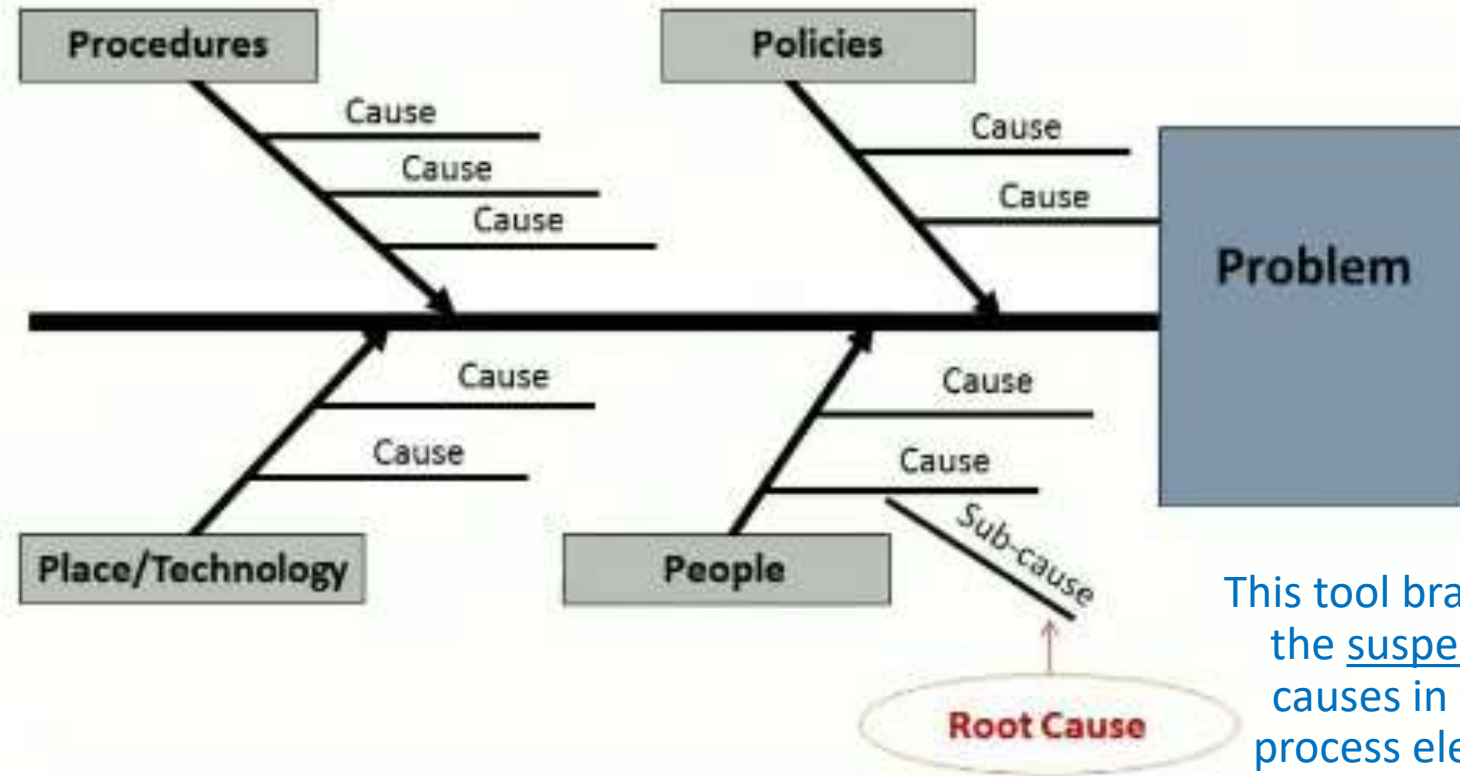
- **LM is naturally occurring** in soil in growing regions from which iceberg lettuce was sourced. **ENVIRONMENT**
 - Soil from those fields got onto the product during harvest. **MATERIAL**
 - The harvest tools and equipment were carrying the contamination. **EQUIPMENT**
 - The tool sanitation practices were not sustaining a reduced **microbial** load to safe levels. **METHOD**
 - The equipment was not hygienically designed and there were niche and harborage points making sanitation more difficult to sustain safe levels on **microbial** loads. **EQUIPMENT**



Tips:

1. Construct the diagram or use a template
2. Add problem statement
3. Assemble right brainstorm team
4. Take one element at a time: draw out ideas for suspect cause
5. Branch the ideas!
6. Narrow down to actual root causes by process investigation

Fishbone Diagram



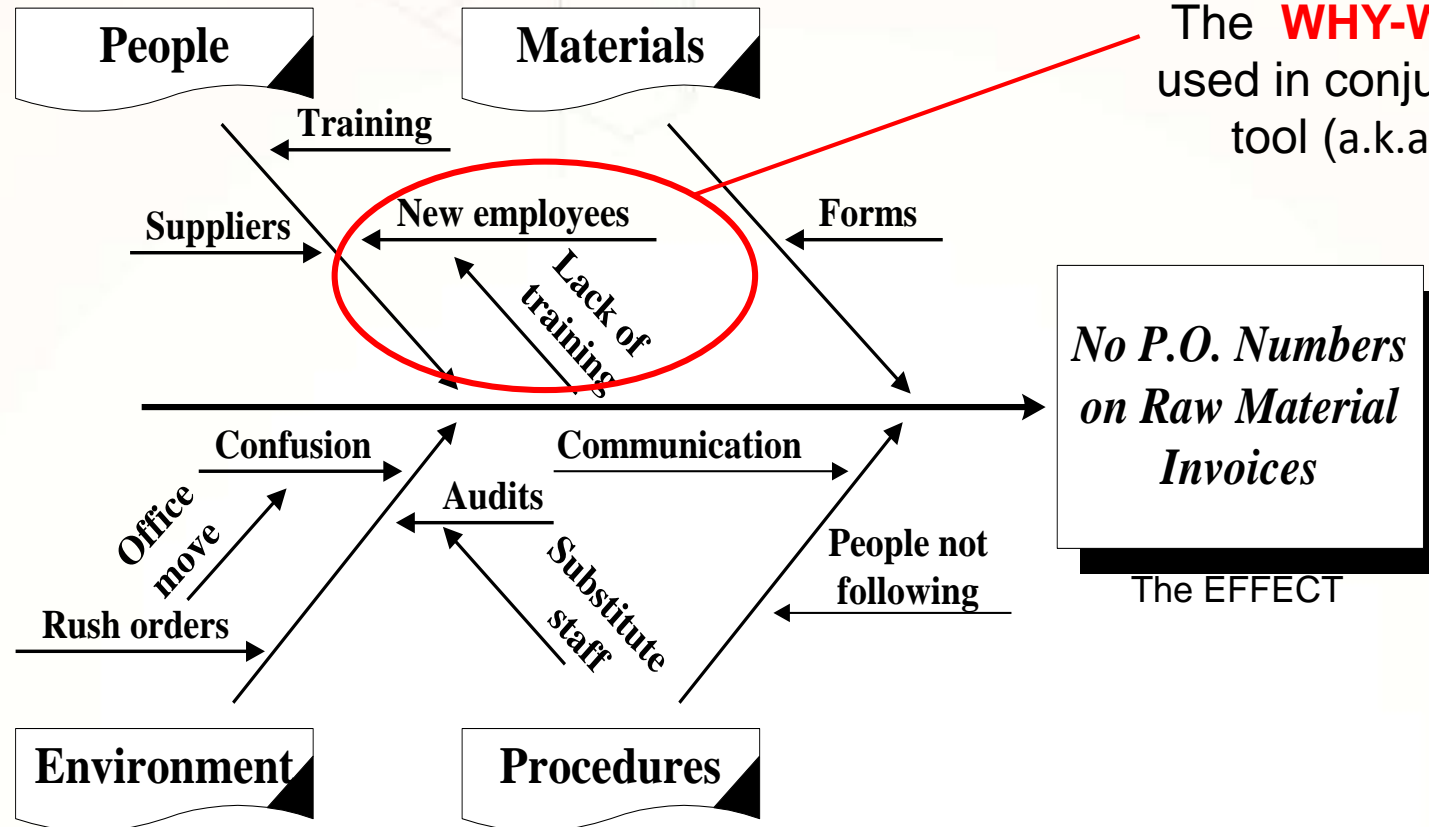
This tool brainstorms the suspect root causes in the six process elements.



Cause-and-Effect Diagram (aka "fishbone")

PROCESS ELEMENTS

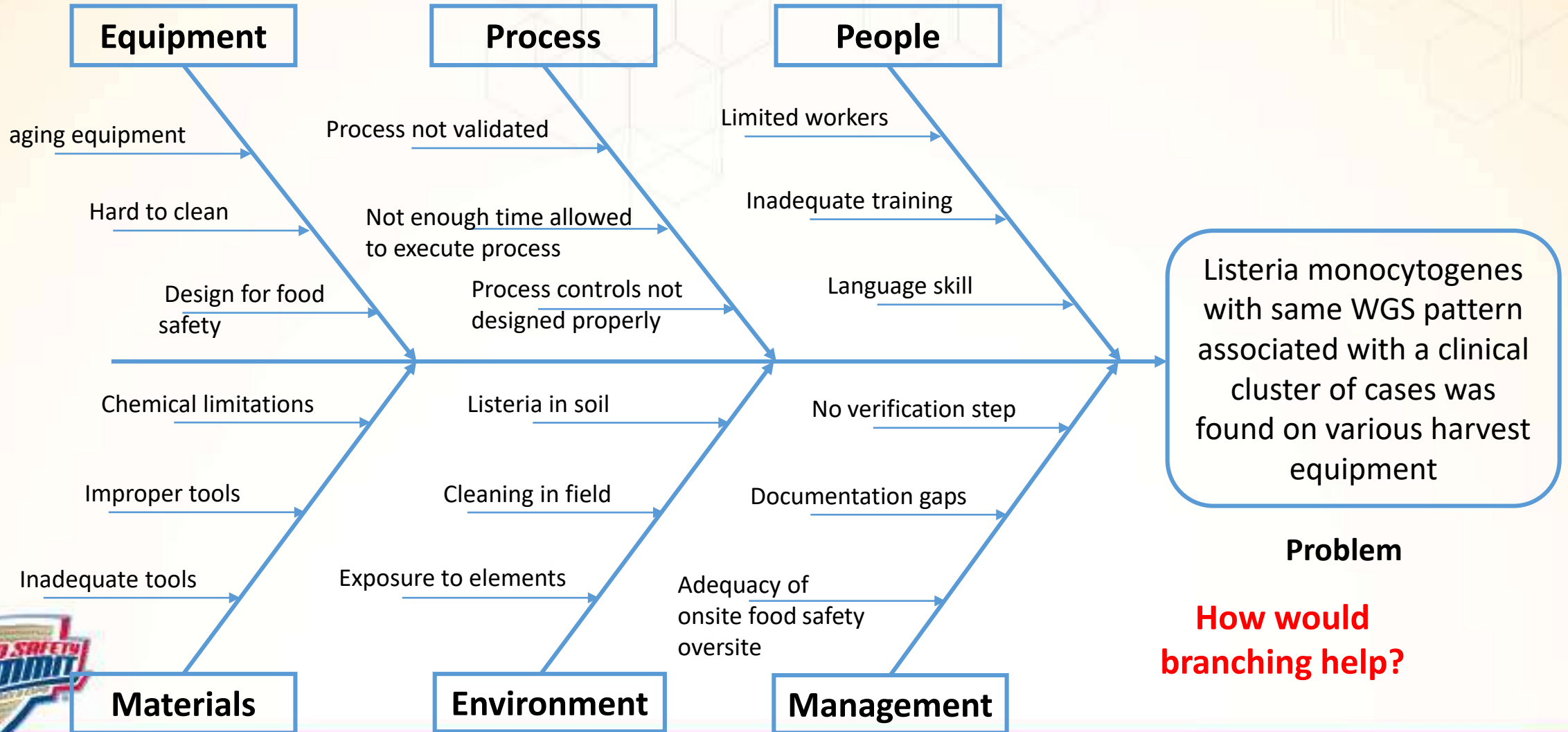
Not using: Measurement or Equipment/Tools



The **WHY-WHY** method is used in conjunction with this tool (a.k.a. branching)



Fishbone Diagram – Ag operations



The Best of Both Worlds- Cause-Effect Matrix

- Shape simplicity
- Covers the 6 process elements
- Allows for some why-why analysis
- Converges to focus investigation



Cause Effect Matrix

Created by: Tim King

Quality Matters LLC timking@qualitymattersusa.com
 Copyright 2023 Course of Workshop Attendees Given Right to Use

Write a problem statement below (state the item, the relevant requirement, and the NC condition):

7 Key Process Areas	A) How could any aspect of this process area have possibly caused the problem?	B) Why would the aspects in "A" happen?	C) Why would the aspects in "B" happen?	80/20 Analysis: What in this row will be investigated to determine if this process area was a part of the cause?
<i>Method</i> : how the process is done per SOP or work instruction ; or if deviations could have happened				
<i>Materials</i> : any form of supplies, parts, assemblies used in the process				
<i>Machinery</i> : any type of tool, equipment, fixture, trags, bins, storage racks				
<i>Personnel</i> : Any aspect of competency & aptitude (knowledge, skills, experience, ability to perform consistent work)				
<i>Environment</i> : temperature, humidity, obstacles, lighting, distractions, morale, oversight and presence				
<i>Measurement/Information</i> : accuracy, precision, access, lack of, vague, has errors, timeliness, communication				
<i>Design</i> : any aspect of the product design that may be causing the problem				

- Guidelines for use:** Always assemble a team of process experts
- 1) Fill in Column "A"
 - 2) For each entry on Column "A" fill in the remainder of the row
 - 3) Create a plan (who, what, by when) to complete the 80:20 investigations.
 - 4) Narrow down to root cause(s) and contributing factors; be sure to validate your conclusions

Cause Effect Matrix

Created by: Tim King

Quality Matters LLC

timking@qualitymattersusa.com

Write a problem statement below (state the item, the relevant requirement, and the NC condition) :

Copyright 2023 Course of Workshop Attendees Given Right to Use

Listeria monocytogenes matching an outbreak strain was found in two different bags of iceberg containing salads

7 Key Process Areas	A) How could any aspect of this this process area possibly caused the problem	B) Why would the aspects in "A" happen?	C) Why would the aspects in "B" happen?	80/20 Analysis: What in this row will we investigated to determine if this process area was a part of the cause?
Method: <i>how the process is done per SOP or work instruction; or if deviations could have happened</i>	Harvesters walk behind rig to harvest; rig could kick up soil or drag contamination across heads	Rig is moving too fast through the field		
Materials: <i>any form of supplies, parts, assemblies used in the process</i>	Product is trimmed as it is harvested			
Machinery: <i>any type of tool, equipment, fixture, trays, bins, storage racks</i>	Raw material is harvested with knives then placed directly on a belt on harvest equipment	Belt and harvest equipment could be contaminated with LM	Sanitation was inadequate or design of equipment made it difficult to clean	Review sanitation SOP Review execution of sanitation process Test equipment for contamination
Personnel: <i>Any aspect of competency & aptitude (knowledge; skills, experience, ability to perform consistent work)</i>	Improper harvest techniques could cause contamination, particularly if moving quickly			
Environment: <i>temperature; humidity, obstacles, lighting, distractions, morale, oversight, and presence of human error factors</i>	Muddy fields could increase the potential for the product to be contaminated during harvest	Rain or irrigation event immediately before harvest		
Measurement/Information: <i>accuracy; precision, access, lack of, vague, has errors, timeliness, communication breakdowns</i>	Crew are only to harvest designated areas which could not be marked clearly			
Design: <i>any aspect of the product design that may be causing the problem</i>	Lettuce has natural latex which could cause the soil to stick to a cut surface and not wash off			

Any Questions or Comments?



Next session: Considerations for Success
Angie Siemens





CELEBRATING
25 YEARS
Produced by **FoodSafety**
MAGAZINE

MAY 8 - 11 | 2023

Donald E. Stephens Convention Center | Rosemont, IL

COMMUNITY · EDUCATION · SOLUTIONS

Tim King

Senior Partner & Founder

Quality Matters LLC

timking@qualitymattersusa.com

802-598-7333

Natalie Dyenson

Vice President, Food Safety & Quality

Dole Food Company, Inc

Natalie.Dyenson@dole.com



CELEBRATING
25 YEARS
Produced by **FoodSafety**
MAGAZINE

Considerations for Success

Speaker:
Angie Siemens

Be strong



Common Watch Outs

Commitment

- Lack of Leadership commitment
- Not all voices included – team activity
- Implementation Drag
- Improper facilitation
- Not enough time allotted
- Waiting until a crisis to implement

Problem Definition

- Defining the problem as the solution
- The statement is too vague
- Solving the wrong problem



Common Watch Outs

Event / Factor Analysis

Identify symptoms / contributing factors

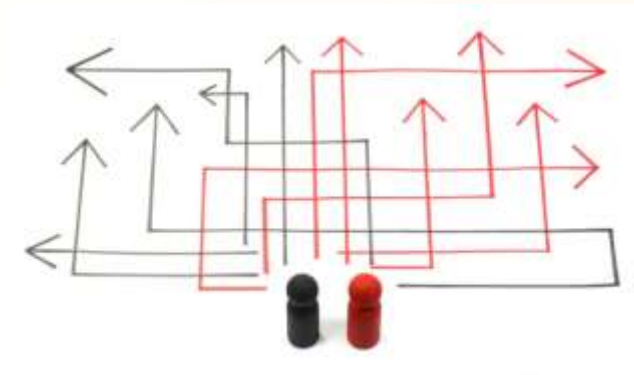
Focus on containment factors

- Not identifying root cause

Jump to blaming operator

Not considering organizational system deficiencies

- Management failed to follow-up on audit deviations
- Design of training program insufficient
- No formal receiving program
- Line / equipment not designed for success



Human Performance Improvement

80% of critical or serious events are due to human performance

Of those, **30%** are due to individual weaknesses or errors, and **the rest** are due to organizational system deficiencies.

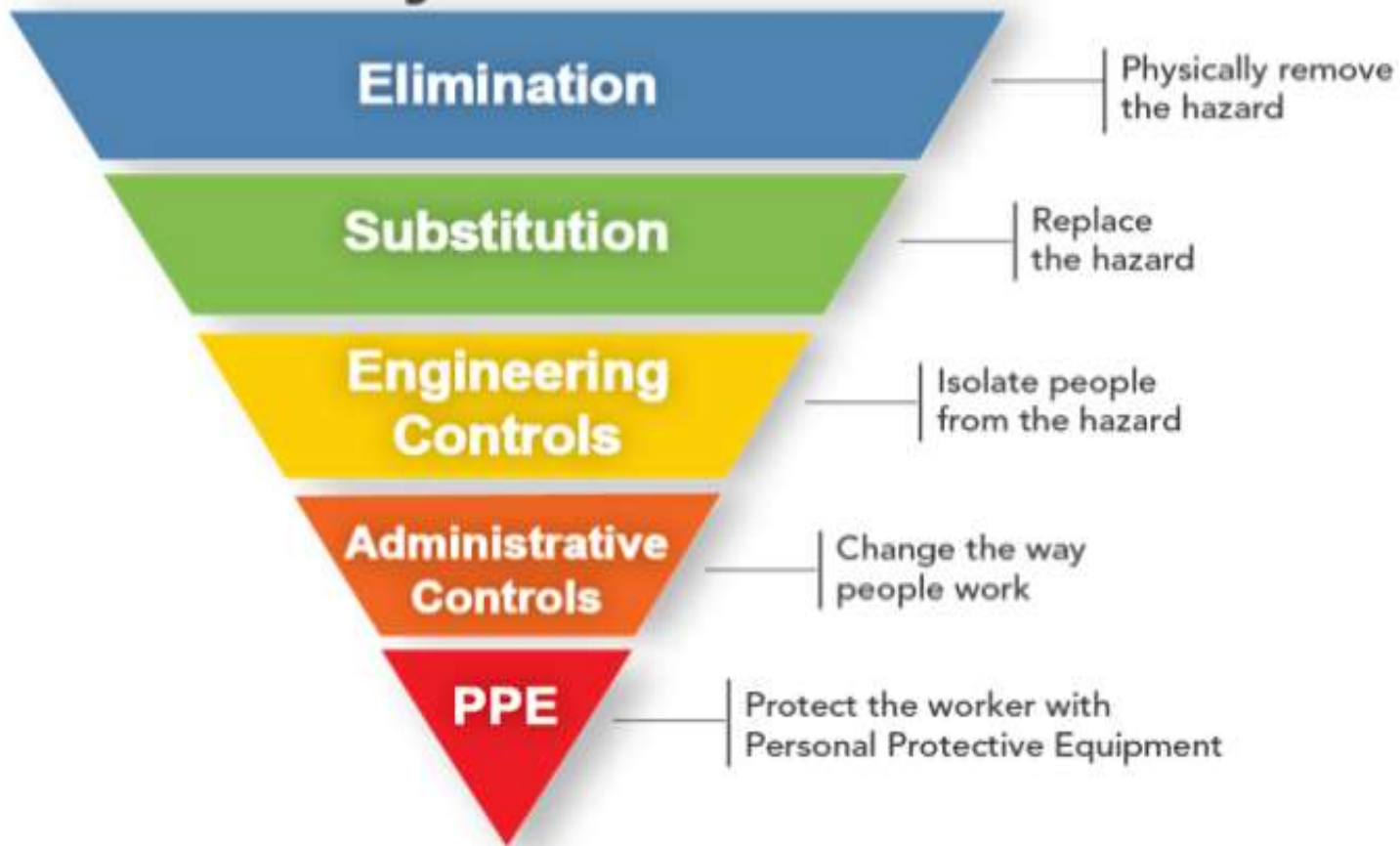


Hierarchy of Controls

Most effective



Least effective



Common Watch Outs

Corrections

Perceived to be preventative controls

Corrective Actions

Only focus on administrative controls

Short-term, unsustainable fixes

Lack of ownership for process changes

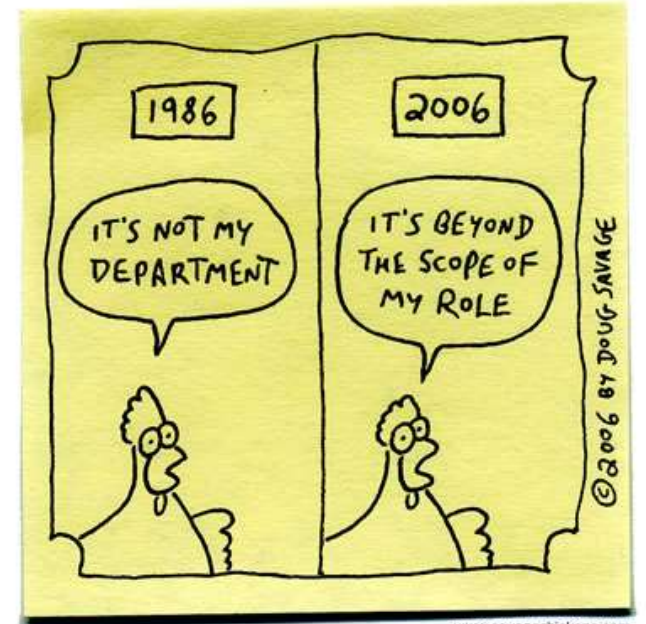
Preventive Controls

Using corrective actions as PC

Lack of validation

Savage Chickens

by Doug Savage



www.savagechickens.com



CELEBRATING
25 YEARS
Produced by Food Safety

Any Questions or Comments?



Next session: Interactive Session (after the Break)



CELEBRATING
25 YEARS
Produced by FoodSafety



CELEBRATING
25 YEARS

Produced by **FoodSafety**
Magazine

MAY 8 - 11 | 2023

Donald E. Stephens Convention Center | Rosemont, IL

COMMUNITY · EDUCATION · SOLUTIONS

Angie Siemens,
Vice President, Food Safety,
Quality & Regulatory, Cargill
Angie_Siemens@cargill.com



BREAK – 15 MINUTES

CELEBRATING
25 YEARS
Produced by **FoodSafety**
MAGAZINE



CELEBRATING
25 YEARS
Produced by FoodSafety
MAGAZINE

Interactive Session

Moderators:

On-site: Brendan Niemira & Robert Prevendar

Virtual: Tim Jackson & Natalie Dyenson



ROUND 1 EXERCISE

CELEBRATING
25 YEARS
Produced by **FoodSafety**
MAGAZINE

Round 1 – Scenario

Scenario: Today you are informed that *Listeria monocytogenes* was identified in frozen appetizer produced at your facility on 3/24/23. This finding comes from a random regulatory sample collected at retail several weeks ago

- Product is par-cooked
- Product is marketed as ready-to-cook; however, the product appears to be fully cooked
- RTE products made in the same facility



Round 1 Background Information

- Facility is old, equipment was not hygienically designed
- The equipment was retooled and partially upgraded in April 2022 to improve energy efficiency by the freezer
- Post-sanitation and pre-operational checks did not identify any issues on the production date in question
- Facility has a long-tenured, consistent sanitation staff of permanent workers
- Product was designed to be par-cooked; therefore, the process was not developed to achieve a thermal treatment of components prior to packaging
- The par-cooking process may allow the product to hit an internal temperature of 165°F during processing



What tools would you use to get to the answer?

What other data would you need to get to the Root Cause?





ROUND 2 – EXERCISE CAUSE-EFFECT MATRIX

CELEBRATING
25 YEARS
Produced by **FoodSafety**
MAGAZINE

Round 2 Information

1. Maintenance records indicate oven calibration on 3/17/2023.
2. FSQA oven validation records for RTE products for that facility were completed on 12/12/22.
3. Facility EMP program identified presumptive positive Listeria species in the raw material handling area of the facility from swabs collected on 4/1/23.
4. No presumptive positive Listeria species swabs have been isolated from areas after the oven.
5. The SOP calls for foot baths in transitional areas.
6. Review of internal audit conducted on 2/28/23 identified the use of high-pressure hoses for cleaning.
7. Sanitation team does not have a robust color code program for sanitation tools.
8. Master sanitation schedule did not include periodic equipment break down cleaning.
9. Hygienic zoning does not ensure proper traffic flow. In order to get to the spiral freezer, employees need to walk through a raw material corridor.



What is your answer?

What is the Root Cause for the Contamination?



CELEBRATING
25 YEARS
Produced by FoodSafety



THE BIG REVEAL!

CELEBRATING
25 YEARS
Produced by **FoodSafety**
MAGAZINE

Scenario

Scenario: Today you are informed that *Listeria monocytogenes* was identified in frozen appetizer produced at your facility on 3/24/23. This finding comes from a random regulatory sample collected at retail several weeks ago

And the answer is...

Unvalidated process changes led to post-freezing contamination immediately prior to packaging



Cause Effect Matrix

Template Created by: Tim King

Quality Matters LLC

timking@qualitymattersusa.com

Write a problem statement below (state the item, the relevant requirement, and the NC condition) :

Copyright 2023 Course of Workshop Attendees Given Right to Use

Listeria monocytogenes on a frozen appetizer

7 Key Process Areas	A) How could any aspect of this this process area possibly caused the problem	B) Why would the aspects in "A" happen?	C) Why would the aspects in "B" happen?	80/20 Analysis: What in this row will we investigated to determine if this process area was a part of the cause?
Method: <i>how the process is done per SOP or work instruction; or if deviations could have happened</i>	Product is par-cooked, sent to a spiral freezer, then into portioning and continuous roll packaging	Point contamination of the spiral freezer, portioning & packaging machines, or packaging material		
Materials: <i>any form of supplies, parts, assemblies used in the process</i>	Raw ingredients, par-cooked finished product, packaging materials			
Machinery: <i>any type of tool, equipment, fixture, trays, bins, storage racks</i>	Materials handling during prep, freezing, portioning, packaging	Belts and conveyors post-freezer exposed to condensate, Listeria biofilm buildup	Sanitation was inadequate or design of equipment made it difficult to clean	Test equipment for contamination, focusing on hard-to-reach areas
Personnel: <i>Any aspect of competency & aptitude (knowledge; skills, experience, ability to perform consistent work)</i>	Improper sanitation – high pressure hoses, lack of color coding	Excessive spray in confined area near freezer outlet.	Workers used high-pressure hoses to get into difficult-to reach areas	Review sanitation SOP, including execution of sanitation process.
Environment: <i>temperature; humidity, obstacles, lighting, distractions, morale, oversight, and presence of human error factors</i>	Cross-contamination due to poor workflow. Movement through raw ingredient area to freezer	Legacy problems in workflow layout from equipment retooling, repairs, change in footprint. Made access difficult.	Constraints from several re-toolings. Ad hoc additions, changes. No coherent plan for traffic flow, controls.	Review layout of equipment, traffic flow, ingredient storage and flow
Measurement/Information: <i>accuracy; precision, access, lack of, vague, has errors, timeliness, communication breakdowns</i>	Monitoring not robust. Did not indicate facility-wide Listeria issue			
Design: <i>any aspect of the product design that may be causing the problem</i>	Surface of cold product will re-freeze contaminating droplets			

Root cause: Why *Listeria monocytogenes* was identified in frozen appetizer – the “narrative” version

1. Equipment changes (upgrades and retooling) led to changes in the footprint and layout in the facility
 1. Caused improper flow of traffic and ingredients, which increased risk of raw material crossing finished product
 2. Constricted access to the area at the spiral freezer outlet.
2. Difficulty in sanitation of the freezer outlet area: hard to reach, hard to swab test properly.
3. Decision to use high pressure hoses to reach hard-to-access areas.
4. Water impingement on the freezer outlet, which led to *L. monocytogenes* biofilm buildup and contamination of frozen product, pre-packaging.





CELEBRATING
25 YEARS
Produced by FoodSafety
MAGAZINE

Root Cause: Validation & Verification

Speakers:
John Butts & Natalie Dyenson

Validation Summary – Dole 2021 Outbreak

Root Cause	Validation of Source	Preventive Control (s)	Validation of Preventive Controls ¹	Verification of Preventive Controls
Harvesting equipment was contaminated.	Listeria on the equipment matched outbreak strain.	Enhanced sanitation protocols throughout ecosystem.	Disassemble below normal and Periodic levels after sanitation and before operation. Sample for pathogen, its indicator and APC. Results: Negative for pathogen, indicators with APC below Upper Specification Limit.	field level verification metrics for sanitation.
		Initial and at least annual Decon-7 treatments for plants and between growing regions for harvest equipment.		Verification treatments were completed. Verification sampling of harvesting equipment and plant environment.

^[1] Assure potential harborage sites and growth niches are being effectively managed.

Validation Process

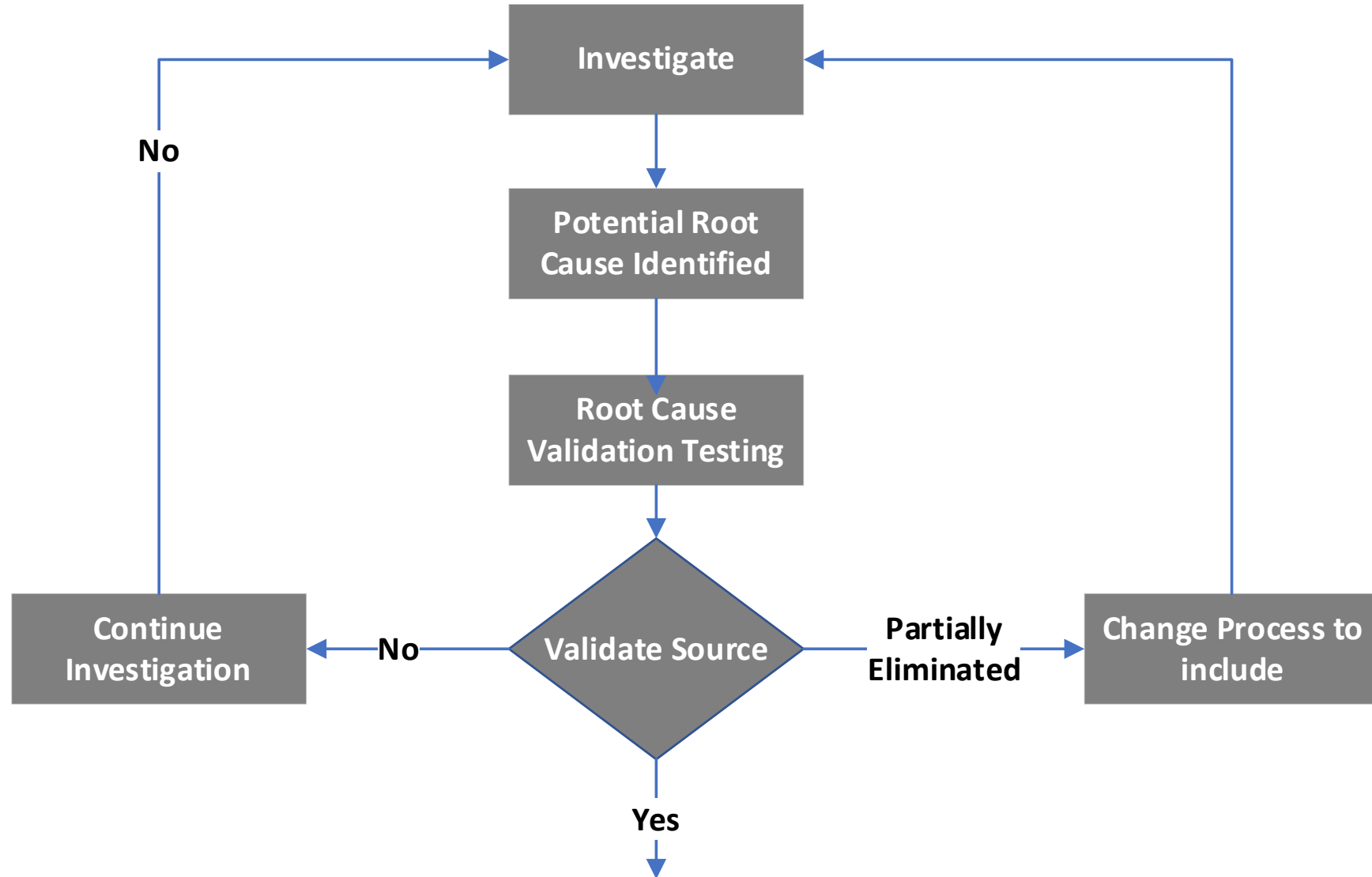
The Validation Process includes

1. Testing to Validate the Root Cause
2. Preventive Controls to Manage
3. Validate Effectiveness of the Preventive Controls and,
4. Verification Monitoring to Hold Gains Long Term



Testing to validate the root cause

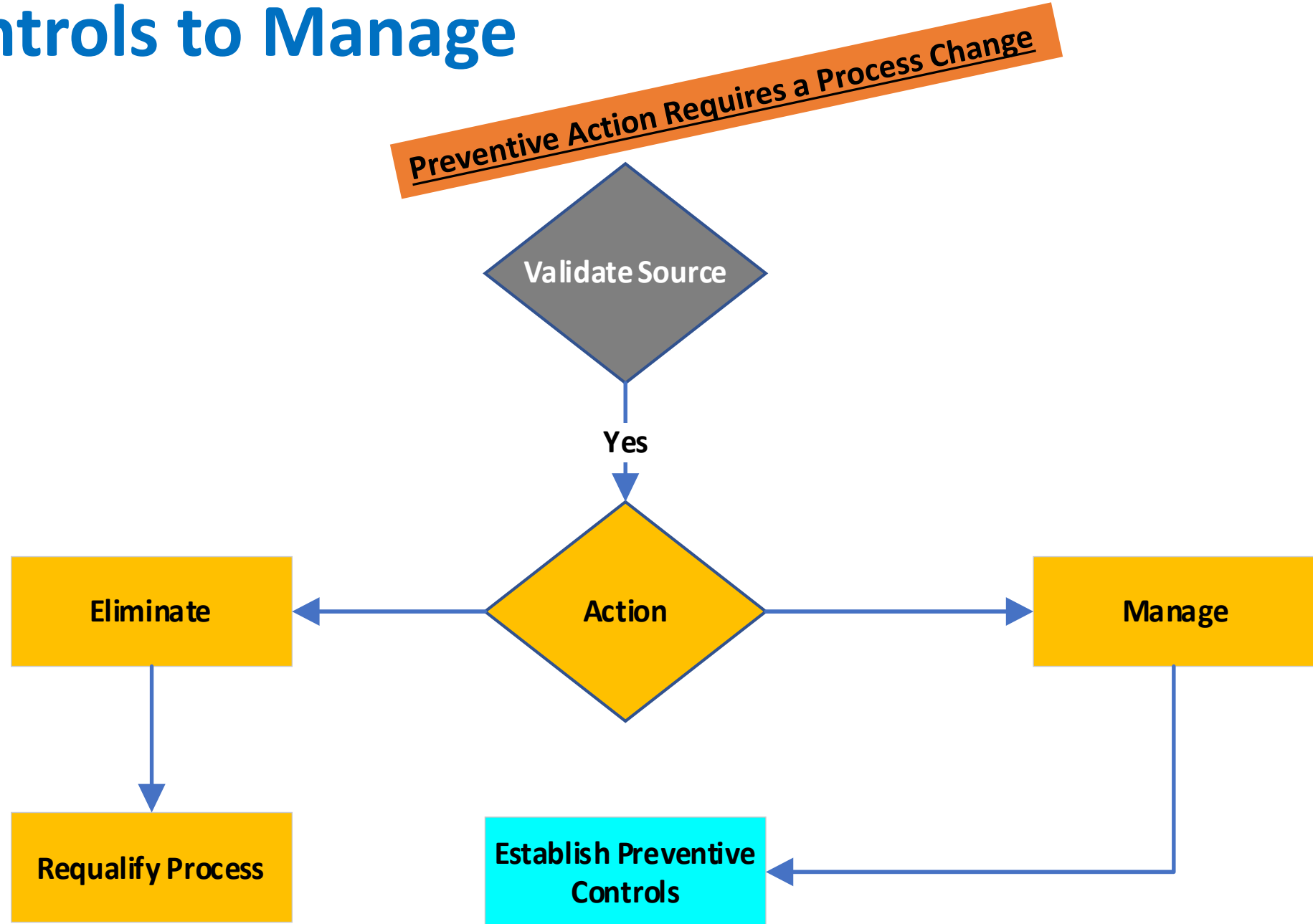
- Process must be data driven
 - Too often the true root cause is missed, or problem only partially solved
- Testing is designed to prove failure or uncontrolled variation leading to failure if the root cause remains in the system without effective preventive controls



Preventive Controls to Manage

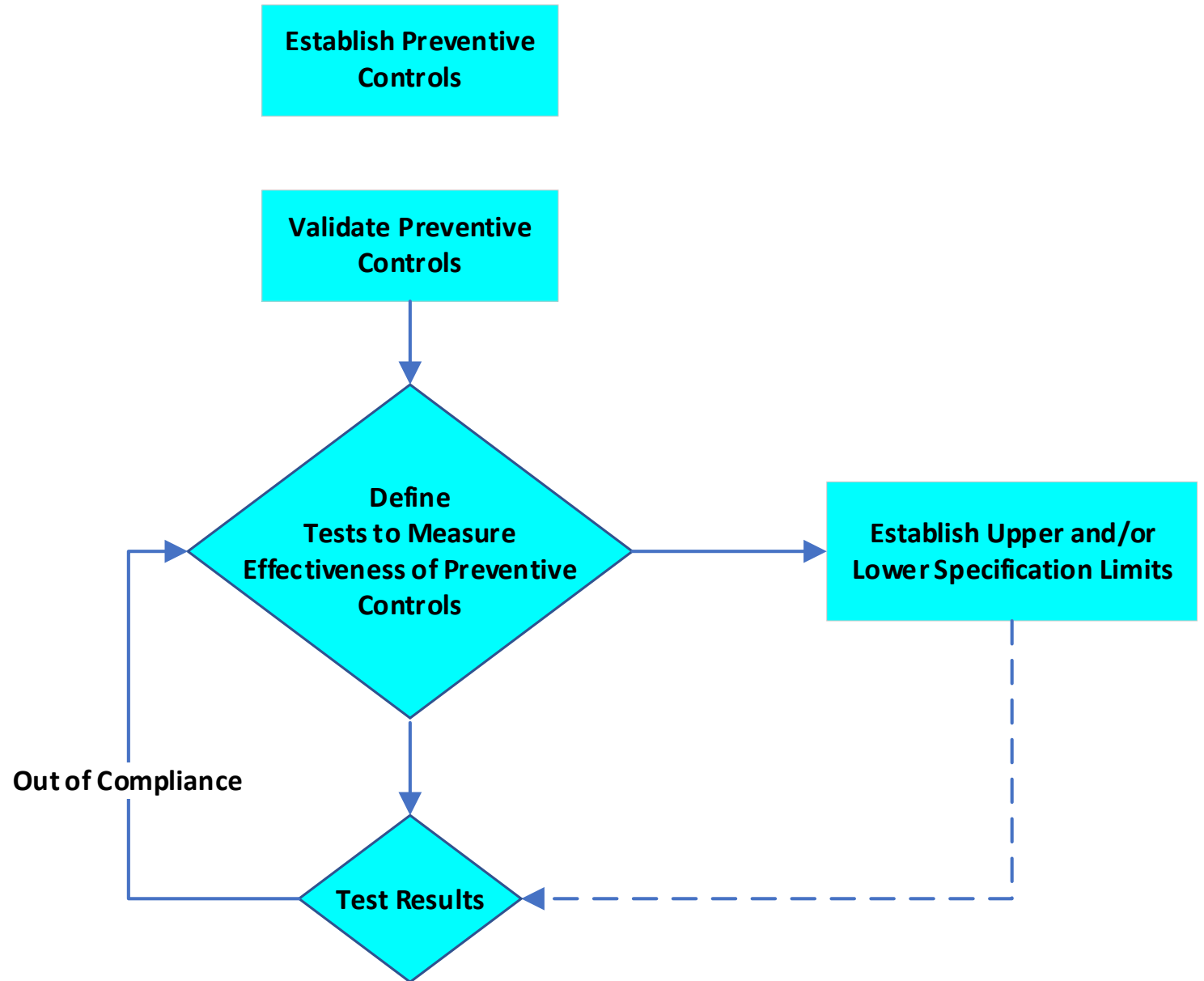
Root cause must be either Eliminated or Managed

- Eliminate example is removing a machine from the process.
- Managed means preventive controls are deployed to make the process capable and in statistical control.



Validate Effectiveness of the Preventive Controls

- This is the step most often missed or glossed over.
- Tests must be designed to challenge the system.



Validation Process

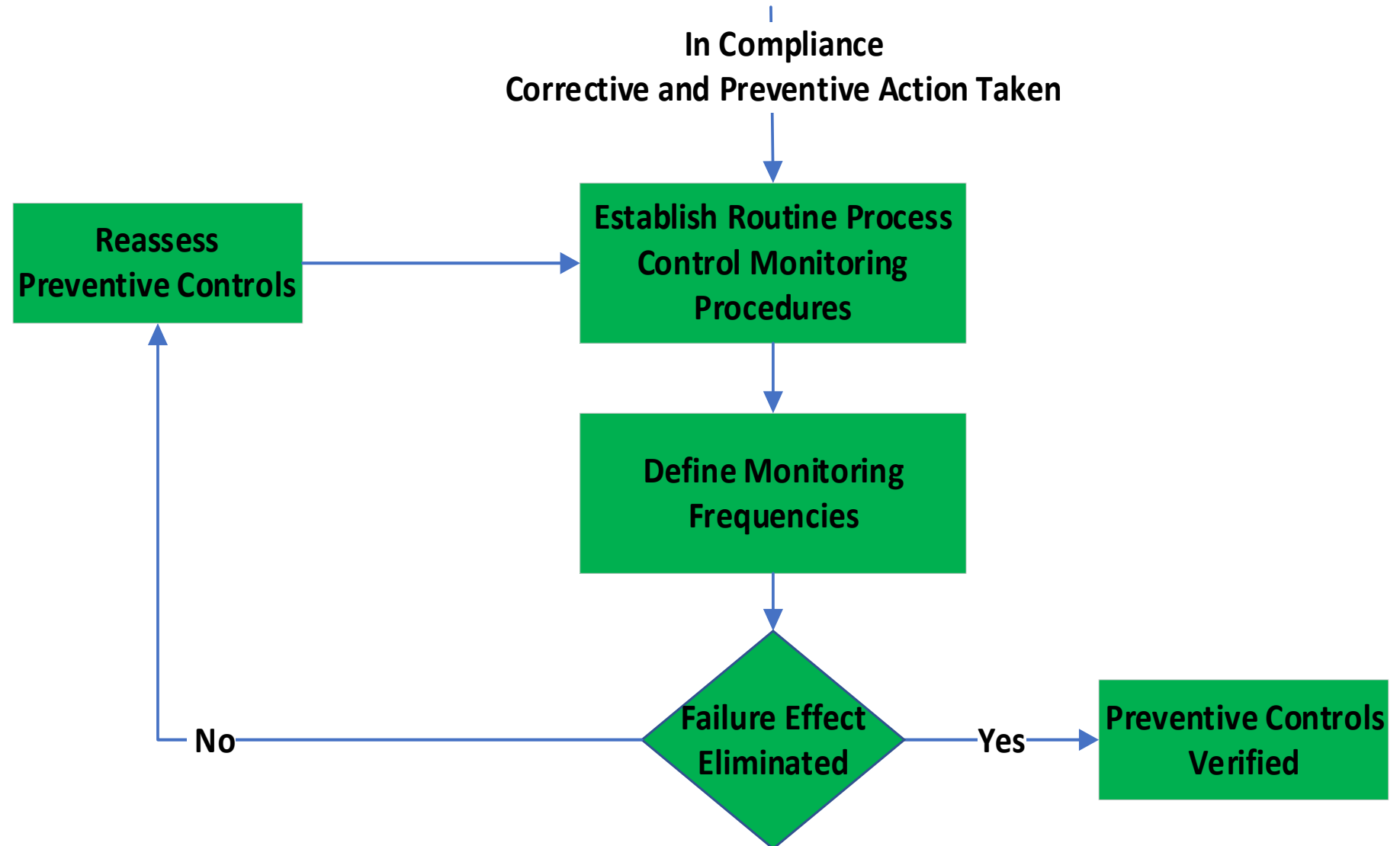
Validate Effectiveness of the Preventive Controls

- Examples
 - Failure effects measured after controls challenged.
 - Seek & Destroy Investigation (Complete disassembly) on equipment with root cause being managed.
 - Entry way hurdle challenged with dirty footwear.
 - Greasy contaminated tool cleaned then pasteurized in COP tank.
 - Dye test & Swabathon on corrected CIP system.
 - Examine integrity of process shedding foreign material after running dry or with inexpensive or pseudo product.



Verification monitoring to hold gains long term

- In process assessment or testing to assure preventive controls were applied and effective.
- Post process or finished product testing.



Validation Summary – Frozen Appetizer Exercise

Root Cause	Validation of Source	Preventive Control (s)	Validation of Preventive Controls ¹	Verification of Preventive Controls
<p>Unvalidated process changes led to post-freezing contamination immediately prior to packaging.</p>	<p>Seek & Destroy Investigation preformed found harborage site in exit area of freezer</p>	Reroute traffic flow and contain movement	Audit of pathways of movement show effective barriers separating raw and RTE areas	
		Hygienic zoning at all entry points to RTE area to include soil removal with sole or boot scrubber and 1000 ppm quat spray. Dry quat is placed after sole scrubber / boot wash.	Test footwear contaminated with pathogen free spoiled product was traversed through system. Log reduction > 5-7 log.	Observe presence and Measure Sanitizer application and concentration Sampling of Z4 to Z3 pathways demonstrate control.
		Cleaning tools in RTE Area are unique and separate from other areas in plant	COP Time and Temperature determined on contaminated cleaning tools	Monitor Time and Temperature
		SSOP changed to include Periodic disassembly to level of harborage site prior to cleaning and sanitization.		Audit SSOP and Master Sanitation Schedule
		Freezer exit area was redesigned for one tool disassembly and ease of accessibility	Seek & Destroy Investigations preformed in exit area of freezer at the defined time between Periodic Disassembly and Cleaning.	Is and APC verification sampling in the freezer exit area included in the routine EMP program

^[1] Assure cause of failure is being effectively managed.

Validation of Root Cause

- Provides data to educate and train future operators, maintenance process managers and management in general.
- Simply put “Why” is answered.





CELEBRATING
25 YEARS
Produced by **FoodSafety**
magazine

MAY 8 - 11 | 2023

Donald E. Stephens Convention Center | Rosemont, IL

COMMUNITY · EDUCATION · SOLUTIONS

John Butts

Principal

Food Safety By Design, LLC

foodsafetybydesign@gmail.com

219.718.5640

Natalie Dyenson

Vice President, Food Safety & Quality

Dole Food Company, Inc

Natalie.Dyenson@dole.com



Closing, lessons learned

CELEBRATING
25 YEARS
Produced by FoodSafety
MAGAZINE

Speakers:
Tim Jackson & Tim King

RCA in FDA's New Era of Food Safety



Smarter Tools and Approaches for Prevention and Outbreak Response

1. **Invigorate Root Cause Analyses**
2. Strengthen Predictive Analytics Capabilities
3. Domestic Mutual Reliance
4. Inspection, Training, and Compliance Tools
5. **Outbreak Response**
6. Recall Modernization

People-led, FSMA-based, Technology-enabled.

New Era 2.1: Invigorate Root Cause Analyses

- 2.1.1 Advance, standardize, and socialize **root cause analysis protocols** for food safety.
- 2.1.2 Address concerns about **protection of confidentiality and proprietary interests in data analysis** while advancing transparency.
- 2.1.3 Strengthen root cause analysis procedures
 - **Ensure rapid deployment** as soon as an outbreak is traced to a specific site.
- 2.1.4 **Standardize criteria and format for producing reports** on root cause analyses of outbreaks
- 2.1.5 Enhance communication tools, to **rapidly and transparently relay the outcomes of root cause analysis**, both internally and externally
- 2.1.6 **Incorporate root cause analysis data into the agency/s risk ranking and predictive analytical systems** to increase the likelihood of predicting and mitigating future contamination events.



Smarter Tools and Approaches for Prevention and Outbreak Response

What Are Your Key Take-aways?

What have you learned from us?

What have you learned from others?

What do you plan on doing going forward?



Moderator/Speaker Bios & Contact information

John N. Butts, Principal, FoodSafetyByDesign, LLC, foodsafetybydesign@gmail.com

Natalie Dyenson, VP, Food Safety & Quality, Dole Food Company, natalie.dyenson@dole.com

Tim Jackson, Sr. Science Advisor, FDA, Timothy.Jackson@fda.hhs.gov

Deb Kane, VP, Food Safety, Quality, & Regulatory, J&J Snack Foods Corp., dkane@jjsnack.com

Tim King, Senior Partner & Founder, Quality Matters LLC, timking@qualitymattersusa.com

Brendan Niemira, Research, USDA, brendan.niemira@usda.gov

Robert Prevendar, Director of Global FSQA, Yum! Brands, Robert.Prevendar@yum.com

Angie Siemens, VP, Food Safety, Quality & Regulatory, Cargill, Angie_Siemens@cargill.com

