International Association for Food Protection WEBINAR

Root Cause Analysis: Adopting Standard Practices for the Food Industry

June 5, 2024

3:00 PM – 4:30 PM Eastern Time

Moderator: John Sheehan, FDA

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International Association for Food Protection

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- **This webinar is being recorded and will be available for access by IAFP members within one week.**

Today's Panelists

International Association for Food Protection WEBINAR

Vernon Guthrie, Presenter	ABS Group
Tim King, Presenter	Quality Matters, LLC
Karen Krueger, Presenter	Kraft-Heinz
Mark Moorman, Presenter	FDA
John Sheehan, Presenter and Moderator	FDA

John Sheehan, FDA

John Sheehan is the Senior Advisor for Compliance and Enforcement to the Director, Office of Food Safety, at FDA's Center for Food Safety and Applied Nutrition. Prior to that, he was the Director of the Division of Dairy, Egg and Meat Products within the Office of Food Safety (2015-2020). Between 2006-2014, he was the Director for the Division of Plant and Dairy Food Safety within that same office. Prior to that he was the Director for the Division of Dairy and Egg Safety within the Office of Plant and Dairy Food Safety at that same Center. He has been with FDA since July of 2000.

Prior to joining FDA, Mr. Sheehan was a mid-level manager within the dairy industry for 18 years. He has worked for some of America's largest and most progressive dairy foods organizations.

Mr. Sheehan is an attorney who is an active member of both the California and U.S. Patent Bars.

From 2002 -2020 he served as the U.S. Alternate Delegate to the Codex Committee on Milk and Milk Products. He was also FDA's member of the Executive Board of the United States National Committee for the International Dairy Federation from 2004-2020. He was FDA's member of the Executive Board of the National Conference on Interstate Milk Shipments from 2007-2019.

Mark Moorman, FDA

Mark Moorman is the Director of the Office of Food Safety at the Food and Drug Administration within the Human Foods Program. Mark leads a team of food safety professionals pushing forward the many levers of prevention that will improve the safety of our food supply.

Prior to joining the FDA, Mark was the Senior Director of Global Scientific & Regulatory Affairs for the Kellogg Company in Battle Creek, MI with responsibilities for emerging food safety and nutrition technical and regulatory issues.

Prior to joining the Kellogg Company in 1998, Mark spent 10 years with Silliker Laboratories as the Technical Director of Microbiology.

Mark has his undergraduate and Ph.D. degrees from Michigan State University in Microbiology and Food Science.

Vernon Guthrie, ABS Consulting

Mr. Guthrie has over 45 years of experience in providing thought-leadership in the development and application of risk analysis methods and tools with the applications often involving the management and facilitation of large groups of technical experts. Mr. Guthrie's entire career has focused on assisting clients in understanding what risk-based information is needed for supporting good decision making and determining the most efficient approach for providing that information.

Mr. Guthrie is also an instructor for Incident Investigation/Root Cause Analysis (II/RCA), Risk Assessment (RA) and Enterprise Risk Management (ERM) courses offered through our Training Services division. Mr. Guthrie has performed numerous II/RCA/cultural cause analyses within the United States and internationally for food manufacturing, marine, refinery, petrochemical, offshore and nuclear clients. Mr. Guthrie has taught a 2-day ERM course and led ERM efforts for both commercial and public clients including support for assessing and guiding ERM at the Bureau for Safety and Environmental Enforcement (BSEE). Mr. Guthrie has participated in and facilitated numerous tasks for the U.S. Coast Guard to develop and deploy national and port security risk assessment tools and to assess other procurement, project, safety and security risks.

Before joining the ABS Consulting Knoxville Office, Mr. Guthrie provided thought-leadership in risk assessment and risk management for the Nuclear Division of Union Carbide Corporation at the Department of Energy facilities in Oak Ridge, Tennessee. Areas of expertise include enterprise risk assessment, incident investigation/root cause analysis, risk and reliability analysis, and development of computer software for risk assessment applications.

Tim King, Quality Matters LLC

Tim King is founder of Quality Matters LLC, a training and consulting company specializing in quality education, quality system auditing and implementation guidance, process improvement methodology and, root cause analysis tools and techniques. Tim is an also an expert trainer for the American Society for Quality in various courses and topics.

He holds a BS and MS in Mechanical Engineering. He served in various capacities in GE. Tim is an ASQ certified Quality Manager, Auditor, Inspector and Quality Improvement Specialist. He obtained his Lean Six-Sigma Master Black Belt from Dartmouth College. Tim served as an examiner for the Malcolm Baldrige Quality Award for thirteen years.

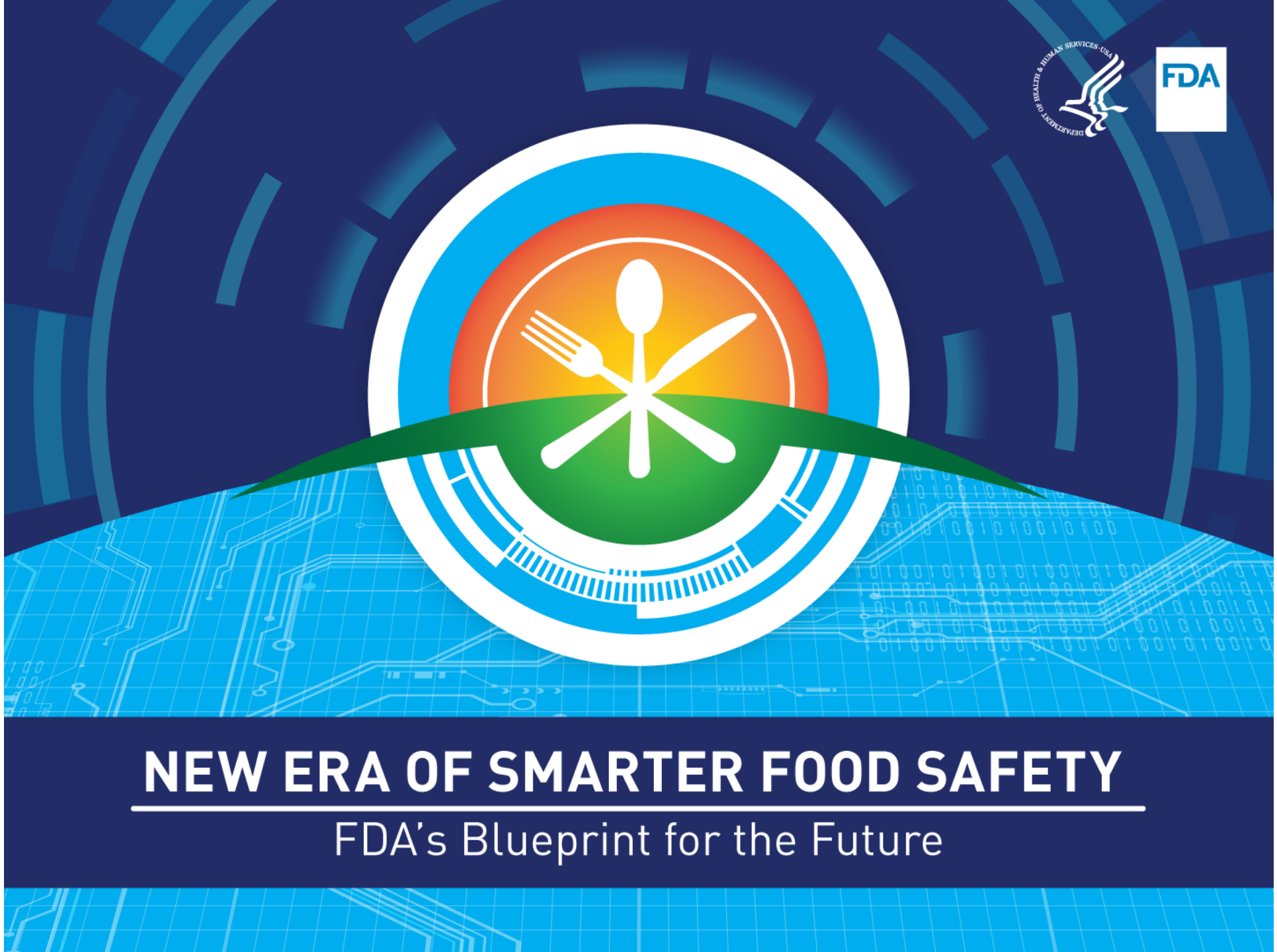
Karen Krueger, Kraft Heinz

Karen Krueger is the North America Associate Director for Quality Systems & Consumer Relations at the Kraft Heinz Company. She manages implementation of the Kraft Heinz Management System, establishing the Digital Quality Roadmap and supporting In-Line Product Protection (Xray, Metal detection, Air Rinser, 2D label verification), internal and external and warehouse quality, data reporting, sales inquiries and consumer escalations, product launch acceleration and Small Batch Manufacturing (2018 to current as the role expanded). Her career experiences help drive improvements, educate others and simplify processes while working with functional business partners and helping implement initiatives.

Prior to that, she was part of the Kraft Foods Corporate Quality Team where she supported, Meals & Desserts, Beverage & Snack Nuts, Enhancers and Innovation quality support in additional in a Field Quality role where she Planters external manufacturers and suppliers (2012 – 2018).

Kraft Foods Corporate Product Protection & Hygienic Design role supporting the Canadian factories and transitioned through the different business units a as their corporate sanitation support (2009 – 2012).

Karen stated working for in manufacturing for Kraft, Nabisco and Favorite Brands International in a variety of roles within the factory from sanitation, quality, maintenance and operations (1991 – 2009)


FDA
NEW ERA OF SMARTER FOOD SAFETY
FDA's Blueprint for the Future

Tech-enabled Traceability

Smarter Tools and Approaches for Prevention and Outbreak Response

Welcome to FDA's New Era of Smarter Food Safety

New Business Models and Retail Modernization

Food Safety Culture

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

Core Element 2

Smarter Tools and Approaches for Prevention and Outbreak Response

Why is root cause analysis needed?

- FDA is good at the "what and the where" of an outbreak
  - Need to get better at the "how and the why“
- Foster a culture of learning in the food industry
  - Goal: Tell the story of the outbreak and root cause
- You can’t solve a problem you don’t understand
  - The investigation and analysis of RCA determines the problem(s) to be solved
- Firm leadership support for organization to be ***curious*** after a potential food safety event – to conduct the RCA
  - Food safety culture: A move on mindset impedes a culture of learning

U.S. FOOD & DRUG ADMINISTRATION

FDA's Initiative to Advance Root Cause Analysis Protocols for Food Safety

The Impetus for Action

- New Era of Food Safety Blueprint, July, 2020
- Core Element 2: Smarter Tools and Approaches for Prevention and Outbreak Response
- Sub-Element 2.1 ***Invigorate Root Cause Analyses***
- Collaborate with federal, state, industry, consumer, and academic stakeholders to ***advance, standardize, and socialize root cause analysis protocols for food safety.***
- ***Strengthen root cause analysis procedures*** – coordinating with federal, state, local, tribal, and territorial partners – to ensure rapid deployment as soon as an outbreak is traced to a specific site.
- ***Standardize criteria and format for producing reports on root cause analyses of outbreaks*** and determine the most expedited process for disseminating information and required actions to prevent a reoccurrence.

First Action

- FDA did not have an SOP for RCA.
- There was an RCI manual that was developed for produce safety investigations
- That did not include a procedure for performing a root cause analysis
- FDA researched RCA protocols and practices domestically and internationally, both for industry and governments.

First Action

- Drafted an SOP
- Involved personnel from ORA, CVM and CFSAN – (OC, CORE and OFS).
- SOP stops at solution identification, since FDA would not be implementing solutions or verifying their efficacy.
- The SOP contains a standardized template for RCA reports, so it is immediately responsive to two of the work items identified under CE 2.1 and it enables us to now do the advancing, standardizing and socializing actions under 2.1
- SOP internally published 08/22/2022

The SOP

- The SOP describes the process of conducting a Root Cause Analysis from initiation to reporting.
- It is written in the format of a CFSAN SOP.
- Purpose, Scope and Definition Sections precede the main sections (Roles and Responsibilities, Procedures for conducting an RCA and RCA Tools Step by Step Protocols).
- After those sections there is a Reference section and an Appendices section.

The SOP

- The SOP describes the process to be used in the identification of root cause(s) and contributing factors for food-related trigger events.
- RCA is initiated after an investigation/inspection.
- It is applicable to all food safety trigger events.
- The SOP includes usage of several tools and approaches described within the literature and ASQ training.
- Is/Is Not Analysis, SIPOC, Flowcharting, Ishikawa diagram, Five Whys (the latter two being combined into a single tool developed by FDA)

Other Actions

- Developed a training module for the CFSAN SOP
- Trained FDA, State and CDC personnel on RCA using an external (American Society for Quality)
- 146 people trained by the end of 2023
- Those same FDA personnel were also trained on the CFSAN RCA SOP

Other Actions

- Modified the Investigations Operations Manual to install specific data requirements for RCA - It appears within Section 8.2.2.5.5 of the latest edition.
- Will help to ensure that the data collected or generated during the course of a Root Cause Investigation includes the data types that will facilitate identification of root causes.
- Modified the RCI Manual to include the CFSAN SOP as a reference
- Tested the SOP and the software which will be used to perform RCA

Other Actions

- Will conduct a pilot program for the CFSAN RCA SOP
- Benchmark study on Root Cause Analysis standards, procedures and practices by the food industry and governments domestically and internationally completed by a third party contractor
- Developing a Guidance for Industry on Root Cause Analysis
- Guidance will reflect FDA's SOP and contain basic instruction on how to perform Root Cause Analysis through some of the more commonly used tools
- RCA Webpage – will contain all things RCA developed by or for FDA

RCA and PCHF Rule

- There is no specific requirement within 21 CFR 117 to perform an RCA for any reason.
- PCHF Rules text which might be read to infer that RCA is required when investigating a food safety incident can be found at:
- 21 CFR 117.150 "Corrective actions and corrections"
- 21 CFR 117.150 (a)(2)(i) recites in pertinent part: " Appropriate action is taken to identify and correct a problem that has occurred……"

RCA and PCHF Rule

- 21 CFR 117.150 (b)(2)(ii) recites that:

- "The corrective action procedures must describe the steps to be taken to ensure that:

- "Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur"

RCA and PCHF Rule

- RCA is discussed in the preamble to the Rule in a response to a comment (no. 472)

- "The rule does not use the term ''root cause'' but it does require the facility to take appropriate action, when necessary, to reduce the likelihood that the problem will recur (see § 117.150(a)(2)(ii)). Root cause analysis is simply part of a common approach to complying with this requirement. (Knowing the root cause is key to reducing the likelihood that a problem will happen again.)"
- We will be amending PCHF Rule Guidance to discuss Root Cause Analysis

What should result from all of this?

- ***Advance, standardize, and socialize root cause analysis protocols for food safety with our state regulatory partners and ultimately industry*** - The standardization and co-ordination will be first effected through training.
- Will be on root cause analysis practices generally and the FDA procedure in particular.
- Subsequent to the training, the ambition is to ask the states to participate in root cause analysis with us.
- If states are trained on RCA generally and FDA's protocol in particular, they will be able to fully participate with FDA in an RCA.
- Should a state do an RCA itself, given that it will have received the same training as FDA, it might use a procedure that is not inconsistent with our own.

Questions?

- Thank you for the invitation to present to you today on our work involving Root Cause Analysis
- Questions?

FDA Sponsored Research on the Status of the Use of Incident Investigation and Root Cause Analysis Focused on Response to Foodborne Illness Outbreaks

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Webinar: Root Cause Analysis: Adopting Standard Practices for the Food Industry

Date: June 5, 2024

Outline

1. Introduction
    1. About ABS Group
    2. Research Sponsors and Team
2. Scope
    1. Research Scope
    2. Key Questions Considered
3. Methods
4. Findings
    1. Geographically Related – Primarily from Web Searches

       (By continent; by country for all activities; by country for only the Establishing activity; for all states in the United states of America; and for a selected state)
    2. II/RCA Phase Related *(Establishing, Planning, Implementing and Improving)* Related – Primarily from Interviews with Corporations
5. Conclusions
    1. Question Related
    2. II/RCA Phase Related
6. Recommendations and Closing Remarks

ABS Group

Introduction

Company Overview

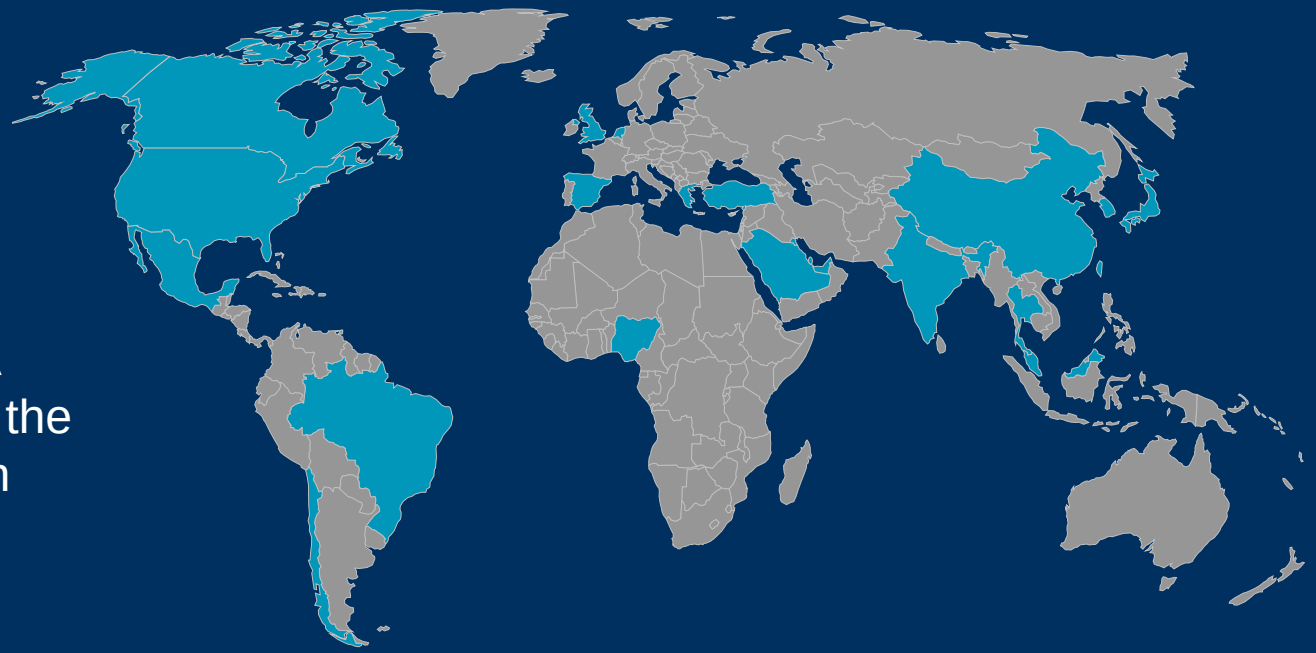
ABS Group provides data-driven risk and reliability solutions and technical services that help clients confirm the safety, integrity, quality and environmental efficiency of critical assets and operations.

ABS Group is focused on adding value to the industries served and strategically capturing synergies with the American Bureau of Shipping (ABS).

1000+
Employees

20+
Countries

50
Years



ABS Group is headquartered in Spring, TX, USA and is an independent subsidiary of ABS, one of the world's leading marine and offshore classification societies founded in 1862.

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Research Sponsors and Team

Investigation Sponsors:

John Sheehan, Senior Advisor for Compliance and Enforcement, Office of Food Safety (FDA Technical Lead)

Esther Lazar, Project Manager (FDA Project Supervisor)

Investigation Team Members:

Vernon H. Guthrie (ABS Consulting Inc., Technical Lead)

Tom McCoig (ABS Consulting Inc., Project Lead)

Donald B. Stinnett (ABS Consulting Inc., Research Assistant)

Kate Stuhrke (Brillient Corporation, Contract Project Manager)

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Scope

Research Scope

This research was funded by the FDA (Food and Drug Administration) to perform a literature search (primarily web-based) of what Industry, Regulatory, and Trade organizations are doing to promote or apply root cause analysis to improve food safety.

ABSG Consulting Inc. (ABS Consulting) performed this work under contract with the Brillient Corporation.

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Key Questions Considered

Some of the key questions considered by this research included the following:

1. What percent of the food-related Industry, Regulatory, and Trade organizations worldwide have incident investigation/root cause analysis (II/RCA) activities?

2. For organizations found to have some II/RCA activity, was there activity in each of the four areas/phases of II/RCA (i.e., Establishing, Planning, Implementing, and Improving) considered by this research?

3. What is the range of practice observed for II/RCA (i.e., specifically for the areas/phases of Establishing, Planning, Implementing, and Improving)?

4. What are the best practices observed in using II/RCA to improve food safety (i.e., specifically for the areas/phases of Establishing, Planning, Implementing, and Improving)?

5. What are the differences in II/RCA best practices for small versus large food Industry-related organizations?

6. What are the II/RCA challenges observed for the range of organizations considered?

Methods

Research Methods/Approach

- Data Gathering
  - Developed extensive list of II/RCA related questions
  - Sought answers to questions
    - Website reviews
    - Interviews
- Data Analysis
  - Developed dashboards to show cumulative results using PowerBI
  - Performed interviews because of relatively sparce web information

Findings – Geographically Related

Searches performed on organizations by continent

Continents	Industry	Regulatory	Trade	**Total**
Africa	9	54	3	**66**
Asia	16	48	2	**66**
Australia		23		**23**
Europe	5	49	9	**63**
North America	76	61	11	**148**
South America	1	14		**15**
Total	**107**	**249**	**25**	**381**

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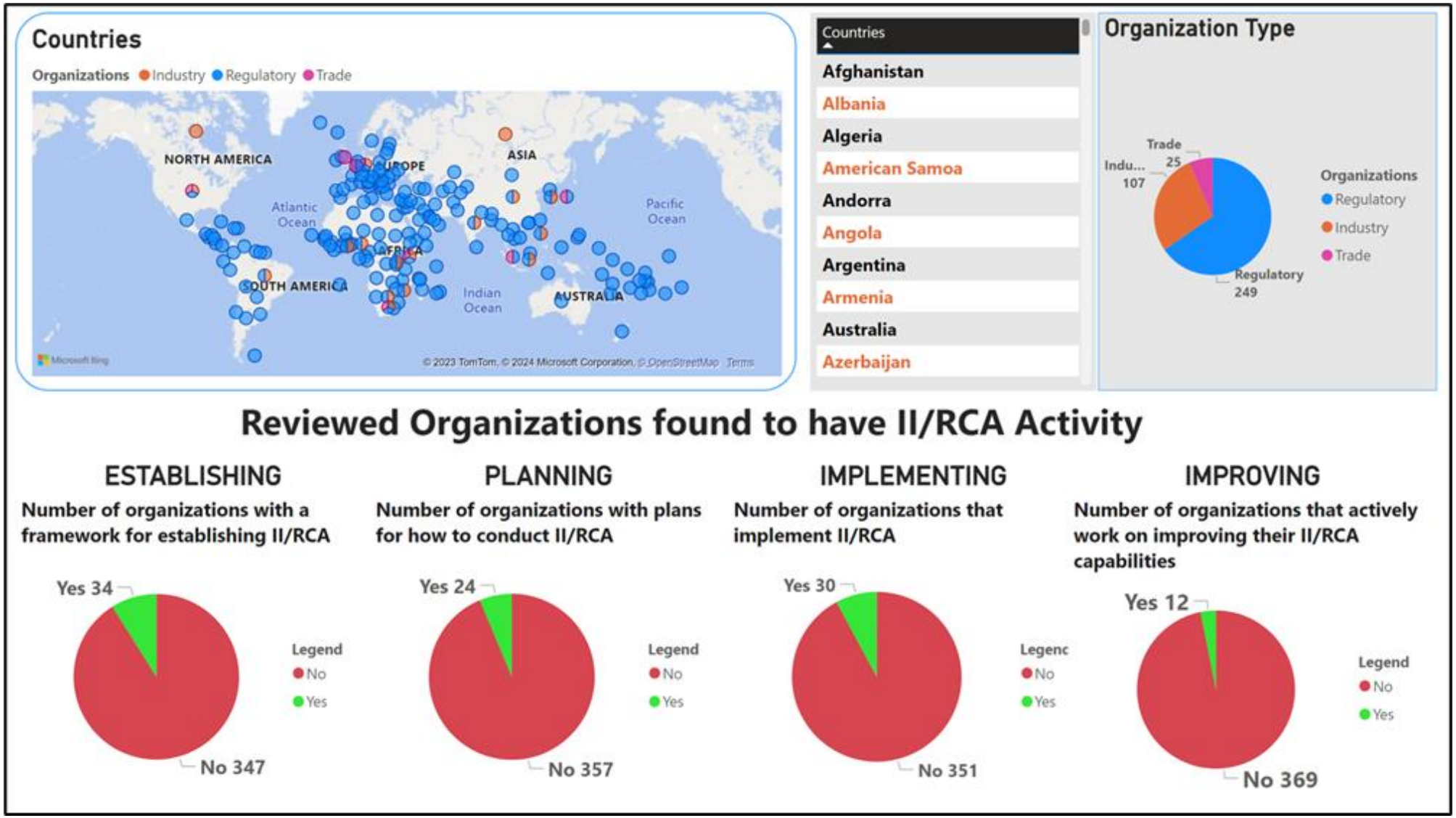
High-level charting of II/RCA search results showing organizations reviewed by country and whether any activity exists



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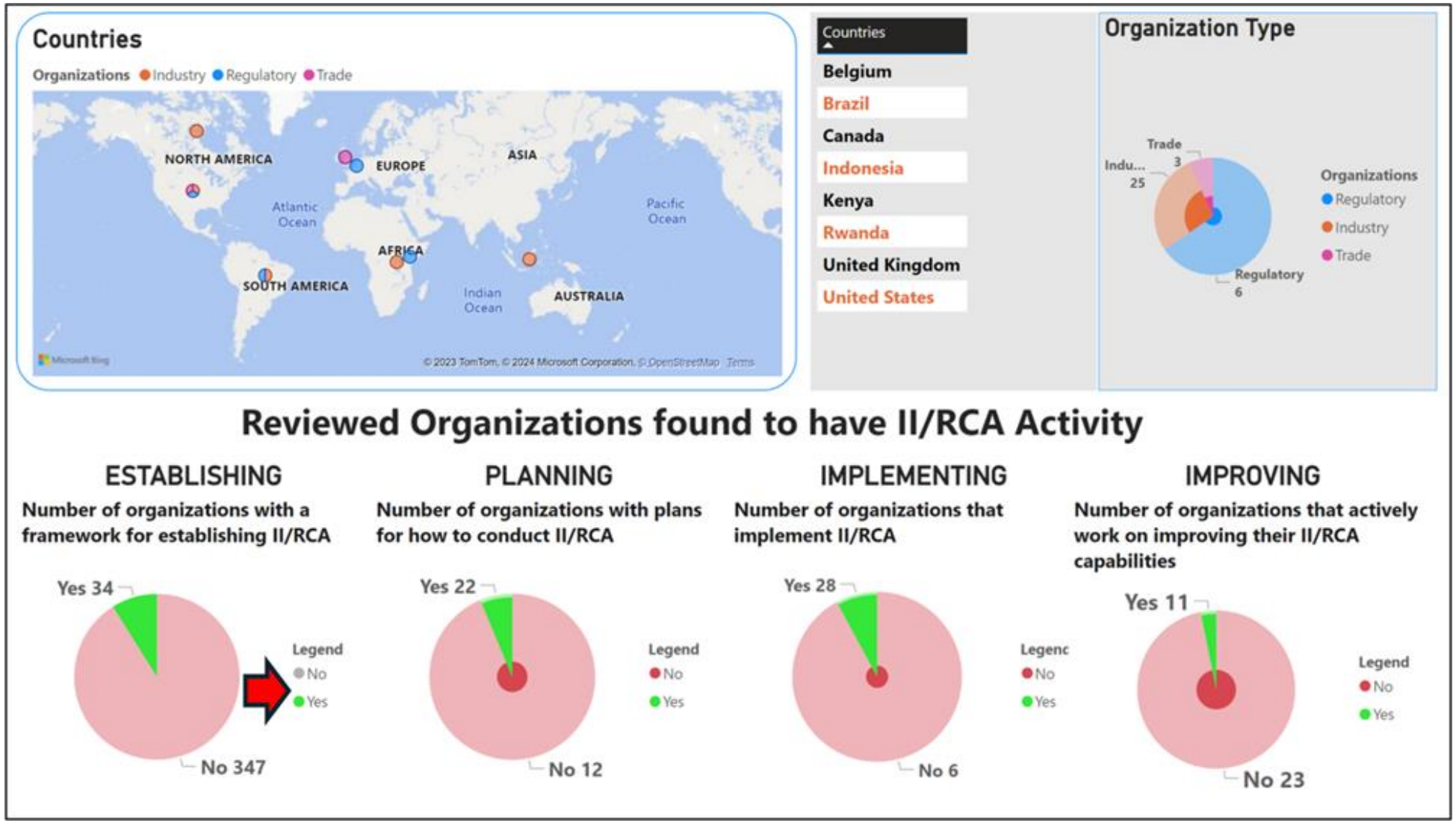
High-level charting of II/RCA search results showing countries having at least one organization with the Establishing activity



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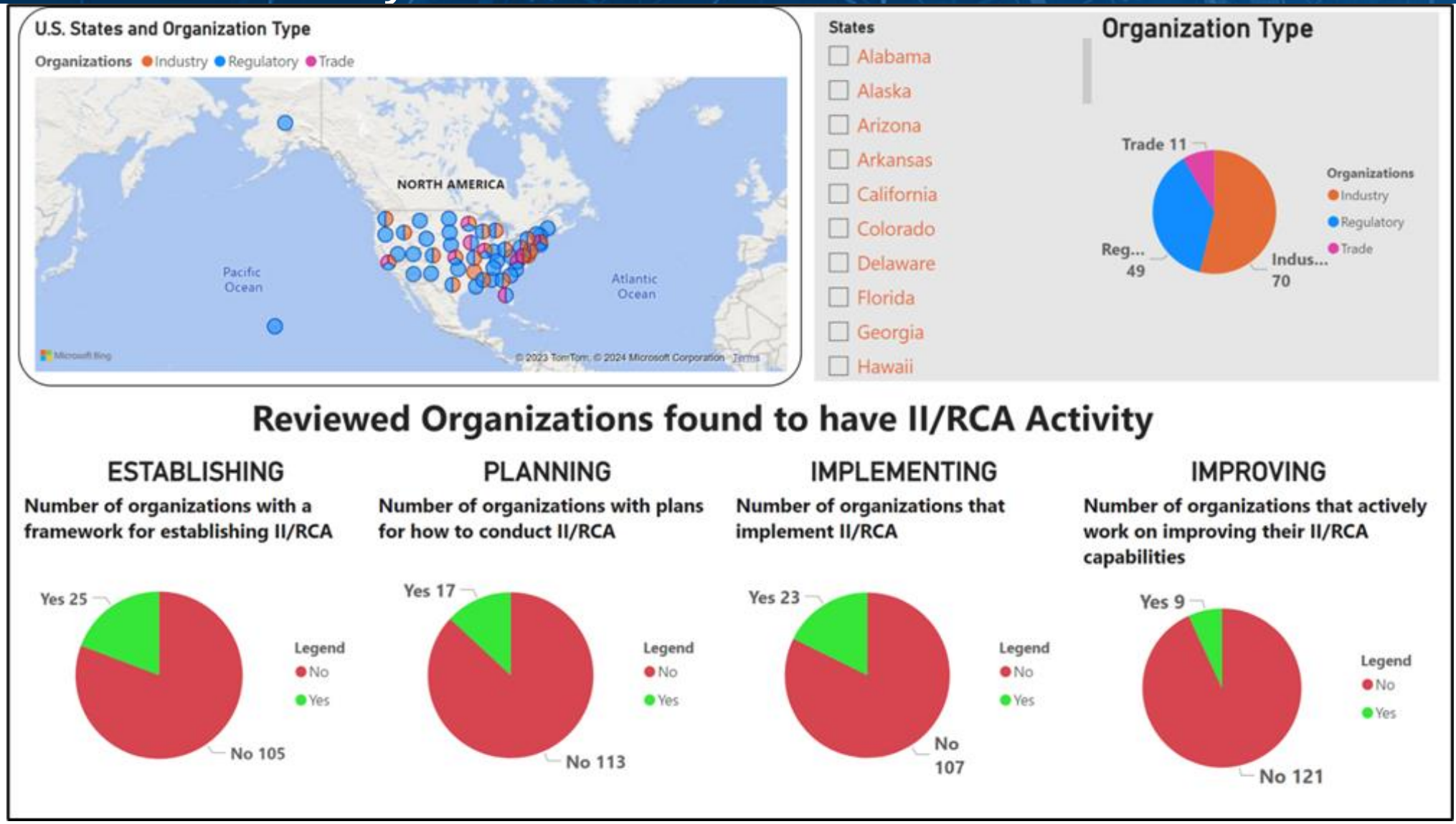
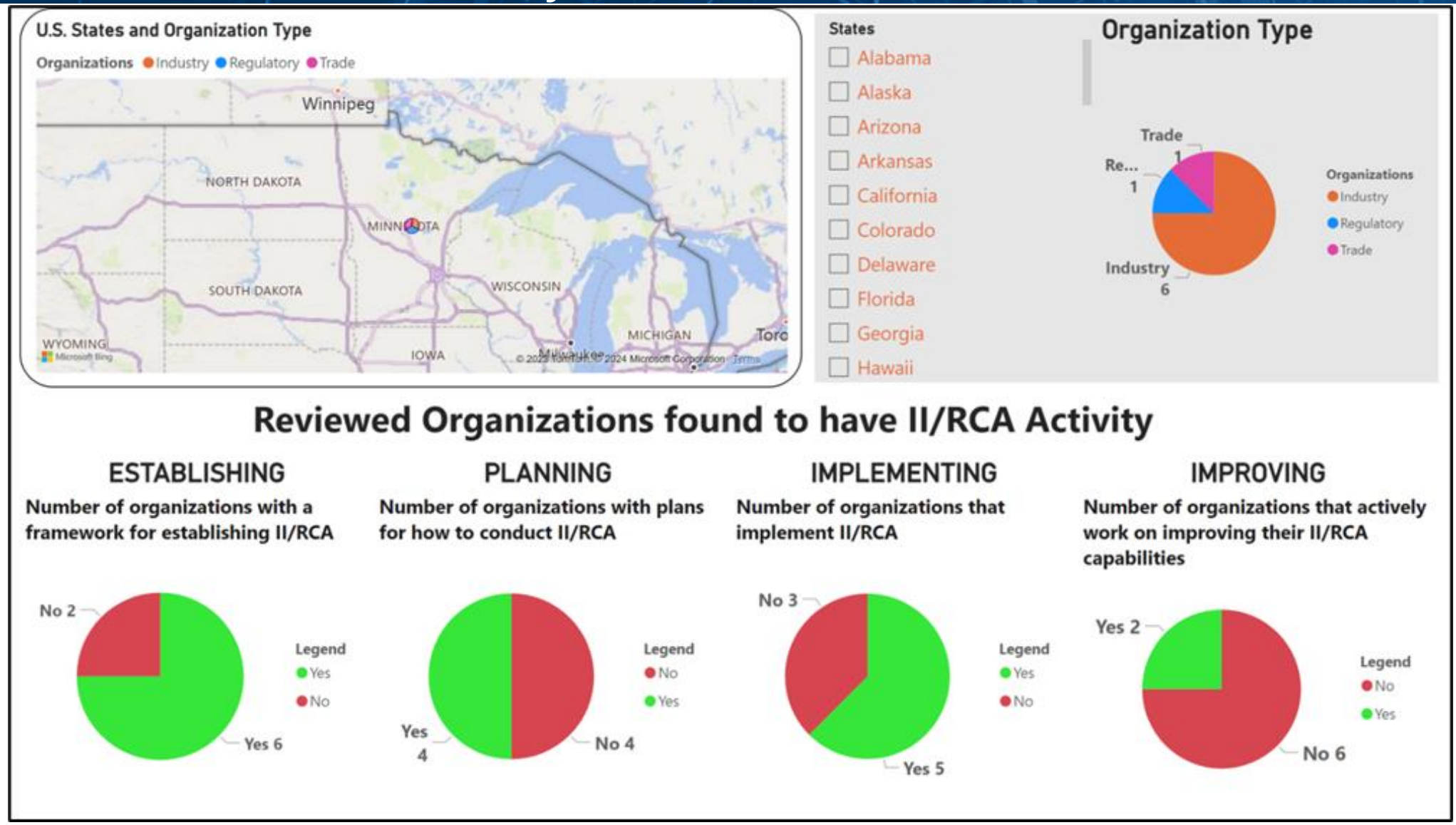
Charting of II/RCA search results focused on states in the United States and what activity was found in each state



Charting of II/RCA search results focused on a specific state in the United States and what activity was found in the selected state



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Conclusions – Question Related

Question 1: What percentage of food-related Industry, Regulatory, and Trade organizations worldwide have II/RCA activities?

- Most food-related organizations have not considered applying II/RCA, have just begun applying II/RCA, or are applying II/RCA but do not have it listed on their website.
- The percentage of food-related organizations providing publicly available information regarding their II/RCA activities was typically below 25% of those reviewed across all the areas of inquiry.
- Apparently, most organizations have at least a minimum level of II/RCA activities as part of their efforts to define corrective actions.

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Question 2: For organizations with some II/RCA activity, was there activity in each of the four areas/phases of II/RCA?

- No, the results varied, but typically Establishing had the most activity and Improving had much lower activity.

Question 3: What is the range of practice observed for II/RCA

- There is a wide range of practices by food-related organizations regarding their use of II/RCA in addressing or supporting food-borne incidents from no activity (the most common) to very mature systems/processes.

Question 4: What are the best practices observed in using II/RCA to improve food safety?

- The research team was able to observe and document best practices as described in the “Findings” slides.

Question 5: What are the differences in II/RCA best practices for small vs large food Industry-related organizations?

- While the best practices at large Industry organizations tended to be similar, as documented in the benchmarking section, it was difficult to discern what practices exist in the smaller Industry organizations.
- There appear to be significant differences between practices for small versus large food-related organizations, with small companies having little or no formal program for II/RCA methods, training, implementation, or follow-up.

Question 6: What are the II/RCA challenges observed for the range of organizations considered?

- Current publicly available guidance for conducting II/RCAs for food safety is limited, with most food-related organizations providing either no or limited information regarding their II/RCA activities either on their website or in documents located via web searches.
- Providing II/RCA resources to food-related organizations that range from supporting the simplest to the most complex food-borne incidents is challenging.
- There needs to be more clarity in much of the publicly available II/RCA guidance regarding a distinction between identifying initial causes or CFs during the incident investigation and the subsequent pursuit of intermediate and root causes for each identified initial cause during the root cause analysis.
- Many organizations that perform II/RCAs and communicate their methods do not clearly distinguish between the initial causes of an incident and the intermediate and root causes of an incident. The perception is that this can confuse the focus and boundaries of the II/RCA.

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Question 6: What are the II/RCA challenges observed for the range of organizations considered? (Continued)

- Potentially beneficial support from the FDA
  - Food-related organizations, particularly in the United States, would benefit from the FDA providing new II/RCA resources to help:
    - Understand the range of II/RCA program maturity, what maturity level the organization might want to achieve, and what is required to go from their current maturity level to the desired maturity level.
    - Understand the steps in performing an II/RCA along with suggested tools for a wide range of investigations from simple to complex with worked examples.
    - Obtain answers to specific II/RCA questions promptly and, perhaps, anonymously.
    - Consistent terminology, report content, and incident categorization.

Conclusions – Phase Related

Establishing

- Only a small fraction of food-related organizations have founding documents that formalize/frame their intended II/RCA program.
- The food-related organizations with the most mature II/RCA programs had clear founding documents establishing the organization’s commitment to planning, implementing, and improving II/RCA.

Planning

- Most food-related organizations do little or no planning for II/RCA (e.g., designating II/RCA roles and responsibilities and providing II/RCA guidance, training, and competency testing).
- The food-related organizations with the most mature II/RCA programs had extensive planning.
- Many food-related organizations do distinguish between a CF or initial cause and intermediate and root causes of the CF.
- Most food-related organizations do not explicitly require the identification of CFs before pursuing the intermediate and root causes of each CF.

Implementing

- Food Industry organizations' responses to non-compliance or food safety incidents vary significantly
  - Organizations with less mature II/RCA programs:
    - Often provide little or no II/RCA response.
    - May respond by relying on II/RCA support from outside resources. (in part because they have no prior planning and have no defined internal resources).
  - Organizations with more mature II/RCA programs had extensive Implementing activities.
- Typically, Regulatory organizations verify that the relevant Industry organizations are involved in the II/RCA for a food safety incident but are not themselves directly involved in the II/RCA after the Regulatory organization is satisfied that the pathogen or physical contaminant and source are known.
- Typically, Trade organizations provide II/RCA guidance and a forum for discussion for a food safety incident, but are not themselves directly involved in the II/RCA

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Improving

- Most food Industry, Regulatory, and Trade organizations could benefit from a more focused approach to defining what they would like their II/RCA program to achieve, where they are now, and how they will move from where they are now to where they want to be.

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Recommendations - General

General Recommendations

- Perform follow-on food safety research for II/RCA using surveys of Industry, Regulatory, and Trade food-related organizations to obtain a more direct and complete understanding of each organization's II/RCA activities. ABS Consulting's research was mostly confined to web-based reviews that often, because of little or no information on the website, provided very little insight regarding what the organization was doing for food safety-related II/RCA activities. Such a survey effort will need to conform to Paperwork Reduction Act requirements.
- Perform periodic updates to the project's Excel database documenting answers to the questions developed by this research for each of the four II/RCA phases. For an update, both refine the results for organizations currently reviewed and review other organizations.

Recommendations – Phase Specific

Phase Related Recommendations - Establishing

- Develop resources for food-related Industry, Regulatory, and Trade organizations with examples of a range of governing documents for detailing an II/RCA program from the smallest of beginning efforts to highly ambitious programs.

Phase Related Recommendations - Planning

- Develop an II/RCA handbook that provides a wide spectrum of guidance addressing the simplest of non-compliances to the most complex of incidents with a range of tools and techniques that can be helpful to organizations from the smallest to the largest. Make this handbook or these handbooks available for download by any organization. Other governmental agencies have existing documents that could provide a model for the FDA food safety handbook.
- Once developed, make the document readily available to food-related organizations.
- Encourage food-related organizations with extensive II/RCA planning efforts to make more of these resources publicly accessible.

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Phase Related Recommendations - Implementing

- Provide a helpline for any food processing Industry organization to obtain anonymous (perhaps third-party) help addressing food non-compliances and incidents. Assistance could range from answering or getting answers to questions to directing to available resources to providing detailed guidance in using various II/RCA tools and techniques.

Phase Related Recommendations - Improving

- Develop an II/RCA maturity model with a range of maturity levels (e.g., Level 1 - Very Low Maturity to Level 5 – Very High Maturity) addressing a wide range of relevant characteristics (e.g., founding documents, goals, mission statement) for each II/RCA phase (e.g., Establishing, Planning, Implementing, and Improving).
- Providing such an II/RCA maturity model to organizations could help them better understand potential options for improving their II/RCA programs, where they currently are, and the progression of steps required to reach their desired maturity level.
- Providing examples of organizations that elect to be at various levels of II/RCA maturity based on the size and nature of their organization helps organizations understand the II/RCA capabilities that have been useful to similar organizations.

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Closing Remarks


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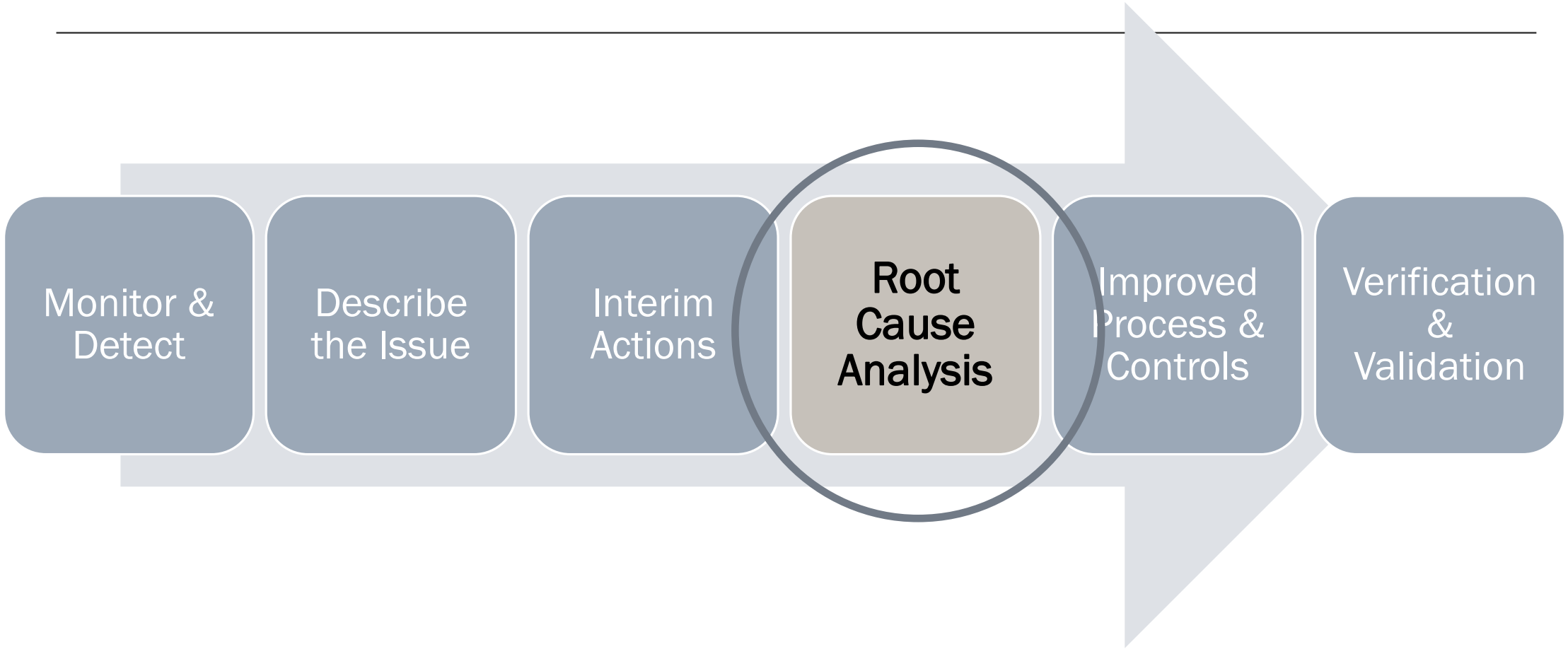
Root Cause Analysis Tools to Use

Speakers:
Tim King

RCA- The Gateway to Improvement



Process Approach- Six Sources of Process Conditions That Can Cause Quality Issues
(these are used on the "fishbone" diagram)

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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

"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.

Factors Behind Human Error

Skill aptitude

Knowledge access

Memory/recall lapse

Cognitive decision making

Personal discipline… “stamina” for consistent work

Tools, equipment

Ergonomics- stress/strain/fatigue

Information, communications

“Environment” issues

Sensory challenges (seeing, hearing, touch, 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 **(quality & safety system)**

→ example: systemic competency problems; lack of adequate competence in key roles

RCA- Tools That Assist RCA Determination

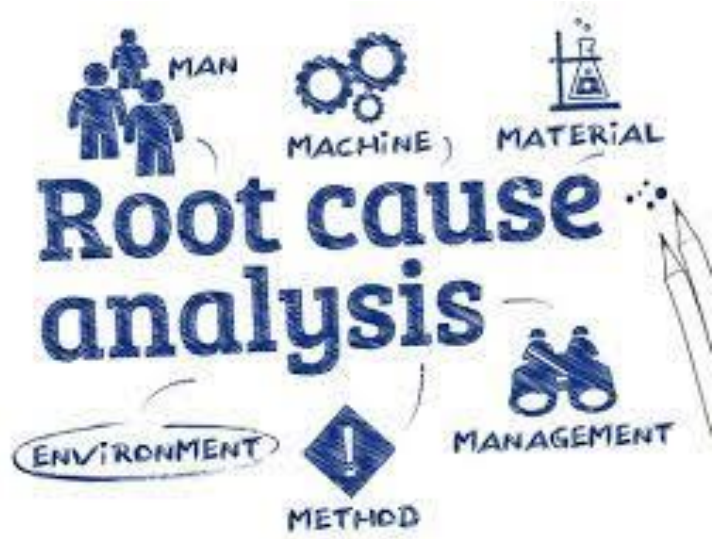
Common ones:

5-Why Investigation

→ Hybrid: Cause Logic Map

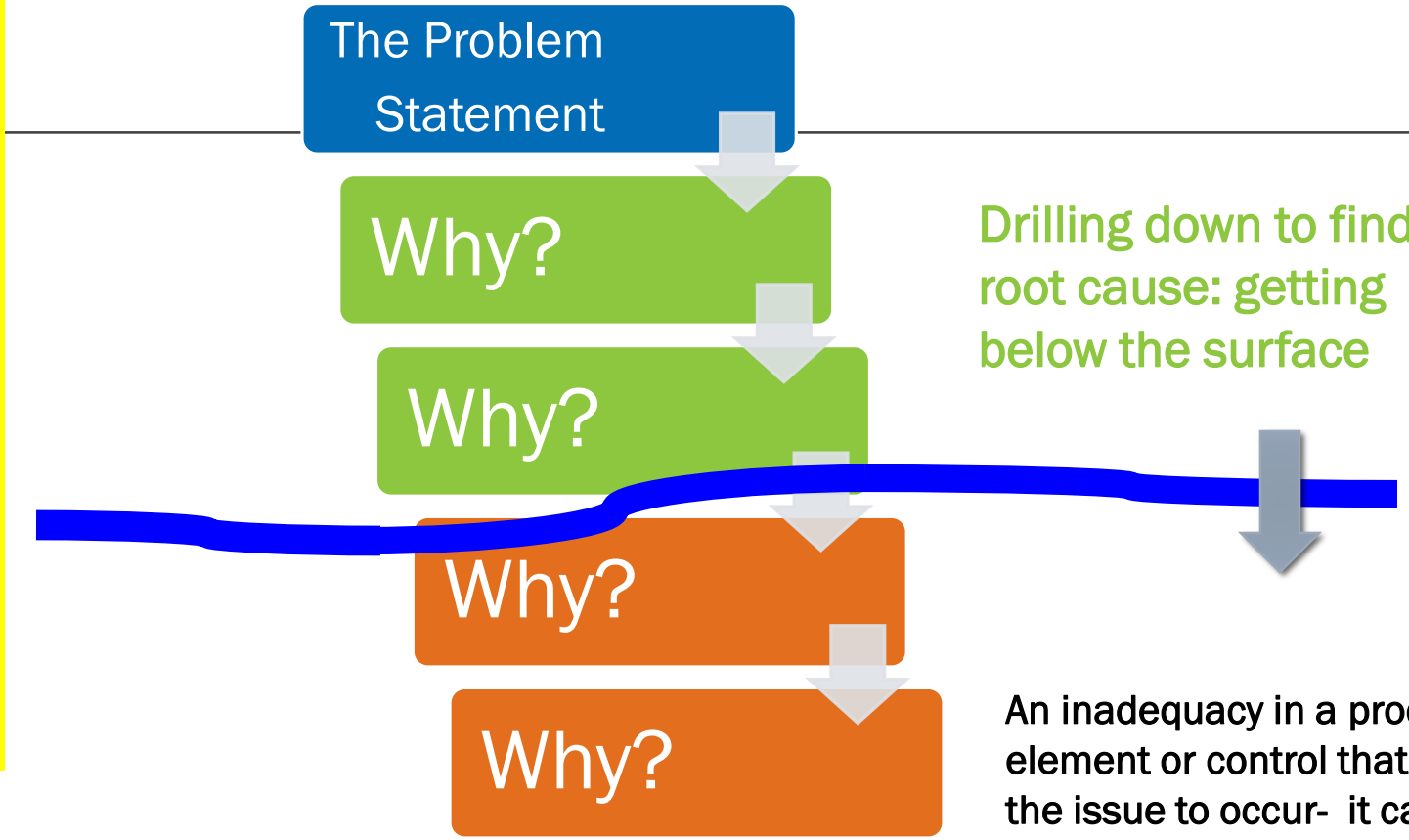
Cause-Effect Diagram (a.k.a. fishbone)

→ Hybrid: Cause-Effect Matrix



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"



Drilling down to find root cause: getting below the surface

An inadequacy in a process element or control that caused the issue to occur- it can be made adequate with a corrective action

Hybrid: Cause Map

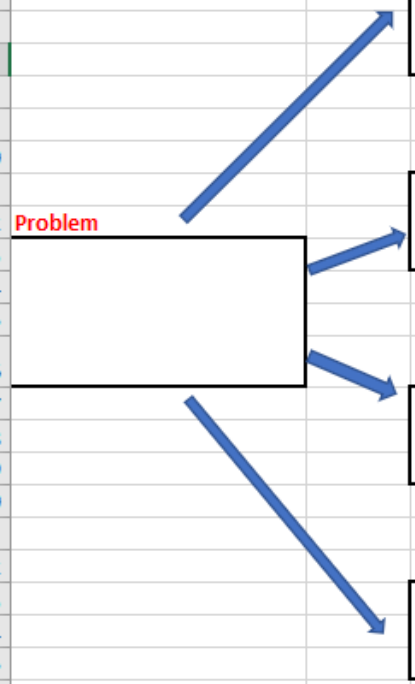
Shape simplicity

Allows for cause areas to be chosen based on problem type

Allows for some why-why analysis

Intuitive, quick to use

Cause Mapping Template



4 Main Cause Sources	What aspect of the source?	Note: If unsure that an aspect was at cause; or could be later, you might want to address it Yes= involved in problem; No= no evidence (also note how Yes/No was determined)	If YES: How we will prevent recurrence: This Column list your Corrective Action(s)

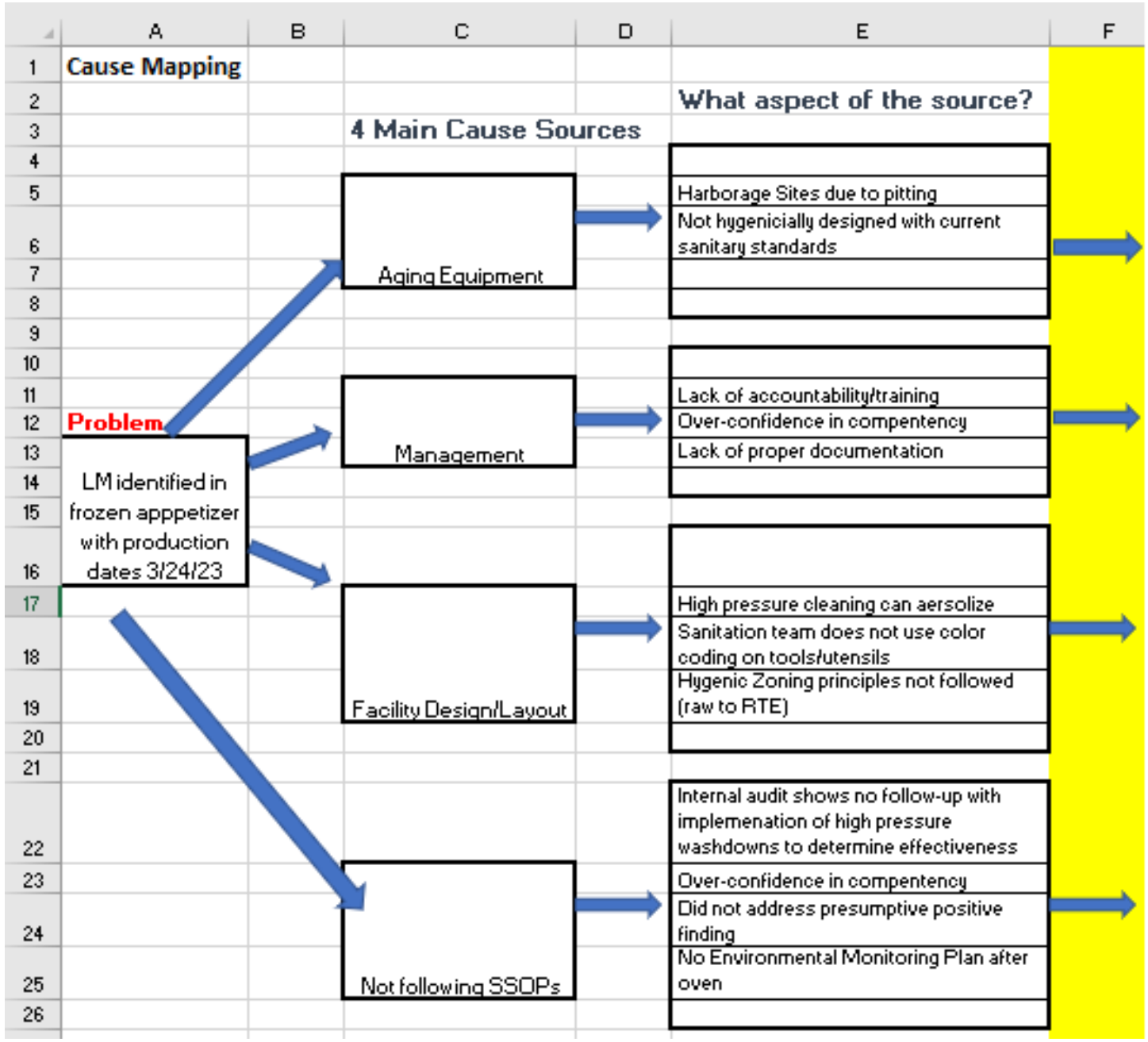
Left Side= The Map

Right Side: Fill in for a specific problem

This Column list your Corrective Action(s)

Note: If unsure that an aspect was at cause; or could be later, you might want to address it

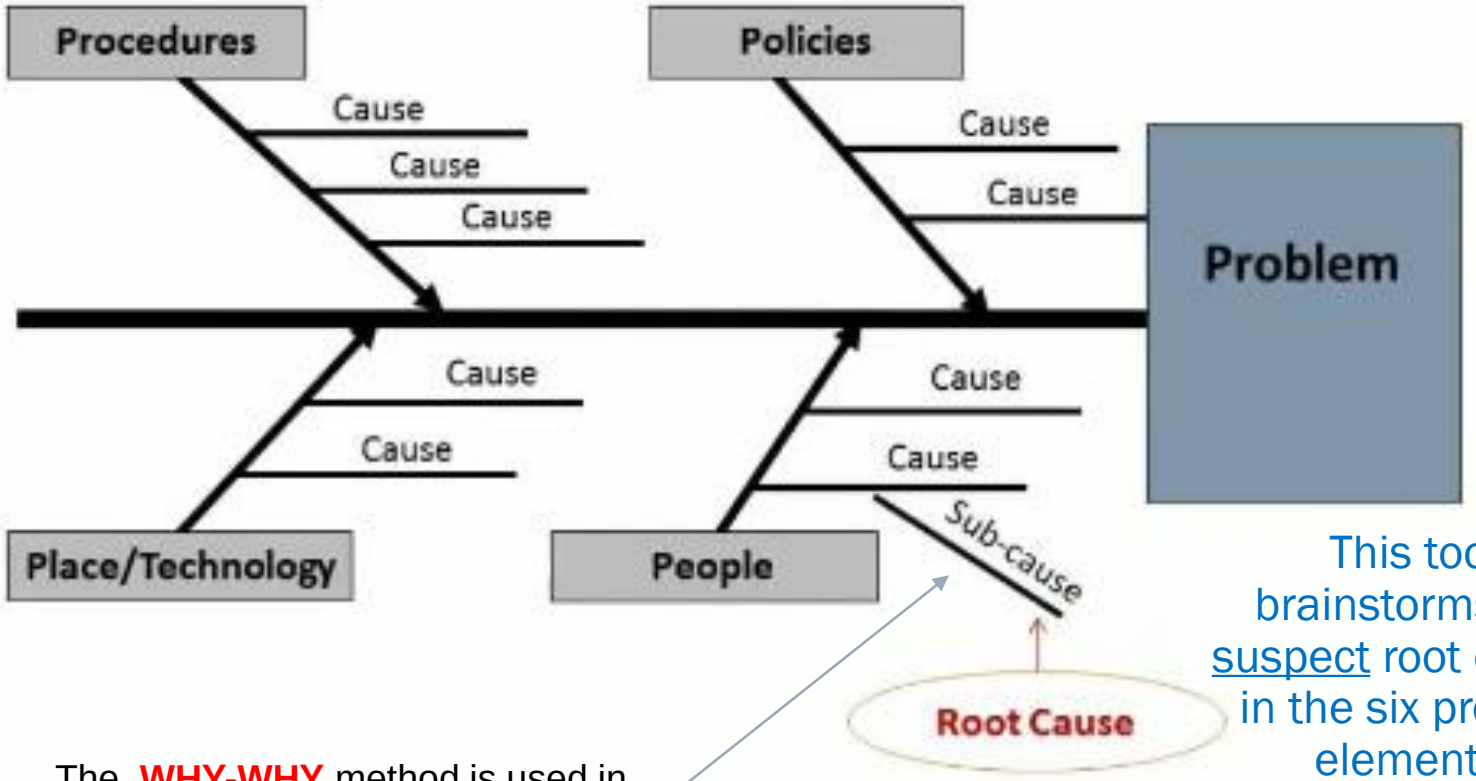
Principle: Be safe now, not sorry later!


Cause Mapping
What aspect of the source?
4 Main Cause Sources
Problem
LM identified in frozen apppetizer with production dates 3/24/23
Aging Equipment
Harborage Sites due to pitting
Not hygenicially designed with current sanitary standards
Management
Lack of accountability/training
Over-confidence in compentency
Lack of proper documentation
Facility Design/Layout
High pressure cleaning can aersolize
Sanitation team does not use color coding on tools/utensils
Hygenic Zoning principles not followed (raw to RTE)
Not following SSOPs
Internal audit shows no follow-up with implemenation of high pressure washdowns to determine effectiveness
Over-confidence in compentency
Did not address presumptive positive finding
No Environmental Monitoring Plan after oven

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

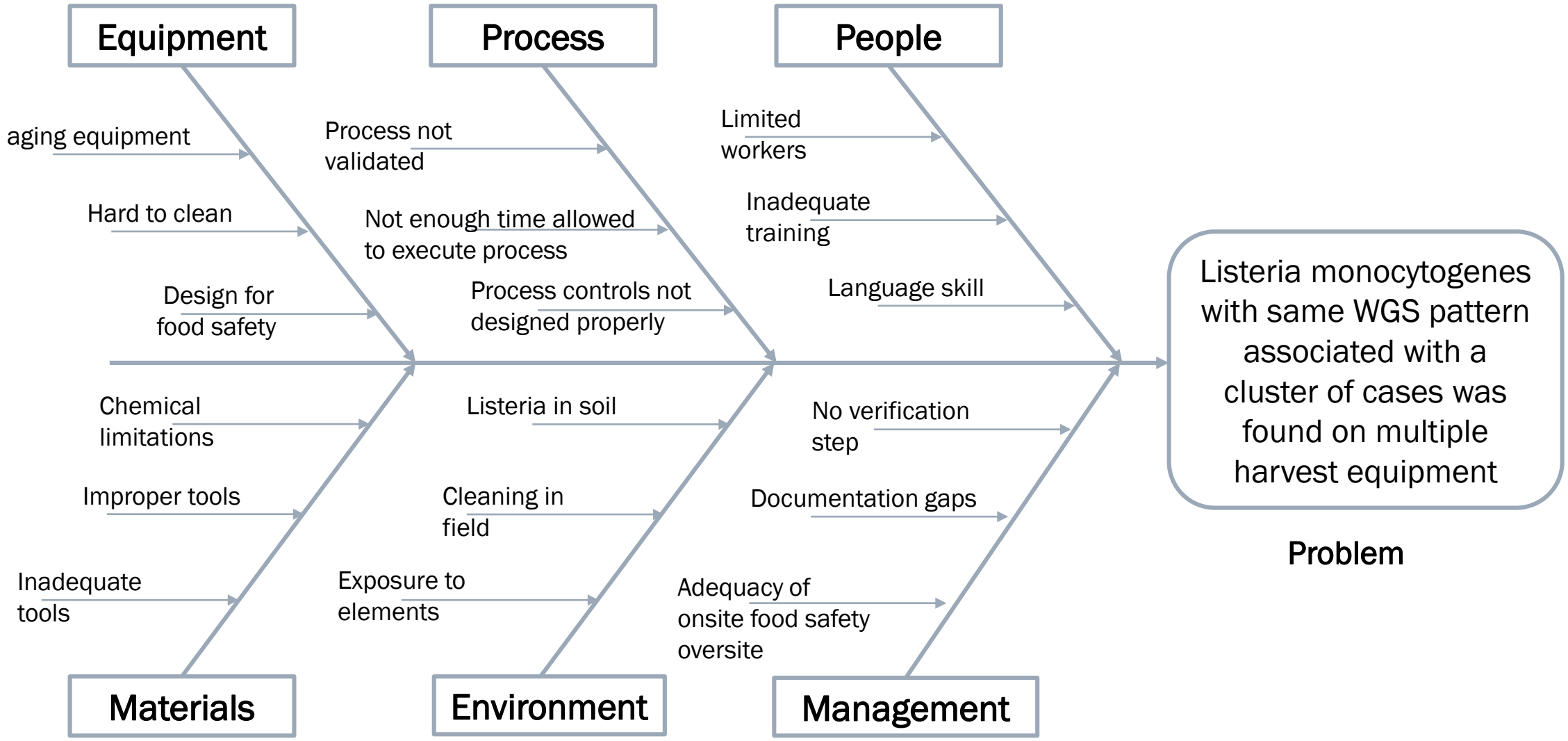
Fishbone Diagram



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

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

Fishbone Diagram – Farm operations



Hybrid: Cause 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@qualitymatterusa.com

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?
Method *: how the process is done per SOP or work instruction ; or if deviations could have happened*				
Materials *: any form of supplies, parts, assemblies used in the process*				
Machinery: *any type of tool, equipment, fixture, trays, bins, storage racks*				
Personnel: *Any aspect of competency & aptitude (knowledge; skills, experience, ability to perform consistent work)*				
Environment: *temperature; humidity, obstacles, lighting, distractions, morale, oversight and presence*				
Measurement/Information: *accuracy; precision, access, lack of, vague, has errors, timeliness, communication*				
Design *: 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: how the process is done per SOP or work instruction; or if deviations could have happened	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: any form of supplies, parts, assemblies used in the process	Product is trimmed as it is harvested			
Machinery: any type of tool, equipment, fixture, trays, bins, storage racks	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: Any aspect of competency & aptitude (knowledge; skills, experience, ability to perform consistent work)	Improper harvest techniques could cause contamination, particularly if moving quickly			
Environment: temperature; humidity, obstacles, lighting, distractions, morale, oversight, and presence of human error factors	Muddy fields could increase the potential for the product to be contaminated during harvest	Rain or irrigation event immediately before harvest		
Measurement/Information: accuracy; precision, access, lack of, vague, has errors, timeliness, communication breakdowns	Crew are only to harvest designated areas which could not be marked clearly			
Design: any aspect of the product design that may be causing the problem	Lettuce has natural latex which could cause the soil to stick to a cut surface and not wash off			

RCA Tool Summary

Tool:	Good For:	Watch Out For:	Additional Notes:
5- Why	Drilling down through symptoms to root causes	Being too narrow; missing an area of cause.	Each why must be verified; this is not a brainstorming tool. Each why must explain the cause of the why above it.
Cause Effect Diagram (fishbone)	Full coverage of the 5Ms & E aspects of a process. Commonly used and familiar to many	In adequate "branching" to get into more details on items that are 1st placed on the cause lines. Hopping around between cause areas.	Need a good template to document it; or take a picture. Some feel it is a bit "messy" of a tool. The outcome needs a way to narrow down the options ;listed to the ones that caused the problem.
Cause Map Template	Investigating cause areas relevant to the nature of the problem instead of defaulting to the 5Ms & E.	Missing one of the 5Ms & E areas. If in doubt add it to the Cause Map areas being investigated.	Easy to fill in and document in Excel. The right side makes for a good way to document the investigation.
Cause Effect Matrix	A linear version of the Cause Effect Diagram; east to fill-in using Excel.	Tricky to branch at each why; template would need additional excel rows in each why cell to allow for that.	Provides for 3-why drill down. The "80:20" columns allows for narrowing of the investigation at the get go. Modify the template to allow for more branching in each why-column

Any Questions?

Resource:
article on human error

Questions?

LET'S MAKE LIFE Delicious

Kraft Heinz

Significant Incident Reporting and Investigation Process

IAFP Webinar

2024

Karen Krueger

Associate Director, Quality Systems & Consumer Relations

The Kraft Heinz Company inspired by our purpose,

Let's Make Life Delicious!

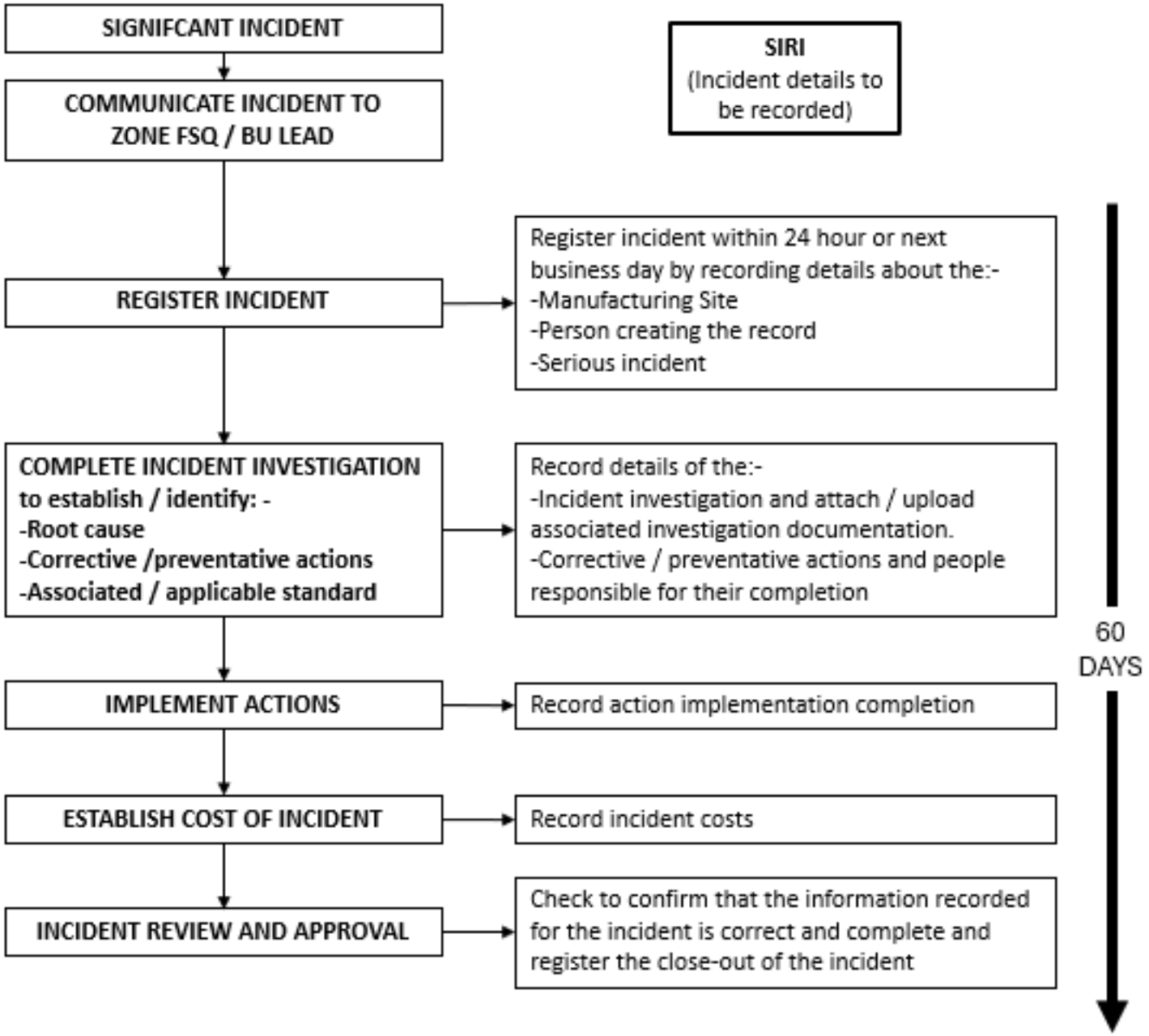
Consumers are at the center of everything we do.

We are driving transformation and committed to efficiency that enables us to drive actions with results.

Why did we standardize our approach?

- To managed quality incidents ensuring corrective and preventative controls
- To eliminate / reduce risk of a repeat or similar incident occurring
- To minimize the business impact

Significant Incident Reporting and Investigation Process Summary



What qualifies as an incident

- Any issue that initiates a recall or withdrawal of product
- Regulatory Non-Compliance
- Audit findings Critical or Major
- Site-critical observation/ findings
- High Complaint Rate or a Significant / Sensitive / Egregious complaint
- Product specification non-compliance

Communication

Key to the business!

Inform FSQ leadership to ensure the business is aware.

FSQ leadership provides guidance to help mitigate immediate risks to ensure the incident does not escalate into a crisis.

The Register

All significant incidents must be recorded in the Kraft Heinz Significant Incident Reporting Database (SIRI) within 24hours (or next business day) of the incident being identified.

- Recording the incident:
  - Location
  - Date & Time
  - Who report
  - Who identified the issue
  - Type
  - Status
  - Descriptions
  - Defined accountabilities
  - Define timescales

Incident Investigation – Why, Why, Why, …….

Training:

- All employees are made aware of the site incident reporting and investigation process and their responsibilities under the process.
- All contractors and visitors should have an understanding of the site incident reporting and investigation process as part of their induction.

The investigation process, which could include:

- Who will record the incident findings
- Evidence / data gathering
- Discussion with the person who reported the incident
- Discussions with other people working within the affected area or department

Investigation to be carried out by multi disciplined teams e.g. Operations (management and / or line representative) engineering, quality representative, other expert specialists

Incident Investigation – Why, Why, Why, …….

What tool will be used:

- 5 Why
- Fishbone diagrams
- Root Cause Failure Analysis (RCFA)
- Plan, Do, Check, Act (PDCA)
- 5W1H (What, Who, Where, When, Which, How much)

Using the tool

- Define the problem with details and focus.
- Keep asking WHY?
- Do not go to the next WHY until you have verified the cause.
- Force to “drill down” PAST the symptoms
- Call in other to help when needed
- Determine what standard was most associated with the incident
- Included the costs

If we do not define the problem correctly, we will never be able to solve the problem --- PERMANENTLY.

Actions

Corrective Actions

- Immediate actions taken to:
  - Control the incident and reduce the risk of the incident escalating
  - Determine product disposition
  - Typically corrects the immediate finding (or the “what”)

Preventative Actions

- Actions devised to eliminate /reduce re-occurrence or similar incidents.
  - Addresses the WHY (or WHYS) determined from the ROOT CAUSE (e.g. RCA, 5 WHY)
  - Look across other areas that have the potential to have the same problem to prevent an occurrence

All corrective and preventative actions are tracked to completion in order to eliminate or reduce the risk of a repeat or similar incident occurring.

Close-out & Review

Close-out criteria

- All verify all actions implemented
- Employees made aware of the incident
- Any ways of working updated and retraining complete

Reporting incidents to defined stakeholders

Review

- Could this incident could occur elsewhere on site?
- Investigate the need to review any associated risk assessments
- Determine required communications to be given to each level of the site organization?

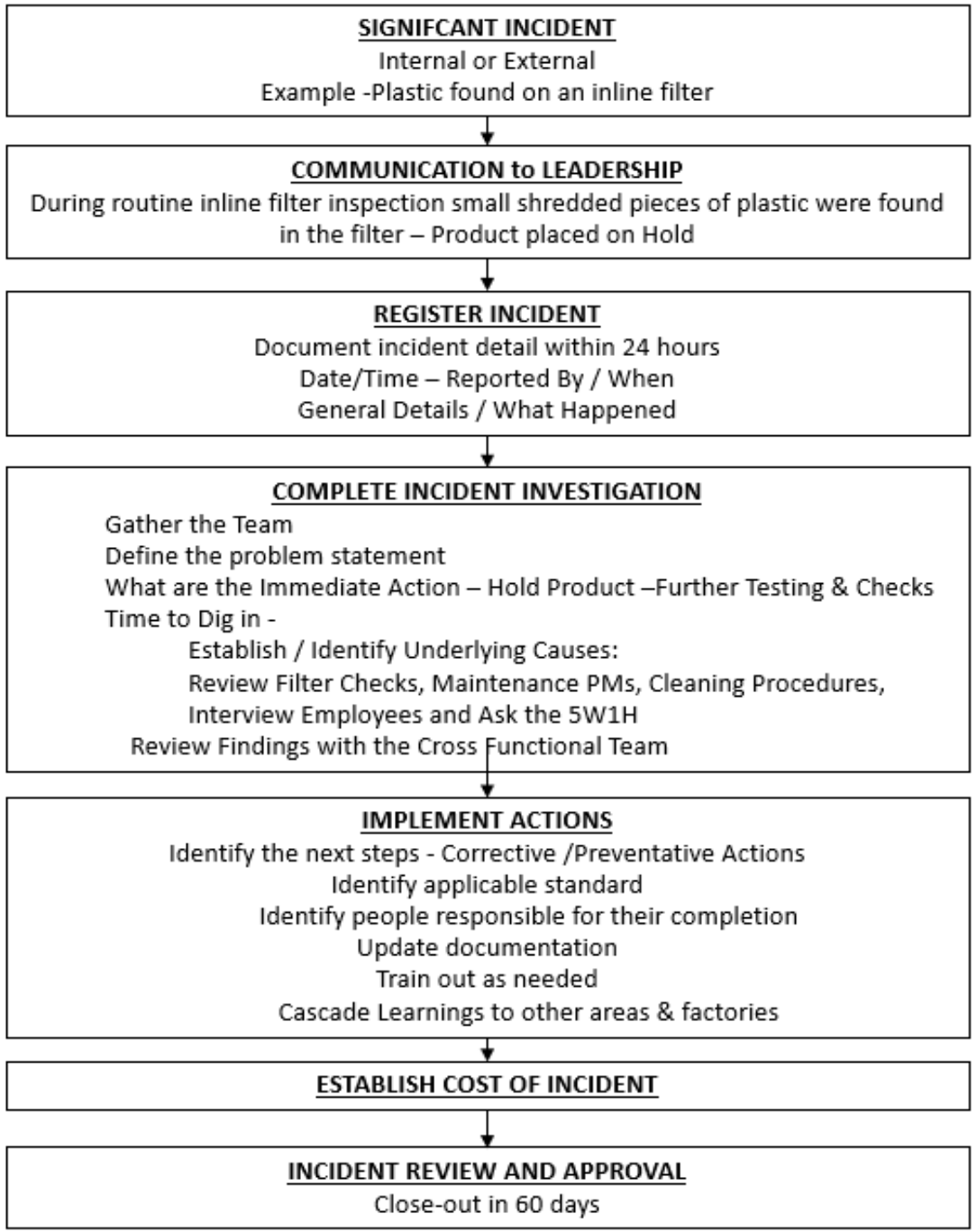
Approval & Trending

Approval

- Risks associated with the incident have been verified to effectively mitigated and actions are fully implemented that limit the possibility of re-occurrence.
- Approval are then completed by the site Quality Manager
- Then approval notification will then be sent to the 2nd level Approver.
- After approval is agree, the case status (CLOSED) will be populated in the register.
- Significant incidents must be closed out (approved) within 60 days.

Significant Incident Data is trended to ensure there is not a ways of working gap.

Significant Incident Reporting and Investigation Process Example



Summary

Our Significant Incident Reporting and Investigation Process:

- helps to reduce incident
- helps us work collaboratively cross-functional team to resolve issued
- helps ensure we do not have a similar or repeat issue
- helps to drive continuous improvement

All of us at Kraft Heinz sh
loyal consumers and cus
high quality, safe products,

Upcoming Webinars:

International Association for Food Protection WEBINAR

June 17, 2024 How Can We Effectively Reuse Water End-To-End: Creating Equitable Future

June 26, 2024 Prioritizing Hazards in Infant Foods

Scan for link

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International Association for Food Protection® WEBINAR

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Scan to link

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