



Produced by
FoodSafety
magazine™



ROOT CAUSE ANALYSIS: PUTTING IT TO WORK FOR YOU

Produced by
FoodSafety
magazine™

Meet Our Speakers



Brendan Niemira, Ph.D.
U.S. Department of Agriculture



Deb Kane, M.S.
J&J Snack Foods Corp.



John Butts, Ph.D.
FoodSafetyByDesign LLC



Tim Jackson, Ph.D.
U.S. Food and Drug Administration



Tim King, M.S.
Quality Matters LLC



Session Overview

- **Why Root Cause Analysis is Important: Brendan Niemira**
- **FDA Perspectives on RCA: Tim Jackson**
- **Problem statements, case study introduction: John Butts**
- **RCA tools – group exercise: Tim King & John Butts**
- **Common pitfalls, enlisting management support: Deb Kane**
- **Conclusions, Q&A: Brendan Niemira**



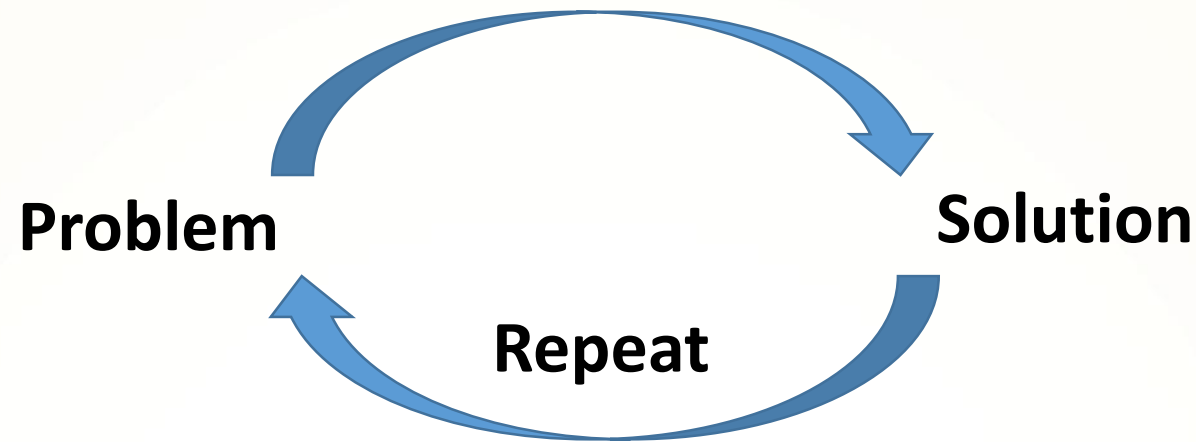
Produced by
FoodSafety
magazine™

Why Root Cause Analysis is Important

Brendan Niemira, USDA

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?



The “fix” that doesn’t fix it

- Problems occasionally happen in every workflow
 - Contaminations, compliance failures, equipment issues
- Superficial analysis of problems is common
- Mistakenly developing “solutions” that don’t solve the problem
 - Lost time and effort
 - Recurrence of the original problem
 - Impacts on productivity, profitability, morale



SALES

PRESS



Brand

**FUTURE
OPPORTUNITIES**



**SOCIAL
MEDIA**



Produced by
FoodSafety
magazine

What is the 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
- **Root cause analysis (RCA)** – a collective term that describes a wide range of approaches, tools, and techniques used to uncover causes of problems (nonconformances)

Doing RCA the right way

- RCA tools are powerful techniques that lead to process improvements
 - Equipment, layout, workflow, operations, worker competencies
- Neither ad hoc nor arbitrary
- Once learned, can be applied in many areas of R&D, production, and manufacturing

RCA culture

- RCA mindset, RCA culture
- Investment of time, energy, resources to go beyond repeated quick fixes
- Commitment of management, front line workers
 - Long-term health and resiliency of brands and companies
- Best practices for RCA are based on training and practice when things are going RIGHT, so you can respond when things go WRONG



Produced by
FoodSafety
magazine™

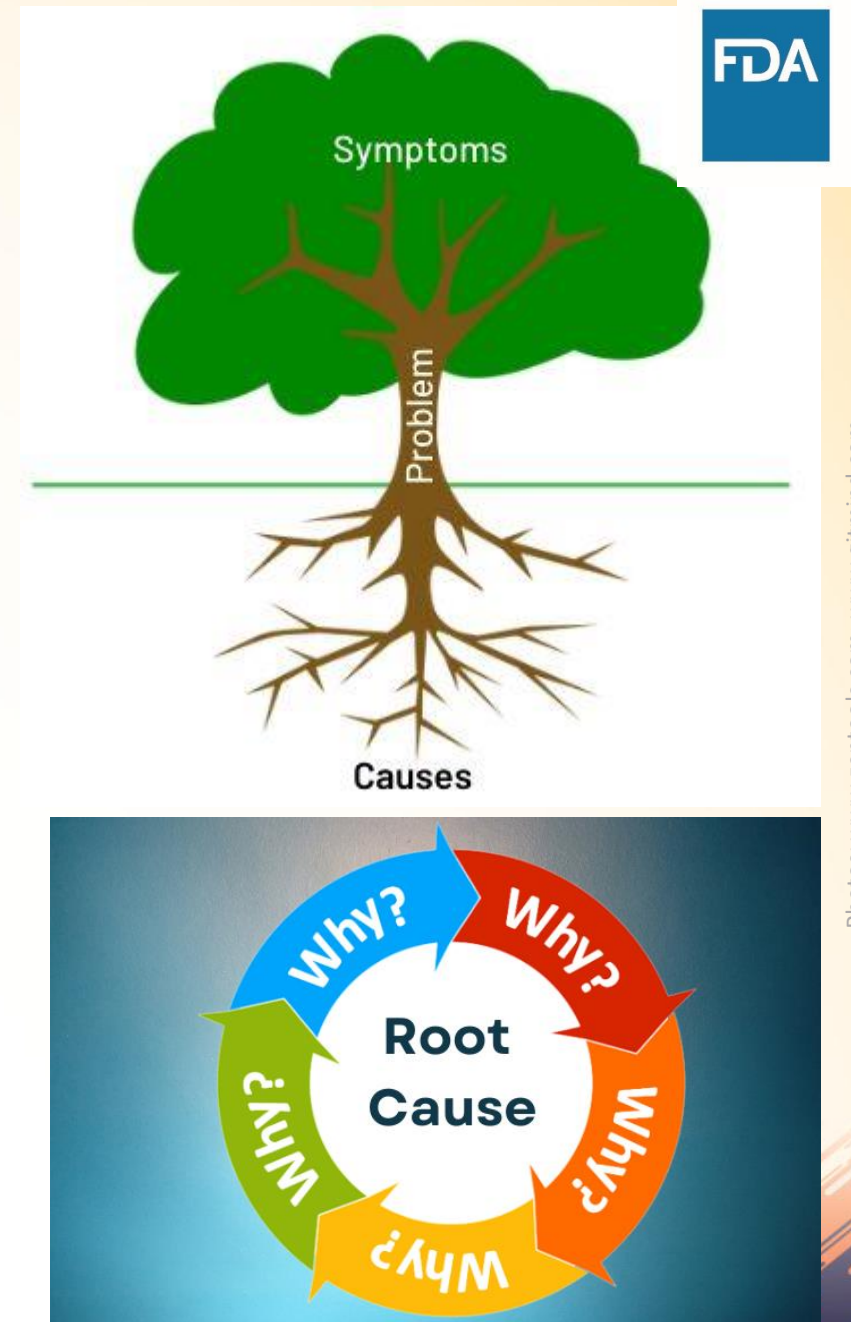
FDA Perspectives on RCA

Tim Jackson, FDA

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

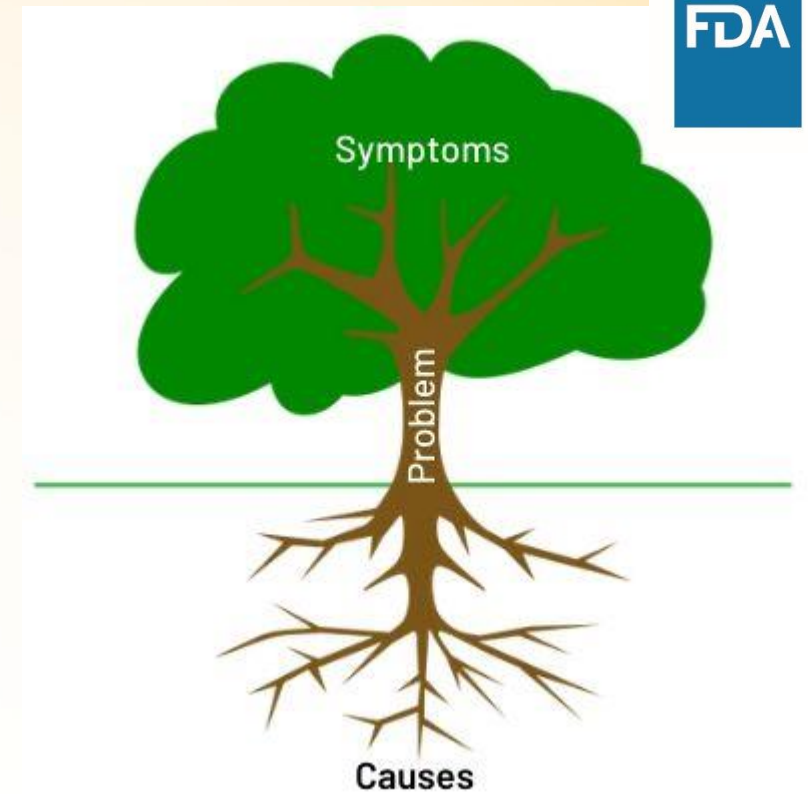


FDA's Expectations of industry

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

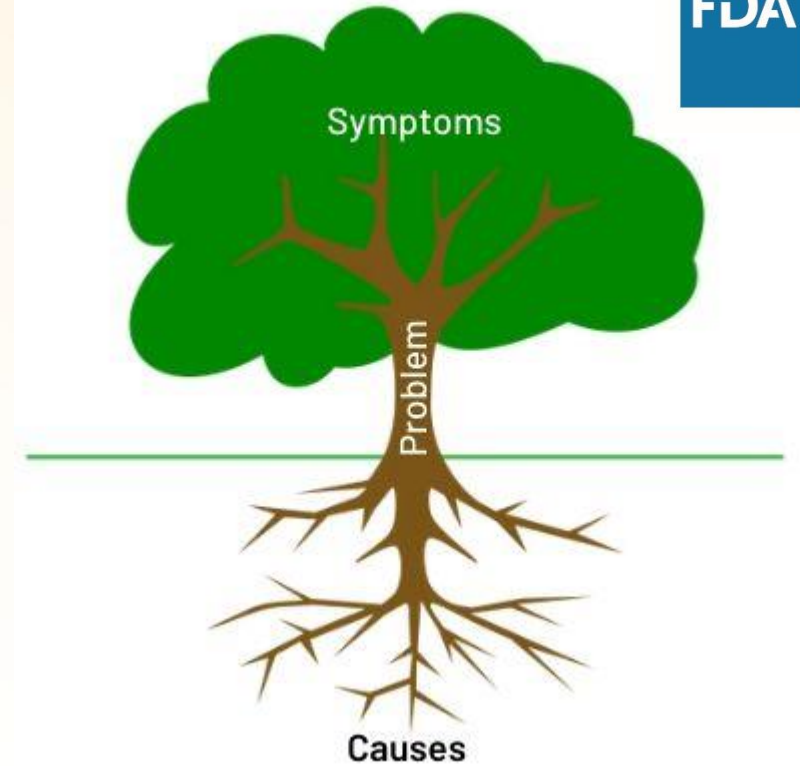
- Correctly identify the root causes of food safety problems
- Determine the origin and scope of a problem
- Determine appropriate corrective actions to prevent recurrence

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



Outcome of RCI and RCA

- Identification of failure(s) that led to the issue
- Identification of underlying factors that led to the failure
- Information to characterize/determine scope of underlying factors
 - Inform needed corrective/preventive actions
- Often there is not “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 is needed to identify, confirm or characterize root cause

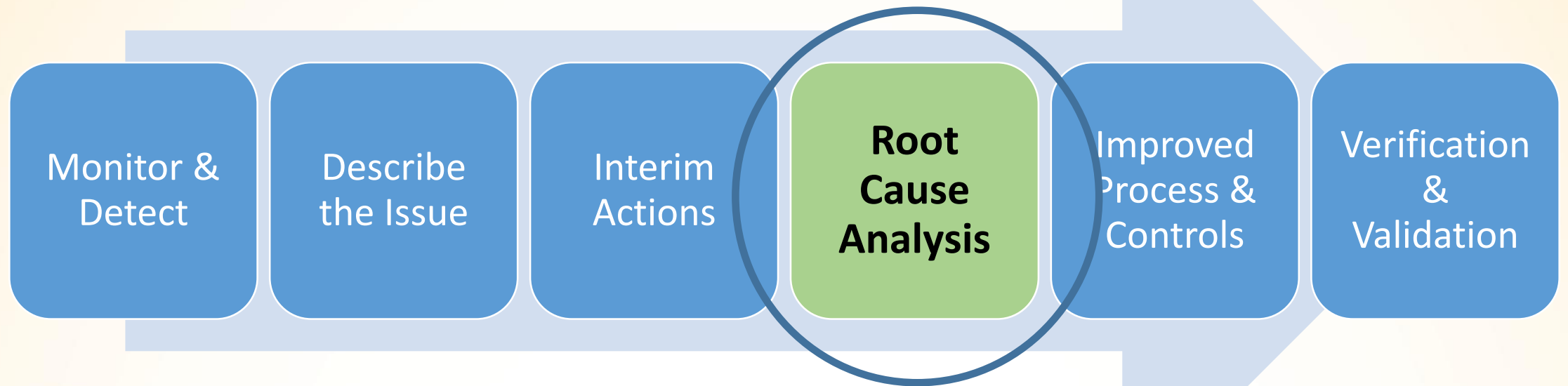


Produced by
FoodSafety
magazine™

Root Cause Analysis Tools to Use

Tim King, Quality Matters LLC

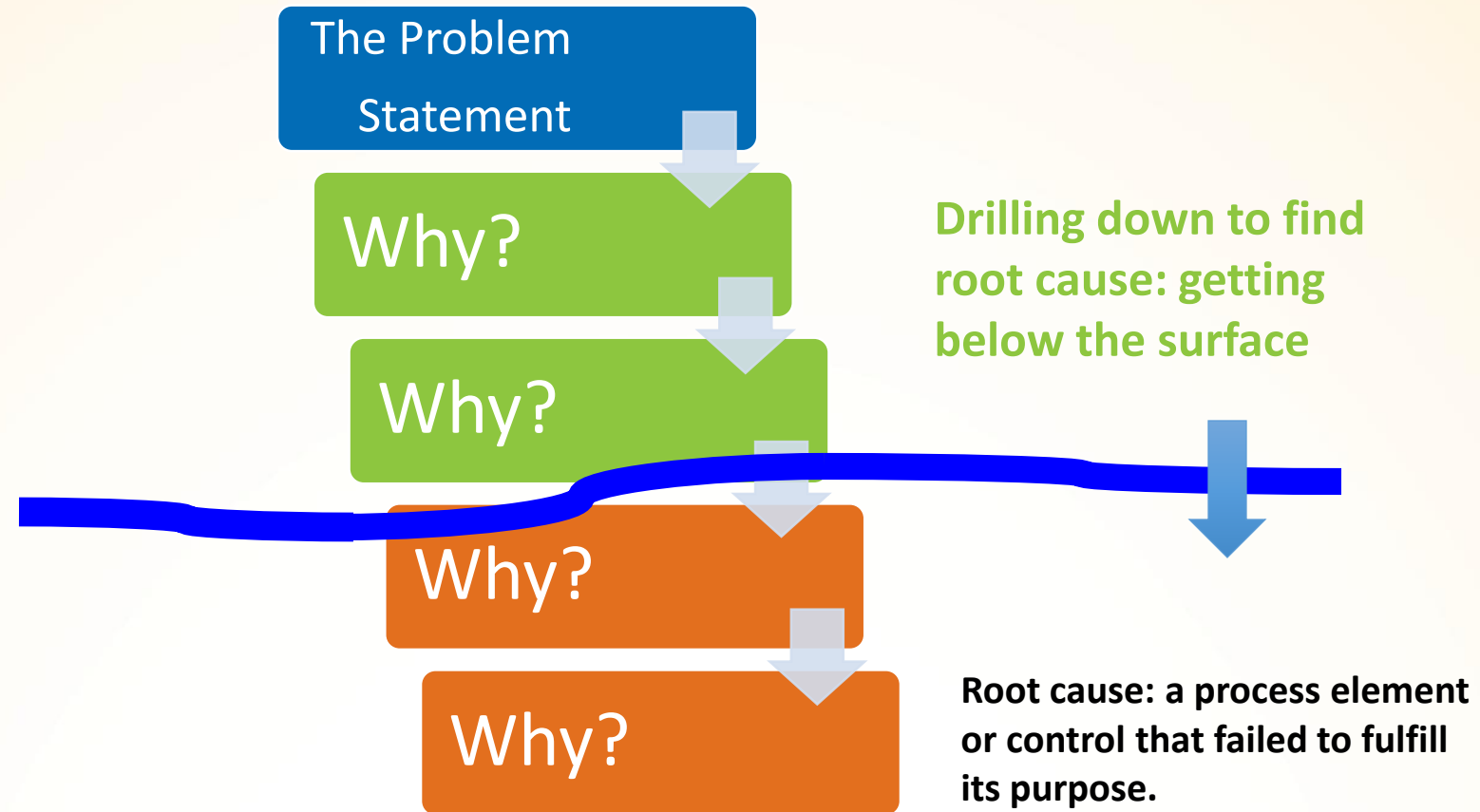
RCA- The Gateway to Improvement



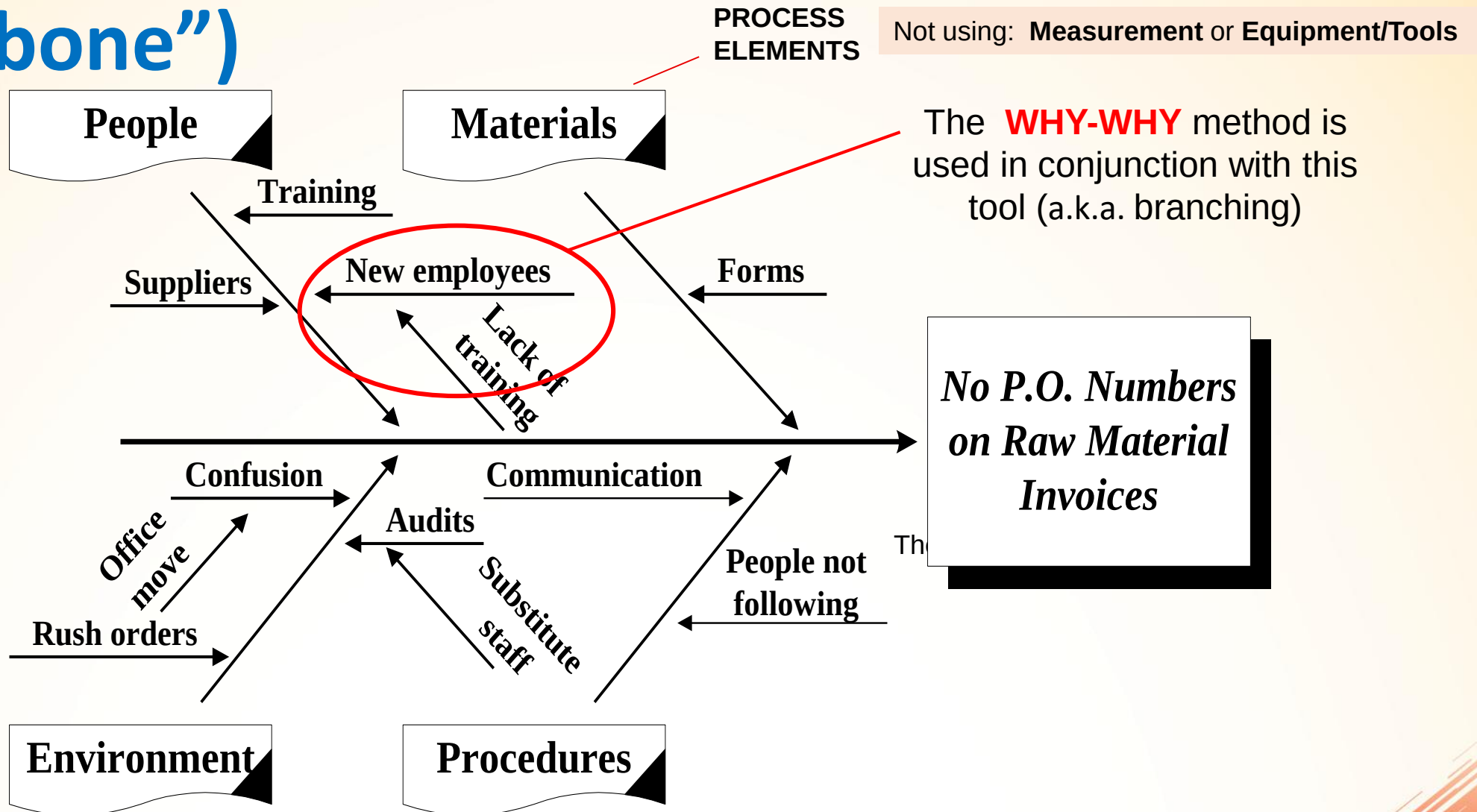
Process Approach- Process Elements That Can Harbor the Root Cause

1. **M**anpower (employee competency; aptitude)
2. **M**ethod (process steps; layout; sequencing)
3. **M**aterials (chemicals, supplies, bins)
4. **M**achines (equipment, tools, devices)
5. **M**easurement (accuracy, lack of; type; use of)
6. **E**nvironment (ergonomics; distraction; complacency; temperature, humidity, lighting...)

RCA Tool: Five Why Analysis



RCA Tool: Cause-and-Effect Diagram (aka “fishbone”)



Introducing: The Cause Logic Map

	A	B	C	D	E	F	G	H
2					What aspects of the source?		How would you investigate this aspect?	How could recurrence be prevented?
3			4 Main Cause Sources					This Column list your Corrective Action(s)
4								
5								
6								
7								
8								
9								
10								
11								
12	Problem							
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23								
24								
25								
26								
27								
28								This Column list your Corrective Action(s)
29								Note: If unsure that an aspect was at cause; or could be later, you might want to address it
30								Principle: Be safe now, not sorry later!

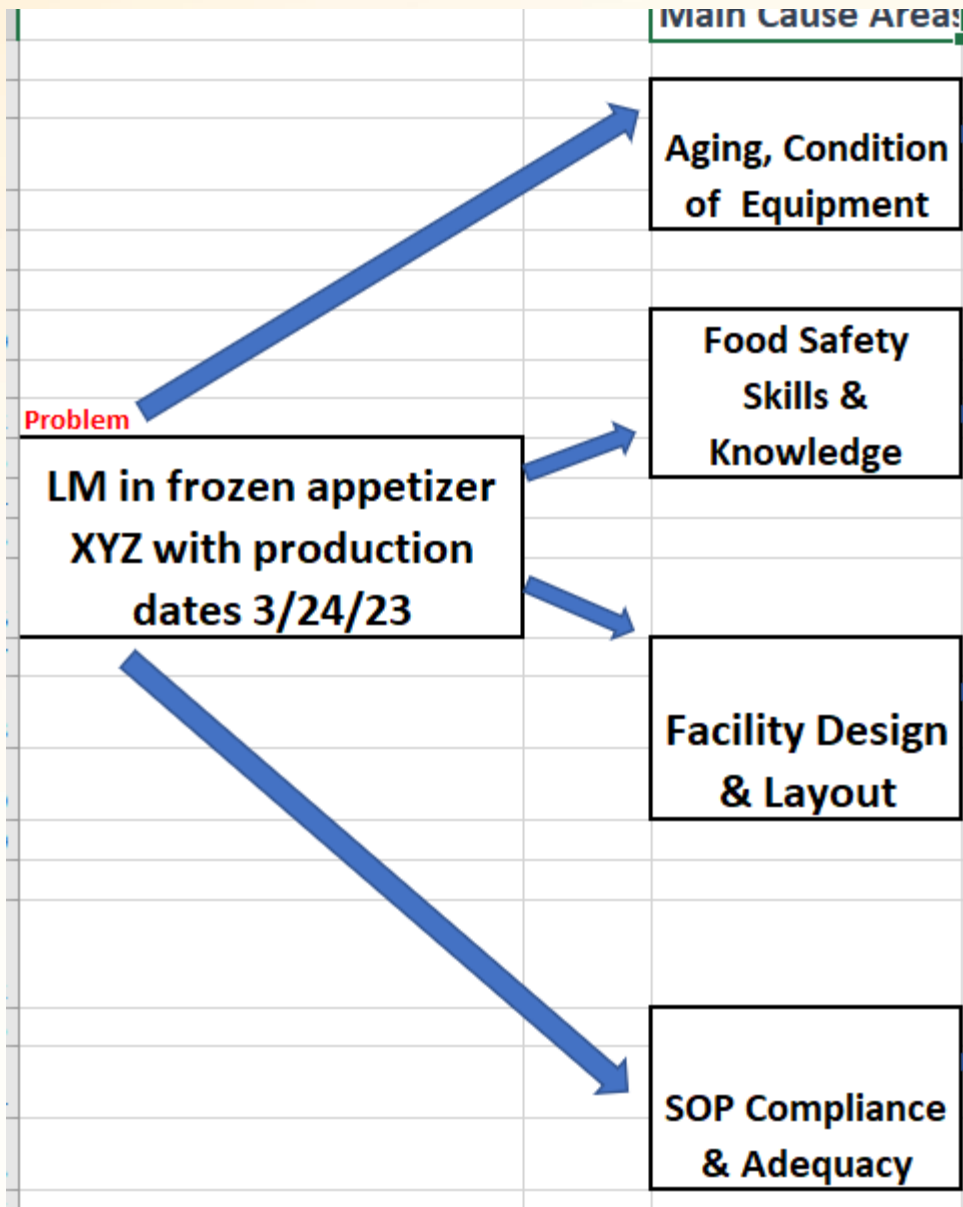
Left Side= The Map

Right Side: Fill in for a specific problem

Problem

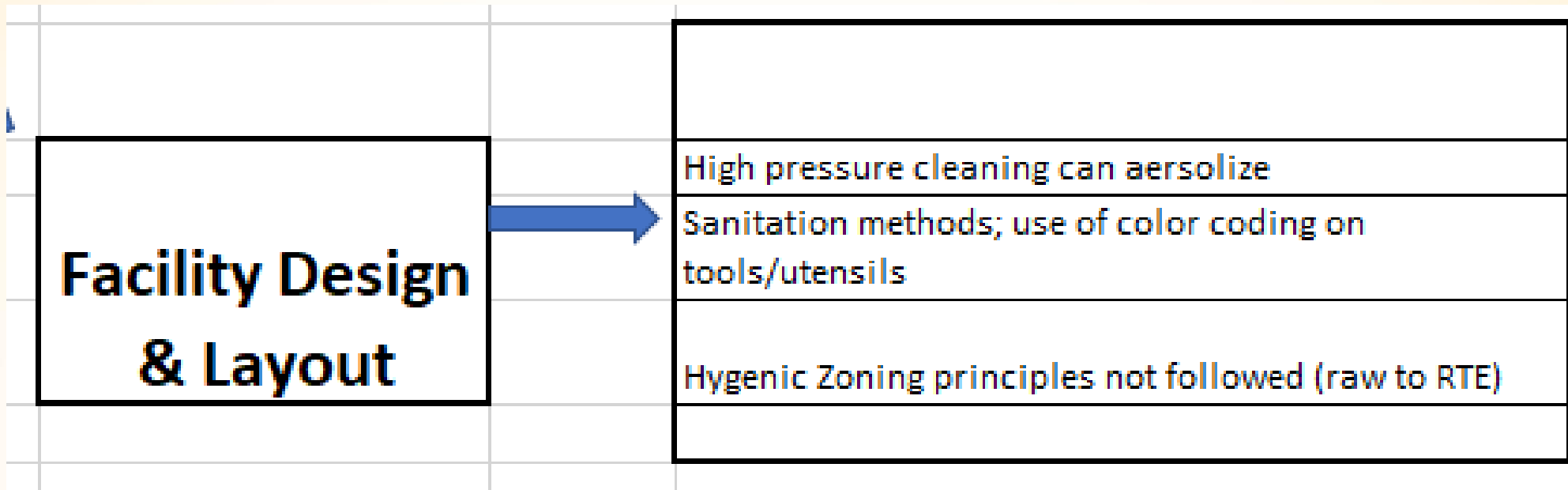
LM in frozen appetizer
XYZ with production
dates 3/24/23

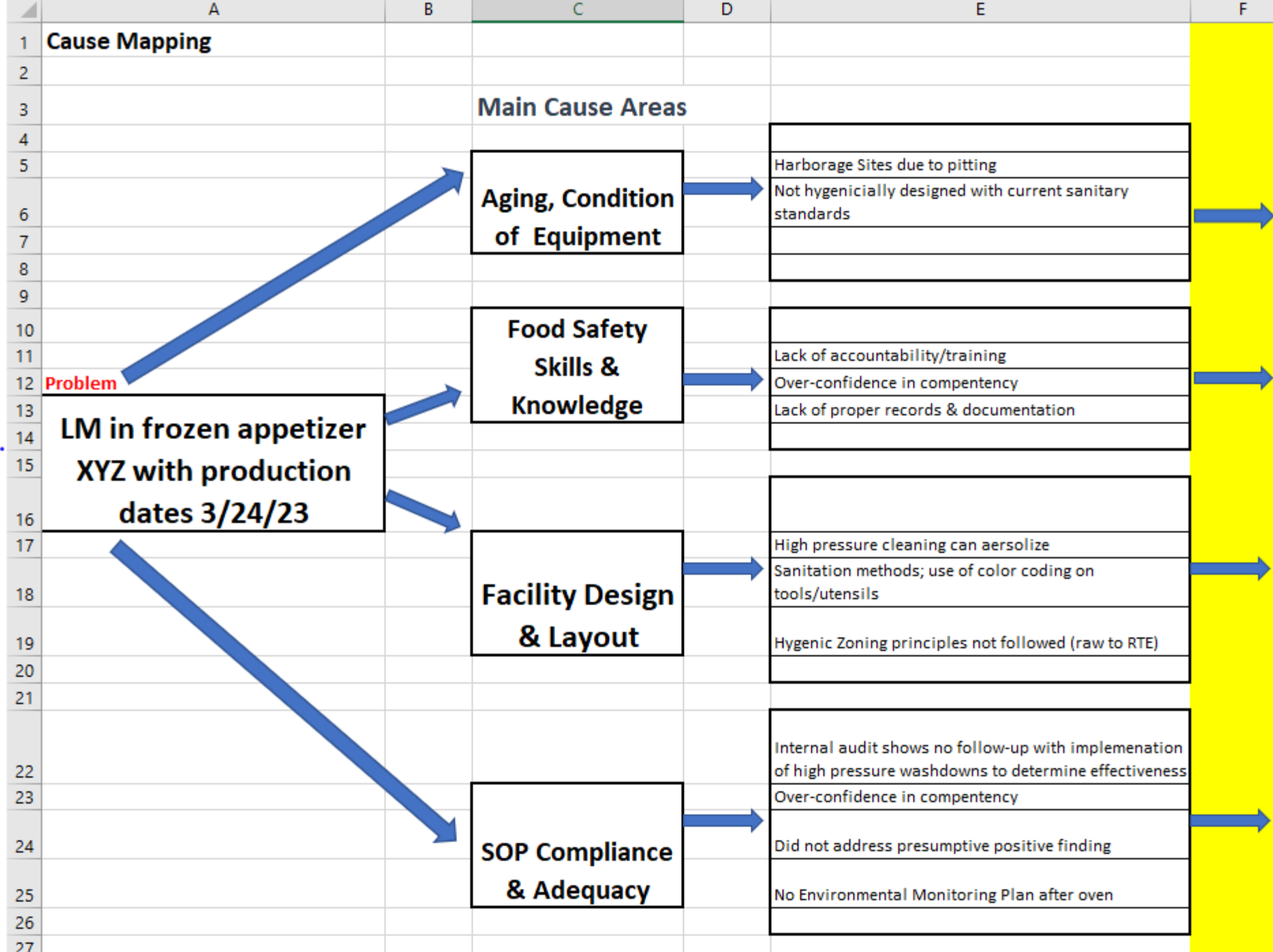




Step 2: Identify Main Cause Areas: 6Ms or areas “technically relevant” to the problem

Step 3: For each Cause Area identify what should be investigated





Your Cause Map is Ready to Go!



Case study with Foreign Material (FM) Issue

Produced by
FoodSafety
magazine™

John Butts, FoodSafetyByDesign, LLC
Tim King, Quality Matters LLC

Scenario – CBD Gummy Bears

- The **I Am High (IAH) Company** has entered the fast-growing CBD market with enhanced Gummy Bears
- Their business is booming so they recently moved their production from a small copacker to their own facility
- After scale-up and after a couple of months of production they are now faced with a foreign material recall
- A consumer has reported to FDA that they cut their mouth on something in the gummy bear
- FDA has notified IAH Company
- The code information indicated the product was from the third lot produced dd/mm/yyyy

Production Data

- The stainless-steel object was returned, and it was large enough to be detected by the metal detector
- The calibration of the detector was verified before production and each hour afterwards
 - Per records of dd/mm/yyyy A stainless-steel shaving was found late in the second hour of production
 - That entire hour 2 lot was retained
 - The calibration and operation of the detector was verified, and production of the third hour was started
 - Part of hour 3 lot was shipped to fill an order; the remainder was moved to inventory

Problem Statement

- Consumer injured by sharp metal object found in a 3 oz package of IAH Gummy Bears produced on dd/mm/yyyy Hr.3

Case Study: IAH Gummy Bear FM in Product

We will work through creating the cause map for this!

- 1. Introduce the scenario** (what we know right now)
- 2. Create a problem statement:** Nonconforming item, actual condition of it, requirement for compliance (if not obvious)
- 3. Decide on Cause Areas to investigate**
- 4. Identify aspects of each Cause Area to be investigated**
 - Process areas
 - Inspection, test activities
 - Data, records
 - Personnel
 - History of similar events
 - _____ ?

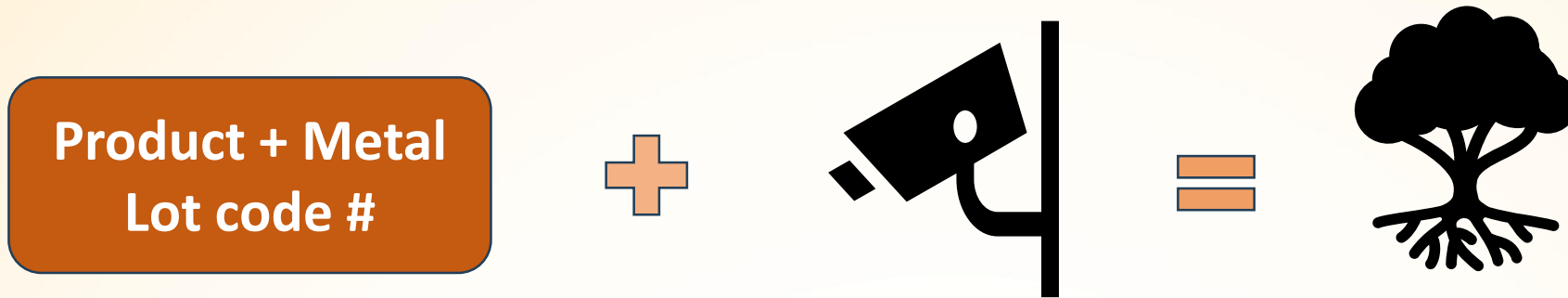


Produced by
FoodSafety
magazine™

Common pitfalls, enlisting management support

Deb Kane, J&J Snack Foods Corp.

Company A example

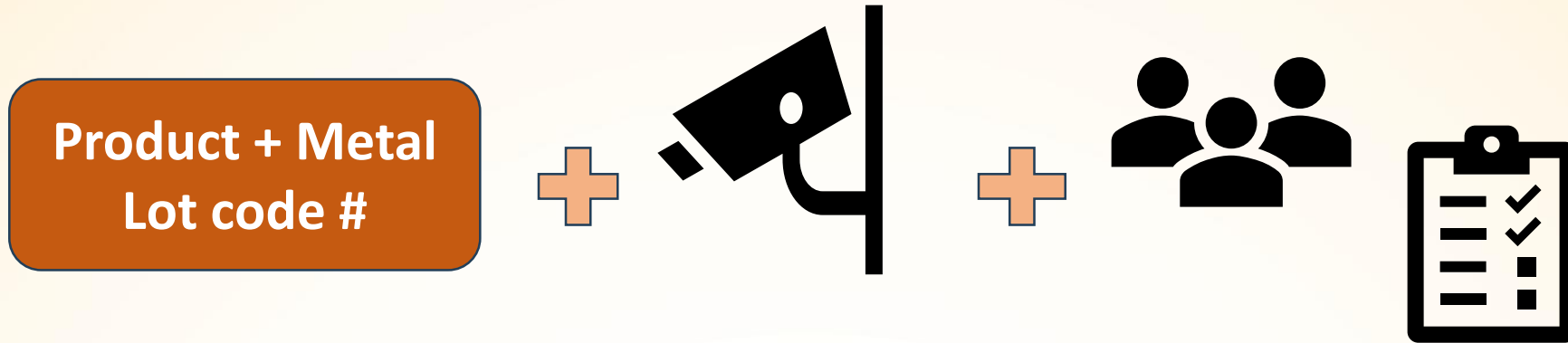


RCA – failure to properly conduct metal detector challenges, wands were not permitted to drop in the reject bin

Corrective action – retraining of operators

Preventive action – updated WI on metal detector challenges

Situation #2 – recurrence



Metal made it out the door in product a second time, lot code information was provided



Investigation led to a thorough process audit by several team members over several runs



Videos were collected, and viewed by several team cross-functional team members

Process audit observations

- Product would accumulate at metal detector conveyor
- Air reject mechanism was not strong enough
- Product could get caught from the conveyor to reject bin
- Potential for contaminated item to get pushed into the normal product stream – escape



Root Cause / CAPA

- Failure to properly validate the metal detector CCP
- Corrective actions – revalidated CCP
 - Worst case scenarios
 - Spiked samples / challenges
- Corrective actions led to equipment and process changes
- Preventive action – replaced air reject mechanism with drop conveyor for rejects (elimination)

Hierarchy of Controls

Most
effective



Least
effective

Elimination

Physically remove
the hazard

Substitution

Replace
the hazard

**Engineering
Controls**

Isolate people
from the hazard

**Administrative
Controls**

Change the way
people work

PPE

Protect the worker with
Personal Protective Equipment

Common Watch Outs

Problem Definition

- Defining the problem as the solution
- Problem statement is vague
- Solving the wrong problem

Event / Factor Analysis

- Bias, opinions, turf issues, blame game
- Focus on containment factors for symptoms, bandage
- Not considering organizational system deficiencies

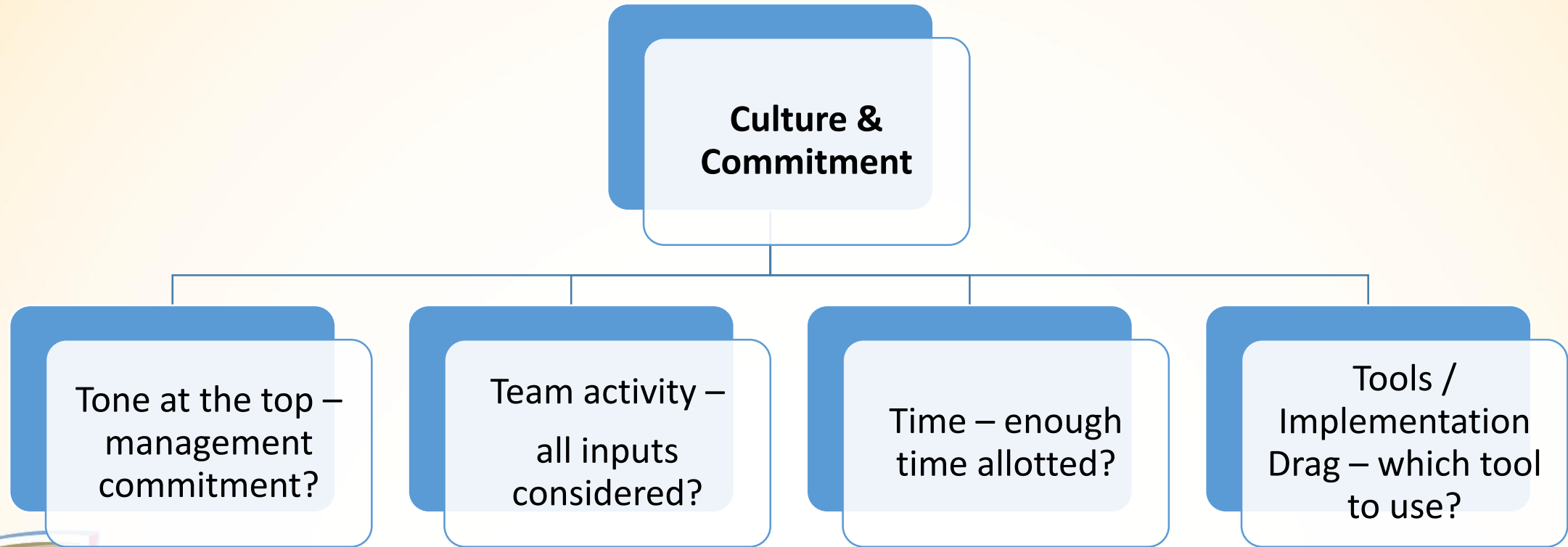
Failure to follow-up on audit deviations

Design of training program insufficient

*Line / equipment not designed for success

Considerations for Success

Common Pitfalls, Considerations for Success





Produced by
FoodSafety
magazine™

Conclusions

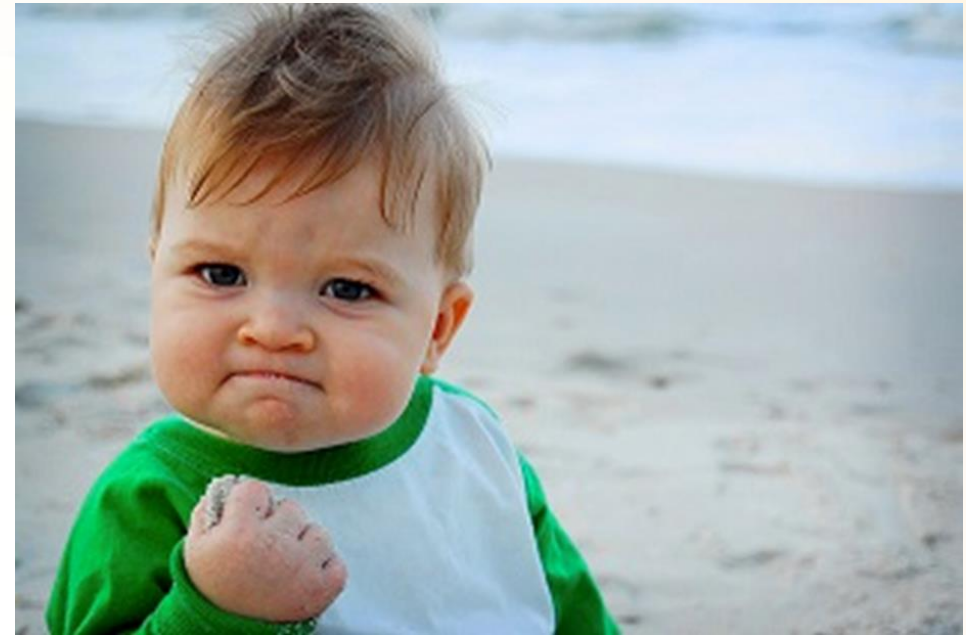
Brendan Niemira, USDA

Goal: fix it so it stays fixed

- RCA can't be an ad hoc process and be fully successful
- Begin with the right team, the right tools, the right focus
- Think critically, ask the important questions
 - Is this tool getting us to the root cause(s)?
 - Are we using the tool properly? Can a different tool also help our investigation?
 - Are we missing an aspect of the problem that could shed light on the root cause?
 - Can we defend our logic- to management, regulators, auditors, or our customer?

Develop effective, efficient solutions to prevent problems from recurring

RCA helps break the cycle



Questions?

RCA article, Food
Safety Magazine

RCA webinar



Produced by
FoodSafety
magazine



Speaker Bios & Contact information

John N. Butts, Principal, FoodSafetyByDesign, LLC,
foodsafetybydesign@gmail.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, Lead Scientist, USDA, brendan.niemira@usda.gov





Produced by
FoodSafety
magazine™

MAY 6-9
2024

Donald E. Stephens
Convention Center

ROSEMONT, IL

COMMUNITY • EDUCATION • SOLUTIONS