

# Identifying the Root Cause: In Plant Investigations

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**NAMI** NORTH AMERICAN  
MEAT INSTITUTE

# Dealing with FM Requires Thought

- Often dealing with sporadic events, variable personnel, and complex processes.
- Because of the complexity involved with investigations, truly identifying the root cause can be difficult.



# Consumer Protection

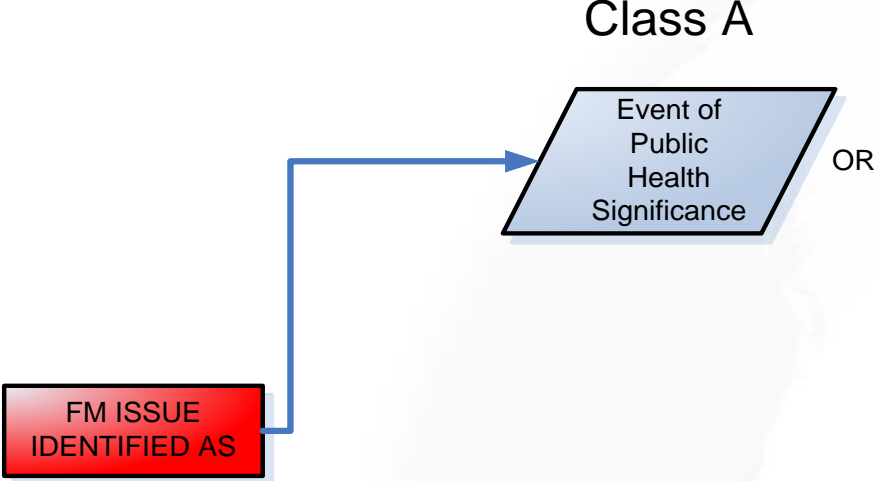
- Ethical duty of the processor
- Food safety is expected characteristic of our products. It is part of our culture.
- Consumer intolerance to food safety issues
  - Legal liability of the processor
  - Our current global media presence can create further issues

# You SHALL...

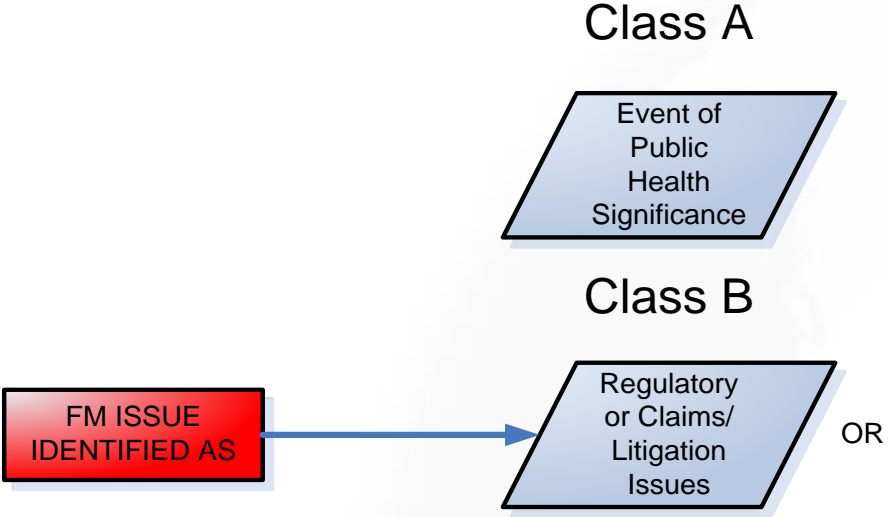
- Keeping our products free of filth, impurity and physical hazards is required by Law
- The USDA, FDA, and State Agencies can take action against the company, the facility or the individual responsible for product oversight
- Export requirements can cause costly rejection at the point of importation
- No Deminimus Risk is Defined



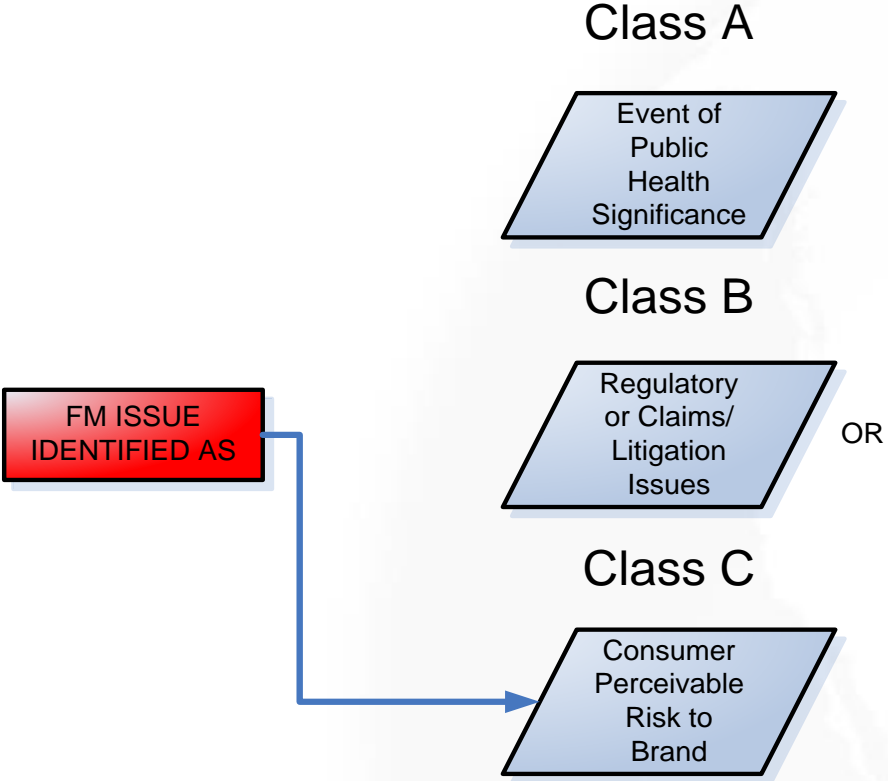
# Risk Classification of FM



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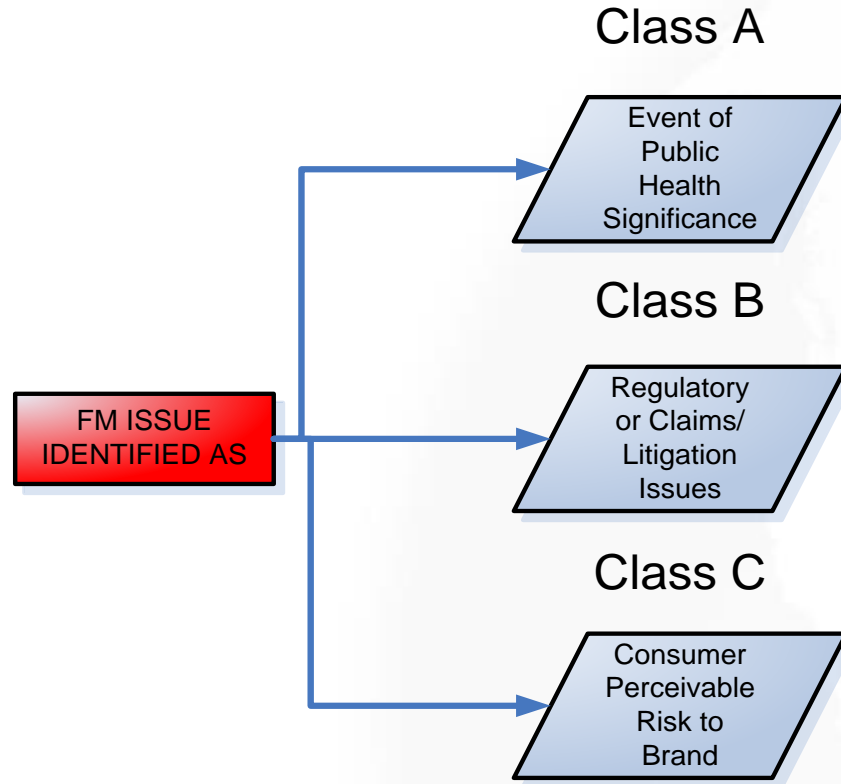


# Risk Classification of FM





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# Class A- FM and Public Health

FM as a physical hazard has been well documented by the public health and regulatory communities. The criteria are:

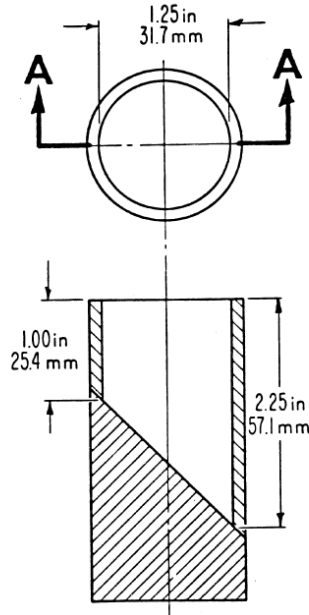
- Hard and sharp foreign objects >7 mm and <25 mm in any dimensional aspect
- Hard and sharp foreign objects >2 mm and <25 mm in any dimensional aspect when dealing with sensitive populations



# Class A -Public Health Choking

Consumer Product Safety Commission

§ 1501.5



16 CFR 1501(a) and (b)



Defined by  
dimensional or other  
characteristics

April 10, 1999: nine year old Michelle Enrile choked while eating a Konjac Mini Gel Snack. The candy completely obstructed her windpipe, and all efforts by her parents and paramedics to dislodge the blockage were fruitless. She fell into a vegetative state and died two years later. A jury found the defendant, Sheng Hsiang Jen Foods Company, Ltd., liable for the choking death of Michelle Enrile and awarded her parents a \$16.7 million dollar verdict.

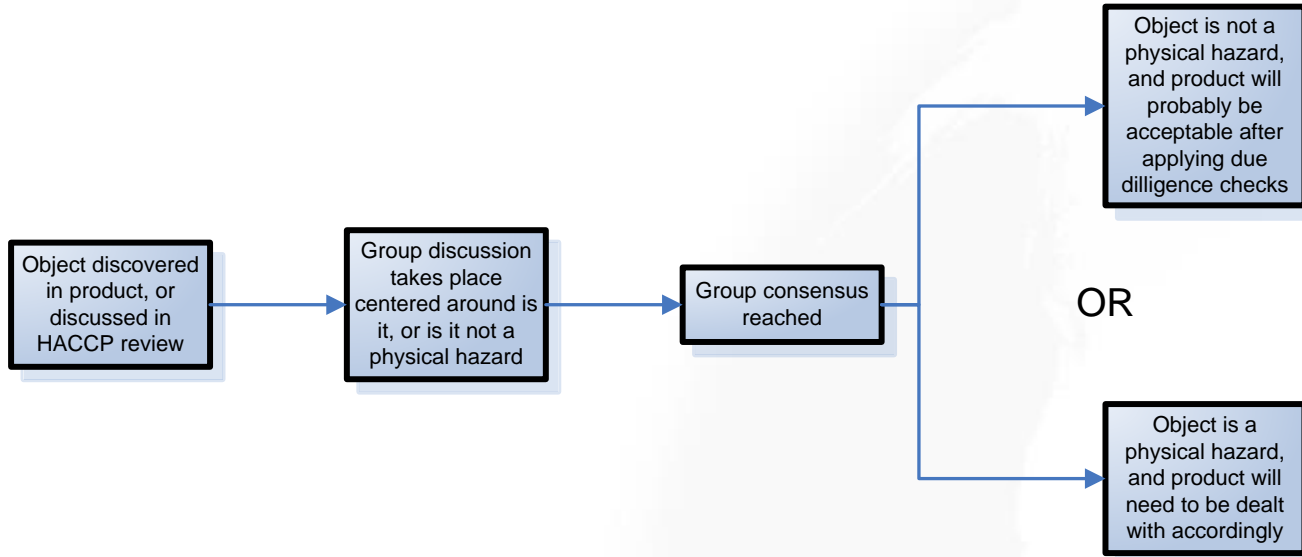
# Class A- Public Health Bio/Chem

Biological and Chemical Hazards Associated with FM are not so clear:

- Many teams fail to identify interaction scenarios when analyzing hazards.
- FM events can also contain a chemical or biological hazard that must be part of the risk assessment discussion!



# Flawed Logic Loop from Operations



# Class B- FM as a Regulatory Concern

- Even if the FM of concern isn't a hazard you must understand the relevant regulations.
- Consider implications of product being deemed adulterated due to the FM present
- Risk may be present even though object derived from a product related source. Bone in hot dogs for example.

# Expectations of Customers

- Food Service Operations and Quick Service Restaurants will not tolerate repeated FM incidents.
- A history of FM finds may lead to loss of business due to a no-confidence scenario
- Contract manufacturing for retailers can be detrimentally affected in the same manner as well

# A revised definition of FM

*“...any material(s) whose quantity and presence within a food product is unanticipated by the customer or consumer purchasing the product and/or the regulatory body that has jurisdiction over the processing and distribution of the product.”*

**Peariso - Preventing Foreign Material Contamination of Foods. (Blackwell Publishing 2005)**



# What's Your Strategy

- Random Sample Vs. 100% Detection?
  - Depends on your cost structure
  - Depends on your processing conditions
  - Depends on your ingredients
  - Depends on your suppliers
  - Depends on your target consumer

# Use a HACCP Based Approach

## KNOW YOUR THREAT!

- Common Enemies
  - Wood
  - Glass
  - Plastic (hard and pliable)
  - Metal
  - Bone
  - Stones
  - Stems/Plant Material
  - Personal Effects

# Steps in In-Plant FM Investigation

- FM is found in product during processing.
- Examination of FM – appropriate forensic tools.
- Establish Internal or External source if possible – Blue poly plastic is commonly used in food processing.
- Define scope of impacted product.
- Establish product disposition.
  - Does detection capability exist to address both physical hazard and adulteration.
- Conduct investigation to determine means by which FM entered product.
- Redesign process to eliminate root cause or implement systems to manage the risk.

# Steps in In-Plant FM Investigation

- Did the FM originate from our facility, the ingredient supplier, or ?



# Steps in In-Plant FM Investigation

- Damaged equipment reported.
- Isolate product manufactured since intact condition was last verified.
- Establish product disposition
  - Does detection capability exist to address both physical hazard and adulteration.
  - Will subsequent processing have an impact on distribution or ability to detect the FM?
- Determine source of damage.
  - Incorrect equipment setup, inadequate PM, impact of FM in the product stream, etc.
- Redesign process to eliminate root cause or implement systems to manage the risk.

# Steps in In-Plant FM Investigation

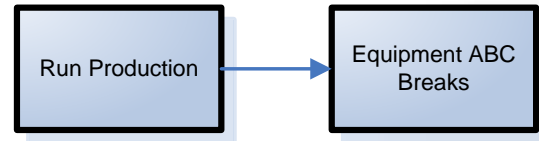
- What was the cause of the damage? When did it happen?



# FM and Maintenance Practices

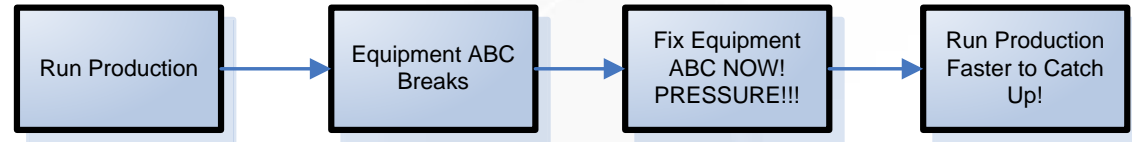
- Many facilities are addicted to emergency maintenance scenarios.
- Unfortunately this practice can exacerbate a whole host of problems....including FM contamination events.
- Running Equipment to Failure is NOT a Desirable Practice and Should be Avoided!!

# The Run to Failure Mode

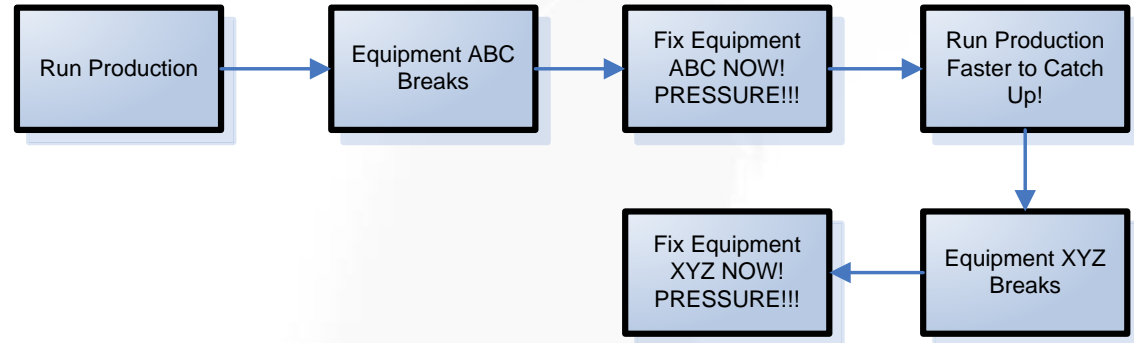




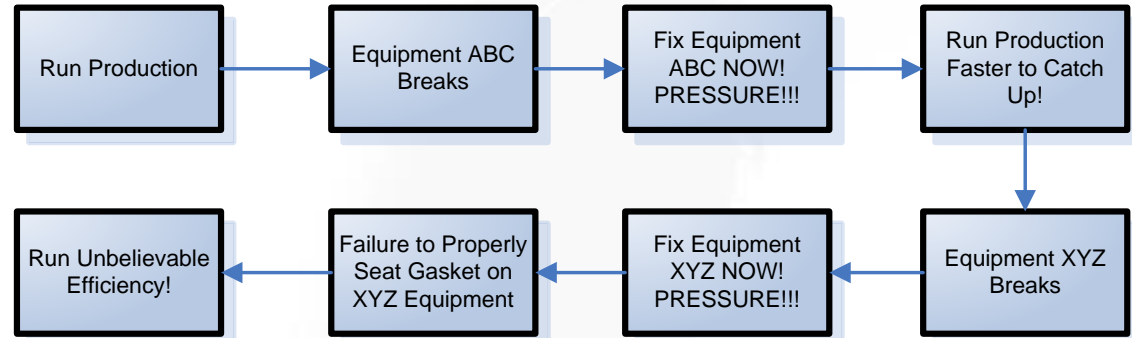
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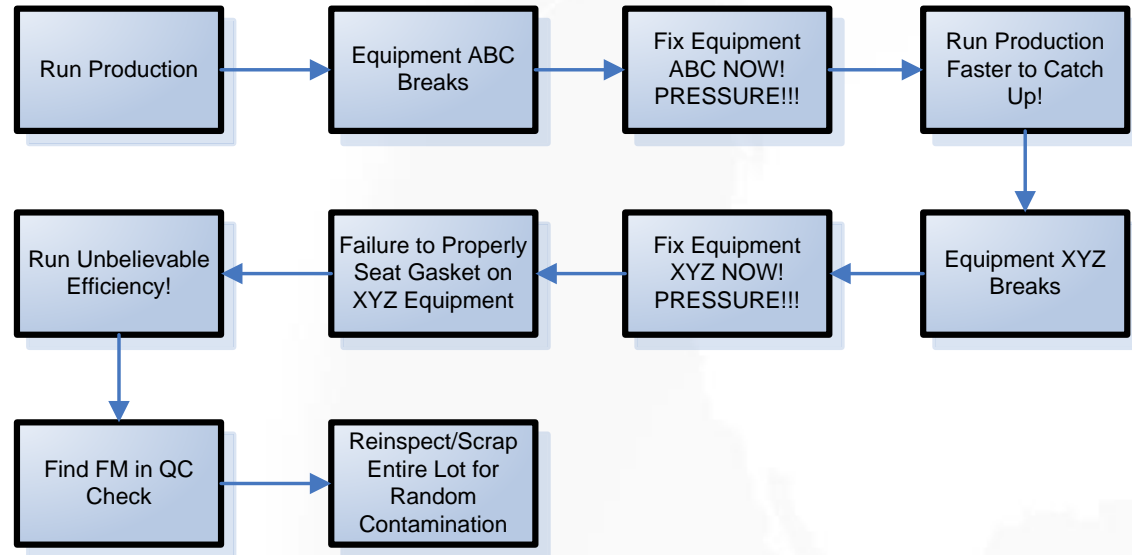
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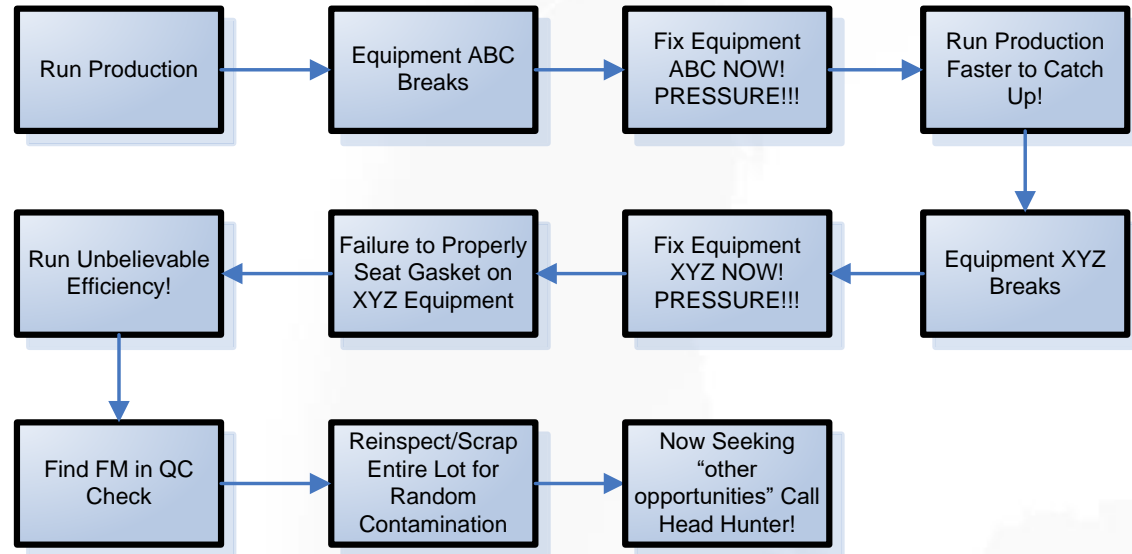
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# Migration From Run to Failure

- Develop preventative maintenance systems-conditional maintenance at a minimum
- Designate scheduled maintenance periods for planned maintenance events (PME) sequencing is key
- Perform root cause analysis of failures and capture service life data
- Have appropriate spare parts on hand

# Root Cause Analysis

ROOT CAUSE =

- The causal or contributing factors that, if corrected, would prevent recurrence of the identified problem
- The “factor” that caused a problem or defect and should be permanently eliminated through process improvement
- The factor that sets in motion the cause and effect chain that creates a problem
- The “true” reason that contributed to the creation of a problem, defect or nonconformance

# What is Root Cause Analysis?

A standard process of:

- Identifying a problem
- Containing and analyzing the problem
- Defining the root cause
- Defining and implementing the actions required to eliminate the root cause
- Validating that the corrective action prevented recurrence of problem



# By eliminating the root cause...

- You Protect the Consumer
- You save time and money!
- Problems are not repeated
  - Reduce rework, retest, re-inspect, poor quality costs, etc...
- Problems are prevented in other areas
- Communication improves between groups and
- Process cycle times improve (no rework loops)
- Secure long term company performance and profits

# That's Nice, But I Want to hold Someone Accountable!

- Most human errors are due to a process error
- A sufficiently robust process can eliminate human errors
- Placing blame does not correct a root cause situation
  - Is training appropriate and adequate?
  - Is documentation available, correct, and clear?
  - Are the right skillsets present?

“

**“THE GOAL OF THE FOOD SAFETY  
PROFESSIONAL SHOULD BE TO CREATE A FOOD  
SAFETY CULTURE NOT A FOOD SAFETY  
PROGRAM**

”

- Frank Yiannas

Control by Effect Measures vs Preventive Practices

# The Food Safety Culture Equation

“Values” + “Why” + Preventive Practices → Strong Food Safety Culture

*Define* and *Measure* Preventive Practices deployed to mitigate hazards.

# Person(s) Responsible for Food Safety

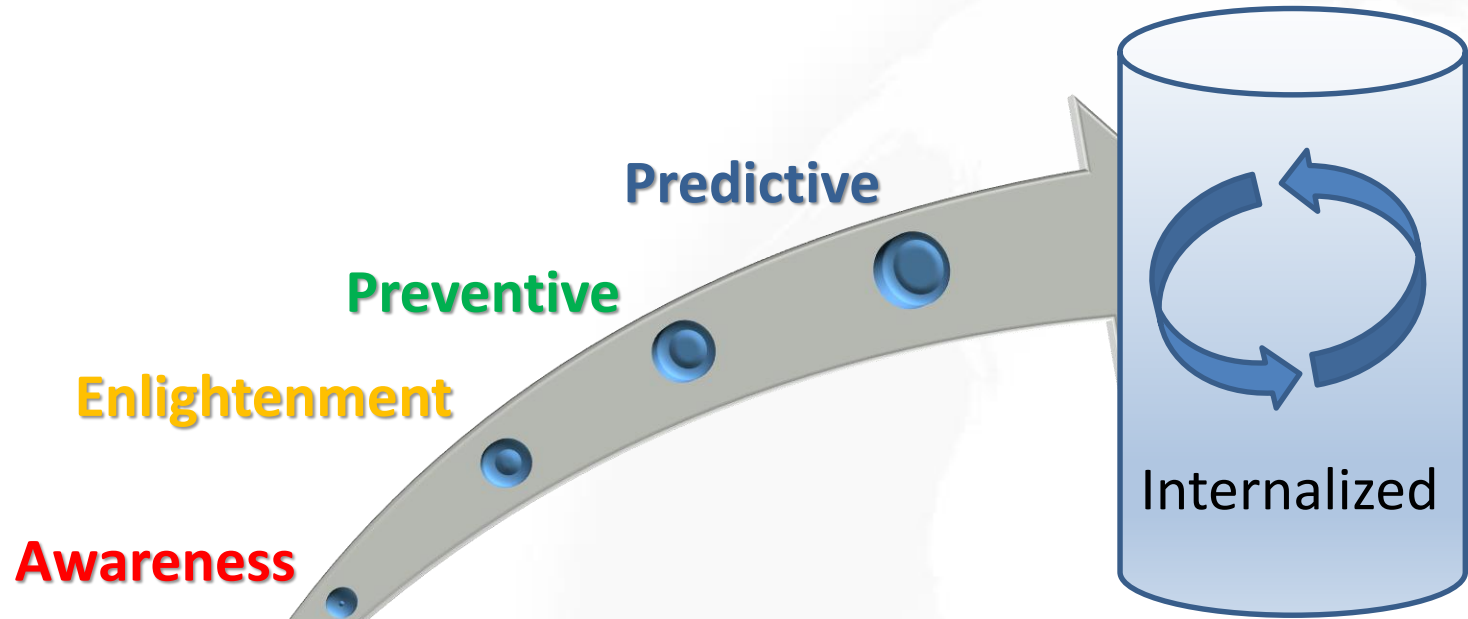
## TEAM

The involvement of a multidiscipline team or group to take corrective action is a great benefit over a single person with limited scope.

- Engineer
- Microbiologist
- Sanitation
- Production operations
- Maintenance
- Food Safety or QA

Always remember to involve frontline associates. They often have the answers.

# The Food Safety Culture Journey



Credit to Lone Jespersen  
Maple Leaf Foods

Firefighting Intensity

**FOOD SAFETY BY DESIGN**

AWARENESS ENLIGHTENMENT PREVENTATIVE PREDICTIVE

# Questions?

- Thank You

