Identifying the Root Cause: In Plant Investigation and Risk Assessment

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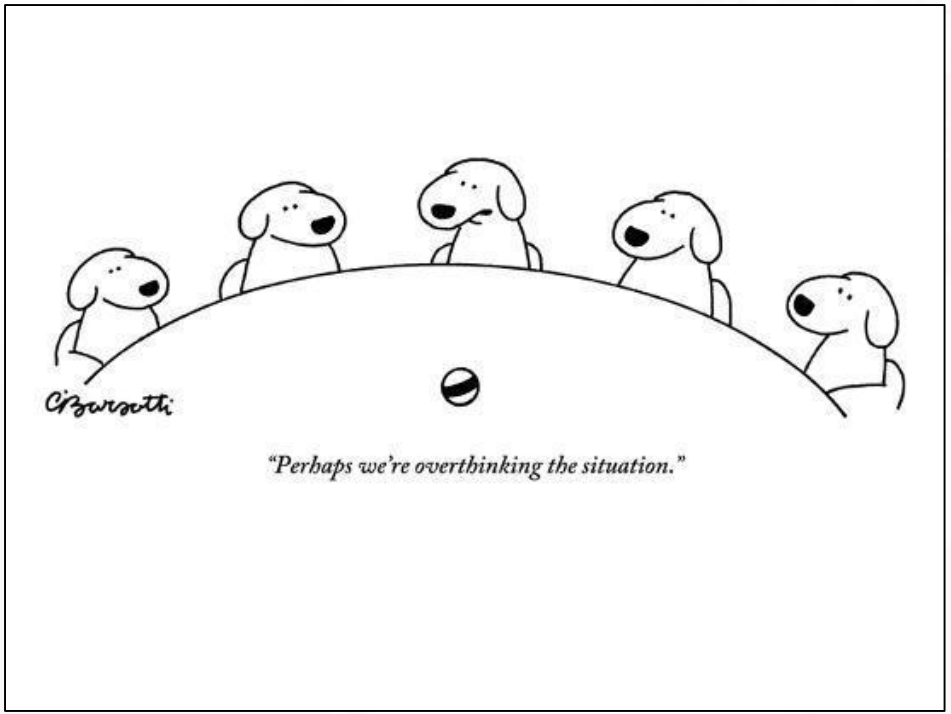
NORTH AMERICAN MEAT INSTITUTE

Dealing with FM Requires Thought

- Frequently dealing with sporadic events, variable personnel, and complex processes.
- Because of the complexity involved with investigations, 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
  - Global media presence can create further issues

You SHALL...

- Keeping our products free of filth, impurity, and physical hazards is required by Law
- Regulatory agencies can take action against the company, the facility, or the individual responsible for product oversight
- Export requirements can cause costly rejections
- Product must be free of adulteration

The Typical Scenario…

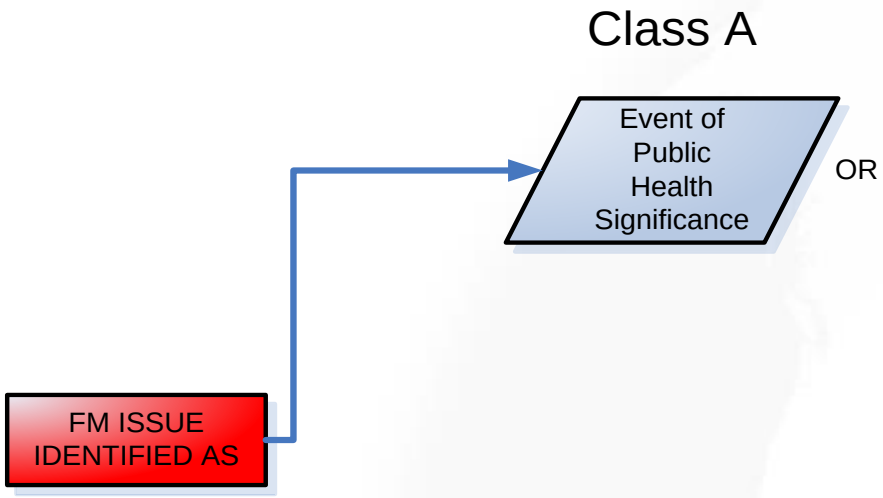
We just received a call and the consumer found…”

NOW
WHAT!?!

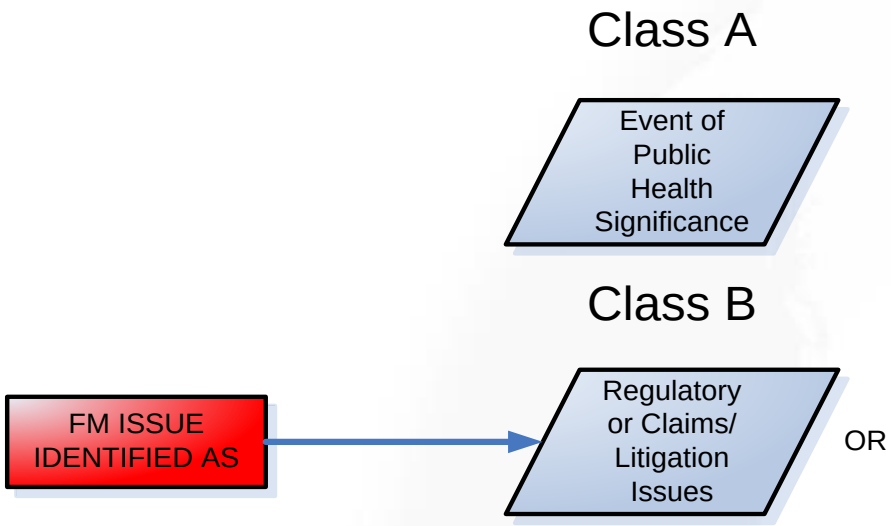
Credit to Jim Mino Hormel

FM ISSUE IDENTIFIED AS

Risk Classification of FM



Risk Classification of FM



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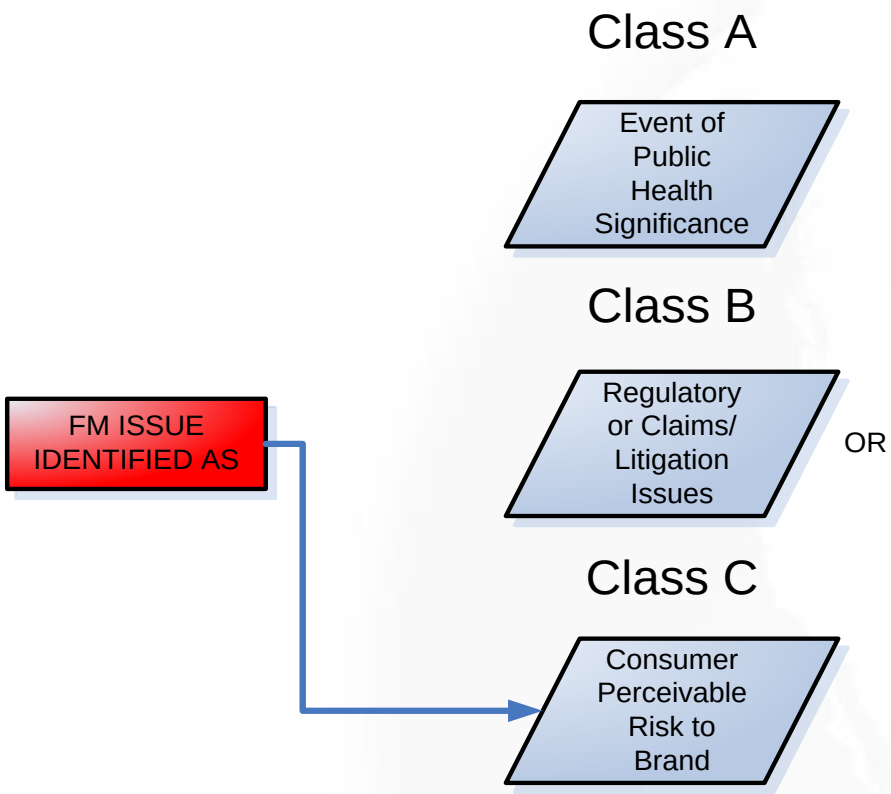

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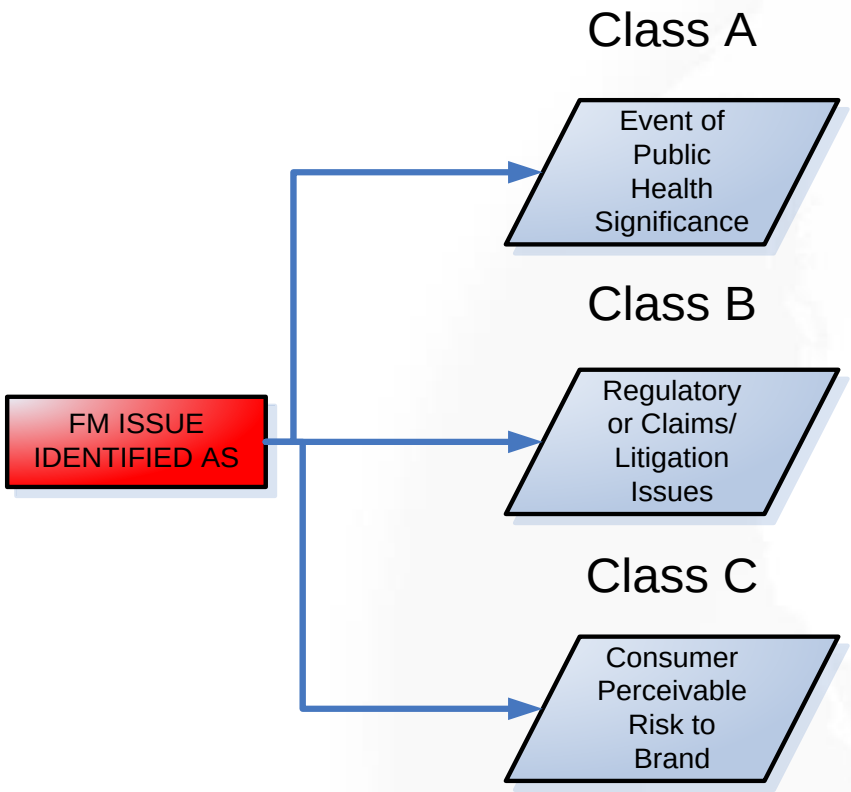
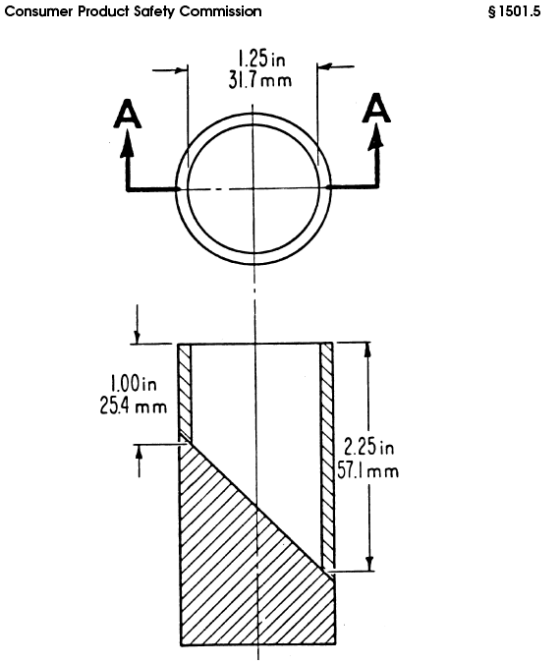


Class A- FM and Public Health

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



16 CFR 1501(a) and (b)

Defined by dimensional or other characteristics

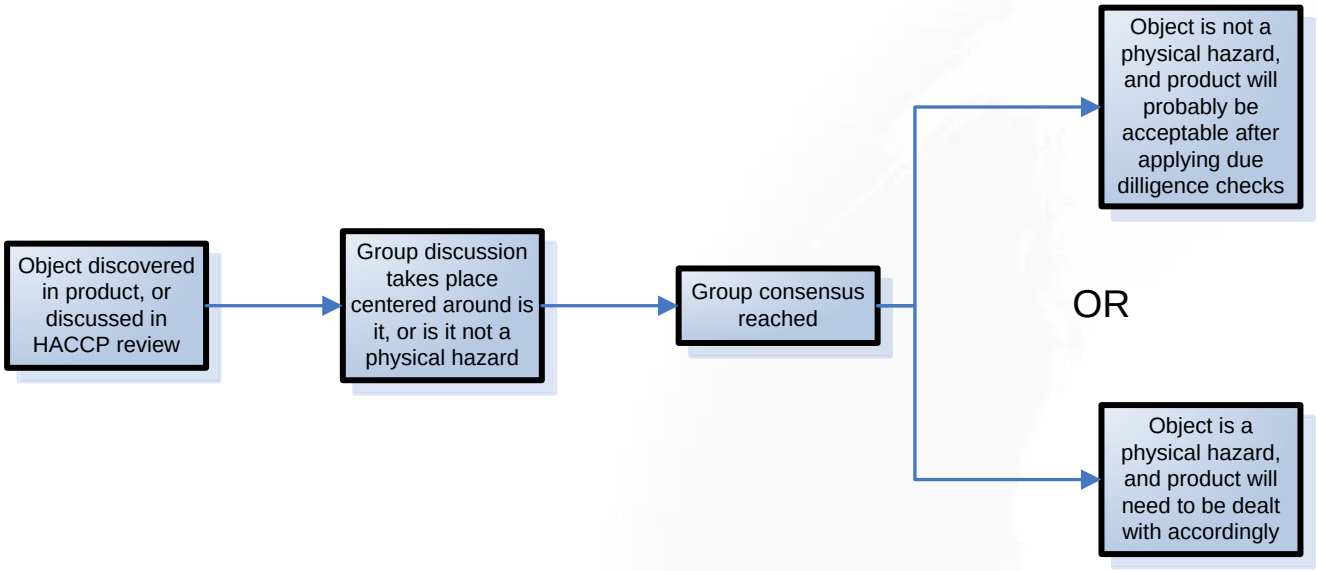
April 10, 1999: nine year old Michelle Enrile choked while eating a Konjac Mini Gel Snack. The candy completely obstructed her windpipe, and all efforts by her parents and paramedics to dislodge the blockage were fruitless. She fell into a vegetative state and died two years later. A jury found the defendant, 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 – Biological and Chemical

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

Risky Logic Based on Hazard Assessment Alone



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 is indigenous to ingredients. Bone in hot dogs for example.

Expectations of Customers

- Food Service customers 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

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

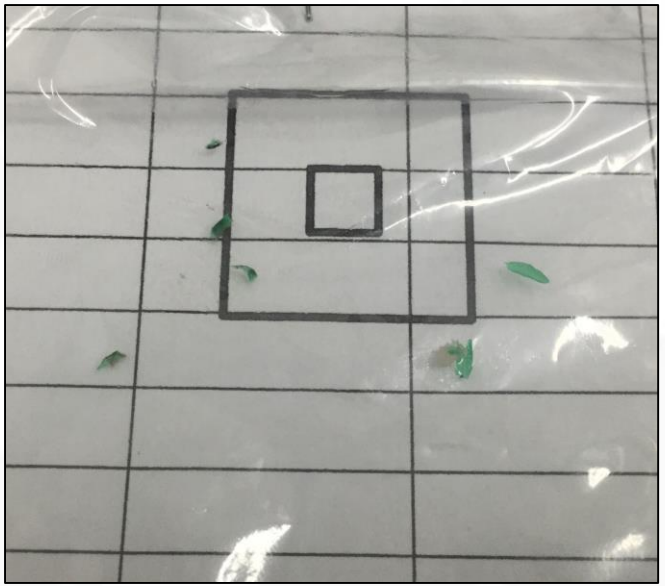
Steps in In-Plant FM Investigation

- 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 ?

As opposed to:



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.

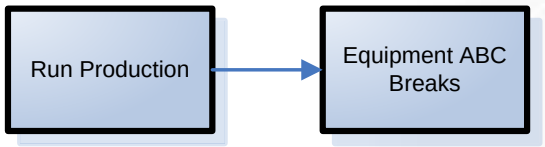
Steps in In-Plant FM Investigation

- 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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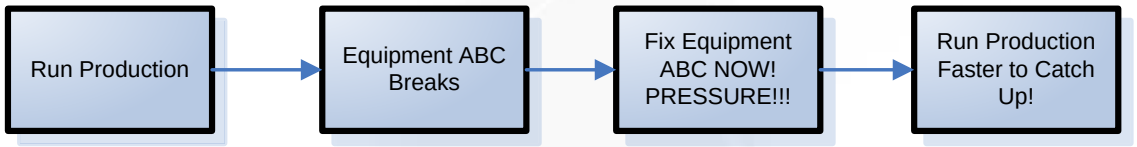

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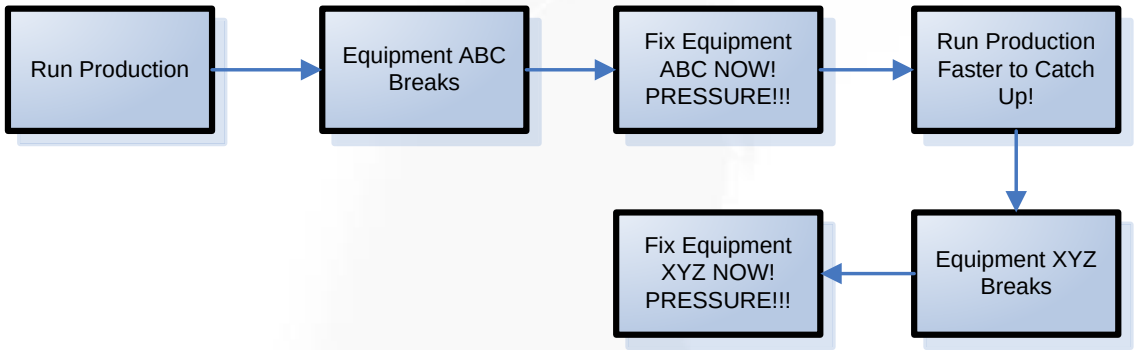

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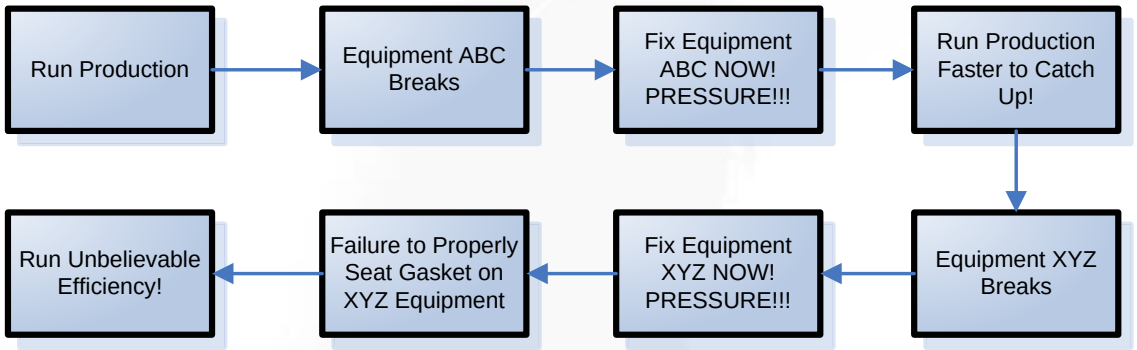

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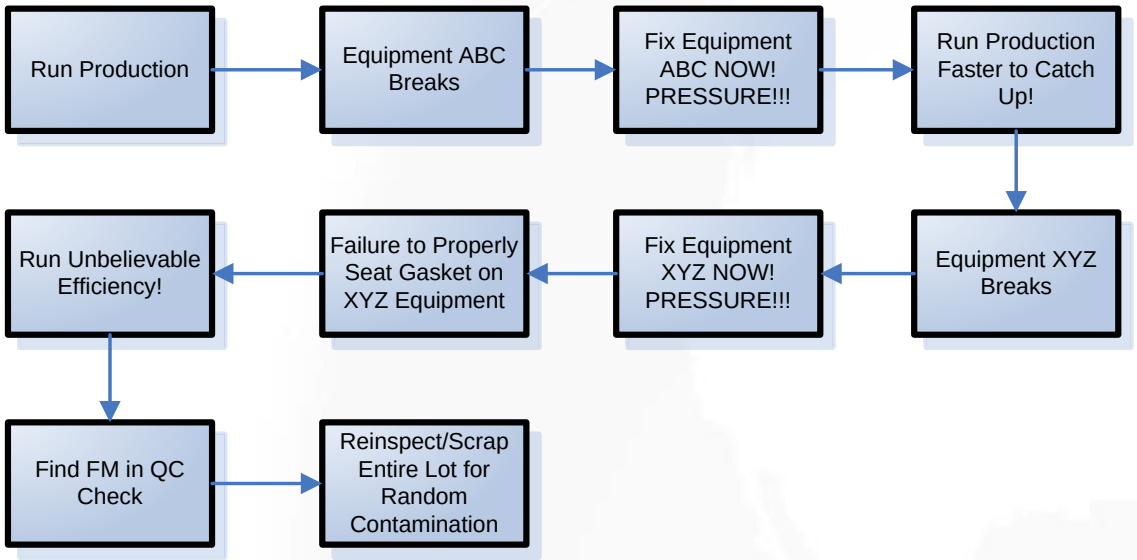

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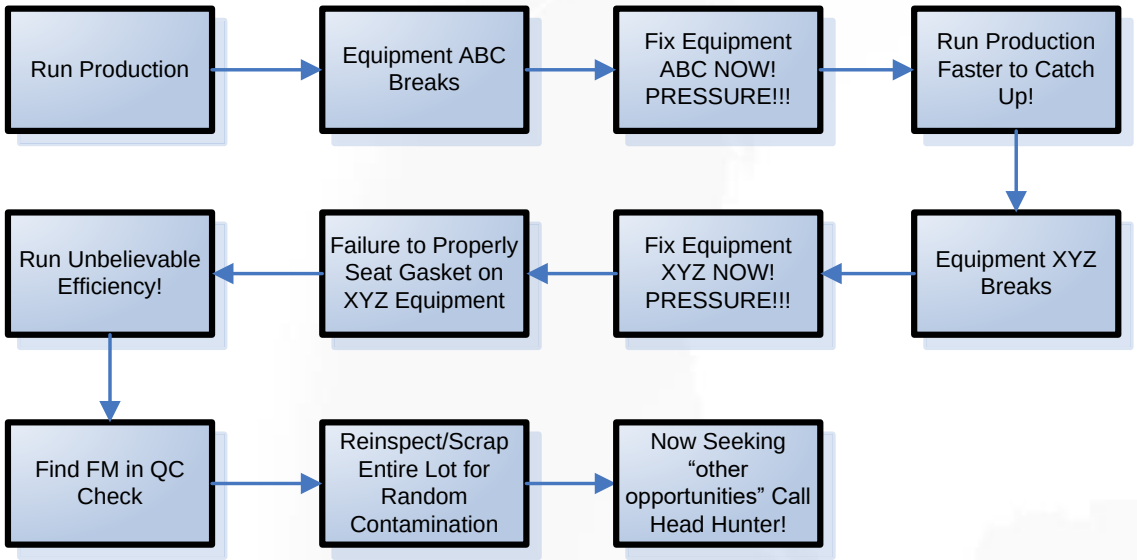


Emerging From Run to Failure

- Develop and execute preventative maintenance systems
- Designate scheduled maintenance periods for planned maintenance events (PME)
- 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 great but who is to blame!

- 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 adequate and communicated effectively?
  - Is documentation available, correct, and clear?
  - Do those performing the job have the skills to be successful?

“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

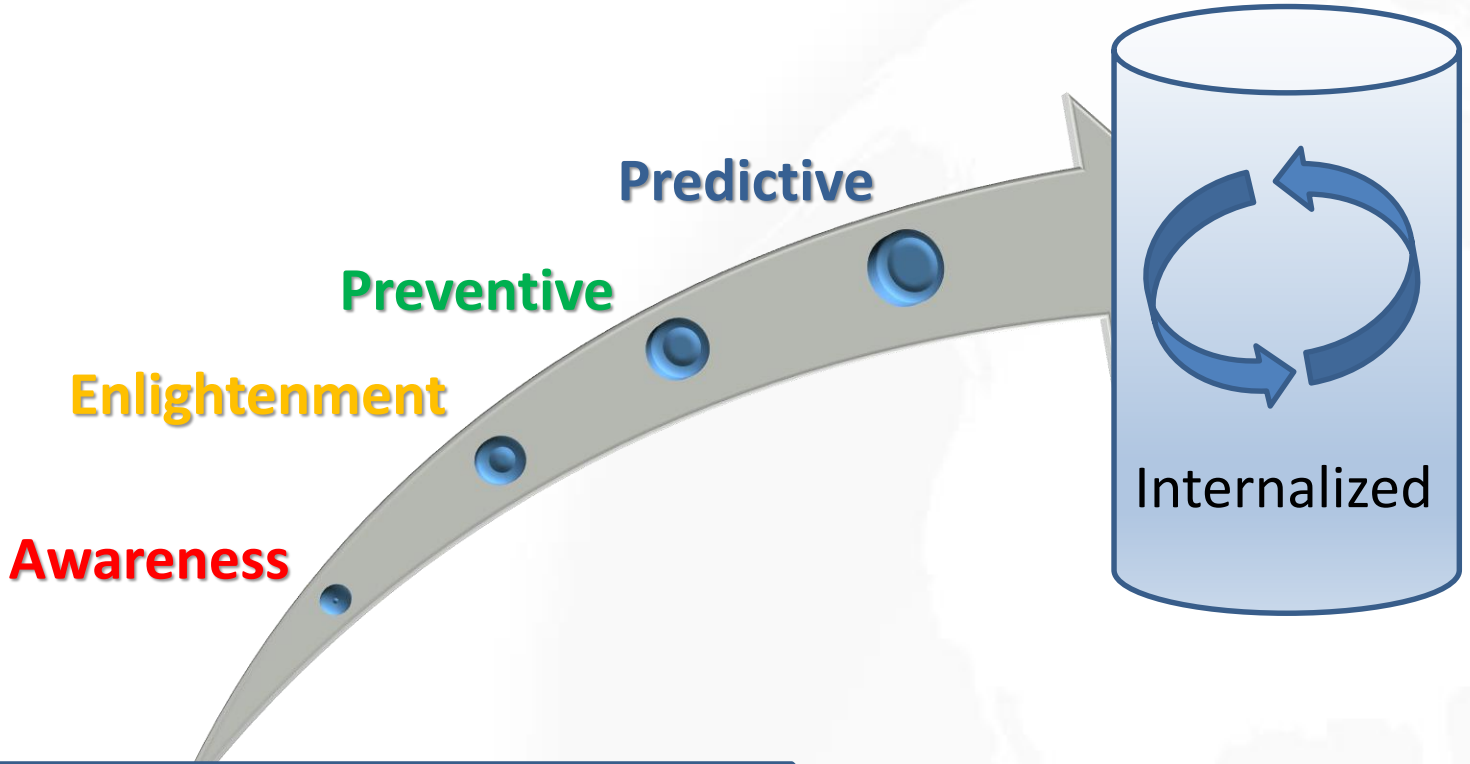
TEAM

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

Questions?

- Thank You