Top 5 Ways to Prevent Foreign Material Contamination

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Let’s Meet Your Speakers

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Today’s Discussion

1. Reasons for Escalation of Recalls
2. Types of Foreign Material Risks
3. Top 5 Ways to Prevent Foreign Material Contamination
4. Management of Foreign Material Findings
5. Available Resources
6. Questions and Answers
Reasons for Escalation of Recalls
Reasons for Escalations inRecalls

• Customer Complaints
• USDA Recall Regulations
• FSMA & FDA Recall Authority
• Media & Social Media Risks
• Litigation Risks
• Brand Protection
• Improved Lot Traceability
Types of Foreign Material Risks
Types of Foreign Material Risks — Examples

• **From Materials:**
  Wood, plastic, buckshot, stones, needles, bullets, pits

• **From Processes:**
  Nuts, bolts, conveyor pieces, gaskets, seals, packaging material

• **From Employees:**
  Jewelry, candy, gum, hair, knives, tools, tape, paper, pens, instruments

• **From Environment:**
  Insulation, paint, insects, rodents, caulk, glass, plastic
Why is “Zero Defects” the Foreign Material Standard?

No adulteration is allowed!
Top 5 Ways to Prevent Foreign Material Contamination
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Three “Traditional” approaches to reduce Foreign Material + Two “Intensified” approaches combining Technical Expertise with Employee Engagement = Five “Combined” strategies that work in coordination to significantly reduce and prevent foreign material risks
Top 5 Ways to Prevent Foreign Material Contamination

1. Raw Materials Foreign Material Management
2. Machinery and Equipment Focus
3. Foreign Material Detection & Removal
4. Food Safety Culture & Engagement Initiative
5. Failure Mode and Effects Analysis (FMEA)
1. Raw Material Management

• Supplier certification program

• Supplier Foreign Material Defects per Million Units

• Supplier FMEA Process Management

• Supplier Lot Testing Upon Receipt

• X-Ray or Metal Detection of Raw Material if needed
2. Machinery & Equipment Focus

• Belt inspection protocols before & during operations
• Preventative maintenance FM checks
• Tools & parts accountability program
• Gasket & seal accountability program
• Equipment repair check-off process
3. Foreign Material Detection & Removal

- X-rays
- Metal detection
- Filters
- Vacuums
- Magnets
- Visual hand sifting

- Lighted tables
- Screens
- Optical imaging
- Many reject option

*Placement early vs. late in process requires risk assessment.*
4. Food Safety Culture & Engagement Initiative
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Focus on F.S. Systems
- People (manpower)
- Processes (machines)
- Procedures (methods)
- Procurement (materials)

Focus on F.S. Purposes
- Mission
- Values
- Metrics
- Learning
- Investment
- Proactivity
- Teamwork
- Communication
- Engagement
4. Food Safety Culture & Engagement Initiative

Food Safety Culture Implementation Steps:

1. Senior Management Food Safety Culture Awareness
2. Food Safety Culture Training & Assessment Pilot
3. Implement FS Culture Assessment for Each Process
4. Identify FS Culture Strengths and Gaps
5. Implement Strategies to Address FS Culture Gaps
6. Annual or Periodic Culture Re-Assessments
5. Failure Mode & Effects Analysis (FMEA)

FMEA is a systematic method for identifying potential failure modes in systems or processes and assessing relative risk rankings associated within a process by evaluating the likelihood, severity, and detectability of risks at each step.
What Are Some Applications of FMEA?

• Military has used FMEA for decades under Mil-Std-1629A to ensure reliability of weaponry

• Automotive manufacturers have required FMEA by parts vendors to prevent failures

• Hospitals and Health Care settings

• Engineering and Product / Equipment Design

• Can be applied to any type of risk; i.e. safety, quality, economic risk, downtime risk, etc.
What Are Some Common Uses of FMEA?

- When risks are unknown
- When risks are high
- When new regulations are implemented
- During product or equipment design
- Before implementing a new process
- After a failure
- After a customer request
- During continuous improvement efforts
FMEA is a Way of Applying the “Pareto Principle”

• **80:20 rule applies**: most problems or failures are caused by a few of the most common failure modes

• FMEA stresses working on the **biggest causes of risk first**, and managing to reduce the largest sources of risk

• The 3 factor equation of $P \times S \times D$ creates clarity in determining which areas need the most attention, especially due to the multiplier of “detectability”
Why Implement the FMEA Risk Assessment?

• **Risk is inevitable & inherent** in manufacturing

• In a poll by Quality Progress (May, 2010), when participants were asked “what is the best way to avoid a product recall?”, the top response was: “**Identify potential sources of risk**”

• The FMEA process is one of the best tools available to **understand & reduce the potential sources** of product risk
Does the FMEA Cost Money or Save Money?

• It **costs far less to prevent a failure** than detecting, analyzing, and correcting a failure

• “An ounce of prevention is worth a pound of cure”.

• **Preventing system failures is critical** to the sustainability of processes and customers, and the prevention of harm to people and company reputation.
FMEA is a Dynamic Process

1. Assemble FMEA Team
2. Map All Process Steps
3. Determine Probability of Failures
4. Determine Severity of Failures
5. Determine Detectability of Failures
6. Calculate RPN
7. Implement Risk Mitigation Strategies
The Risk Priority Number (RPN)

**Risk Priority Number (RPN)** = 

Probability x Severity x Detectability \((P \times S \times D)\)
The Risk Priority Number (RPN) = P x S x D

- **Probability** = based on how often the risk occurs or is expected to occur
- **Severity** = how severe the occurrence would be to a person, organization, customer, or operation
- **Detectability** = how easy a hazard occurrence is to detect or locate when it happens

*Determine appropriate scale for your organization (i.e. 1-10 for each, 1-5 for each or other custom)*
Determine Risk Exposure based on RPN

- Exposure determination is a relative scale based on RPN
- Example for a 1-10 scale for each:

<table>
<thead>
<tr>
<th>RPN Range</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 25</td>
<td>Low Risk</td>
</tr>
<tr>
<td>26 - 70</td>
<td>Moderate Risk</td>
</tr>
<tr>
<td>71 – 294</td>
<td>High Risk</td>
</tr>
<tr>
<td>295 – 1,000</td>
<td>Very High Risk</td>
</tr>
</tbody>
</table>
FMEA Implementation Guidance

• Start the FMEA process with a few **pilot lines**

• Use a **multi-disciplinary team** of maintenance, engineering, production, QA, safety, procurement, and plant employees.

• Use the **5-Why’s & Ishikawa root cause analysis** of failures

• **Anticipate & celebrate** improvements with Management.

• **It takes time.** The FMEA process can be tedious, but is highly effective at prioritizing risk reduction strategies
Management of Foreign Material Findings
Perform trend analysis to determine the actual frequency of findings:

- By time (ex. findings per month, quarter, etc.)
- By Foreign Material Type
- By volume (ex. Findings per million lbs., units, etc.)
- By supplier
- By process line
Managing Internal & External FM Findings

Complete a detailed investigation to identify the root causes and 5-why’s of the event:

- Manpower
- Materials
- Methods
- Machinery
- Environment
Managing Internal & External FM Findings

• Implement appropriated corrective actions & preventive actions
• Respond to customer complaints effectively
• Complete Failure Modes & Effect Analysis (if needed)
  – Determine likelihood of event recurring along with severity & detectability
  – Calculate updated RPN
  – Evaluate & implement new mitigation strategies
Managing Internal & External FM Findings

Communicate mitigation plan and preventive measures to key stakeholders, using a standardized protocol.

✓ Customers
✓ Management
✓ Mechanics
✓ Regulators
✓ Line Workers
✓ QA technicians
✓ Sanitation workers
✓ Suppliers
Available Resources
An Integrated Solution for Continuous Engagement

Alchemy enables “smart action at work” with integrated training, reinforcement, and compliance solutions.
Provide Engaging Training

• Create content in employee’s primary language
• Base content on employee’s role (HACCP, GMPs, GAPs)
• Ensure comprehension with open discussions and educational games
Reinforce Critical Concepts

Mobile Coach App
• Increase supervisor/employee interaction & communication
• Validate employee understanding

Digital Signage
• Reinforce key training topics
• Improve control & message quality to entire company

Huddle Talk Guides
• Blueprint to engage & instruct workers
• Time-saving tool for supervisors & trainers

Coordinated Posters
• Reinforce discussion topics with strategically placed posters
• Make an emotional impact
Ensure Audit-Readiness

Leverage technology to verify:

- Training attendance
- Training comprehension
- Correct application of training
- On-the-floor reinforcement & corrective actions

Eliminate time-consuming record keeping!
Alchemy’s Consulting Solutions

- **Foreign Material Control Assessments** – FMEA Training and Risk Assessments to identify sources and mitigate risks
- **SQF, BRC and FSSC 22000 Consulting** – Gap Analysis, Program Development, Internal Audits, Audit Support
- **HACCP Plan / Food Safety Plan Reassessment or Validation** – Detailed review of your food safety system to verify accuracy and effectiveness
- **Food Safety Training** – On-site Basic HACCP, Advanced HACCP, Preventive Control for Human Food, Preventive Control for Animal Food, Internal Auditor Training

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  - SQF, BRC, FSSC 22000, and IFS

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