Food Industry Use of Risk-Based Inspections for Corporate Oversight and Governance

Submitted by: General Mills
Food Industry Use of Risk-Based Inspections for Corporate Oversight & Governance

WeeNee Ng | General Mills
Head of Regulatory Affairs - Asia / Middle East / Africa Region
Food must be trustworthy
Goals for Today

• Brief Overview of General Mills Global Business
• Elements of Strong Governance & Oversight
• Policy and Standards
• Levels of audit & inspection used in risk-based prioritization
Worldwide People turn to General Mills for Breakfast, Lunch, Dinner and Snacks

Today people will eat....

- 60 million servings of ready-to-eat Cereal
- 14 million Nature Valley bars
- 5 million Pillsbury cookies
- 9 million of our KFC biscuits
- 343,000 packets of Nature Valley Granola at McDonald’s
- 2 million Wanchai Ferry dumplings
- 2 million pounds of Green Giant vegetables
- 1 million servings of Häagen-Dazs ice cream

Sixth largest Food Company operating in 130+ countries, with over 35,000 employees
## Global Supply Chain Dimensions

<table>
<thead>
<tr>
<th>Category</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw Materials - Ingredients</td>
<td>~2,000 Producing Locations</td>
</tr>
<tr>
<td>Raw Materials - Packaging Food</td>
<td>~420 Producing Locations</td>
</tr>
<tr>
<td>Contact</td>
<td></td>
</tr>
<tr>
<td>General Mills Owned - Manufacturing plants</td>
<td>61 (+25 Joint Venture)</td>
</tr>
<tr>
<td>Contract Manufacturing Locations</td>
<td>180+</td>
</tr>
<tr>
<td>Countries of Business</td>
<td>130</td>
</tr>
<tr>
<td>Employees</td>
<td>18,000+</td>
</tr>
</tbody>
</table>
• Pioneered in the 1960's by Pillsbury
  – First used when foods were developed for the NASA space program

• U.S. National Advisory Committee published seven HACCP principles in 1989

• Codex Alimentarius published HACCP principles in 1993

• Adopted by many food processors and governments
What Does World Class Food Safety Governance Look Like

Integrated Safety Management System

1. Strong Culture & Leadership
   - Management commitment
   - Policies and principles
   - Goals, objectives and plans
   - Culture of reporting Safety incidents

2. Appropriate Structure
   - Line management accountability and responsibility
   - Safety personnel
   - Integrated organization structure
   - Motivation and awareness

3. Processes & Actions
   - Effective communication
   - Incident investigation
   - Procedures and performance standards
   - Inspections and audits

4. Learning & Development
   - Organizational Capability and Capacity Needs Assessment
   - Education, Training and Development
Food Safety & Regulatory Policy & Standards
General Mills Food Safety and Regulatory Matters Policies and Standards

Corporate Policy 1

- Each employee, worldwide, is responsible for knowing the policies and acting in accordance.
- Signed by Chief Executive Officer – Head of General Mills

Corporate Policy 7

- Quality & Regulatory Operations (QRO) department is accountable for establishing & maintaining Food Safety and Regulatory Matters policies
- Everyone implements
- QRO verifies through Corporate internal audits and 3rd party assessments

Food Safety & Regulatory Matters Policies & Standards

- Company requirements, not a department/function requirements
- 16 global policies with supporting standards and guidance
Global Foundation for Food Safety & Regulatory Matters

Global
Simple
Useful
Consistent
Complete

Policy “Always True”
- Clear & Concise
- Meaningful
- Timeless

Standard “Must Do”
- Specific & Actionable

Guidance Documents
- “How to do/Nice to know”
Food Safety Overview

Food Safety & Regulatory Matters
Policies, Process & Content

Form Basis for Risk-Based
Inspections & Ratings
GMI Risk-Based Process
INCIDENT FREE

We lead with safety

Every incident is preventable

We are all accountable
Effective Inspections, Audits and/or Investigations require Multifaceted Approach

Food Safety System Core Elements

1. Robust Global Policy, Standards and Guidance
   - Informed by Laws and Regulations
   - Developed with broad Stakeholder Input
   - Signed by Senior Leadership

2. Capacity Building to Assure Understanding & Building Effective Control Programs
   - Policy changes – typically 12 months to fully implement
   - Outreach requires multiple touches and approaches – on-line materials, webinars

3. Risk-based Verification Activities
   - All “auditable entities” conduct self-assessments
   - Corporate teams undertake risk-based inspections
   - 3rd Party Inspections & Audits provide Independence
   - Regulatory inspections verify control programs in place & effective
Risk Ranking Philosophy

• Tool to Quantify Food Safety Risk
  – Inherent
  – Plant Controllable

• Prioritize Resources
  – People
  – Capital

• Measure Progress
Risk Ranking Process

Data Inputs
- Internal Audit
- External Audit
- Microbiology
- Regulatory

Resources
- Allocation
- Prioritization
- Food Safety Risk Assessment (FSRA) plans
GMI Facility Risk Ranking Tool

- Opportunity = Actual risk – Plant lowest possible
- Opportunity is plant controllable risk
- Used to build improvement targets

<table>
<thead>
<tr>
<th>Facility</th>
<th>Division</th>
<th>ACTUAL</th>
<th>PLANT LOWEST POSSIBLE SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Microbiological</td>
<td>Physical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25.0</td>
<td>18.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>37.0</td>
<td>15.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25.0</td>
<td>22.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>17.0</td>
<td>18.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>27.0</td>
<td>12.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21.0</td>
<td>10.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19.0</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.0</td>
<td>21.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11.0</td>
<td>7.5</td>
</tr>
</tbody>
</table>
### Audit Finding Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Food safety or regulatory condition leading to likely/actual contamination or major deviation for GHP's or GMI policy. Follow-up documentation required.</td>
</tr>
<tr>
<td>Finding</td>
<td>Gap(s) noted during physical inspection or program/record review. Does not reach critical finding status. Follow-up documentation required.</td>
</tr>
<tr>
<td>Observation</td>
<td>Insignificant deviation form requirements. Isolated or minor food safety gap(s). No follow-up documentation required.</td>
</tr>
</tbody>
</table>

### Audit Considerations

- **Supply Chain Complexity**
  (cases produced, type of products, distribution reach, single source plant)

- **Previous Audit & Certification Results**

- **Internal/External Activity**

- **Plant & Leadership Team History**

- **Auditor Judgment**

  *Audit plans are approved and signed by senior leadership. Summary reports issued annually.*

- **Most GMI facility receive a independent Corporate/ 2nd party audit annually. Consideration impact length of audit.**

- **All GMI facilities received a Corporate-Managed 3rd party GHP audit or Food Safety System Certification (FSSC) audit.**
GMI 3rd Party Certification
Global Food Safety Initiative (GFSI)

GFSI Mission & Objectives

Reduce food safety risks
Manage cost in the supply chain
Develop competencies and capacity building
Knowledge exchange and networking

GFSI Benchmarked Schemes

Collaboration between some of the world’s leading food safety experts from retail, manufacturing and food service industry, as well as service providers associated with the food supply chain. Based on globally recognized standards such as HACCP.

GFSI is a non-profit foundation.
Raw Materials Example: Risk Assessment Process

**FY14**

<table>
<thead>
<tr>
<th>Raw Material Risk Assessment Process</th>
<th>FY14 RAV Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Country of Manufacture</strong></td>
<td>20%</td>
</tr>
<tr>
<td><strong>Previous Audit Rating</strong></td>
<td>30%</td>
</tr>
<tr>
<td><strong>Internal/External Activity</strong></td>
<td>25%</td>
</tr>
<tr>
<td><strong>Vendor History</strong></td>
<td>25%</td>
</tr>
</tbody>
</table>

**FY14 Maintenance Plan**

- **Priority one:**
  - Levels 4 and 5
    - Elevated and imminent food safety risks
    - Active, no audits

- **Priority two:**
  - FY13 qualifications re-audits
  - IM adds
  - International Support

- **Priority three:**
  - 2 year (↑ Impact, ↑ Exposure)

- **Priority four:**
  - 3 year (↑ Impact, ↑ Exposure) and (↑ Impact, ↓ Exposure)

- **Priority five:**
  - 5 year (↑ Impact, ↓ Exposure)
Audit and Inspection Process

**Pre-Work**
- Previous audits – internal and 3rd party
- Incident history
- Management Changes
- Regulatory & Consumer Contacts

**Plant Audit**
- Physical Facility Inspection
- Program Reviews
- Documentation Review
- Training Records
- Close-out Meeting

**Follow Up**
- Issue Audit Report
- Track Corrective Action Completion
- Update Audit Database
Food Safety Management Continuum

Understanding Where a Facility/Company is on the Continuum

Level 0:
- Transactional
- No Specifications
- No Audits
- No Approval Procedures

Level 1:
- Customer/Buyer Relationship
- Technical Data Sheet
- Supplier Surveys
- Approval Procedures

Level 2:
- Core Suppliers
- Technical Data Sheet
- Specifications
- Supplier Surveys
- Approval Procedures
- 3rd Party Audits

Level 3:
- Partnerships
- Core Suppliers
- Technical Data Sheet
- Specifications
- Supplier Surveys
- Approval Procedures
- 3rd Party Audits
- 2nd Party Audits
- Supplier Scorecards
- External Technical Experts

Level 4:
- Industry Leaders
- Partnerships
- Core Suppliers
- Technical Data Sheet
- Specifications
- Supplier Surveys
- Approval Procedures
- 3rd Party Audits
- 2nd Party Audits
- Supplier Scorecards
- Internal Technical Experts
- Training & Education
- Food Safety Investment
### Share Many Common Elements

#### “Regulated Industry”

<table>
<thead>
<tr>
<th>Expectations</th>
<th>Policy &amp; Standards</th>
<th>Laws &amp; Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educactions &amp; Awareness</td>
<td>Guidance Documents &amp; Training</td>
<td>Outreach &amp; Guidance Documents</td>
</tr>
<tr>
<td>Skills Needed</td>
<td>Process &amp; Systems to Produce Safe Food</td>
<td>Knowledge &amp; Critical Thinking to Assess Food Safety Control Programs</td>
</tr>
<tr>
<td>Risk-based Assessment</td>
<td>Qualitative &amp; Quantitative Data</td>
<td>Qualitative &amp; Quantitative Data</td>
</tr>
<tr>
<td>Outcome</td>
<td>Compliance</td>
<td>Compliance</td>
</tr>
<tr>
<td></td>
<td>Safe food for Consumers</td>
<td>Verification of Control Programs that lead to Safe food for Consumers</td>
</tr>
</tbody>
</table>
Mission Accomplished!

Your Brand is your REPUTATION

The job isn’t finished until our BRAND, our PRODUCTS is safely consumed by our consumers
Thank You!
WeeNee Ng
Head of Regulatory Affairs – Asia / Middle East / Africa Region

General Mills
168 Robinson Road . #26-01
Capital Tower . Singapore 068912
Phone: (65) 6305 6680
Mobile: (65) 9856 6699
Email: Weenee.Ng@genmills.com