



**Asia-Pacific
Economic Cooperation**

2014/SCSC/WKSP1/010

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

Submitted by: General Mills



**Workshop on Improved Food Inspection
Capacity Building Based on Risk Analysis
Seoul, Korea
21-23 May 2014**



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

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Head of Regulatory Affairs - Asia / Middle East / Africa Region



Food must be trustworthy



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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



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General Mills Overview

Worldwide People turn to General Mills for Breakfast, Lunch, Dinner and Snacks



Sixth largest Food Company operating in 130+ countries, with over 35,000 employees

Championship Brands



Championship Products



Global Supply Chain Dimensions

Raw Materials - Ingredients	~2,000 Producing Locations
Raw Materials - Packaging Food Contact	~420 Producing Locations
General Mills Owned - Manufacturing plants	61 (+25 Joint Venture)
Contract Manufacturing Locations	180+
Countries of Business	130
Employees	18,000 +



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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

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Championship Brands





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HACCP

- 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



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Governance and Oversight



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



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Food Safety & Regulatory Policy & Standards



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Food Safety Overview

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

Policy "Always True"
Clear & Concise
Meaningful
Timeless

Simple

Standard "Must Do"
Specific & Actionable

Useful

Consistent

Guidance Documents
"How to do/Nice to know"

Complete



Policy Team with Global Representation

Food Safety & Regulatory Matters Policies, Process & Content



Alex Li
QRO Director
China



Adriana Ojeda
QRO Manager ESC
Mexico



Heather Ranney
Lead Policy Center



Tammy Hogan
Supply Chain Manager
USA



Iain Thomson
Europe/Australia/NZ



Julia Mitobe
Canada



Kuldeep Mulik
QRO Manager India



Matt Clay
Refrigerated Dough -
USA



Doug Gross
Frozen - Vegetables USA



Aranzazu Alzueta
Latin America Region



Mary Harrington
Dairy - USA



Paul Cordes
Corporate Auditor



Gail Denny
Cereal - USA



Form Basis for Risk-Based Inspections & Ratings



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Policy Team with Global Representation



Alex Li
QRO Director
China



Adriana Ojeda
QRO Manager ESC
Mexico



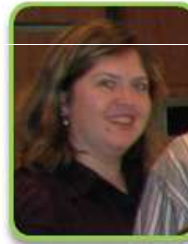
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Food Safety & Regulatory Matters

Policies, Process & Content

- Registrations
- Inspections
- Sampling

Regulatory



- Lot Integrity
- Mock Recalls
- Hold Program

Trace Recall



- Policies
- HACCP
- Training

QMS



- Metal Detection
- Sifters
- Glass Program

Physical Hazards



- Cleaning
- Scheduling
- Segregation

Allergen Control



- Environmental
- Finished Product Testing

Biological Control



- Infrastructure
- Personnel Practices
- Maintenance

GMPs



- SSOPs
- MSS
- Pest Control

Sanitation & Pest Control



- Specs
- Supplier Approval
- Guarantees

Ingredients & Packaging



- Current Spec
- Label Verification

Product Specs & Labeling



- Inspection
- Bills of Lading
- Seals

Transportation



- Identification
- Access
- Crisis Management

Food Security



*Form Basis for Risk-Based
Inspections & Ratings*



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GMI Risk-Based Process

INCIDENT FREE



We lead with safety

Every incident is preventable

We are all accountable

INCIDENT FREE



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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



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Risk Ranking Philosophy

- **Tool to Quantify Food Safety Risk**

- Inherent
- Plant Controllable

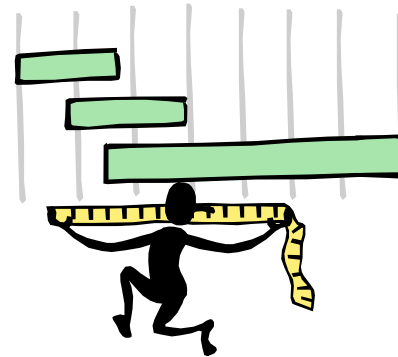


- **Prioritize Resources**

- People
- Capital



- **Measure Progress**





Risk Ranking Process

Data Inputs

Internal Audit



External Audit



Microbiology



Regulatory



**Risk Grid
Generated**

Resources

- Allocation
- Prioritization
- Food Safety Risk Assessment (FSRA) plans



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GMI Facility Risk Ranking Tool

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

Facility	Division	ACTUAL						PLANT LOWEST POSSIBLE SCORE						Opportunity	
		Microbiological	Physical	Chemical	Facility Characteristics	External Factors	Total	Microbiological	Physical	Chemical	Facility Characteristics	External Factors	Total		
		25.0	18.8	20.8	23.1	25.0	●	112.7	13.0	7.5	13.0	9.1	4.0	46.6	66.1
		37.0	15.0	26.0	20.3	10.0	●	108.3	13.0	5.0	13.0	9.1	10.0	50.1	58.2
		25.0	22.5	28.6	18.9	10.0	●	105.0	13.0	7.5	13.0	9.1	4.0	46.6	58.4
		17.0	18.8	26.0	25.9	16.0	●	103.7	13.0	5.0	13.0	9.1	6.0	46.1	57.6
		27.0	12.5	28.6	18.9	16.0	●	103.0	17.0	7.5	13.0	7.0	10.0	54.5	48.5
		21.0	10.0	18.2	23.1	6.0	●	78.3	13.0	5.0	13.0	9.1	4.0	44.1	34.2
		19.0	5.0	31.2	17.5	4.0	●	76.7	17.0	5.0	13.0	7.0	4.0	46.0	30.7
		6.0	21.3	10.4	23.1	4.0	●	64.8	6.0	7.5	7.8	9.1	4.0	34.4	30.4
		11.0	7.5	7.8	16.1	4.0	●	46.4	9.0	5.0	7.8	7.0	4.0	32.8	13.6



GMI Owned Audit Plan

Audit Finding Categories

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

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.

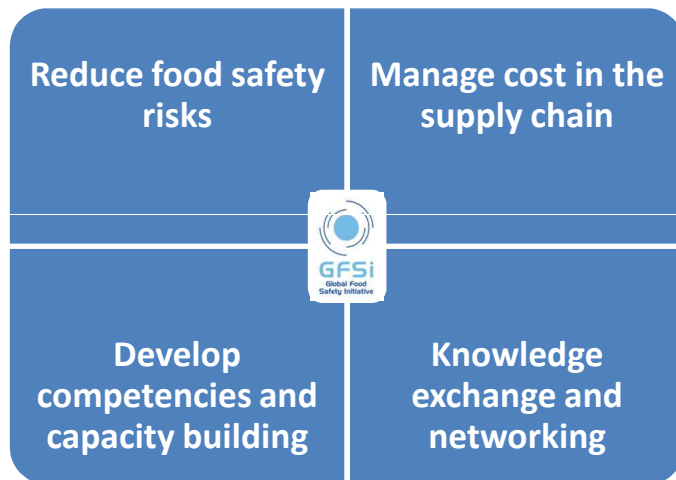
- Most GMI facility receive a independent Corporate/ 2nd party audit annually. Consideration impact length of audit.
- All GMI facilities received a *Corporate-Managed* 3rd party GHP audit or Food Safety System Certification (FSSC) audit.



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GMI 3rd Party Certification Global Food Safety Initiative (GFSI)

GFSI Mission & Objectives



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.

GFSI Benchmarked Schemes

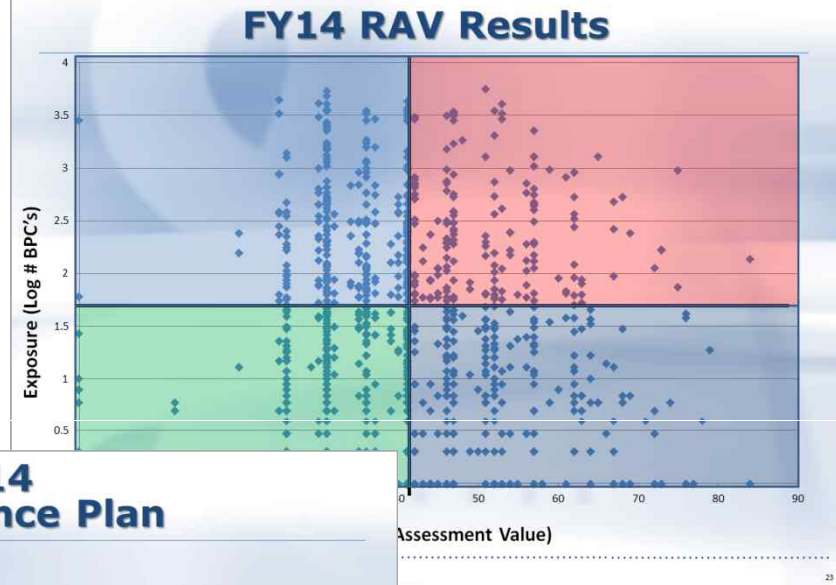
SQF Scope Extension		CanadaGAP	
Primus GFS		Global Red Meat Standard	
IFS PACsecure		IFS Scope Extension	
The Global Aquaculture Alliance		IFS	
GlobalGAP		BRC	
FSSC 22000		SQF	



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Raw Materials Example: Risk Assessment Process

FY14	
Country of Manufacture	20%
Previous Audit Rating	30%
Internal/External Activity	25%
Vendor History	25%



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)

3-Year Audits	2-Year Audits
5-Year Audits	3-Year Audits

Maintenance Plan

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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



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Food Safety Management Continuum

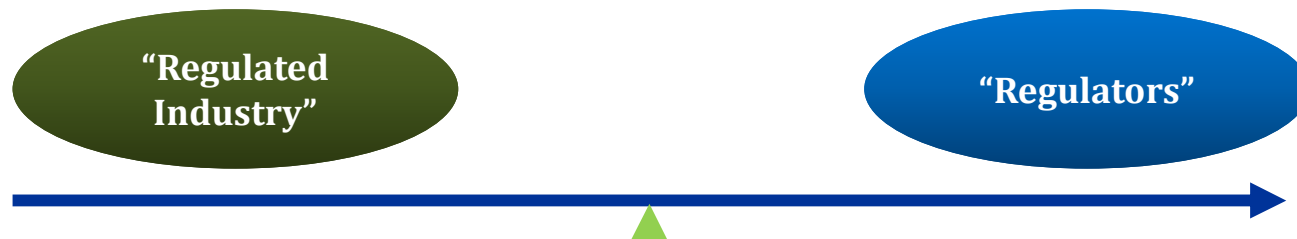
Understanding Where a Facility/Company is on the Continuum





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Share Many Common Elements

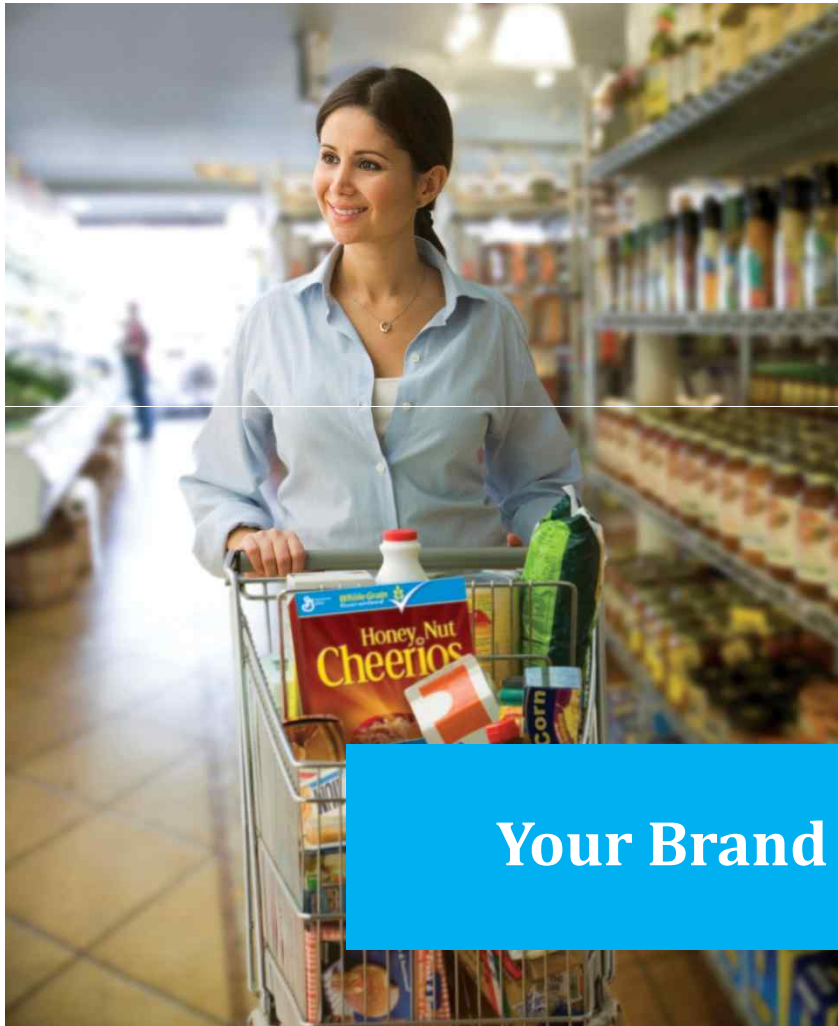


Expectations	Policy & Standards	Laws & Regulations
Educations & Awareness	Guidance Documents & Training	Outreach & Guidance Documents
Skills Needed	Process & Systems to Produce Safe Food	Knowledge & Critical Thinking to Assess Food Safety Control Programs
Risk-based Assessment	Qualitative & Quantitative Data	Qualitative & Quantitative Data
Outcome	Compliance Safe food for Consumers	Compliance Verification of Control Programs that lead to Safe food for Consumers



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Mission Accomplished!



*The job isn't finished
until our BRAND, our
PRODUCTS
is safely consumed by
our consumers*

Your Brand is your REPUTATION



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Thank You!



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