

FSMA: An Industry View

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AFDO, June 2016




Our Legacy: Nearly 150 Years of Making Food People Love



Our Brands



FSMA: What is Changing

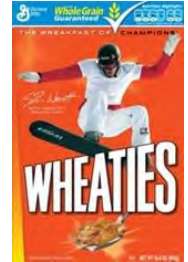
- New Terminology
 - HACCP  Preventive Controls
- New Inspection Protocols
 - Systems Based Auditing
 - Increased Access to Records
- New Enforcement Tools
 - Classification of Inspection Findings
 - Deficiency Letters

FSMA: What is Not Changing

- Lead with Safety Culture (Human and Food)
- History of Strong Food Safety Programs
- Continuous Improvement

Food Safety Across the Product Life Cycle

From Concept to Consumer



Product Design

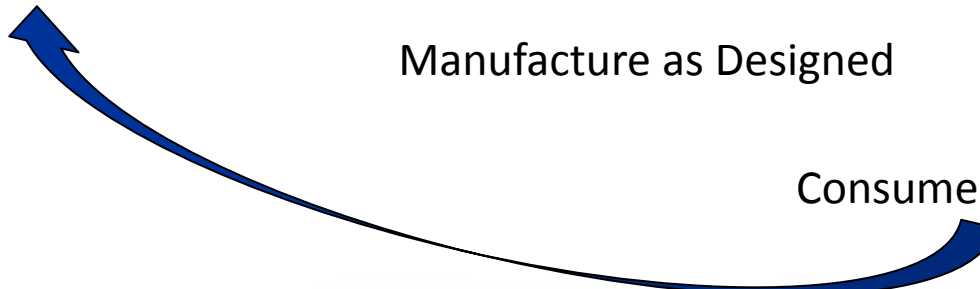
Supply Chain

Marketplace

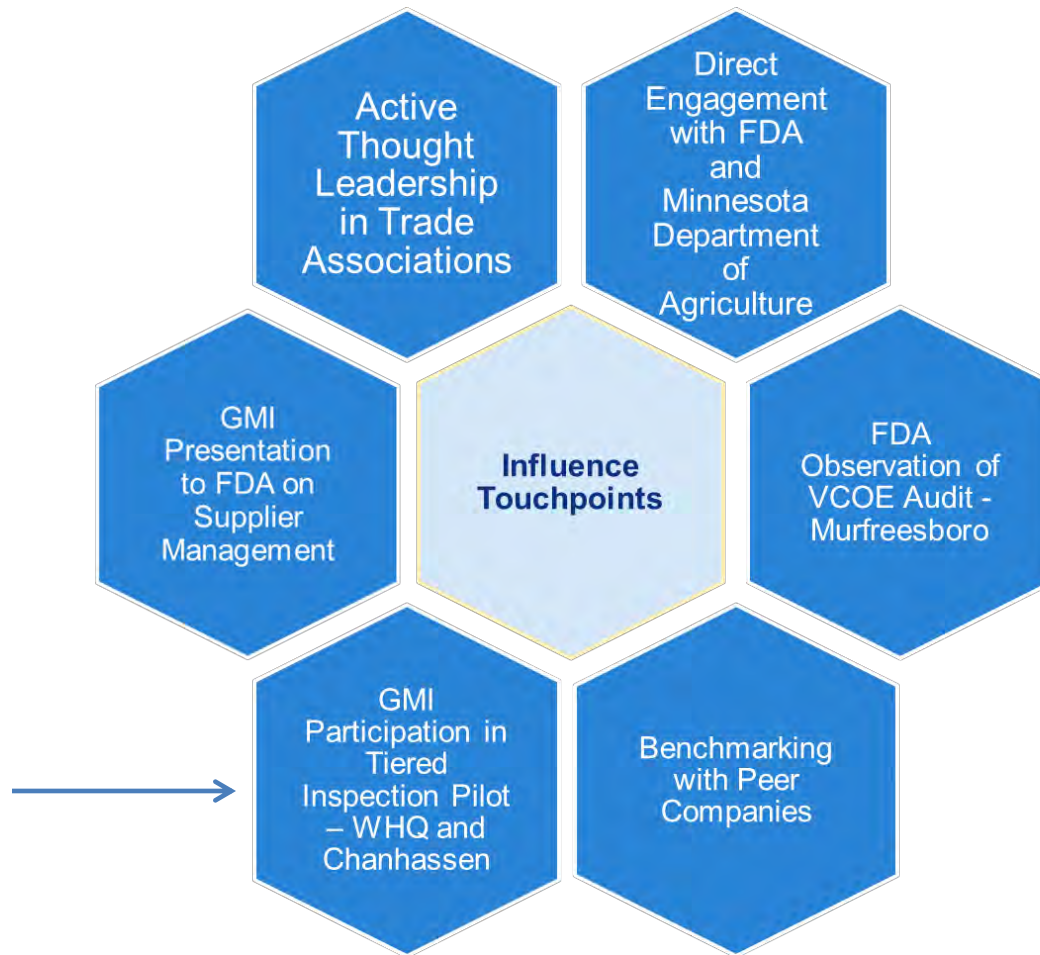
Design Safety In

Manufacture as Designed

Consumer and Customer Feedback



General Mills Partnership on FSMA



Tiered Inspections: Background

- For those firms that have more than one operating facility, certain food safety programs are often **not** managed at the factory level, such as:
 - Supplier management
 - Recalls
 - Validation
 - Records accompanying the above and
 - Expertise accompanying the above.
- SMEs who direct and manage the program may not be located at the facility.
- Inspecting the same corporate program at every facility is inefficient and may not result in a full understanding of the program.

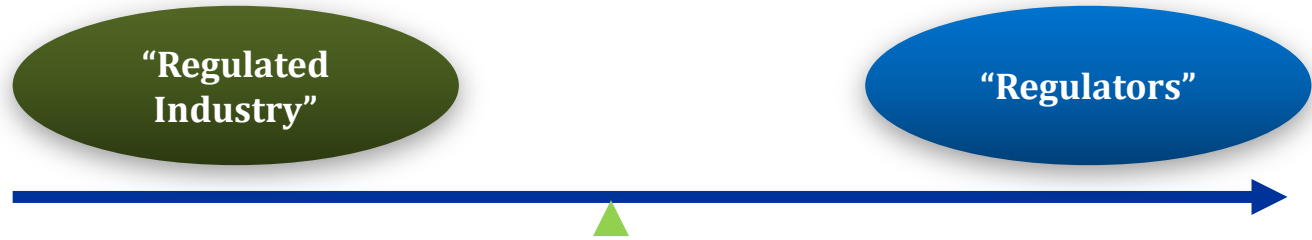
Tiered Inspections: Key Principles

- Concept
 - Tier 1 – Assesses adequacy of programs at central location (e.g. corporate)
 - Tier 2 – Assesses implementation of programs at manufacturing facility
- Key Principles
 - Participation would be voluntary.
 - Tier 1 is a pre-assessment rather than an inspection.
 - The specific food safety programs evaluated during the Tier 1 will vary by company.
 - FDA would provide the company with written feedback after the Tier 1 program assessment.
 - Pre-inspection program assessments would occur at a frequency that brings efficiency to the system.
 - Inspectional observations and enforcement actions would be based on findings at the plant during the inspection.

Tiered Inspections: Benefits and Challenges

- Benefits
 - Efficient in-plant inspections
 - Consistent inspection determinations
 - Public health benefit
 - Best practice sharing
- Challenges
 - Complexity
 - Infrastructure: IT/Communication Challenges

We 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



Food must be trustworthy

INCIDENT FREE



We lead with safety

Every incident is preventable

We are all accountable

INCIDENT FREE