Good Morning and Welcome

Marketing Innovations, Issues and Impacts on Regulatory Compliance in Food Safety

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Contents

- Existing FDA Compliance Requirements
- GFSI Requirements
- Food Safety Modernization Act Impacts
- Key Areas of Conformance in Product Life Cycle Management and Marketing Innovation
- Risks
- Best Practices

Food Safety Modernization Act (FSMA)

- Food Safety Modernization Act (FSMA) Signed into Law January 4, 2011
- Most Significant -- Comprehensive Legislative Change in Food Safety since the 1938 Passage of the Federal Food, Drug -- Cosmetic (FDC) Act
- Directly -- Immediately Affects FDA-Regulated Facilities

Highlights of FDA Food Safety Legislation in the U.S. Prior to 2011 FSMA

- **1906:** The original food safety laws that make-up much of the laws existing prior to the FSMA was passed
- **1938:** Federal Food, Drug -- Cosmetic (FDC) Act is passed by Congress -- signed into law, replaces the 1906 Act
- **1958:** FDA publishes first list of nearly 200 Substances Generally Recognized as Safe
- **1969**: FDA begins administering sanitation programs for certain facilities
- **1980:** Infant Formula Act establishes FDA controls to ensure safety
- **1995:** Seafood HACCP Implemented
- **1998:** Juice HACPP Implemented
- **2002**: Public Health Security -- Bioterrorism Preparedness -- Response Act
- **2006:** Food Allergen Labeling -- Consumer Protection Act

Why Was the FSMA Considered Necessary?

- **Continued Outbreaks**
- **Increased Supply Chain Risks**
- **Improved Detection -- Prevention Capability**
- **More Vulnerable Demographics**
- **Consumer Concerns**
- **Consumer Preferences – product proliferation**
- **Media Attention**

FSMA Regulatory Rollout & Implementation

- **Time to Make the Rules**. FDA must now make the rules -- guidance documents that implement the laws of the FSMA
- **Incremental Process**. The process will be ongoing for several years with dates benchmarked into the process
- **Budget Issues**. The currently approved budget is still far less than what is needed for full implementation
- **Public Meetings**. There are a number of public meetings ongoing related to implementation

FDA Consumer Health Information
www.fda.gov/consumer

Food Bill Aims to Improve Safety

Recent data from the Centers for Disease Control and Prevention show that one in six people in the United States suffers from food-borne illness each year. Over the past few years, high-profile outbreaks related to various foods, from spinach and peanut products to eggs, have underscored the need to make continuous improvements in food safety.

The Food Safety Modernization Act (FSMA) gives FDA a mandate to pursue a system that is based on science and addresses hazards from farm to table, putting greater emphasis on preventing food-borne illness. The reasoning is simple: The better the system handles producing, processing, transporting, and preparing foods, the safer our food supply will be.

Under the provisions of FSMA, companies will be required to develop and implement written food safety plans. FDA will have the authority to better respond and require recalls when food safety problems occur, and FDA will be able to better ensure that imported foods are as safe for consumers as foods produced in the U.S.

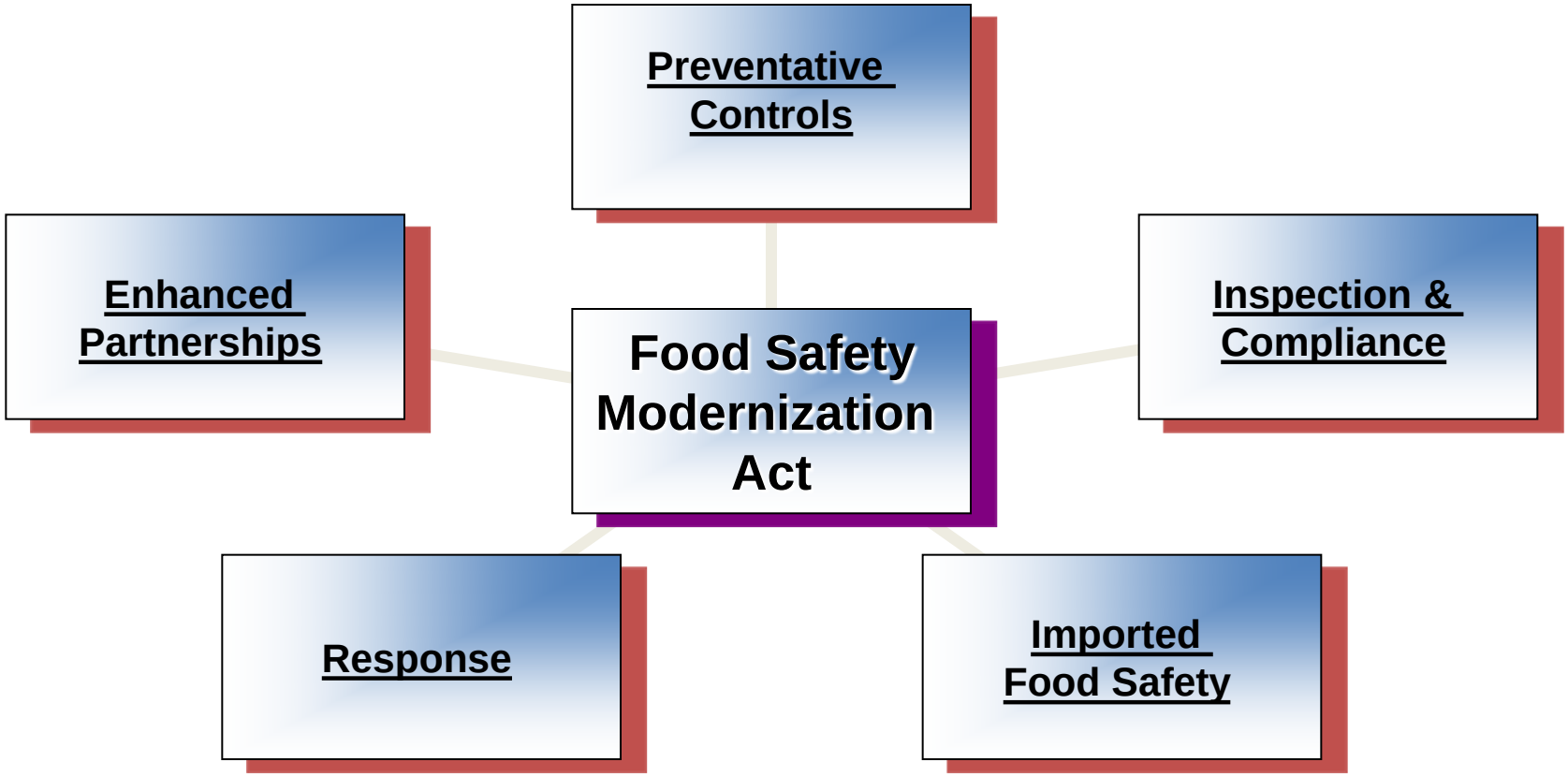
FDA Commissioner Margaret A. Hamburg, M.D., says the bill—which President Barack Obama is expected

1 / FDA Consumer Health Information / U.S. Food and Drug Administration DECEMBER 2010

Highlights of FSMA

- **The FDA has authority to issue direct recalls**
- **Food producers are required to develop written food safety plans**
- **FDA can require food producers to provide all information related to a food product on demand**
- **The Secretary of Health and Human Resources is required to create a food safety tracing system to streamline the source of outbreaks**
- **Importers are required to verify the safety of all imports**
- **All imported foods must meet the U.S. regulatory food safety guidelines**

FSMA: The 5 Key Industry Changes



FSMA: The 5 Key Industry Changes

- **Inspection & Compliance**:
  - Mandated inspection frequency
  - Records access
  - Testing by accredited laboratories
- **Preventative Controls**:
  - Mandatory preventive controls for food facilities
  - Mandatory produce safety standards
  - Authority to prevent intentional contamination
- **Enhanced Partnerships**:
  - State -- local capacity building
  - Foreign capacity building
  - Reliance on inspections by other agencies
- **Imported Food Safety**:
  - Importer accountability
  - Third Party Certification
  - Certification for high risk foods
  - Voluntary qualified importer program
  - Authority to deny entry
- **Incident Response**:
  - Additional Recordkeeping for “High Risk” Foods
  - Expanded administrative detention
  - Enhanced product tracing abilities
  - Suspension of registration
  - Mandatory recall

FSMA Implementation Highlights Timetable

Key Dates

July 4 2011	• Registration of Food Facilities • Food Safety Plans • Tracking -- tracing of food • Administrative detention of food	**October 4 2011**	• Hazard analysis -- risk based preventative control
January 4 2012	• Enhancing tracking -- tracing • Surveillance • Enhancing food safety • Foreign supplier verifications	**July 4 2012**	• Intentional Adulteration • Sanitary Transportation • Performance Standards
January 4 2013	• Domestic Capacity • Lab Accreditation • Foreign Supplier Verification	**July 4 2013**	• Lab Accreditation

Current State of Regulatory Controls

- USDA vs. FDA Facilities

  Protocol -- Procedures

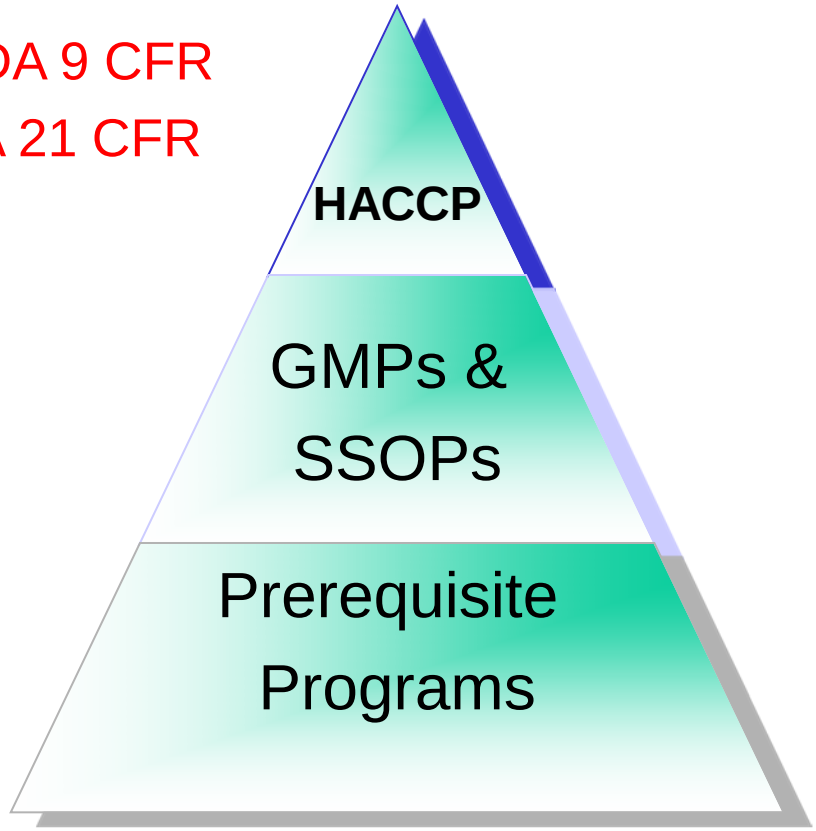
  Agency Resources to Enforce

  Preventative Controls (HACCP)

- Current Good Manufacturing Practices (GMPs)
- Sanitation Standard Operating Procedures (SSOPs)
- Hazard Analysis Critical Control Points (HACCP)
- Prerequisite Programs

USDA 9 CFR

FDA 21 CFR



The Reality of Regulatory Compliance Today

- Need for internal situation assessments including product innovation
- Confirm the current levels of compliance with FDA & GFSI
- Determine level of development of overall Food Safety Plan as relates to innovation and marketing
- Determine enhancement to existing programs
- Determine requirements attributed to FSMA (as they evolve)

Marketing and Innovation Impacts to FSMA

- What impacts does the marketing process have?
- Will specific information and data including data meet needs?
- Will the innovation process meet FDA and FSMA?
- How will innovation impact existing operational processes that have been previously established?
- What changes need to be addressed under management of change to ensure updated verification to new products, processes and verification programs including testing and verification?

Immediate Steps to Take for FSMA Compliance

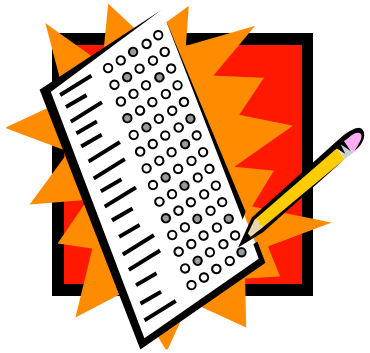
- Immediate Steps – Assess Marketing and Innovation to:
  - The Development Process
  - Documentation
  - Written Food Safety Plan considerations
  - Gap Analysis and CAPA
  - GFSI Compliance requirements
  - Supplier Reviews and Management (qualification)
  - Tracking, Tracing and Database Management

GFSI (Global Food Safety Initiative)?

- Benchmark owned by the GFSI Foundation
- Managed by **The Consumer Goods Forum (CGF).**
- The scope is limited to ***FOOD SAFETY***.
- GFSI does NOT make policy.
- Reduction in audits through common acceptance

GFSI?

- The core of the standards are equivalent but the standards are not equal.
- Apply to Food Manufacturing (Primary Production ~Pre Farm Gate and Manufacturing)



GFSI-Recognized Standards

Pre-Farm Gate

SQF 1000

GLOBALG.A.P.
The Global Partnership for Good Agricultural Practice

CANADAGAP™

Post-Farm Gate

SQF 2000

primus GFS™

Global Red Meat Standard (GRMS)

Synergy
Global Standardisation Services

PRP 22000:2009

Food Safety System Certification 22000

Dutch HACCP Option B

The “Big 4”

Of the standards there are four which are the most widely used:

FS 22000
(http://www.fssc22000.com/en/)

IFS – Food
(http://www.ifs-certification.com)

BRC – Food
(http://www.brcglobalstandards.com)

SQF 2000 Level 2
(http://www.sqfi.com/)

SQF 2000

Examples - Differences

- ALL Require that the facility have a HACCP plan – in compliance with certification

  HACCP – Certified or Meeting Certification Requirements

  - Based on 12 Step Development and Implementation
  - 7 Principles according to Codex Alimentarius or NACMCF (*National Advisory Committee on Microbiological Criteria for Foods*)

- ALL Require an Internal Audit Program ~ however the specifics are different

  FS 22000 -- IFS Food

  - Audits are defined – planned

  BRC Food

  - Audits conducted ANNUALLY against the BRC standard.

  SQF 2000 Level 2

  - The methods -- frequencies are defined -- are against the SQF 2000 standard

Issues and Impacts

- Proper HACCP Program new product or innovation updates
- Prerequisites including building, GMP's and SOP's
- Comprehensive SOP's that encompass Administrative Policy and Procedures for related processes including Product Life-Cycle Management
- Ability to track and trace product and product specification through internal development and production as well as the extended Supply Chain
- Supplier Qualification and vetting for raw material, supply and support services – all products, raw materials and packaging (verified/approved)
- Product realization, update data and approval and IT data management
- Product documentation, labeling, warnings, storage and use fully determined and verified

Opportunities

- Proper HACCP Program process integration
- Prerequisites including building, GMP's and SOP's as part of development
- Comprehensive SOP's that encompass Administrative Policy and Procedures for related processes including Product Life-Cycle Management
- Ability to track and trace product and product specification through internal development and production as well as the extended Supply Chain
- Supplier Qualification and vetting for raw material, supply and support services – can the procurement supply chain meet requirements
- Complete product realization and update data and approval

Product Realization

Product Realization Requirements

7.1 Planning of product realization

- Product realization is the term used to describe the work that the organization goes through to develop, manufacture and deliver the finished goods or services. An effective Quality Management System (QMS) includes a comprehensive approach to getting from the product concept to the finished product. This approach, sometimes called a *quality plan*, includes the following:
  - product requirements and quality objectives,
  - creation of the processes, documents, and resources needed for product realization,
  - required verification, monitoring, inspection, and test activities,
  - the records to be kept.

Common Functional Challenges

- On-site or in-company Quality and/or Micro Laboratory
- Third-party Laboratory Qualification and Management
- Maintaining updates with Federal Guidance requirements
- Import testing and Third-Party Laboratory Management
- Information Technology
- Laboratory and PLCM integration with ERP
- Integrated Responsibility From Top-Down and through the SC

Corrective And Preventive Actions (CAPA)

- **Key Requirement Of All Management Systems**
- **Requires Means of Collecting Information On:**
  - **Non-Conformances**
  - **New Risk Remediation**
  - **Improvements**
- **Based on a Management System Standard Requirements**
- **Requires an Initial Prioritization -- Determined Action**
- **Must Support Immediate Actions**
- **Top Management Involvement, Review -- Approval**

CAPA

Organizational Impacts -- Consequences

- Food Safety – Food Product Realization, Quality Administration -- Management Must Oversee Implementation of Corrective -- Preventative Actions
- Management -- Operations Personnel -- Other Key Areas are Responsible For Cooperating -- Driving Implementation of CAPA in Their Areas of Influence

PLCM Challenges

Integration throughout the organization:

- Material test and approval control communication and workflow
- Material activity date control
- Lack of business process supporting PLCM
- Too much reliance on dated and disparate systems
- Inventory management issues related to changes
- Lack of involvement of key technical resources
- Human Factors
- Internal audits, CI and management of change

Supply Chain Challenges

Marketing Innovation Impacts

- Food development timing (having time to do things right)
- New product and brand maintenance planning horizon
- Change forecasting for PLC Management situations
- Material and product ID and codification (item level activity control)
- Product change team concept – proper functional deployment
- Determined lead position – who has the responsibility when
- IT Integration of PLCM and ERP
- Verification and Validation

Technical Challenges

Product, Process and Raw Material Testing

- Technical and Lab capability
- Technical and Food Safety relationships and integration
- Validation and Verification process
- Food Technology controls and oversight
- Testing Schemes and Schedules
- Technical Integration of standards pre-launch
- Confirming validation of process and product

Questions

Q & A

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