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Serving the Food Industry Since 1919

# Food Safety Modernization Act

## How Can You Prepare

### A Practical Approach

# Introduction

## Food Safety Modernization Act (FSMA)

- S.510 (SA 4890)
- January 2011
- Changed Food, Drug, and Cosmetic Act (FD&C)



# Components of the Act

- Laboratory Accreditation
- Reportable Food Registry
  - Consumer Notification
  - Grocery Store Announcements
- Administrative Detention
  - Credible evidence or information
  - Reason to believe



# Components of the Act (cont.)

- Third Party Certification
  - Foreign Countries
  - US not specifically excluded
- Whistle blower Protection
  - US companies with overseas operations

# Components of the Act (cont.)

- Mandatory Recall Authority
- Import Requirements
- Inspections
- Plant Registration
- Hazard Analysis and Preventative Controls
- Traceability



# Mandatory Recall Authority

- Authority to recall products
- Responsible party given opportunity to cease distribution
  - Voluntary recall
- FDA
  - Secretary can mandate
  - Informal hearing
  - Press release
  - Command center
  - Failure to comply



# Import Requirements

- Know distributor
- Know supplier
  - Inspection information

# Inspections

- High risk facilities
  - Must define
  - Every three (3) years
- Non-high risk
  - Any facility not “high risk”
  - Every five (5) years

# Plant Registration

- Every two (2) years (October 1-December 31)
- Consent to inspect
- Email address of contact person
- Potentially new food categories



# Plant Registration (cont.)

- Suspension of registration
  - Hearing
- Effect of suspension
  - Shut down facility (FSIS)
- Failure to comply
  - Prohibited act

~~HACCP~~

# Hazard Analysis and Preventative Control

## A. Responsibility

- Owner
- Operator
- Agent
  - In charge of a registered facility
  - Identify and evaluate
  - All known or reasonably foreseeable hazards

# Hazard Analysis and Preventative Control (cont.)

## A. Hazard Analyses

- Biological
- Chemical
- Physical
- Radiological

# Hazard Analysis and Preventative Control (cont.)

## A. Hazard Analyses (cont.)

- Natural Toxins
- Pesticides
- Drug residue
- Decomposition
- Parasites
- Allergens
- Unapproved food and color additives
- Intentionally introduced

# Hazard Analysis and Preventative Control (cont.)

- Written
- Justified
- Defined
  - Science
  - Practical application

# Hazard Analysis and Preventative Control (cont.)

## B. Preventative Control

- Significantly Minimized
  - Control Program
  
- Prevented
  - Critical Control Points

# Hazard Analysis and Preventative Control (cont.)

## B. Preventative Control (cont.)

– May include:

- Sanitation procedures (SSOPs)
- Environmental monitoring (verification)
- Allergen Control
- Recall plan
- cGMPs
- Supplier verification

# Monitoring

- Monitor effectiveness of control
  - Schedule
  - Documentation

# Corrective Action

- If Preventive Controls
  - Not properly implemented
  - Found to be ineffective
- All affected food
  - Evaluated for safety
  - Prevented from entering commerce
  - Appropriate actions to prevent reoccurrence

# Verification

- Verify that:
  - Preventative controls adequate
  - Monitoring performed
  - Corrective action made
  - Periodic re-analysis

# Verification (cont.)

- Verification required to include:
  - Environmental testing
  - Product testing

# HACCP Accreditation / Certification

- Plans will need to be revised
- Current certifications not valid with FDA



# Recordkeeping and Record Access

- Maintained for two (2) years
  - Preventative control plan
  - Monitoring
  - Instances of Non-conformance
  - Corrective Actions
  - Verification
  - Efficacy of preventative controls

# Recordkeeping and Record Access (cont.)

- Availability (Oral or written)
  - Promptly
  - Any other food likely to be affected

# Reanalyze

- At least
  - Every three (3) years
  - Before significant changes occur
- Significant changes
  - New hazard – internal or external
  - Intentional hazard
- Document
  - Changes
  - Basis for no revisions required

# Exemptions (Examples)

- Facilities subject to other food safety requirements
  - HACCP (Fish, Poultry, Thermal Processing)
  - Alcohol
  - Dietary Supplement
  - Animal feed
  - Certain fresh produce

# Summary

- While HACCP not specifically identified, concepts, principles, etc. are essentially all included.
- New analysis groups
  - Radiological
- New potential issues
  - Drug residues
  - Decomposition

# Summary (cont.)

- Specifics for recordkeeping
- Specifics for record availability
- Program Review
  - Every three (3) years

# Traceability

- Little change from previous requirements
- One up / One down
- High risk foods
- Distribution chain
- Mixed lots
- Bulk items
  - Wheat at mills
  - Flour at bakeries

# Traceability

- Records
  - Receiving
  - Storage – Raw material
  - Production
  - Packaging
  - Storage – Finished goods
  - Shipping

# Traceability (cont.)

- Receiving
  - Product
  - Supplier
  - Shipping vehicle
  - Quantity
  - Lot number(s)

# Traceability (cont.)

- Storage – Raw Material
  - Quantity
  - Lot number

# Traceability (cont.)

- Production
  - Date
  - Quantity used
  - Product
  - Quantity produced

# Traceability (cont.)

- Packaging
  - Quantity package
  - Lab identification

# Traceability (cont.)

- Storage – Finished Goods
  - Lot identification
  - Quantity

# Traceability (cont.)

- Shipping
  - First point of distribution
  - Quantity
  - Lot number

# Traceability (cont.)

- Preparation
  - Practice, Practice, Practice