

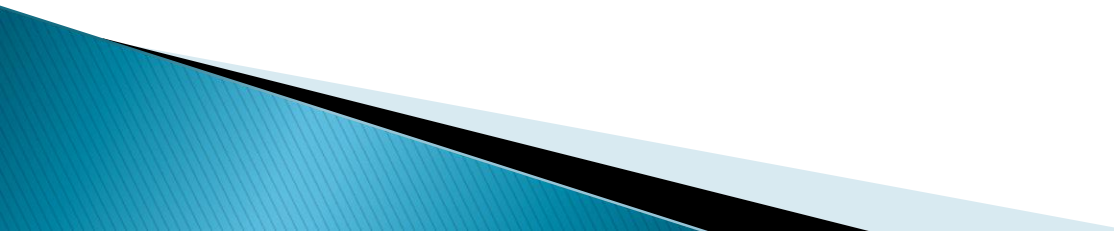
# FSMA Opportunities for the Dairy Industry

2012 Dairy Practices Council  
Presented By  
Gary Pruitt, Food Safety Director  
Sargento Foods

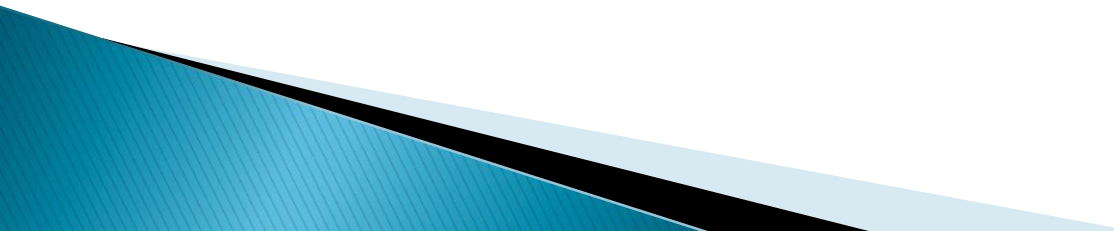
# Agenda

- ▶ FSMA Food Defense Requirements
- ▶ Old Favorites, FSMA-Style
- ▶ FSMA Hazard Analysis and Preventive Controls

# FSMA Sections

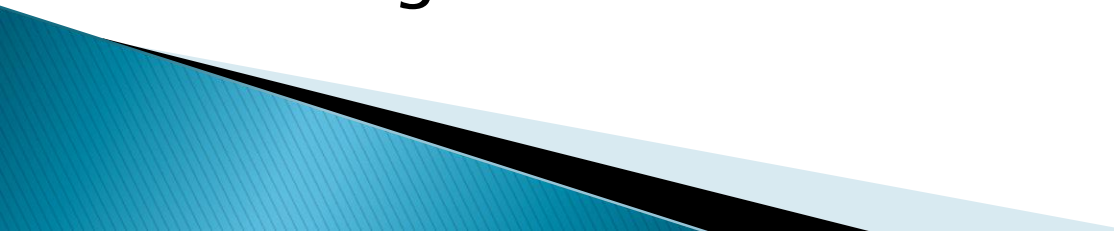
- ▶ Title I – General Food Provisions
  - ▶ Title II – Detection and Surveillance
  - ▶ Title III – Specific Provisions for Imported Food
  - ▶ Title IV – Miscellaneous Provisions
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# FSMA Food Defense Requirements of FDA

- ▶ Section 106: Protection Against Intentional Adulteration
  - ▶ Section 108: National Agriculture and Food Defense Strategy
  - ▶ Section 205: Surveillance
  - ▶ Section 308: Smuggled Food
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## Section 106: Protection Against Intentional Adulteration

### Requirements for FDA

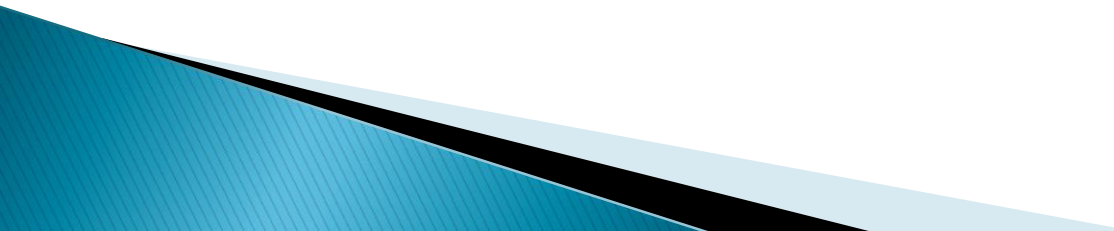
- ▶ Protect against intentional adulteration for food in bulk or batch form prior to consumer packaging
  - ▶ Vulnerability assessments of the food system
  - ▶ Consider risks and costs
    - Identify high risk of adverse health consequences
  - ▶ Determine science-based strategies necessary for food protection
  - ▶ Specify how facilities should assess whether to implement mitigation measures
  - ▶ Issue guidance documents
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# Section 108: National Agriculture and Food Defense Strategy

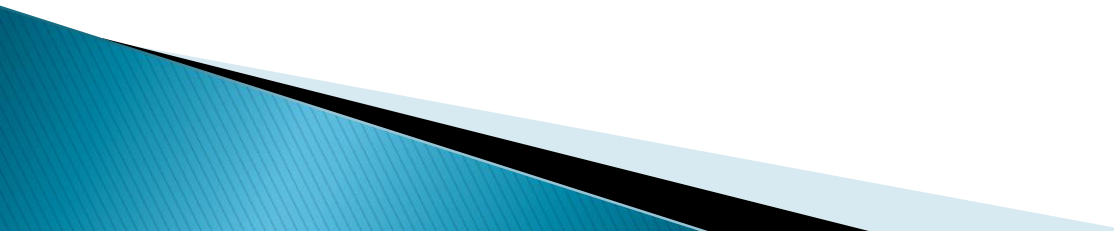
## Requirements for FDA

- ▶ Cooperate with USDA and DHS
- ▶ Submit to Congress a National Agriculture and Food Defense Strategy including a process to meet the following goals:
  - Enhancing preparedness
  - Improving detection capabilities
  - Ensuring efficient response
  - Securing production after an emergency

## Section 205: Surveillance Requirements for FDA

- ▶ Through CDC, enhance foodborne illness surveillance systems
    - Coordinate with federal, state, and local agencies
    - Increase public health participation in national networks
    - Share findings on a timely basis
    - Develop improved epidemiological tools
  - ▶ Implement strategies to enhance state and local food safety and food defense capabilities
  - ▶ Establish expert working group to make recommendations on improving foodborne illness surveillance
- 

## Section 309 : Smuggled Food Requirements for FDA

- ▶ In consultation with DHS, develop and implement a strategy to better identify and prevent the entry of smuggled food
  - ▶ Publicly warn consumers of food that might cause adverse consequences
- 



# Section 106 FDA Activities

- ▶ Vulnerability Assessment
  - CARVER + Shock
  - DHS Protective Security Advisor Site Assistance Visit
- ▶ How facilities implement mitigation strategies
  - Mitigations Strategies Database
- ▶ Guidance Documents
  - Dairy Farms, Bulk Milk Transporters, Bulk Milk transfer Stations, and Milk Processors
  - Food Producers, Processors and Transporters
  - Retail Food Stores and Food Service Establishments
  - Importers and Filers
  - Cosmetic Processors and Transporters
- ▶ Training Programs
  - ALERT and Employees FIRST

# Section 108 FDA Activities

## ▶ Ensuring Efficient Response

### ◦ FREE-B

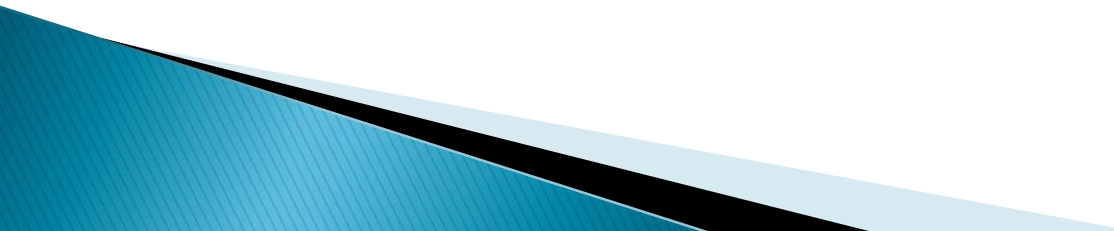
- Three FDA-based scenarios
  - How Sweet it Isn't (food contaminant)
  - Stealthy Situation (cluster of illnesses food service related)
  - Wilted Woes (*E. coli* O157:H7 in produce)
- Two USDA-based scenarios
  - Insider Edition (intentional chemical agent in meat)
  - Highplains Harbinger (intentional FMD)

# DHS Protective Security Advisor

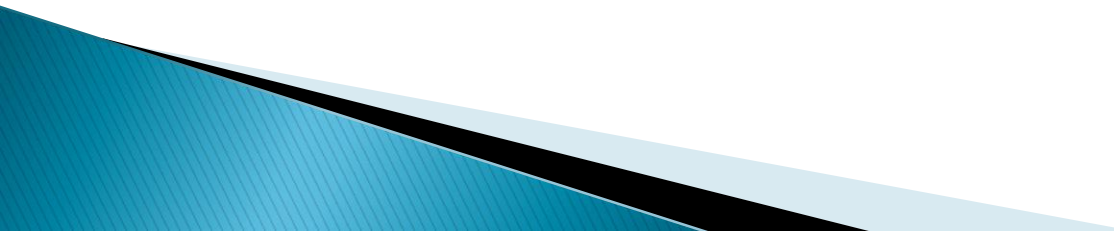
## ► Site Visit

- Identify critical infrastructure key assets
- Identify vulnerabilities in key assets
  - Outside threat
  - Inside threat
- Use assessment to help suggest cost effective mitigations
  - Physical barriers
  - Surveillance cameras
  - Controlled access
  - Security patrols
  - Employee training
    - ALERT and FIRST
    - Scenario-specific crisis plans


# ALERT

- ▶ How do you ASSURE that supplies and ingredients you use are from safe sources?
  - ▶ How do you LOOK after the security of the products and ingredients in your facility?
  - ▶ What do you know about your EMPLOYEES and the people coming in and out of your facility?
  - ▶ Could you provide REPORTS about the security of your products while under your control?
  - ▶ What do you do and who (sic) do you notify if you have a THREAT or issue at your facility?
- 

# Employees are the FIRST Line of Food Defense

- ▶ Follow company food defense program and procedures.
  - ▶ Inspect your work area and surrounding areas.
  - ▶ Recognize anything out of the ordinary.
  - ▶ Secure all ingredients, supplies, and finished product.
  - ▶ Tell management if you notice anything unusual or suspicious.
- 

# C-TPAT (Customer Audit)

- ▶ Physical Security
    - Fences, gates, access control
  - ▶ Surveillance
    - Lights, cameras, patrols
  - ▶ Employees
    - Identification, restricted area access, training, background checks
  - ▶ Visitors
    - ID, access control
  - ▶ Product Security
    - Secure transportation, BOL confirmation, inspection
  - ▶ Information Security
    - Data backup and recovery, password/electronic access protection
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# Old Favorites from the Bioterrorism Act of 2002 Retargeted under FSMA

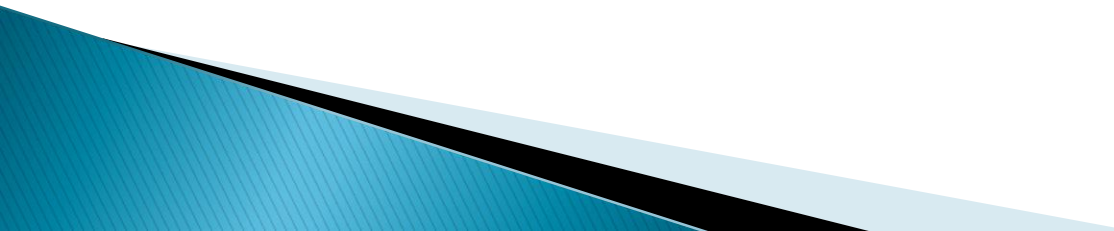
- ▶ Facility Registration
  - Section 102
  - Register Now! Renew Biennially!
- ▶ Traceability, Record-keeping, Records Access
  - Sections 101, 204
  - New Requirements for High Risk Foods from FDA
  - FDA Records Access Authority
    - Reasonable belief that an article of food is adulterated or a threat of serious adverse health consequences to animals or humans
    - Preventive controls plan and related records available to FDA
    - Record-keeping violation subject to criminal penalties

# Import Requirements – Sections 301–309

- ▶ Third-Party Certification – Section 307
  - Requires FDA to create system of FDA accreditation of accreditation bodies that accredit third-party auditors to certify eligible foreign facilities
  - FDA required to develop model accreditation standards, including requirements for regulatory audit reports
- ▶ Foreign Supplier Verification Program – Section 301
  - Requires US Importer to perform risk-based verification activities to demonstrate compliance with hazard analysis and preventive controls, produce standards, record keeping, etc.
- ▶ Inspection of Foreign Food Facilities – Section 306



# Hazard Analysis and Preventive Controls – Section 103

- ▶ Hazard Analysis
  - ▶ Preventive Controls
  - ▶ Monitoring
  - ▶ Corrective Actions
  - ▶ Verification
  - ▶ Recordkeeping and Records Access
  - ▶ Requirement to Reanalyze
- 

# Hazard Analysis

- ▶ Identify and Evaluate All Known and Reasonably Foreseeable Hazards
  - Biological
  - Chemical
  - Physical
  - Radiological
- ▶ Provide Written Hazard Analysis

# Preventive Controls

- ▶ Identify and Implement Preventive Controls
  - Critical control points
  - Hazards identified in the hazard analysis are significantly minimized or prevented
    - Sanitation procedures
    - Hygiene training
    - Environmental monitoring
    - Allergen control
    - Recall plan
    - CGMPs
    - Supplier Verification
  - Hazards that may be intentionally introduced are significantly minimized or prevented
  - Food packed will not be adulterated or misbranded (including allergen labeling)

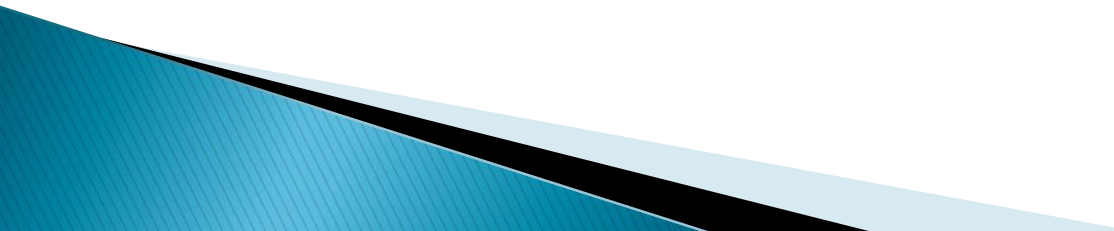
# Monitoring

- ▶ Required to Monitor the Effectiveness of the Facility's Preventive Controls

# Corrective Actions

- ▶ Establish Procedures to Ensure that if Preventive Controls are found to be Ineffective or Improperly Implemented:
  - All affected food is evaluated for safety
  - All affected food is prevented from entering commerce
  - Appropriate action is taken to prevent recurrence

# Verification

- ▶ Required to Verify that the Facility's Preventive Controls Are Adequate to Control Hazards Identified in the Hazard Analysis
    - Monitoring is being performed
    - Appropriate decisions about corrective action are made
    - Periodic reanalysis of the plan is conducted
    - Environmental Testing Program
    - Product Testing Program
- 

# Recordkeeping and Record Access

- ▶ Required to Maintain a Copy of Facility's Preventive Control Program – 2 Year Retention
  - Records of monitoring
  - Instances of non-conformance to food safety
  - Corrective actions
  - Verification
  - Efficacy of preventive controls and corrective actions
- ▶ Records Must Be Made Available to FDA Promptly upon Oral or Written Request

# Reanalysis

- ▶ **Must Reanalyze the Hazard Analysis**
  - At least once every three years
  - Before any significant change is made in the activities conducted at the facility
    - If such change creates a reasonable potential for a new hazard
    - If a significant increase in a previously identified hazard may occur
  - FDA May require reanalysis to respond to
    - New hazards
    - Developments in scientific understanding
    - Due to results of a Department of Homeland Security terrorism risk assessment
  - A record of the revisions or basis for concluding that no revision is necessary




# Exemptions

- ▶ Facilities Subject to Juice or Seafood HACCP
- ▶ Facilities Subject to LACF Regulations
- ▶ Facilities Subject to Fresh Produce Standards
- ▶ Certain On-farm Operations
  - Must register if pack or hold food not grown, raised, or consumed on that farm or another under the same ownership
  - Must register if manufactures or processes food not consumed on that farm or another under the same ownership
- ▶ Qualified Facilities (tbd)

# Additional Detection and Surveillance

- ▶ Improved Reportable Food Registry – Section 211
- ▶ Expanded Administrative Detention Authority – Section 207
  - Authority to detain if “reason to believe” food is adulterated or misbranded
- ▶ Mandatory Recall Authority – Section 206
  - Must give responsible party the opportunity to act
  - May order responsible party to immediately cease distribution
  - May amend the order to require a recall
  - FDA must issue public notice
  - Failure to comply is subject to injunction or criminal prosecution

# FSMA – Miscellaneous

- ▶ Fresh Produce Safety – Section 105
  - ▶ Sanitary Transportation of Food – Section 111
  - ▶ New Dietary Ingredient – Section 113
  - ▶ Update Fish & Fisheries Hazards and Control Guidance – Section 103, 114
  - ▶ Foodborne Illness Surveillance – Section 205
  - ▶ Food Allergy Voluntary Guidelines for Schools – Section 112
  - ▶ Various Jurisdictional Issues – Sections 116, 403, 404
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**Thank You for Your  
Attention!!**

Questions????