Food Safety Modernization Act

Potential Impact for the Dairy Industry

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The Changing Food Safety Landscape

- Global food supply
- Changing science
- Media influence
- New threats
- Consumer expectations

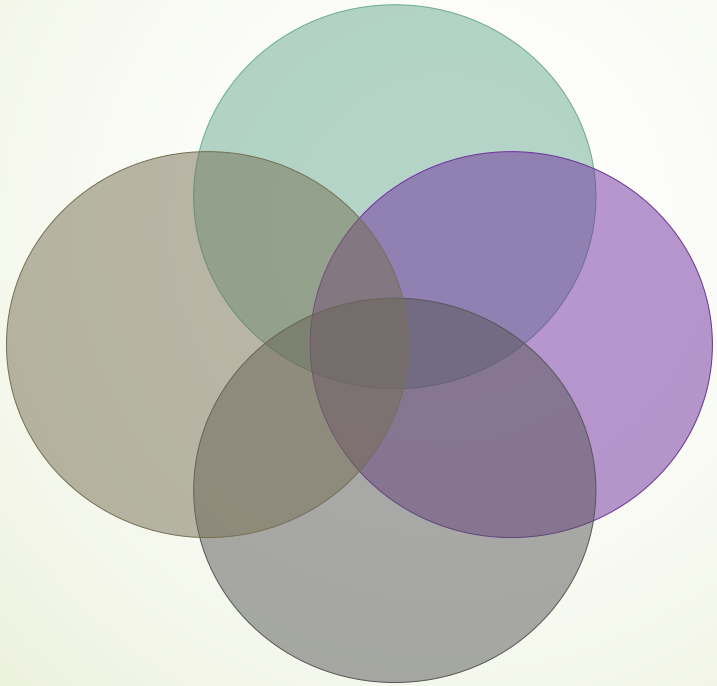
Food Safety Modernization Act

Signed into law on January 4, 2011

Most sweeping overhaul of the food safety system since 1938

Food Safety Modernization Act

Prevention



Enhanced Partnerships

Increased Inspections
Enhanced Response

Import Safety
Apply Domestic Standards to Imported Foods

FDA Expanded Authorities

- Mandatory recall
- Suspension of registration
- Expanded administrative detention
- Inspection of records

Inspection of Records

- Greater access to records
- Need **reasonable probability** that food will cause a serious adverse health consequence
- Records relating to manufacturing, processing, packing, receipt, holding or importation
  - Consumer complaints
  - Testing
- Can expand to other parts of your business

FSMA Status Summary

Proposed Rule	Final Deadline
PC- Human Food	August 30, 2015
PC- Animal Food	August 30, 2015
Produce Safety	October 31, 2015
FSVP	October 31, 2015
Third Party Accreditation	October 31, 2015
Sanitary Transport	March 31, 2016
Food Defense	May 31, 2016

Major Impact on Dairy Industry

- Preventive controls for human food
- Supplier controls
- Sanitary transport of food
- Intentional contamination (food defense)

Food Safety Plan

Qualified Individual

Proposed Preventive Control Rule

HARPC = "Hazard Analysis and Risk-Based Preventive Controls"

- Step 1: Identify all potential hazards associated with each type of food manufactured
  - Must consider biological, chemical and physical (includes radiological)
  - Does not include intentional
- Step 2: Determine if each hazard is significant including
  - Severity of the illness
  - Foreseeable use of the food
- Step 3: If hazard is consider to be significant
  - Identify and implement preventive controls

Proposed Preventive Control Rule

HARPC = "Hazard Analysis and Risk-Based Preventive Controls"

- Examples of Preventive Controls required:
  - Process controls (e.g., pasteurization)
  - Food allergen controls
  - Sanitation controls
  - Recall plan
- Domestic and foreign food facilities that are required to register with FDA are covered
  - Some exceptions and modified requirements being proposed
    - Based on size of business and scope of distribution (distance)
    - Won't have to submit written Food Safety Plan, but need to comply with GMPs
    - FDA retains power to withdraw exceptions

Monitoring Requirements

- Establish and implement written procedures to monitor each preventive control
  - To provide an early warning
  - To correct a deviation before it becomes problem, and if it does, be able to know when a corrective action is needed
- Frequent enough to provide assurances that the preventive control is being consistently performed (may be continuous monitoring)
- Must keep written record of monitoring activity
  - Observations and specific measurements
  - Not just a checklist
- If there is no verification, the preventive control did not happen!

Environmental Monitoring

- As appropriate to the facility, the food, and the nature of the preventive control
- Environmental monitoring would be required
  - Where RTE product is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed
- Where required, must have records, written procedures of your program / what you are testing and corrective action procedures

Finished Product Testing

- Used as a means to verify the adequacy of preventive controls
  - For pathogens or indicator organisms
- Note the language used: “testing programs, when implemented appropriately based on the facility, the food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards”
  - The Agency says “could” which indicates not a mandate
- If finished product testing is used, a facility will need to have a written plan, corrective action procedures and keep records
  - Code/shelf-life considerations in dairy products?

Corrective Action Requirements

- Establish and implement **written** corrective action procedures for each preventive control
- When monitoring activity detects a loss of control the facility must take corrective action and document, including ad hoc corrective actions
- Must ensure that all food affected by the deviation has been evaluated for safety so that no adulterated food is being put into distribution
- Must perform a root cause analysis

Reanalysis

- Food Safety Plans must be reanalyzed and updated as needed
- Minimum = every three years
- Other triggers:
  - Ad Hoc Corrective Actions
  - When a Preventive Control is found to be ineffective
  - Whenever there is a significant change (e.g., supplier, facility, equipment, process, ingredients, etc.)
  - Whenever you become aware of a new hazard (e.g., recent outbreak, scientific study, new technology)
  - Upon notice by FDA

Required Records

- Written food safety plan
- Records that document monitoring of the preventive controls
- Records that document corrective actions
- Records that document verification
- Records that document training for the qualified individual

"Qualified Individual"

- A person who has:
  - Completion of training in development and application of HARPC under a standardized curriculum recognized as adequate by FDA, or
  - Successful completion of training under a program that is at least equivalent to that curriculum, or
  - Be otherwise qualified through job experience
- The proposed rule would establish minimum requirements for the "qualified individual"
  - Government-Industry-Academia partnerships (e.g., Food Safety Preventive Controls Alliance)

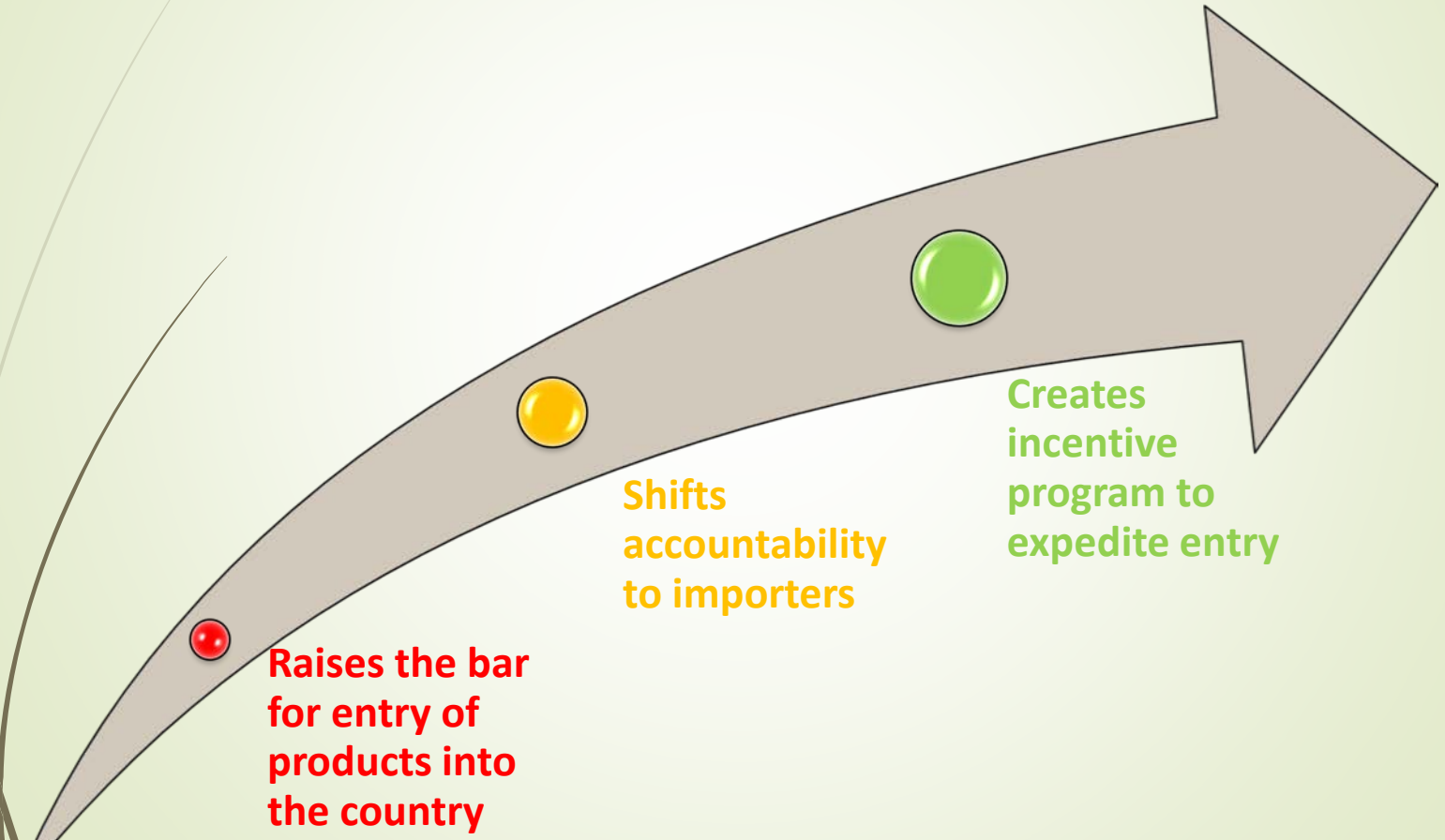
Other Changes to Human Foods Rule

- Economically Motivated Adulteration: A requirement to determine if a public health hazard could result from economically motivated adulteration (FDA specifies that they are concerned about the public health, not quality, impact of this type of adulteration)
- Animal Byproducts
  - Additional requirement in Food Safety Plan
  - Covered under human GMPs
  - Focus on physical and chemical hazards, not microbiological

Supplier Controls

- Requirement to establish a risk-based written supplier verification program for raw materials and ingredients **when** the receiving facility's hazard analysis has identified a significant hazard that is being controlled by the supplier (before receipt of the raw material/ingredient)
- Generally aligns with the Foreign Supplier Verification Program for imported foods
- Need to control the risk even if going further back
  - Distributors vs Supplier's suppliers

Stricter Import Requirements



Import – Related Rules

- Foreign Supplier Verification Program (FSVP)
- Third Party Audit
- Certification for High Risk Foods
- Voluntary Qualified Importer Program

FSVP – In a Nut Shell

- Control supply chain risk wherever it is if you are not controlling the hazard
- Importer has responsibility to ensure compliance with FD&C Act
- Understand risk
- Control the risk by a variety of means
- Develop a written program (FSVP)
- Maintain records
- Reassess the FSVP
  - Use a Qualified Individual

FSVP – In a Nut Shell

- Propose requirements for supplier verification primarily based on who is to control the hazards that are reasonably likely to occur: supplier's supplier, supplier, importer, or importer's customer
- If control is on supplier or supplier's supplier side, and hazard can cause serious adverse health consequences or death to humans or animals (SAHCODHA), onsite auditing is required
  - If not SAHCODHA, options include onsite auditing, sampling and testing, review of supplier's food safety records
- If control is on importer or importer's customer side, importer is required to document at least annually that procedures to control the hazard have been established and are being followed

Food Defense Rule - At A High Level

- Intentional adulteration not currently covered by PMO
- Impacts subset of companies registered with FDA
  - Focused on those that are most likely targets
  - Includes intrastate commerce
- Focus is on insider, terrorist attack
  - Intent is massive public health harm, also economic damage to the company
- Focus is on access, not specific to agent of concern
- Economically motivated adulteration is outside scope
  - Expect to see it in final preventive controls rule

General Approach

- Parallels the proposed human preventive control rule in language and approach
  - Have a plan (HACCP-like, different terminology)
    - Assess vulnerabilities
    - Apply mitigations
    - Monitor, verify, corrective actions
  - Significant training requirements
- Has numerous exemptions
- FDA has good resources online (e.g., Food Defense Plan Builder)

Sanitary Transportation Rule

- Goal is to ensure transportation practices do not create food safety risks
- Focus on key areas of risk
  - Refrigeration
  - Cleaning
  - Protection of food (cross contamination)
- Impacts
  - Shippers
  - Carriers
    - Waiver will likely be issued to "permitted" NCIMS activities (e.g., Grade A milk hauling)
  - Receiver
- Includes USDA regulated foods

Minor Impact on Dairy Industry

- Preventive control for animal foods rule
- Third-party audit/accreditation program
- Produce safety rule

The Animal Rule - At A High Level

- Impacts companies registered with FDA producing food for animals or diverting by-products to farms
- Parallels the proposed human preventive control rule – a few differences
- GMP requirements which is new
- Focus on three key elements
  - The safety of animal food and in turn the health of animals
  - Health of humans who are exposed to animal food
  - Animal derived products for human consumption
- Focus on chemical and physical risks not microbes

Third-Party Audit Program

- Accredited audits used mainly for
  - Mandatory
    - Certification for high risk foods
    - Certification on Voluntary Qualified Importer Program
  - Optional
    - Audits for Foreign Supplier Verification Program

Third-Party Audit Program

- Establish a program to use third party audits
  - Step 1: FDA sets the standards
  - Step 2: FDA approves accreditation bodies
  - Step 3: Accreditation bodies approve and oversee certification bodies
- Tight requirements
  - Conflict of interest
  - Record keeping
  - Providing information to FDA
  - Potential for being de-accredited

Proposed Produce Rules

- **Key Principles**
  - Science and risk based
  - Only focused on microbiological risk
  - Exclusions
    - Certain produce rarely consumed raw
    - Produce to be commercially processed (documentation required)
    - Based on size of operation
  - In dairy may impact some ingredient suppliers (e.g., peppers, etc.)

Standards for Produce Safety

- Animal encroachment
- Equipment, tools and building sanitation
- Worker health and hygiene
- Water – match EPA standards
- Growing, harvesting, packing and holding activities
- Soil amendments of animal origin

Are You Prepared for FSMA?

- Forming a team to understand the impact of FSMA on you
- Understand where you may have gaps
- Determine what you would need to do to fill the gaps
- Focus on aspects of FSMA that are not likely to change much
- Stay current as the rules continue to evolve and become final

Take-Away Messages

- FSMA is major change to current food regulation
  - If currently running robust food safety programs, should become FSMA-compliant fairly easily
- Heavy focus in key areas by regulators
  - Prevention (detailed hazard analysis and PCs)
  - Compliance and record keeping
  - Supplier and import controls
- Need global food safety risk management
- Stay informed of the rapidly changing landscape

Operational Risk | Reputational Risk | Regulatory Risk

- Supply Chain Risk
- Internal Operations
- Crisis and Recall Preparedness
- Environmental & Testing Strategies

- Social Media
- Development of Communication Strategies & Programs
- Strengthen stakeholder relationships

- Food Regulations and Compliance
- Expertise on FSMA
- Crisis Response to regulatory issues, crisis and recalls

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