# Welcome

## OnTrak with FSMA:  A Webinar Series

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# *Today's Presentation:*
# Preventive Controls Rules are Finalized: What Now?

Melanie Neumann, JD, MS
EVP & CFO
The Acheson Group

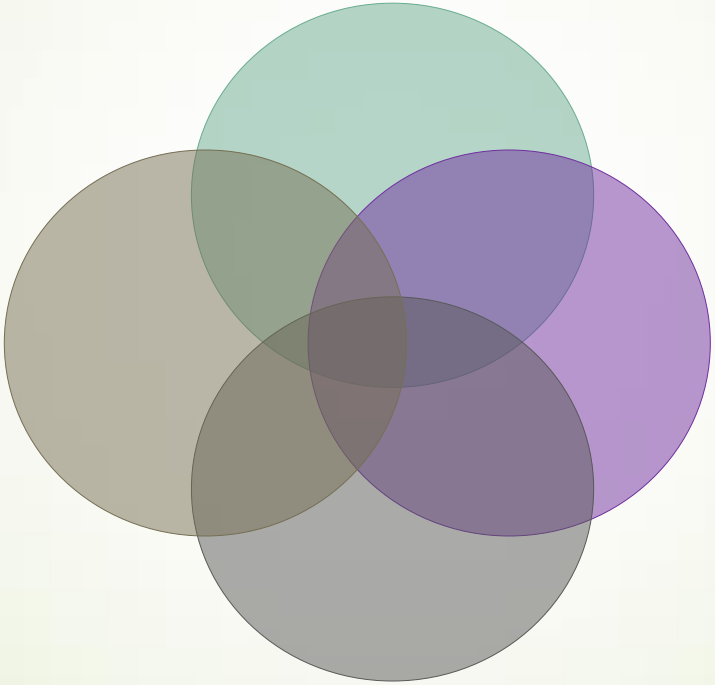
Hilary Thesmar, PhD, RD, CFS
VP, Food Safety Programs
FMI

# Overview

- The Rules are Final!
- Key Changes
- Food Safety plans —Final Content
  - Hazard analysis
  - Identify Preventive Controls
  - The "preventive controls management components" = monitoring, verification, validation, corrective actions, recall plan, supplier program
- Records requirements & the Importance of Documentation
- Compliance Dates
- Other Key observations

# Food Safety Modernization Act (FSMA)

Prevention



Enhanced Partnerships

Increased Inspections
Enhanced Response

Import Safety
Apply Domestic Standards to Imported Foods

# The Seven Pillars of Prevention

- Preventive controls for human food
- Preventive controls for animal food
- Produce
- Foreign supplier verification
- Third party auditor
- Food Defense
- Sanitary Transport

# FSMA Status Summary - “The 7 Pillars”

| Proposed Rule | Final Deadline |
|---|---|
| PC- Human Food-Final | September 17, 2015 |
| PC- Animal Food-Final | September 17, 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 |

# Rules Enacted Upon Signing

- Inspection of records
- Suspension of registration
- Expanded administrative detention
- Authority to require import certificates
- Mandatory recall

# FINAL

Current Good Manufacturing Practice, Hazard Analysis and Risk Based Preventative Controls for Human Food

# Key Changes

- New Definitions
- Training required for first time
- Preventive Controls Qualified Individual and Qualified Individual
- Intrastate commerce impact
- GFSI recognized

***Not a lot of significant changes***

# Facility Registration


- Unless you are exempt, facility registration is due November 16, 2015
- Definition of exempt “Farm” has been established as Primary Production Farm or Secondary Production Farm.
- Both have to be under one *management and in one general location.* (Does not need to be contiguous property.)
- Intrastate Commerce: Facilities that manufacture, process, pack, or hold food that is sold intrastate are also subject to the rules.

# Hazard Analysis

- "Significant Hazard" changed to "Hazards requiring a preventive control"
  - a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.
- Moving away from HACCP mindset / CCP thinking

# What Preventive Controls are Needed?

- Flexibility per facility to determine
- The preventive controls each facility would need to establish and implement would **depend on the facility, the food, and the outcome of the facility's hazard analysis**

# When Preventive Controls are Not Needed

- A manufacturer/processor determines and documents that a specific type of food could not be consumed without application of the appropriate control. i.e. cocoa beans, coffee beans, grains.
- When a hazard requiring a preventive control will be controlled by subsequent entity in supply chain.
  - Three requirements in place for this to be allowed:
    - Documentation direct to commercial customer that the food is not processed to control specific hazard (s) requiring a preventive control [must list each hazard].e.g. “Not processed to control for Salmonella” }
    - Written assurance from receiving commercial customer that they will further process the food to control each hazard requiring a preventive control identified.
    - Commercial customers must document they are performing the written assurance above.

# How the Food Safety Plan Fits Together

# What does the Rule Say about Using HACCP or GFSI Food Safety Plans?

- § 117.330.
- To the extent that an existing HACCP plan or GFSI-compliant food safety plan includes all required information, a facility can use such plans to meet the requirements of this rule.
- Relying on existing records, with supplementation as necessary to demonstrate compliance with the requirements of the human preventive controls rule, is acceptable.
- Could be a set of documents kept in different locations within the facility, with a list of the relevant documents (e.g. Table of Contents).
  - Leverage PRPs as needed

# Qualified Individual

- All employees engaged in cGMPs or Preventative Controls must be a “Qualified Individual”
  - a person who has the education, training, or experience or combination of same, to properly manufacture, process, pack, or hold clean and safe food as according to their job description.
  - All, including supervisors, must receive training in in principles of food hygiene and food safety, including employee health and personal hygiene.
  - Records of same to be kept, frequency of training is up to the facility.
- Training is now required for first time by regulation-key change and documentation becomes critical

# Preventive Controls Qualified Individual—New Definition

- A “Preventative Control Qualified Individual”
  - This is a “qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.”


- This is the person deemed qualified to write the food safety plan, oversee verification/validation, etc.
- Training and documentation again is critical

# Final Preventive Control Rules

- Step 1: Identify all "hazards requiring preventative control" associated with each type of food manufactured
  - Must consider biological, chemical (radiological), and physical
  - Does include economically motivated adulteration
    - Deemed "rare" by FDA but must be assessed nonetheless
- Step 2: Determine all "hazards requiring preventative control" including
  - Severity of the illness
  - Foreseeable use of the food
  - A risk that a food safety professional would want to control
- Step 3: If it is determined that a hazard requiring preventative control exists
  - Identify and implement preventive controls

# The Preventive Controls Management Components

- Monitoring
- Corrective Actions
- Corrections—NEW!
- Verification
- Validation

- *Applied "as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system"*

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# 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)
- Exception records are allowed to demonstrate loss of preventative control as an alternate
- 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

# Corrective Action Requirements

- Establish and implement written corrective action procedures for each preventive control and nature of the hazard requiring a preventive control
  - Response to be proportional to the findings
- 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
- Food Safety Plans are only reanalyzed if a corrective action procedure has not been established.
  - The final rule does not require a specific corrective action procedure for each specific preventive control; only that a corrective action procedure was implemented

# Corrections—New Term in Final Rule

- An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce)
- For minor and isolated problems that do not directly impact product safety; that do not rise to level of corrective action
- §117.150(c) (2)

# Verification Requirements

- Verifying the monitoring and corrective actions are taking place
- Calibration of equipment and measuring tools,
  - Final rule allows accuracy checks
- Records review to verify Food Safety Plan is being effectively implemented
- Validation of preventive controls, conducted in 90 days( longer if written justification by PC QI), required when:
  - Within 90 days after first production; or
  - Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification; or
  - Whenever a change to control measure(s) could impact whether the control measure(s), when properly implemented, will effectively control the hazards requiring a preventive control;
  - During production to show control measure(s) can be implemented as designed
    - FDA putting high scrutiny on proper validation of preventive controls
  - Reanalysis of Food Safety Plan is performed as required

# Reanalysis

- Food Safety Plans must be reanalyzed and updated as needed
  - In specific circumstances a specific component of the food safety plan can be reanalyzed 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 requiring a preventive control (e.g.: recent outbreak, scientific study, new technology)
  - Upon notice by FDA

# Environmental Monitoring

- Virtually unchanged in Final Rule; Verification Step
- 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.
- Routine testing does not have to be conducted by an accredited lab, the test method must be scientifically valid, and results do not need to be sent to the FDA

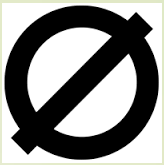
# Finished Product Testing

- Virtually unchanged in Final Rule; Verification Step
- 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.”
- If finished product testing is used, a facility will need to have a written plan, corrective action procedures and keep records (can be stored off site)
- Routine testing does not have to be conducted by an accredited lab, the test method must be scientifically valid, and results do not need to be sent to the FDA

# Supply Chain Applied Controls

- New term= vs. preventive control
  - When the hazard requiring a preventive control is controlled before receipt of the raw material or other ingredient
- Third parties allowed to verify supplier on behalf of receiving facility, if receiving facility approves third party and accepts results (e.g. brokers, distributors may provide this service but ultimately receiving facility's final responsibility)
- Written procedures need to be in place to accept Raw Materials from approved suppliers
- Government inspections can satisfy required third party audits
- Third Party auditor does not need to be accredited
- Receiving facilities only need documentation of conclusions of an audit and any corrective actions taken not full audit report

# When Is A Supply Chain Program Not Required?



- When receiving facility is:
  - an importer,
  - is in compliance with the forthcoming FSVP requirements, and
  - has documentation of verification activities conducted under the forthcoming FSVP program
  - R & D Exemptions: “Food for Research or Evaluation Use”
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# Required Records


- All records can be stored off site, with the exception of the written food safety plan, as long as they are accessible within 24 hours of a request for official review
  - Food Safety Plan records do not need to be stored in one location or in “one binder”
- Record retention begins after the applicable compliance date
- Records must document corrective actions, monitoring / verification of preventive controls, and training
- Electronic records exempt from 21 CFR Part 11, however must be equivalent to paper records and handwritten signatures

# Updated cGMPs (Part 100 becomes 110)

- "Allergen cross-contact" new terminology meaning inadvertently introducing an allergen into food
- New requirements for sanitation of non-food-contact surfaces of equipment in a food plant, and sanitizing portable equipment
- Protection of outdoor bulk vessels holding RAC's that will be further processed is not required
- Plants have flexibility in determining how to prevent Allergen cross-contact, a no-zero tolerance eliminated
- If a product has been found to be adulterated due to faulty/non-calibrated equipment and placed on hold you are allowed to re-examine
- Some situations for food-contact surfaces that do not need to be sanitized (dry cleaning methods allowed)
- Low-moisture foods on food-contact surfaces must be in a clean, dry, sanitary condition before use only (applies to manufacturing, processing, holding)

# Exemptions

- Primary and Secondary Farms
  - A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.
  - A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm.
- Solely engaged in the storage of unexposed packaged foods
- Solely engaged in the storage of RAC's (other than produce) intended for further processing
- Solely engaged in the holding and/or transportation of RAC's (other than produce)

# Exemptions

- “Qualified facility” that submits an attestation statement, are only subject to modified requirements, and must register by July 1 of each year. Additional requirements are listed for very small businesses to be exempt, (< $1million in sales).
- Small business or very small business mixed-typed facilities solely conducting On-Farm Low-Risk activities as described in the risk assessment document
- Alcoholic beverages and food produced at same so long as it is in prepackaged form and constitutes less than 5% overall sales
- Pasteurized Milk Ordinance Regulated Facilities: Compliance date extended to September 17, 2018 to allow the National Conference on Interstate Milk Shipments to align with the preventative controls requirements.

# Compliance Dates for cGMP and PC


- Businesses with 500 + Full-Time Equivalent Employees
  - September 19, 2016. Supply Chain Program has until the later of March 17, 2017, or 6 months after a supplier is required to comply with the applicable rule
- Small Businesses (< 500 FTE Employees)
  - September 18, 2017. Supply Chain Program has until the later of September 18, 2017, or 6 months after a supplier is required to comply with the applicable rule
- PMO Businesses
  - September 17, 2018. Supply Chain Program has until September 17, 2018
- Qualified Facilities (also Very Small Businesses)
  - September 17, 2018. (Except compliance date is January 1, 2016 for records to support the facility's status as a qualified facility). Attestation submissions by qualified facilities is December 7, 2018. Compliance date for consumer notifications by qualified facilities is January 1, 2020

# Where do I start?

- Develop a Plan
- 1. Start with cGMP programs (Subpart B)
- 2. Focus on the Hazard Analysis for each product or category (Subpart C)
  - Known or reasonably foreseeable hazards
    - Biological, chemical (radiological), physical, and economic adulteration
- 3. Have a strong foundation of Internal Programs
  - Training
  - Records
  - Documentation
- 4. Build the program slowly over the next year

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# Records Required by Final Rule

- Training
- Food Safety Plan
  - Recall plan, allergen management plan, corrective actions, monitoring, verification, validation, calibration, reanalysis
- Supply chain program
- Electronic Records are Acceptable
- Records retention policy – effective after compliance date of final rule
- Now – FDA access to all food safety records with cause
- Plan your recordkeeping system now!

# FDA Technical Assistance Network

- Launched on September 10, 2015
- For questions go to http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

Food Safety Modernization Act (FSMA)
The Law, Rules & Guidance
How to Comment on FSMA
Fact Sheets & Presentations
Frequently Asked Questions
FDA Actions to Date
Archive

# How to Contact FDA About FSMA

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

You may contact FDA about FSMA by submitting an inquiry form.

The modified form is designed to facilitate questions that are specific to FSMA and its implementation. Your use of the form will provide the FSMA Technical Assistance Network with the information needed to give accurate and timely responses and to improve our customer service. We hope you find our online form useful in identifying the specific nature of your inquiry and we remain open to suggestions about improving the form to meet your needs.

**Submit Inquiry**

You may also mail your question to the address below:

Food and Drug Administration
5100 Paint Branch Pkwy
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

*NOTE: For Food Safety Preventive Controls Alliance Training questions, please direct inquiries to fspca@iit.edu.*

# For more information

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