



# The Foods Safety Modernization Act

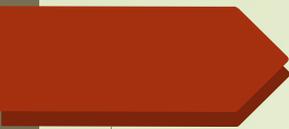
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# Outline

- Constant challenges
- New Regulations
- Staying out in front



# Today's Challenges

- Complex supply chains
- Consumer demands
- Emerging threats
- Improving epidemiology
- Influence of media
- Litigation
- New regulations



# Risks in the Supply Chain Risk

- Who is in your supply chain
- Are there unknown sources
- How do your suppliers ensure they meet your expectations
- How do you achieve your goals of controlling risk
- Do you rely on audits
  - Your people going to suppliers
  - Contracted audit firms going to suppliers under your instruction
  - Independent third party audits
- But where do you go and what do you look for
- Do you have transportation risks

# Changing Science of Food Safety

- New risks identified with foods (peanut butter, cookie dough)
- Greater capacity to link food with illness
- Ability to measure lower levels of chemicals
- Improvements in genetic testing
- Whole genome sequencing

## Foods Linked to New Outbreaks of Foodborne Illness in the United States Since 2006

Bagged spinach	Carrot juice	Peanut butter		
Broccoli powder on snack food	Hazelnuts	Pot pies	Dog food	
Hot peppers	Papayas	White pepper	Raw cookie dough	Pine Nuts

# Consumer Expectations and Media Influence

- ▶ Americans expect all types of food will be available all the time
- ▶ Zero tolerance for unsafe food
- ▶ Consumers place responsibility for safe food on the producer
- ▶ Increased desire for local and unprocessed food
- ▶ Consumers ability to damage a brand
  - ▶ Main stream media
  - ▶ Social media



# Emerging Threats

- New pathogens
  - E. coli O104 – Europe 2011
  - Over 4000 cases
  - 900 case of kidney failure (HUS)
  - Over 50 deaths
  
- Antibiotic resistance
  - Salmonella
  - Campylobacter

# The Reality of Producing Food Today

- Narrow margins
- Drive to minimize procurement costs
- Risk of going out of business if there is a food safety problem
- Risk of going out of business if consumers decided they don't like you
- Dealing with consumer needs
  - High quality
  - Low price
  - Innovative products with global ingredients
  - Zero risk

# 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



# FDA Implementation Activities

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

# Inspection of Records

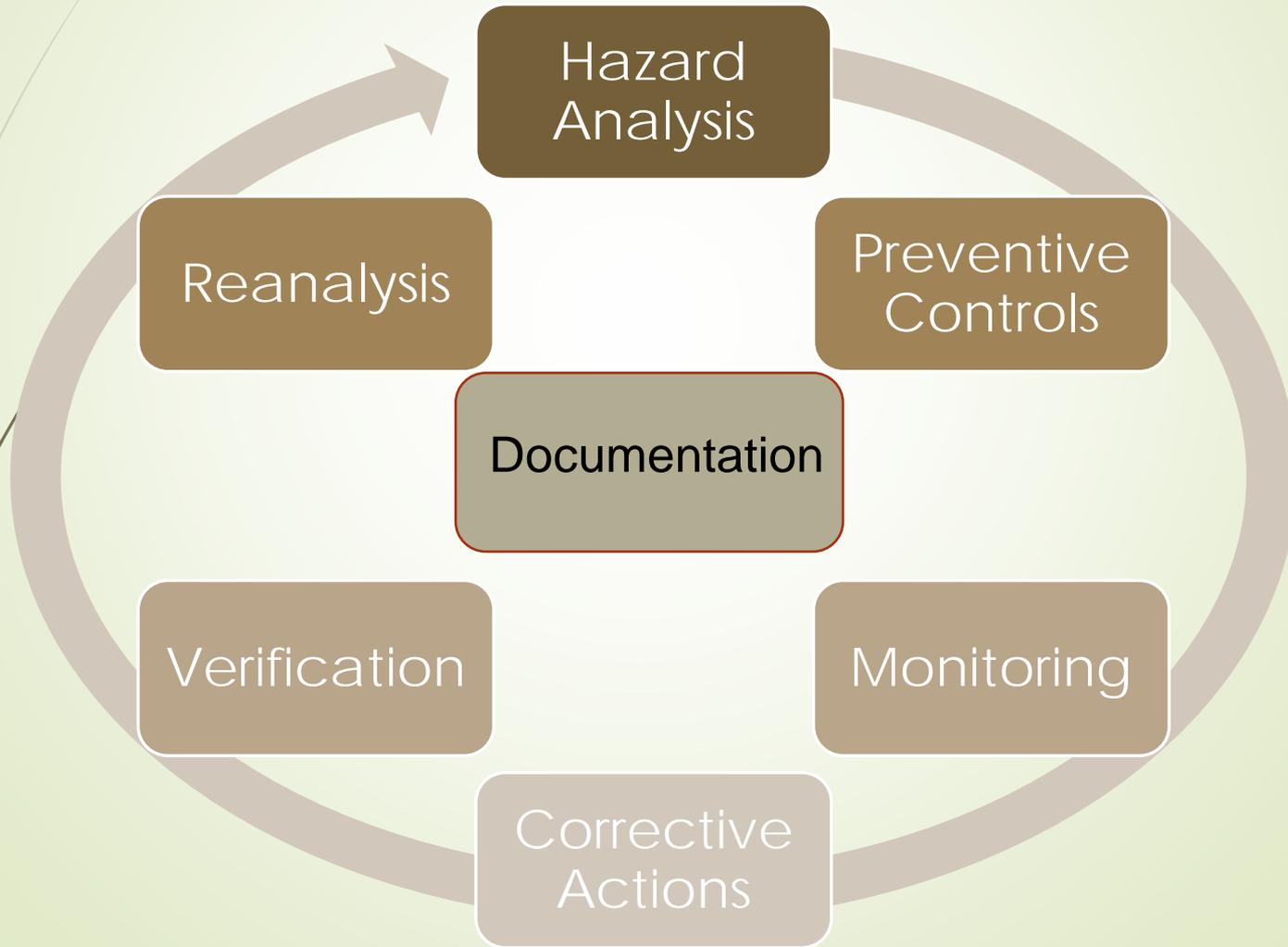
- Greater access to records
- Need **reasonable probability** that food will cause a serious adverse health consequence
- Records relating to manufacturing, processing, packing, receipt, holding or importation
  - Consumer complaints
  - Testing
- Can expand to other parts of your business



# 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

# Food Safety Plan



# Proposed Preventive Control Rules

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

# Monitoring Requirements

- ▶ Establish and implement written procedures to monitor each preventive control
  - ▶ To provide an early warning
  - ▶ To correct a deviation before it becomes a 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

# 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

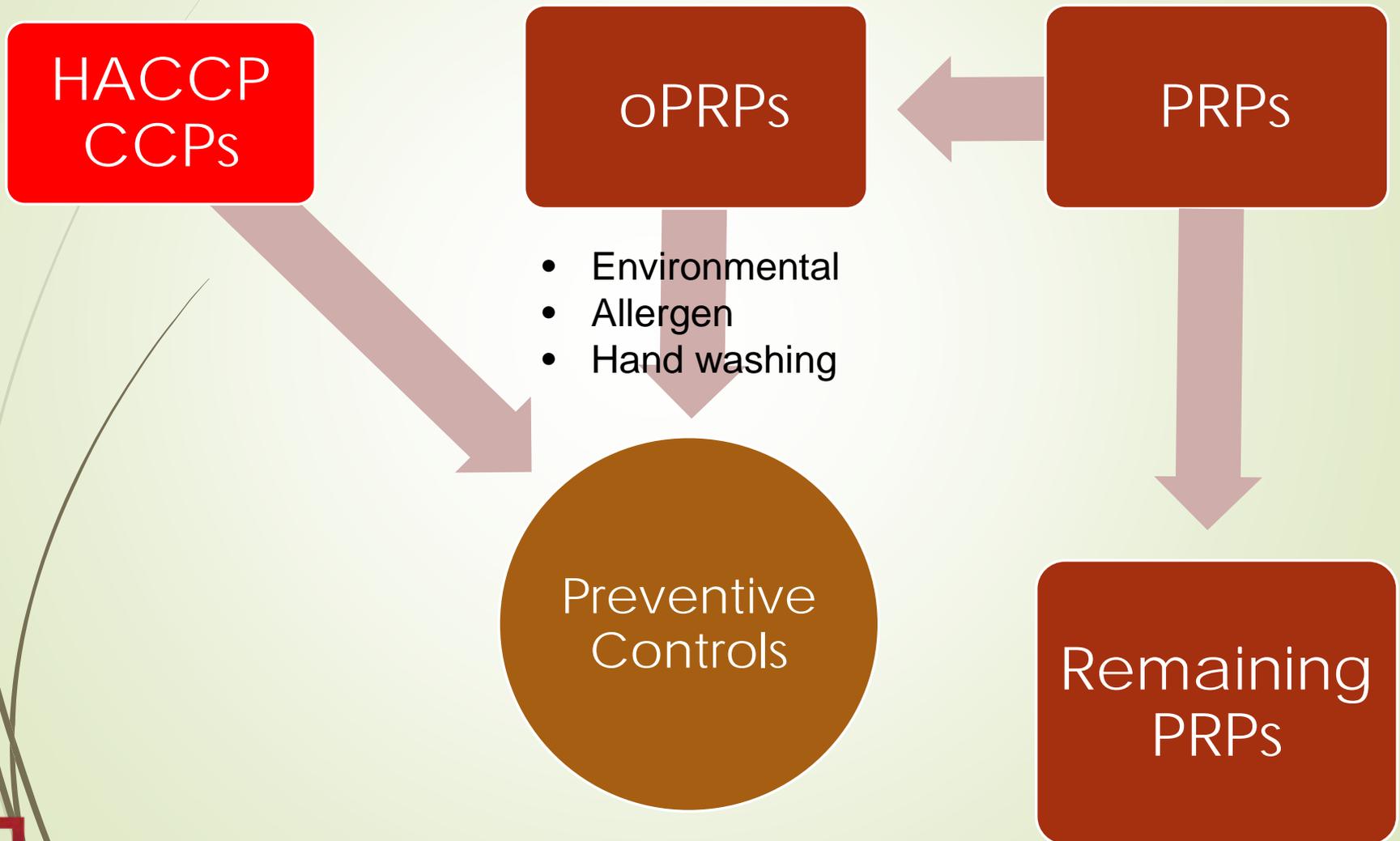
# Pest Control – Preventive Controls

- Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae
- New Language:
  - Replace the phrase “processing area” with the phrase “manufacturing, processing, packing and holding areas”
  - “Pests must not be allowed in any area of a food plant”
  - Take effective measures to exclude pests from the plant. Pests do not belong in any areas where manufacturing, processing, packing or holding of food occurs.



**IS THIS HACCP**

# HACCP vs HARPC vs PRPs



# The “Animal” Rule - At A High Level

- Impacts companies registered with FDA
- 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

# Nutrient Imbalances

- ▶ May be associated with illness
  - ▶ Excessive levels of urea in cattle
  - ▶ Excessive levels of copper in sheep food
  - ▶ Inadequate levels of thiamine in cat food
  - ▶ Inadequate levels of vitamin D in swine food
- ▶ Species differences
  - ▶ Swine can tolerate a relatively large amount of copper in their diet
  - ▶ Sheep are very sensitive to copper



# 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



# Standards for Produce Safety

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



## Pest Control – Produce

- ▶ Take measures reasonably necessary to protect:
  - ▶ Covered produce
  - ▶ Food contact surfaces
  - ▶ Food Packing materials
- ▶ .....from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate



## Pest Control – Produce

- Take measures to exclude pests from fully-enclosed buildings:
  - To prevent pests from becoming established in partially-enclosed buildings (such as by use of screens or by monitoring for the presence of pests and removing them, when present)



## **Pest Control – Produce**

- Need to take those steps reasonably necessary to prevent birds or other animals from building nests in partially-enclosed buildings
- If possible, to find and remove any nests that become established
- Need to comply with applicable wildlife conservation regulations

# Stricter Import Requirements



**Raises the bar  
for entry of  
products into  
the country**

**Shifts  
accountability  
to importers**

**Creates  
incentive  
program to  
expedite entry**

# Import – Related Rules

- ▶ Foreign Supplier Verification Program
- ▶ Third party audit
- ▶ Certification for High Risk Foods
- ▶ Voluntary Qualified Importer Program

# FSVP – In a Nut Shell

- Importer has responsibility to ensure compliance with FD&C Act
- List of suppliers
- Compliance status
- Understand risk
- Control the risk by a variety of means
- Develop a written program (FSVP)
- Maintain records
- Use a Qualified Individual

# 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

# Third-party Audit Program

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

# The “Food Defense Rule” - At A High Level

- 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 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
    - ▶ Assess vulnerabilities
    - ▶ Apply mitigations
    - ▶ Monitor, verify, corrective actions
  - ▶ Significant training requirements
- ▶ Has numerous exemptions

# 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)
- Transport by motor vehicle or rail
- Impacts
  - Shippers
  - Carriers
  - Receiver
- Includes USDA regulated foods



# Are You Prepared

- 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
- Anticipate
  - Final rules August 2015 - March 2016
  - Full implementation August 2016 – March 2017



## Summary

- Major changes to FDA regulated foods
- Global impact
- Heavy focus in key areas
  - Prevention
  - Record keeping
  - Import controls
- Don't wait to get started on being prepared



# Thank You

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