The Food Safety Modernization Act and Its Implications for USDA and Dual Jurisdiction Establishments

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Overview

- Food Safety Modernization Act
- Hazard Analysis and Preventive Controls for Human Food & GMPs
- Hazard Analysis and Preventive Controls for Animal Food
- Foreign Supplier Verification Program
- Sanitary Transportation

FSMA Provided FDA with Expanded Authorities (1-4-2011)

- **Mandatory recall**: FDA has authority to issue mandatory recall
- **Expanded administrative detention**: FDA has more flexible standard for administratively detaining products potentially in violation of law
- **Suspension of registration**: FDA can suspend registration of facility if it determines a food poses reasonable probability of serious adverse health consequences or death
- **Enhanced product tracing abilities**: FDA directed to establish system to enhance its ability to track and trace both domestic and imported foods
- **Additional Recordkeeping for High Risk Foods**

FSMA

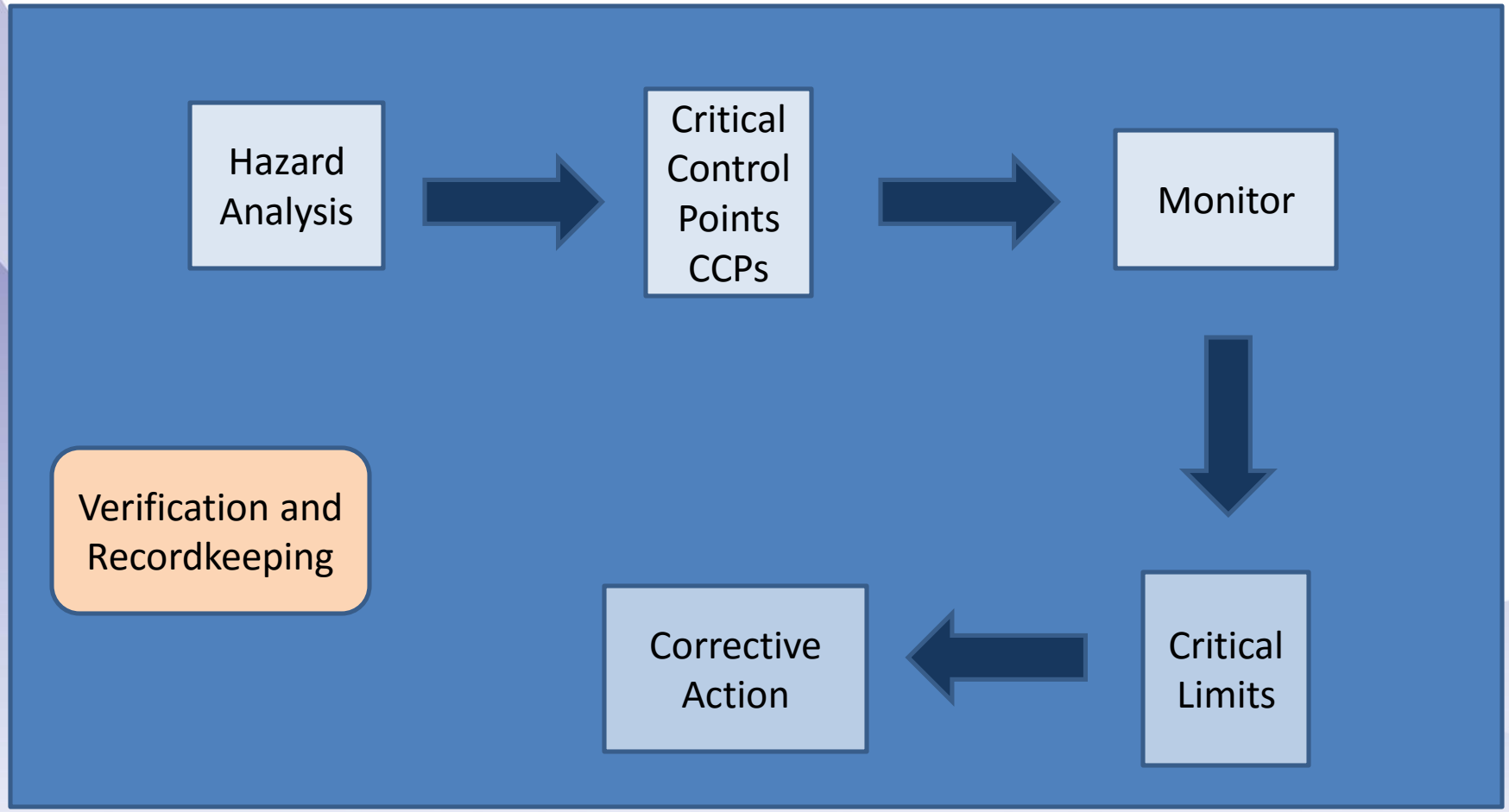
- **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**
- **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals**
- **Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals**
- **Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption**
- **Accredited Third-Party Certification**
- **Sanitary Transportation of Human and Animal Food**
- **Intentional Adulteration** – requires domestic and foreign facilities to address vulnerable processes to prevent acts intended to cause large-scale public harm (May 31, 2016)

Preventive Controls for Human Food

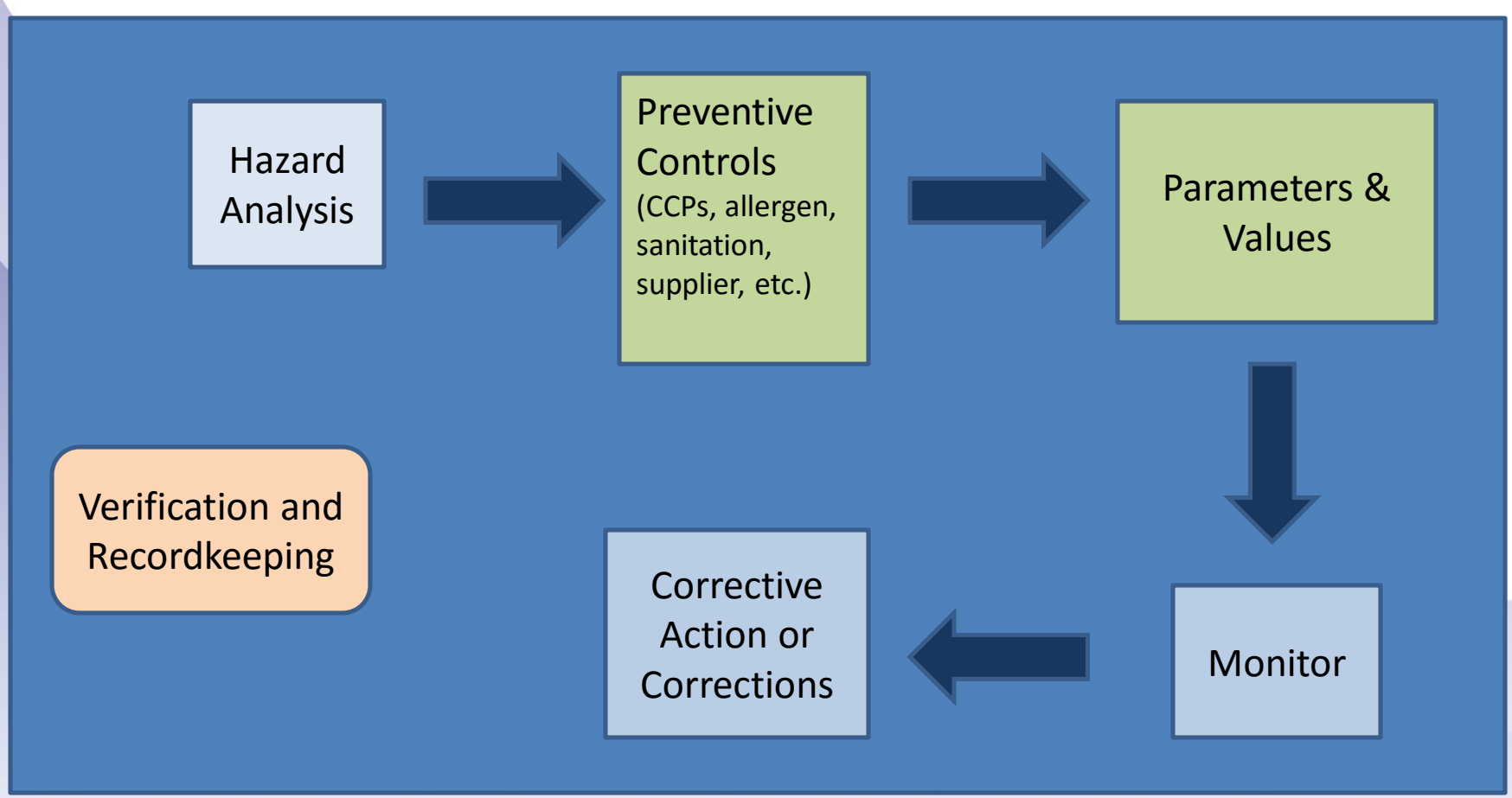
Risk-based Preventive Controls

- Focus on what matters most for food safety
- Preventive, not reactive
- Work in conjunction with and supported by other programs like Good Manufacturing Practices
- Designed to minimize the risk of food safety hazards
  - FSIS HACCP
  - Seafood HACCP
  - Low Acid Canned Foods
  - Juice HACCP

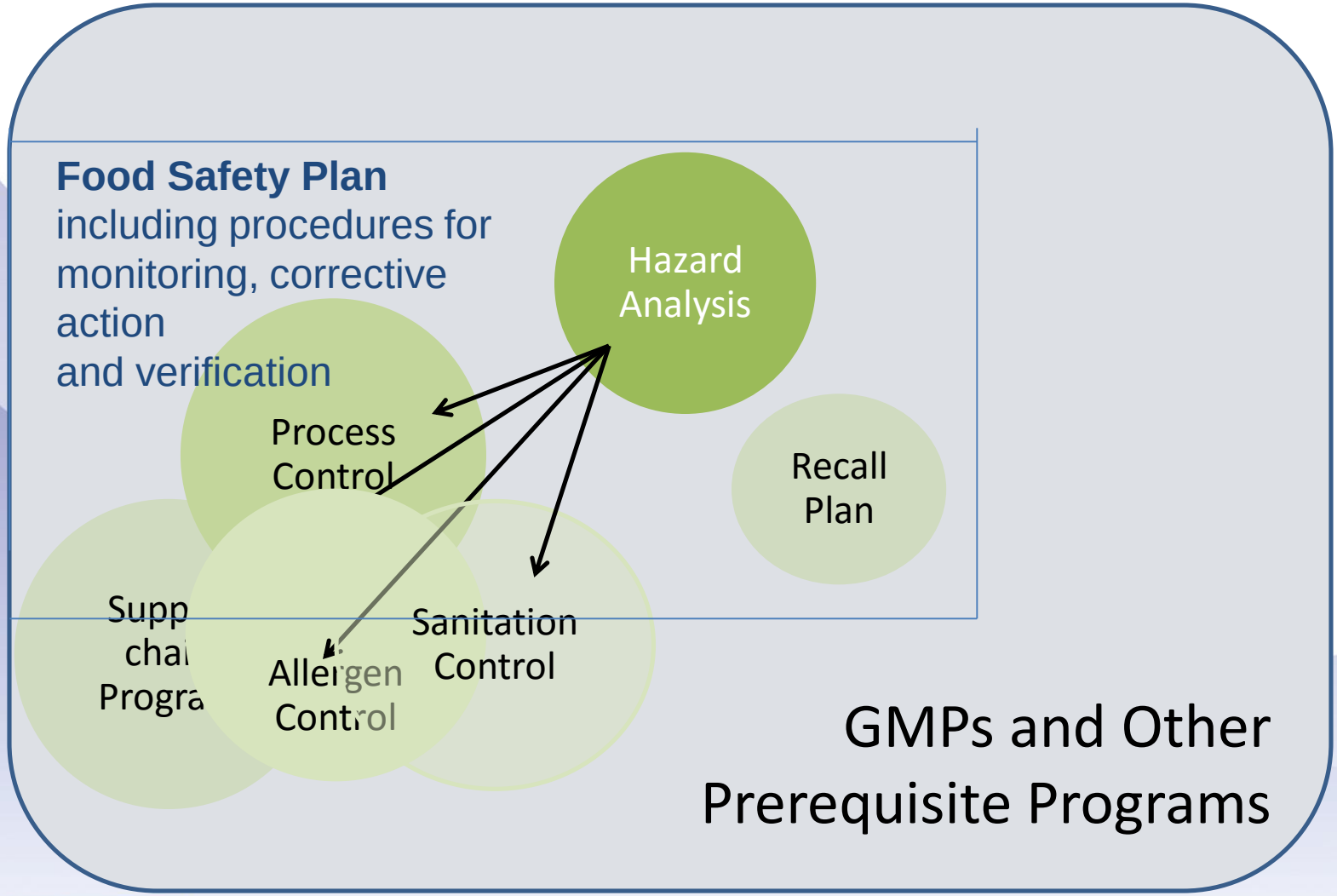
HACCP Focuses on Process



Preventive Controls = HACCP + More



Preventive Food Safety Systems



Contents of a Food Safety Plan

Required by regulation:

- Hazard analysis
- Preventive controls*
  - Process, food allergen, sanitation, supply-chain and other
  - Recall plan*
- Procedures for monitoring, corrective action and verification*

Useful Additions to Plan:

- Facility overview and Food Safety Team
- Product description
- Flow diagram
- Process description

* Required when the need for a preventive control is identified

“Preventive” Controls

- “Process” preventive controls
- “Food allergen” preventive controls
  - Accurate labeling
  - Cross-contact prevention
- “Sanitation” preventive controls
  - Environmental pathogens
  - Cross-contamination, cross-contact
- Other preventive controls
  - If needed (when not obvious where something fits)
- “Supply-chain” preventive controls

Definitions of "Verification" 21 CFR § 117.3

- **Verification**
  - "The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan."
  - *Are the controls in the Plan actually being properly implemented in a way to control the hazard?*
- **Validation**
  - "Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards."
  - *Can the Plan, when implemented, actually control the identified hazards?*

Potential Verification Procedures

- Process verification
  - **Validation of effectiveness**
  - Checking equipment calibration
  - Record review
  - Targeted sampling and testing
- Allergen verification
  - Label review
  - Visual inspection of equipment
- Sanitation verification
  - Visual inspection of equipment
  - Environmental monitoring
- Supply-chain verification
  - 2nd and 3rd party audits
  - Targeted sampling and testing
- System verification
  - Food Safety Plan **reanalysis**
  - 3rd party audits
  - Internal audits

No Validation Required

- You do not need to validate the following:
  - Food allergen preventive controls
  - Sanitation preventive controls
  - Supply-chain program
  - Recall plan
  - Other preventive controls with written justification
- Some sanitation-related controls *may be useful* to validate:
  - How long a processing line can run between cleaning
  - Allergen controls for complex equipment

Required by Regulation

- Hazard analysis
- Preventive controls
  - Process preventive controls
  - Allergen preventive controls
  - Sanitation preventive controls
- Supply-chain program requirements
- Recall plan
- Monitoring procedures
- Corrective action procedures
- Verification procedures

- Preventive control monitoring data
- Corrective actions taken
- Verification (if applicable) activities
- Validation documentation (if applicable)
- Supply-chain program implementation
- Applicable training

The Food Safety Plan **must** be signed and dated by owner, operator or agent-in-charge

- Upon initial completion
- After modifications are made

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Corrective Action Procedures

- Written procedures must describe steps to taken to:
  1. Identify and correct a problem with implementation
  2. Reduce likelihood of occurrence
  3. Evaluate affected food for safety
  4. Prevent affected food from entering commerce if you cannot ensure the food is not adulterated

Records

- Real time, actual values or observations, permanent, legible, **name and plant location**
- Computerized records
  - Must be equivalent to paper records and hand written signatures
  - An electronic record-keep system must:
    - Be authentic, accurate and protected
    - Provide accurate and complete copies of records
    - Protect records for later retrieval
    - Limit access to authorized individuals
    - Provide a secure record audit trail
    - Be reviewed by a trained individual

Required Training

- Individuals must be qualified by education, training, or experience to manufacture, process, pack or hold food
  - "Qualified Individual"
- All individuals **must** receive food hygiene and food safety training – GMP training – and training to perform job
  - This includes temporary and seasonal employees
- Supervisors responsible for ensuring compliance must have appropriate by education, training or experience
- **ALL training must be documented**

Preventive Controls Qualified Individual (PCQI)

- PCQI: 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 (21 CFR § 117.3 Definitions)
- Regulations require that a PCQI perform the following:
  - Perform and oversee the preparation of the food safety plan
  - Validation of the preventive controls
  - Records review
  - Reanalysis of the food safety plan
- The PCQI can be an employee or an outside consultant

Supply-chain Preventive Controls Subpart E

- Hazard analysis identifies hazards requiring a supply-chain-applied control
- Key definitions include:
  - A “supplier” manufactures the food, grows the food or raises the animal
  - A “receiving facility” is a manufacturer/processor
  - A “customer” may or may not be subject to preventive controls regulation
- Supply-chain program must include:
  - Using approved suppliers
  - Determining, conducting and documenting supply-chain verification activities
- Supplier verification activities may include:
  - Onsite audits, sampling and testing, review of the supplier’s relevant food safety records, other activities based on risk
  - An annual onsite supplier audit is required for serious hazards unless another approach can be justified
- Documentation is a key element of supply-chain control

Who Controls The Hazard?

- Raise the animal
- Grow the food

- Manufacturer, processor

- Manufacturer, processor or preparer

Supply-chain Program **Not** Required

1. When no hazards requiring a supply-chain-applied control exist

   OR

2. When you (the receiving facility) control the hazard

   OR

3. When a Customer or downstream entity **provides written assurance** that they control the hazard

*21 CFR 117.136 identifies circumstances when a preventive control is **not** required*

Approved Suppliers & Verification

- Use approved suppliers:
  - Applies to hazards requiring a supply-chain-applied control
  - Approval required *before* receiving the ingredient
  - Temporary exception may be possible with justification
  - Written procedures for receiving
  - Receiving records required
- Supplier verification (before using & periodically thereafter)
  - Onsite audit
  - Sampling and testing
    - By the supplier or the receiving facility
  - Review supplier's food safety records for the ingredient
  - Other if applicable

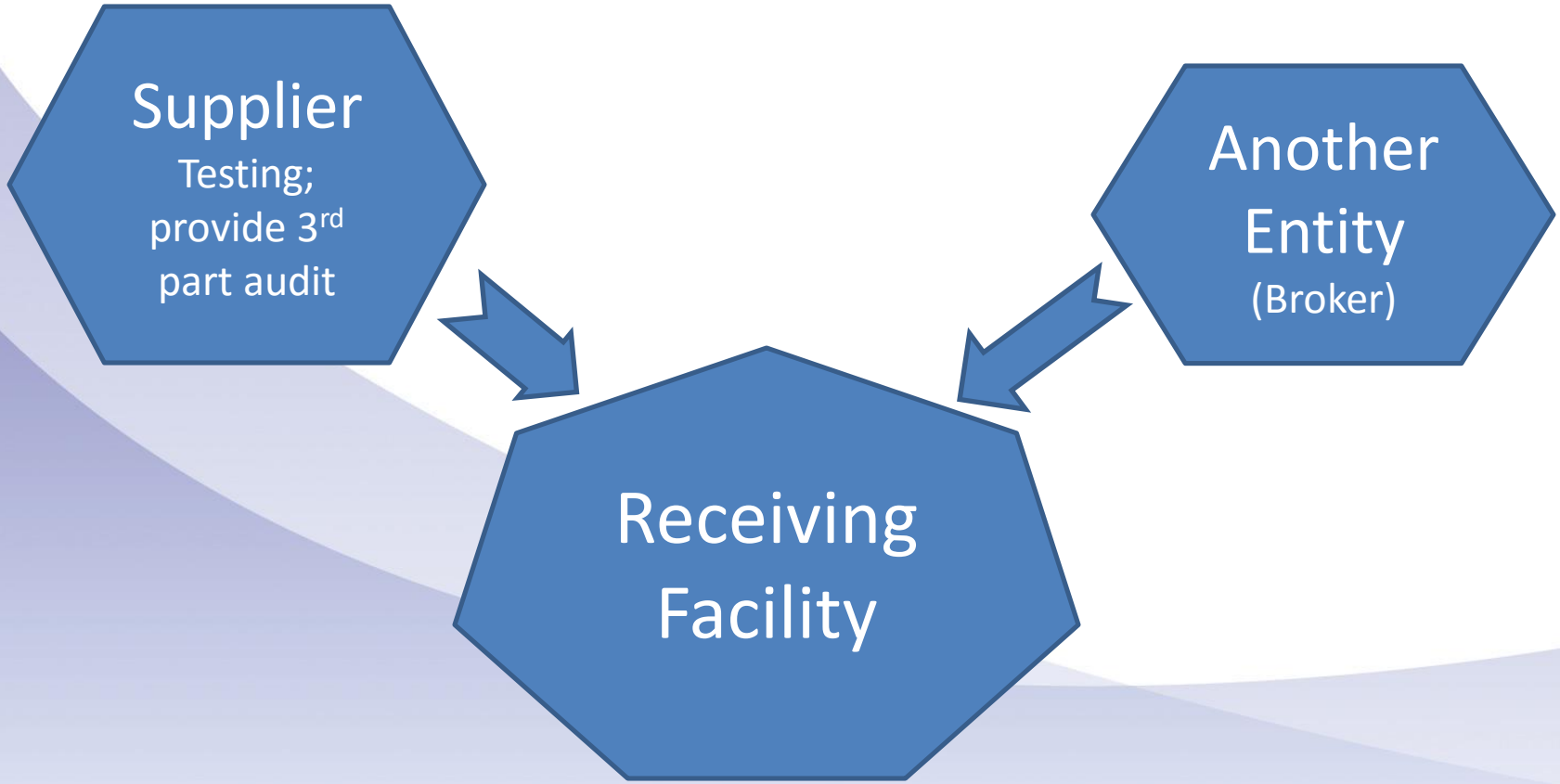
Who Controls the Hazard?

- Manufacturer, processor
- Raise the animal
- Grow the food

- Manufacturer, processor

- Manufacturer, processor or preparer

Conduct & Document Verification



Receiving facility must document review and assessment of documents provided by others

Onsite Audit Requirements & Testing

- For serious hazards requiring a supply-chain-applied control
  - Documented onsite audit *before* using the raw material
  - *At least annually* after the initial audit
- Exception
  - You document that other verification activities or less frequent auditing provides adequate assurance
- Must use a qualified auditor
  - e.g., government, audit agent of certification body
- Review supplier's written HACCP or other Food Safety Plan and implementation documents for hazard identified in your hazard analysis
- Sampling and Testing may be conducted:
  - by the supplier
  - at an outside lab or
  - by the receiving facility
    - Always consider the lot tested
- Can communicate results in a COA
- Methods used must be fit for purpose
- Consult references on appropriate tests for different types of products

Other Verification Activities

- Records reviews
- Requesting certificates of conformance
- Requesting continuing guarantees
- Non-conformance actions focus on:
  - Identification of the issue
  - Steps taken to mitigate the effects of the issue
  - Steps taken to correct the issue
  - Identification of the root cause of the issue
  - Steps taken to modify the system to prevent reoccurrence
- Document all root cause and corrective actions
  - Ensure that corrective actions are implemented
- Records of actions taken for non-conformance are **required**

21 C.F.R. Part 117, Subpart B

- Federal GMP regulations that apply to all facilities that manufacture, process, pack or hold FDA-regulated food
  - Personnel
  - Plant and grounds
  - Sanitary operations*
  - Sanitary facilities and controls
  - Equipment and utensils
  - Processes and controls*
  - Warehousing and distribution, and
  - Defect action levels
- GMPs are used as the basis to determine if food has been processed under sanitary conditions
- Minimum sanitary standards to be met
- **<u>Some GMPs could be designated as a preventive control</u>**
  - Determined in hazard analysis

GMPS – Manufacturing & Warehousing

- Manufacturing:
  - Prevent microbial growth through cooking, time/temperature control, water activity control (pH) etc.
  - Use clean and sanitized equipment, utensils and finished product containers
  - Manufacture ice from potable water in a sanitary manner
  - Prevent Allergen cross-contact and cross-contamination
- Storage and transportation of food:
  - Microbial growth
  - Allergen cross-contact
  - Contamination of the food with hazards
  - Deterioration of the food and the container

GMPs

- GMPs can be considered the “building blocks” for food safety plan
- Even though required by regulation, most will not rise to the level of a preventive control

GMPs for By-Products for Animal Food

- Human food by-products for animal food must comply with GMPs during holding and distribution
  - Must be held under conditions that will protect against contamination
    - Ensure the safety of containers
    - Avoid contamination from trash or garbage
    - Identify the material through labeling
- Companies further processing food or by-products for use as animal food must comply with preventive controls for animal food (21 CFR Part 507)

Hazard Analysis and Preventive Controls for Animal Food

Major Components

- CGMPs (Subpart B)
  - Manufacturing, processing, packing, and holding animal feed
- Preventive Controls (Subpart C)
  - If applicable:
    - Written food safety plan
    - Implement controls to mitigate identified hazards
- Supply-Chain Controls (Subpart E)
  - Risk-based supply chain program to control for hazards identified by facility

Applicability

- All animal food facilities registered under the Bioterrorism Act of 2002
  - Includes feed mills owned by integrators that service contract growers
- "Farms" are exempt
  - Must have common management/ownership of mill, birds, and farm in one general location
  - Mills serving contract growers are ***not*** deemed part of a farm

FDA has indicated it will seek to place integrator mills that qualify as "farms" under the Animal Food Rule in future

Compliance Timelines

Business Size	CGMPs	Preventive Controls
Not “small” or “very small”	Sept. 19, 2016	Sept. 18, 2017
Small Business (Fewer than 500 full-time employees company-wide – including subsidiaries)	Sept. 18, 2017	Sept. 17, 2018
Very Small Business (Averages less than $2.5 M in animal food sales + market value of animal food manufactured)	Sept. 17, 2018	Sept. 17, 2019 (except records to demonstrate VSB status due by Jan. 1, 2017)

Current Good Manufacturing Practices

- The Animal Food Rule CGMPs establish protocols for various aspect's of a plant's operation to ensure that the risk of a foodborne illness outbreak is minimized or eliminated
- Apply to all facilities, regardless of whether Preventive Controls are required

CGMPs

- Covers:
  - Personnel
  - Plant and Grounds
  - Sanitation
  - Water supply and plumbing
  - Equipment and utensils
  - Plant operations
  - Holding and distribution

Preventive Controls

Applicability and Exemptions – Qualified Facility

- Small businesses and very small businesses are subject to modified requirements
- A "qualified" facility must notify FDA about its qualified status and either:
  - Notify FDA that it is addressing hazards (that require controls) through preventive controls and monitoring; OR
  - Notify FDA every 2 years (concurrent with registration renewal) that:
    - It complies with non-federal food safety regulations; and
    - Notify consumers of the name and complete business address of the facility where the feed was manufactured or processed

FDA can withdraw a facility's "qualified" status: (1) in the event of an active investigation of an outbreak linked to the facility; or (2) if FDA determines that it is necessary to protect public health (human or animal) and prevent or mitigate outbreak

Applicability and Exemptions

- Total Exemptions
  - Low-risk, on-farm activities performed by small businesses and very small businesses
    - E.g., re-packaging feed or cracking grains
  - Facilities solely engaged in the storage of raw agricultural commodities
  - Facilities solely engaged in the storage of unexposed, packaged feed that does not require time/temperature controls to minimize or prevent the growth of toxin production by pathogens

Food Safety Plan

- Must be prepared and implemented by a “qualified” individual
- Includes:
  - Written hazard analysis
  - Written preventive controls
  - Written supply-chain program
  - Written recall plan
  - Written preventive controls monitoring procedures
  - Written corrective action procedures
  - Written verification procedures

Hazard Analysis

- Identify and evaluate known or reasonably foreseeable hazards for each feed to determine whether any hazards require preventive controls
  - Biological (including microorganisms)
  - Chemical
  - Physical
- Known or reasonably foreseeable hazards include:
  - Naturally-occurring hazards
  - Unintentionally-introduced hazards
  - Hazards intentionally introduced for economic gain

Preventive Controls

- Process Controls
  - Procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiation, and refrigeration, including:
    - Parameters associated with the control of the hazard; and
    - The maximum or minimum value, or combination of values to which any hazard must be controlled
- Sanitation Controls
  - Procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition to significantly minimize or prevent hazards, such as environmental pathogens and biological hazards
- Supply Chain Controls
  - Must comply with Subpart E (discussed later)
- Recall Plan
  - There must be a recall plan for each feed requiring a preventive control

Preventive Controls Qualified Individual

- PCQI is a qualified individual who has either:
  - Successfully completed certain training in the development and application of risk-based preventive controls; OR
  - Is otherwise qualified through job experience to develop and apply a food safety system
- Each facilities preventive controls and food safety plan must be overseen by a PCQI

Recordkeeping Requirements

- Two-year retention requirement
  - All records required under the Animal Food Rule relating to preventive controls must be maintained for two years
    - Records demonstrating "qualified" status must be kept 3 years
- Remote record storage
  - All records except the written food safety plan may be stored electronically or remotely
    - Must be retrieved and onsite within 24 hours of request
- Food safety plan
  - Physical copy must be maintained onsite
- Use of existing records
  - Records that are kept to comply with other federal, state, or local regulations do not need to be duplicated
  - Records for the Animal Food Rule does not need to be kept in one set
- Records Availability
  - Records required under the rule must be made available to an authorized representative of HHS for official review and *copying upon oral or written request*

Producing Human By-products for Animal Food

- If already implementing human food safety requirements – no need to implement additional preventive controls or CGMP regulations when supplying by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) except to prevent physical and chemical contamination
  - Applies to human food facilities that both donate or sell by-product for use in animal food.
- Labeling identifying by-product by common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed

Producing Human By-products for Animal Food

- Further processing a by-product for use as animal food (e.g., drying, pelleting, heat-treatment) requires compliance with CGMPs to ensure animal food's safety and to make sure processing does not introduce hazards to animal food.
- Company can follow human food or animal food CGMPs when further processing by-product
  - Unless a qualified facility or otherwise exempt from subpart C (hazard analysis and preventive controls); must assess its processing and determine whether there are hazards requiring a preventive control

Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

FSVP

- "Importer" – the U.S. owner or consignee of food offered for import into United States
- If no U.S. owner or consignee, importer is U.S. agency or representative of foreign owner of consignee at time of entry, as confirmed in signed statement of consent
- Compliance – 18 months from November 27,2015
  - If importing from supplier subject to preventive controls or produce safety rules: six months after required to meet relevant regulations;
  - For importer that also manufactures/processes and subject to supply-chain program in preventive controls: date by which must comply with those provisions

What is a FSVP?

- Program that importers must have in place to:
  - Verify their foreign suppliers are producing food in manner that provides same level of public health protection as preventive controls or produce safety regulations, as appropriate, and
  - To ensure supplier's food is not adulterated/misbranded with respect to allergen labeling

Who is Responsible?

- Importers responsible for:
  - Determining known or reasonably foreseeable hazards with each food
  - Evaluating risk posed by a food, based on hazard analysis, and foreign supplier's performance
  - Using that evaluation of risk posed by imported food and supplier's performance to approve suppliers and determine appropriate supplier verification activities
  - Conducting supplier verification activities
  - Conducting corrective actions

Importers & Written Documentation

- Establish and follow written procedures to:
  - Ensure import foods only from foreign suppliers approved based on evaluation of risk posed by imported food and supplier's performance; or
  - When necessary on a temporary basis, from unapproved suppliers whose foods are subjected to adequate verification activities before being imported
- Required to develop, maintain and follow a FSVP for each food/foreign supplier
  - If obtains certain food from different suppliers; separate FSVP required for each supplier
- Not required to evaluate food and supplier or conduct supplier verification activities if receive adequate assurances that subsequent entity is processing food for food safety in accordance with applicable requirements
- Must also disclose in documents accompanying food that food not processed to control identified hazard

FSVP vs. Supply-Chain Preventive Controls

- Foreign Supplier Verification Programs are a form of Supplier Certification
- If you are an Importer and in compliance with FSVP – then you meet the Supply-Chain Preventive Control component of the rule

Sanitary Transportation

Published April 6, 2016

- FDA Webinar on April 25th
- Compliance dates
  - April 6, 2017 for most businesses
  - April 6, 2018 for "small businesses"
    - Businesses having <500 full time employees
    - For motor carriers that are not also shippers and/or receivers, <27.5 million in annual receipts

Exemptions

- Transportation of live food animals, except molluscan shellfish
- Transportation activities performed by a farm
- Transportation of human food byproducts intended for animal food and not further processed
  - NB: The rule otherwise does apply to animal food
- Transportation of food completely enclosed in a container (unless the food requires temperature control for safety)

Exemptions

- Food when it is located in a facility that is regulated, throughout the entire facility, by USDA
  - When the food **leaves** the USDA-regulated facility, it appears to lose its exemption
  - Preamble states FSIS does not "directly" address and this rule "complements" their regulations
- Also, the rule does not apply to transportation of food by air or ship

New Requirements

- Vehicles and Transportation Equipment
  - Must be designed and maintained to prevent food from becoming unsafe
  - Must be stored to prevent contamination or pest infestation
  - When used to transport food that requires temperature control for safety, must be designed, maintained, and equipped to provide adequate temperature control

New Requirements

- Training
  - Only required for carriers that agree in writing to be responsible for sanitary conditions during transportation
  - Carrier's personnel engaged in transportation operations must receive adequate training regarding potential food safety problems, basic sanitary transportation practices, and the carrier's responsibilities
  - FDA will develop an online course

New Requirements

- Provide written specifications to the carrier and, when necessary, the loader with all necessary sanitary specifications for the vehicle and transportation equipment;
- Provide written specifications to the carrier (except a carrier that transports food in a thermally insulated tank) and, when necessary, the loader an operating temperature for transportation (and, if necessary, the pre-cooling phase) of food that requires temperature control for safety60

New Requirements

- Recordkeeping
  - Numerous required records
  - All required records must be made available to FDA promptly upon request

Questions?