FSMA Food Safety Seminar
Japan External Trade Organization

U.S. Food and Drug Administration's Risk-Based Preventive Controls for Human Food
&
Supply Chain Preventive Controls

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Jolyda Swaim

Principal Attorney

Olsson Frank Weeda Terman Matz PC

jswaim@ofwlaw.com

OFW LAW
OLSSON FRANK WEEDA TERMAN MATZ PC

Overview

- Review of Risk-based Preventive Controls for Human Food

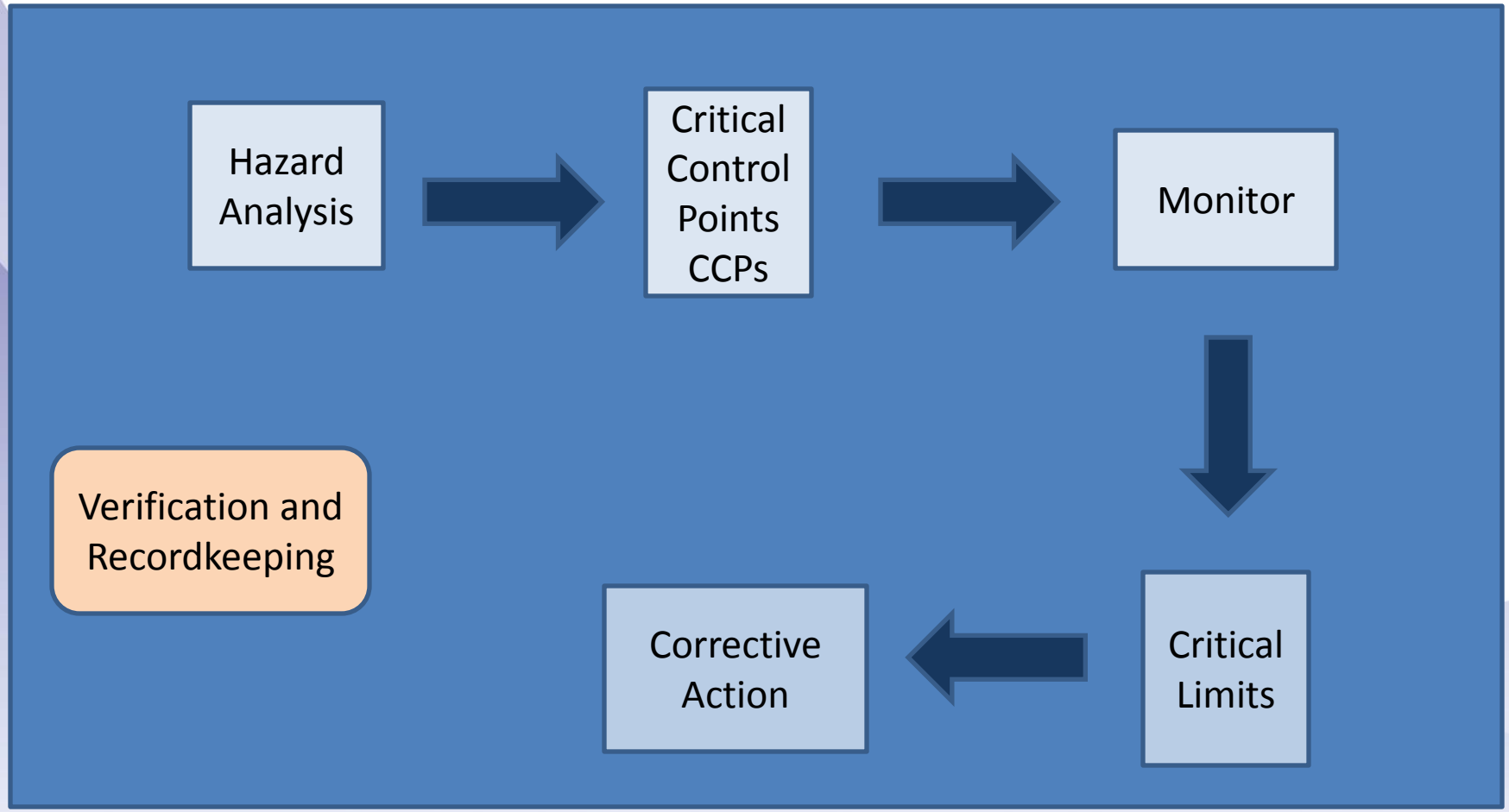
- "Supply Chain Preventive Controls" are a component of the Preventive Controls regulation

Preventive Controls for Human Food

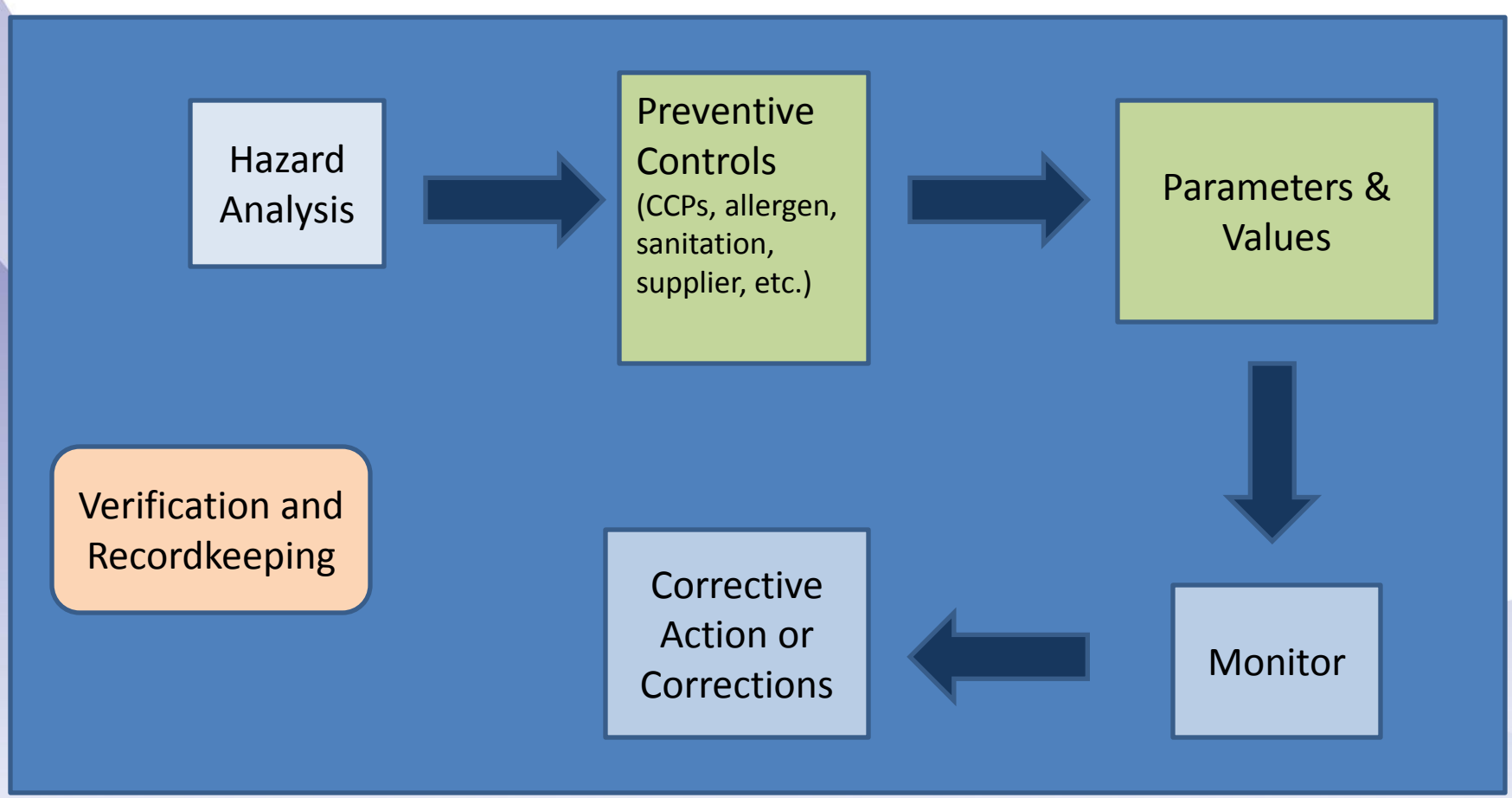
Risk-Based Preventive Controls

- Focus on what matters most for food safety – ***NOT*** quality!
- Preventive, not reactive
- Work in conjunction with and supported by other programs like Good Manufacturing Practices (GMP)
- Designed to minimize the risk of food safety hazards
- Understand what is required by the regulation and what is not

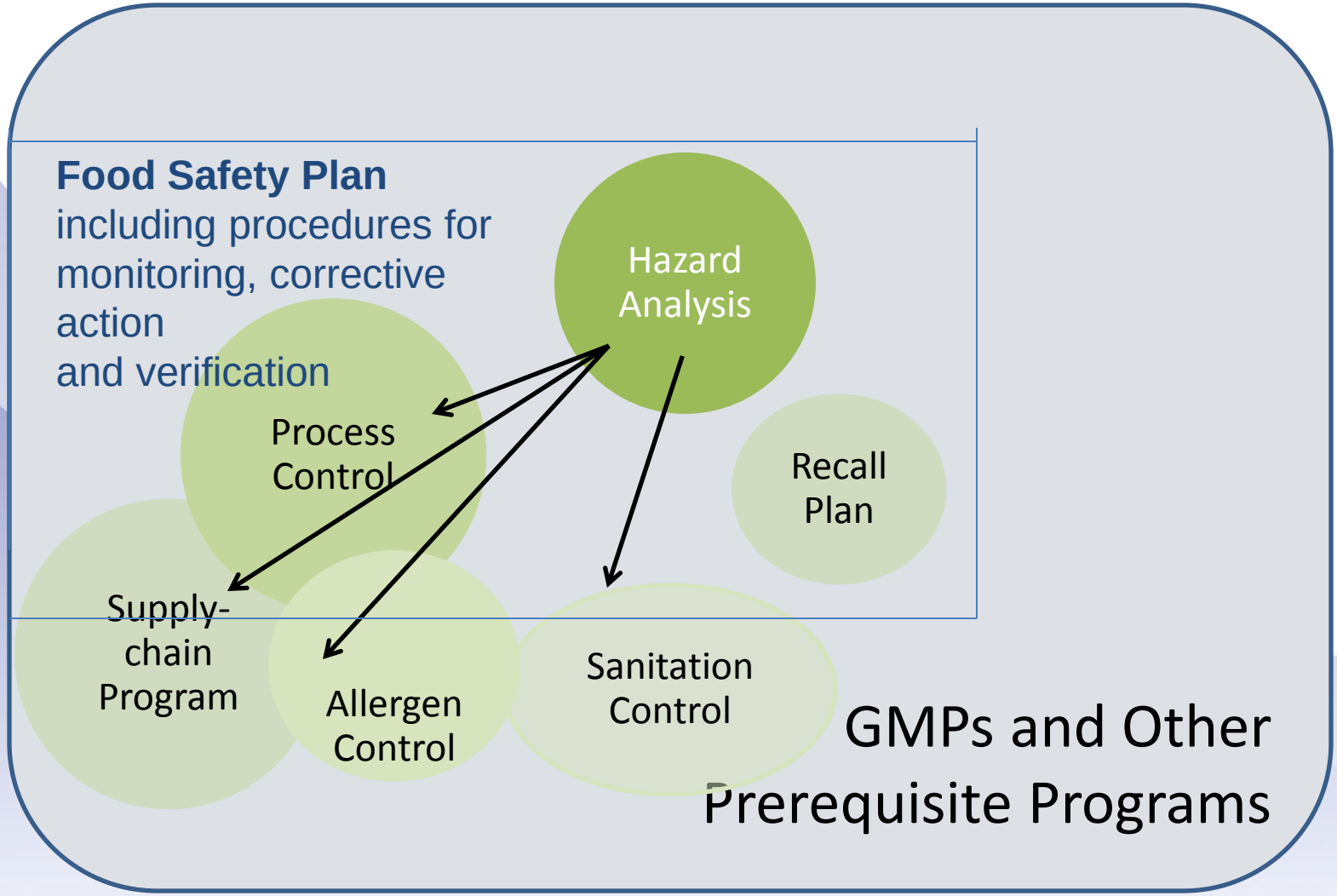
HACCP Focuses on Process



Preventive Controls = HACCP + More



Preventive Food Safety Systems



Contents of a Food Safety Plan

Required by FDA 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 listing of Food Safety Team
- Product description
- Flow diagram
- Process description

* Required when the need for a preventive control is identified

Food Facility's Food Safety Plan

- Must be prepared and implemented by a "qualified" individual and includes::
  - Written hazard analysis
  - Written preventive controls
    - Written supply-chain program, if the supplier is responsible for controlling hazard
    - Supply-chain program is integral part of PCHF – ***not*** a separate regulation
  - Written recall plan
  - Written preventive controls monitoring procedures
  - Written corrective action procedures
  - Written verification procedures

Preventive Controls Qualified Individual (PCQI)

- Regulatory definition:
  - "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 or oversee the following:
  - 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

Hazard Analysis

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

“Preventive” Controls

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

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

Corrective Action Procedures (21 CFR § 117.150(a)(2))

- Written procedures must describe steps to take 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
- Acknowledge facility will comply to the this regulation instead of describing specific corrective actions

Records

- Real time, actual values or observations, permanent, legible, **name and plant location (required)**
- 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

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

Supply Chain Preventive Controls

Subpart G of Preventive Controls Regulation

Supply-chain Preventive Controls

Subpart E of Preventive Controls Regulation

- 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?

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

- Manufacturer, processor

- Manufacturer, processor or preparer

Who was the last "entity" who could impact the hazard?

Supply-Chain Program **Not** Required

1. When no hazard needing control by the supplier is identified

   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*

Preventive Control Not Required (21 CFR § 117.136)

- If you identify the need for a preventive control, but do not control the hazard and rely on an entity in distribution chain to do so:
  - Must provide "disclosure statement" to customer
    - For biological can be general: "microbial pathogens" or "microorganisms of public health concern"
    - For chemical & physical must be specific: *e.g.*, "mycotoxins," "aflatoxins," stones"
- "Not processed to control ____"

Preventive Control Not Required (con't)

- Statement to customer must be provided on documents accompanying food
  - Labels
  - Labeling
  - Bill of lading
  - Shipment-specific certificates of analysis
  - Etc.
- Not recommended for contracts and letters of guarantee as usually not related to specific shipment

Approved Suppliers & Verification

- Use of approved suppliers:
  - Applies to hazards requiring a supply-chain-applied control
  - Approval required *before* receiving the ingredient
    - What does the hazard analysis suggest about the nature of the hazard?
    - Are preventive controls applied by the supplier or the supplier's supplier?
    - What are the supplier's procedures, processes and practices related to safety for the ingredient or raw material?
    - Do your historical test or audit results for the supplier indicate a trend – positive or negative?
    - Have the supplier's corrective actions to past issues been appropriate and timely?
    - Are the supplier's storage or transportation practices appropriate?
  - Temporary exception may be possible with justification
  - Written procedures for receiving
  - Receiving records required

Approved Suppliers & Verification (con't)

- Supplier verification (before using and periodically thereafter)
  - Onsite audits (if supplier controls serious hazard)
    - Second or third party audits are acceptable
  - Conduct appropriate sampling and testing
    - By the supplier or the receiving facility
  - Review supplier's food safety records for the ingredient
  - Other if applicable

Onsite Audit Requirements & Testing

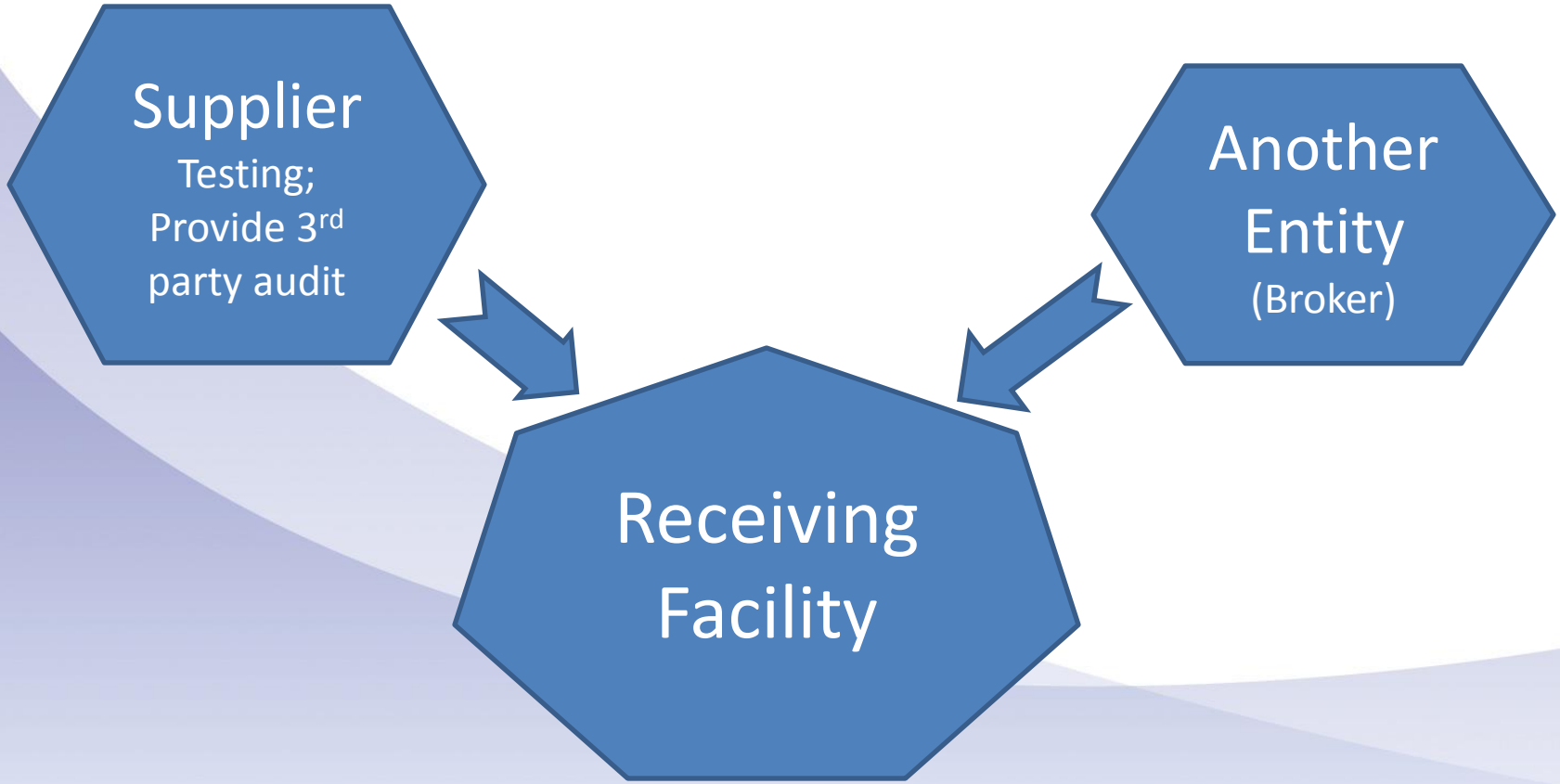
- For hazards requiring a supply-chain-applied control
  - Documented onsite audit *before* using the raw material
  - *At least annually* after the initial audit
- Exception
  - You document that other verification activities or less frequent auditing provides adequate assurance that hazards are controlled
- 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 the hazard identified in your hazard analysis

* "Qualified auditor" is defined only in context to supply chain preventive control

Onsite Audit Requirements & Testing

- 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 Certificate of Analysis (COA)
- Methods used must be fit for purpose
- Consult references on appropriate tests for different types of products

Conduct & Document Verification



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

Other Verification Activities

- Records review
- 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**

Recordkeeping Requirements

- Two-year retention requirement
  - All records required under the Human Food Rule relating to preventive controls must be maintained for two years
    - Records demonstrating "qualified facility" status must be kept 3 years
- Remote record storage
  - All records except the written food safety plan may be stored electronically or remotely
    - Records 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 Human 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 FDA for official review and *copying upon oral or written request*

Questions?