

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR 117.435(d), 117.475(c)(2), and 117.475(c)(13). See section LVI for the compliance dates.

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Western Regional Center to Enhance Food Safety

# MODULE 3

## Overview of Preventive Controls for Human Food (PCHF) rule

Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. The Food and Drug Administration (FDA) is updating its current good manufacturing practice (CGMP) for human food in two fundamental ways. First, we are modernizing the long-standing requirements for domestic and foreign facilities that are subject to our registration and implementation of hazard analysis and risk-based preventive controls for human food. We are revising certain definitions in the regulation for Registration of Food Facilities to clarify the scope of the requirements provided for "farms" and "holdings" to clarify which domestic and foreign facilities are subject to the requirements for hazard analysis and preventive controls for human food. We are taking the action we announced in our current good manufacturing practice requirements since they were first issued in 1986 and to implement statutory provisions in the FDA Food Safety Modernization Act. We intend to build a food safety system for the future that makes science- and risk-based preventive controls the norm across all of the food system. This rule is effective November 17, 2015. For the amendments to the regulation, which is effective September 17, 2015, and the implementation of the provisions of the rule in § 117.3, and §§ 117.5(k)(2), 117.8, 117.405(a)(2), 117.405(c), 117.410(d)(2)(iii), 117.430(d), 117.435(d), 117.475(c)(2) and 117.475(c)(13). FDA will publish a document in the Federal Register announcing the effective dates of the amendments of the definition of "farm" in § 117.3, and §§ 117.5(k)(2), 117.405(a)(2), 117.405(c), 117.410(d)(2)(iii), 117.430(d), 117.435(d), 117.475(c)(2), and 117.475(c)(13).

# Learning objectives

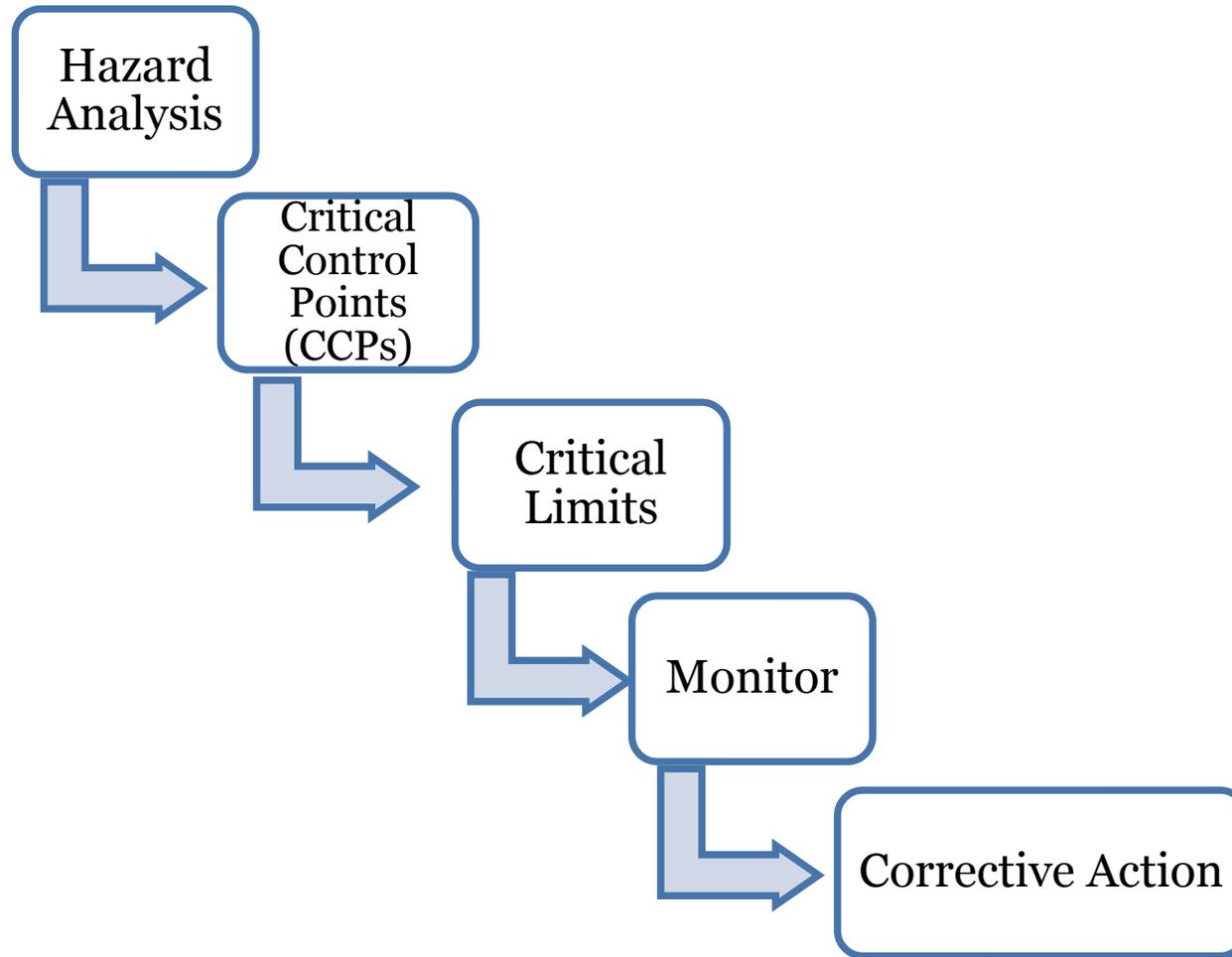
In this module, you will develop awareness of:

- How preventive controls build on established food safety principles
- Components of a Food Safety Plan
- The responsibilities of a preventive controls qualified individual
- Where to find definitions relevant for the course

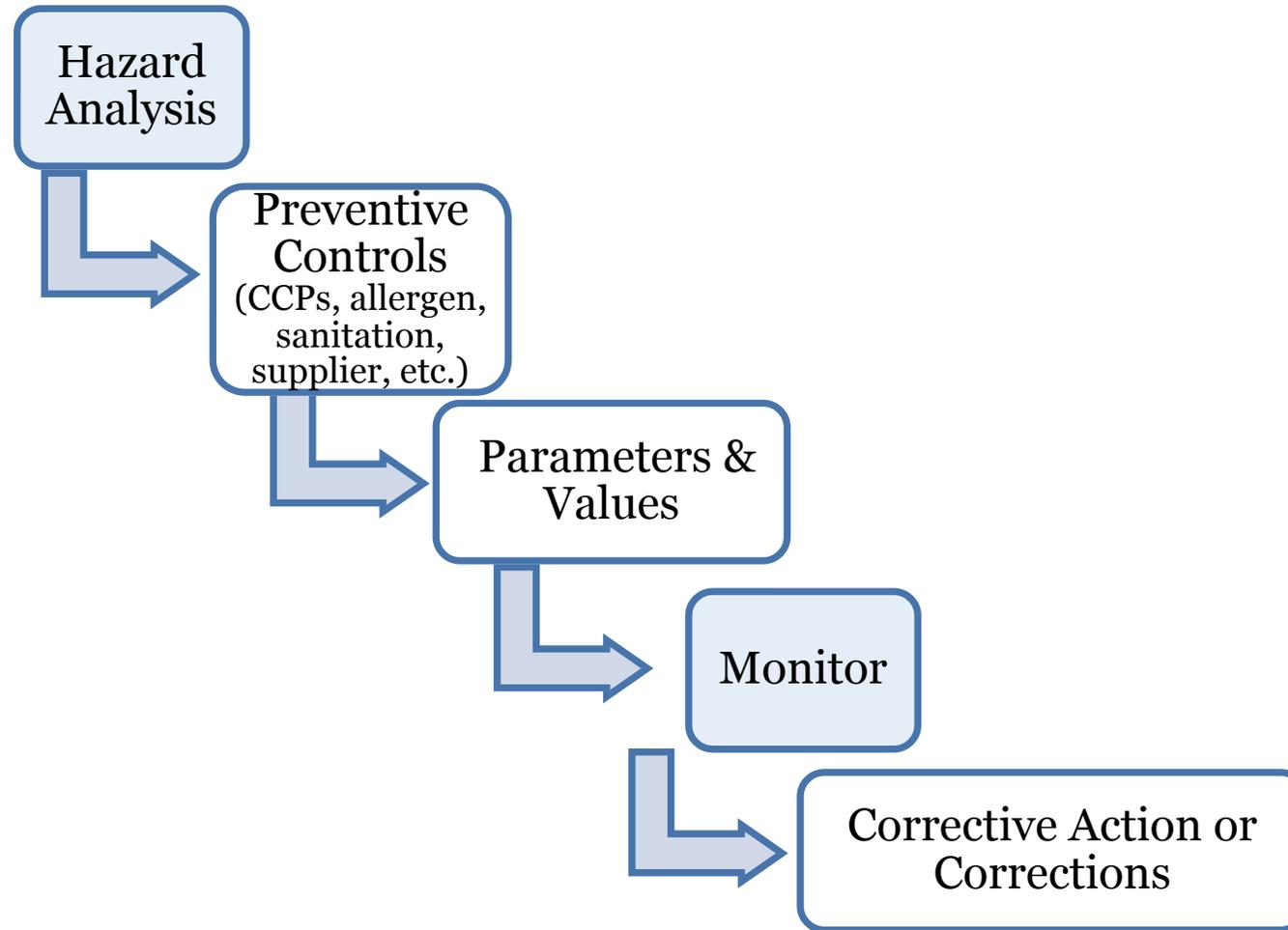
# Risk-based Preventive Controls

- 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

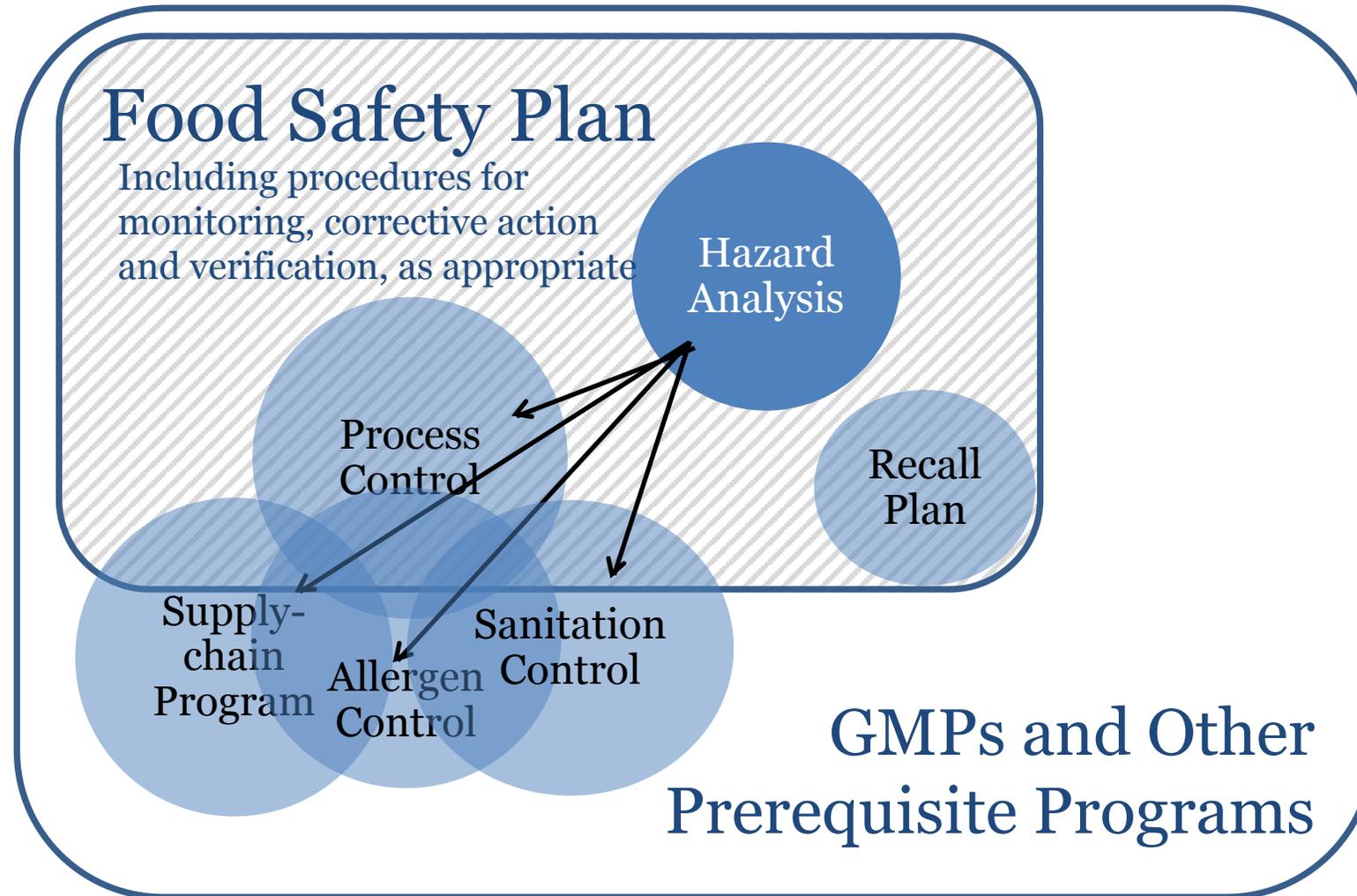
# Historically HACCP Focuses on the Process



# Preventive Controls Include More Than HACCP



# Preventive Food Safety Systems



# What's New in a Food Safety Plan

Element	HACCP Plan	Added in Food Safety Plan
Hazard analysis	Biological, chemical, physical	Chemical hazards to include radiological; consider economically motivated hazards
Preventive controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs
Parameters and values	Critical limits	Parameters and minimum/maximum values (= critical limits for process controls)
Monitoring	Required for CCPs	Required as appropriate for other preventive controls
Corrective actions or corrections	Corrective actions	Corrective actions or corrections, as appropriate
Verification	For process controls	As appropriate for all preventive controls; supplier verification required when supplier controls a hazard
Records	For process controls	As appropriate for all preventive controls
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified

# Preventive Controls Qualified Individual 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

# Critical Limits – A Food Safety Principle

- Key discussion points
  - Definition of critical limit
  - How to determine critical limits for a CCP
  - The relationship between critical limits and operating limits
  - Use of the Process Control Form

# Critical Limit Definition

- The maximum or minimum value, or combination of values, to which any biological, chemical or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.
  - Derived from 21 CFR 117.135(c)(1)(ii)

# Sources of Information on Critical Limits

## ■ What Are Examples of Critical Limits

- FDA
- Hazard Guides; guidelines, tolerances and action levels; Food Code; Pasteurized Milk Ordinance (PMO); Acidified Foods regulations
- Other regulatory guidelines
- State and local regulations, tolerances and action levels; USDA regulations, tolerances and action levels
- Experts (internal and external)
- Process authorities, university food scientists/ microbiologists, consultants, equipment manufacturers, sanitarians, trade associations
- Scientific studies
- In-house experiments, 3rd party challenge studies (universities or contract labs)
- Scientific literature
- Peer reviewed journals, food science texts, microbiology texts, Food Safety Preventive Controls Alliance information

## Critical Limit Considerations

If a critical limit is not met, a hazard is not necessarily controlled and the safety of the product is in question

Critical limits must be achievable

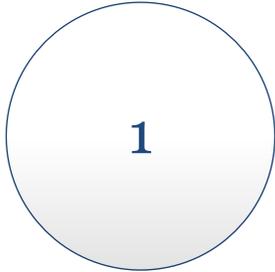
Often a variety of options exist for controlling a particular hazard

The selection of the best control option and critical limit is often driven by practicality and experience

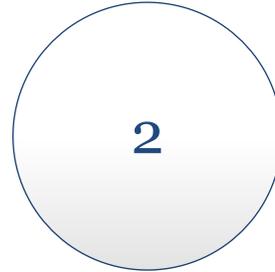
# Monitor Definition

- “To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.”
  - 21 CFR 117.3 Definitions

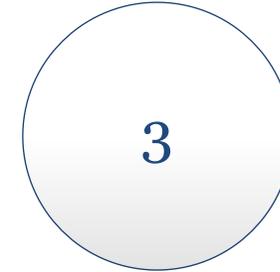
# Purpose of Monitoring Process Controls



To track the operation of the process and enable the identification of trends toward a critical limit that may trigger process adjustments



To identify when there is a loss of control or when a “deviation” from a critical limit occurs



To provide written documentation that can be used to verify that the process is under control

# Elements of Monitoring

1. What to monitor
2. How to monitor
3. Frequency to monitor
4. Who will monitor



# What Might Be Monitored?

Depends on process, examples include:

- Temperature
- Time
- Volume / weight
- Line speed
- Flow rate
- Bed depth
- Acid addition
- pH
- Water activity
- Chemical concentration
- Appearance
- Process performance
- Many others

# How is Monitoring Conducted?

Depends on the nature of the control.  
Examples include:

- Calibrated thermometer
- Calibrated pH meter
- Calibrated chart recorder
- In-line analyzer
- “Real time” laboratory analysis
- Visual checks



# Continuous Monitoring Considerations

Continuous monitoring is preferred

Continuous monitoring examples

- Temperature recording chart
- Metal detector
- Dud detector
- In-line pH probe
- Bar code scanner
- Vision system for foreign material

# Non-continuous Monitoring Considerations

Used when continuous systems are not feasible

Frequency of non-continuous monitoring

- How much does the process normally vary?
- How close are normal values to the critical limit?
- How much product is at risk if the critical limit is not met?

Non-continuous monitoring examples

- Temperature checks at specified intervals
- Batch process water activity checks
- Antimicrobial chemical levels in produce wash water

# Exception Records

- Exception records are generated only when a limit is not met; e.g.,
  - Cooler records when temperature goes above a set limit
  - X-ray that responds only to foreign material
- Often an alarm alerts the operator of a problem
- Exception record systems must be validated

# Qualifications for Monitoring Individuals

- Trained in monitoring techniques through on-the-job training or similar approaches
- Fully understand the importance of monitoring
- Accurately report each monitoring activity
- Understand actions to take when deviation occurs
  - Immediate corrective actions related to the process
  - Timely report deviation for other actions



# Corrective Actions and Corrections

- Key discussion points
  - The definition of corrective action and corrections
  - Procedures for corrective actions
  - Record-keeping requirements for corrective actions

# Definitions

- Corrective action

- Procedures that must be taken if preventive controls are not properly implemented.

- from 21 CFR 117.150(a)(1)

- Correction

- 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).

21 CFR 117.3

# Corrective Actions

- Must be taken when process preventive controls are not properly implemented, resulting in a deviation
  - E.g., there is a deviation from a critical limit
- Unsafe product may have been produced
- Appropriate to the nature of the hazard and preventive control

# 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

# Corrective Action Examples

## Process Examples

- Immediate adjustment of process
- Employees stop line when deviation occurs
- Apply alternate process
- Repair equipment
- Retrain employees
- Evaluate operation

## Product Examples

- Hold product
- Evaluate product
- Determine product disposition
  - Release, rework or destroy product

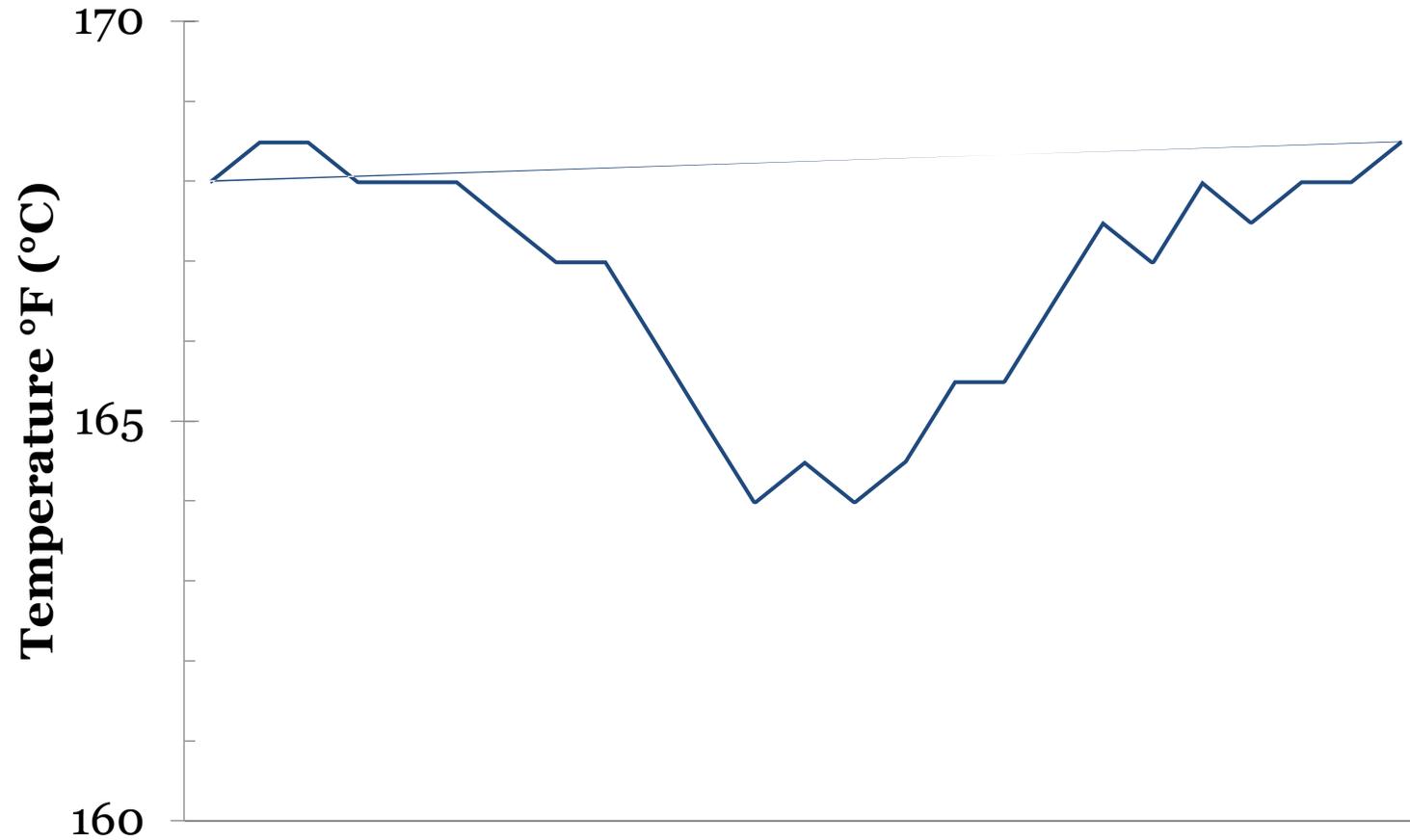
# Corrective Actions Required Records

1. Actions taken to identify and correct the problem,
2. Actions taken, when necessary, to reduce the likelihood that the problem will recur
3. Safety evaluation for all affected food
4. Records demonstrate that food that is potentially injurious to health did not enter commerce

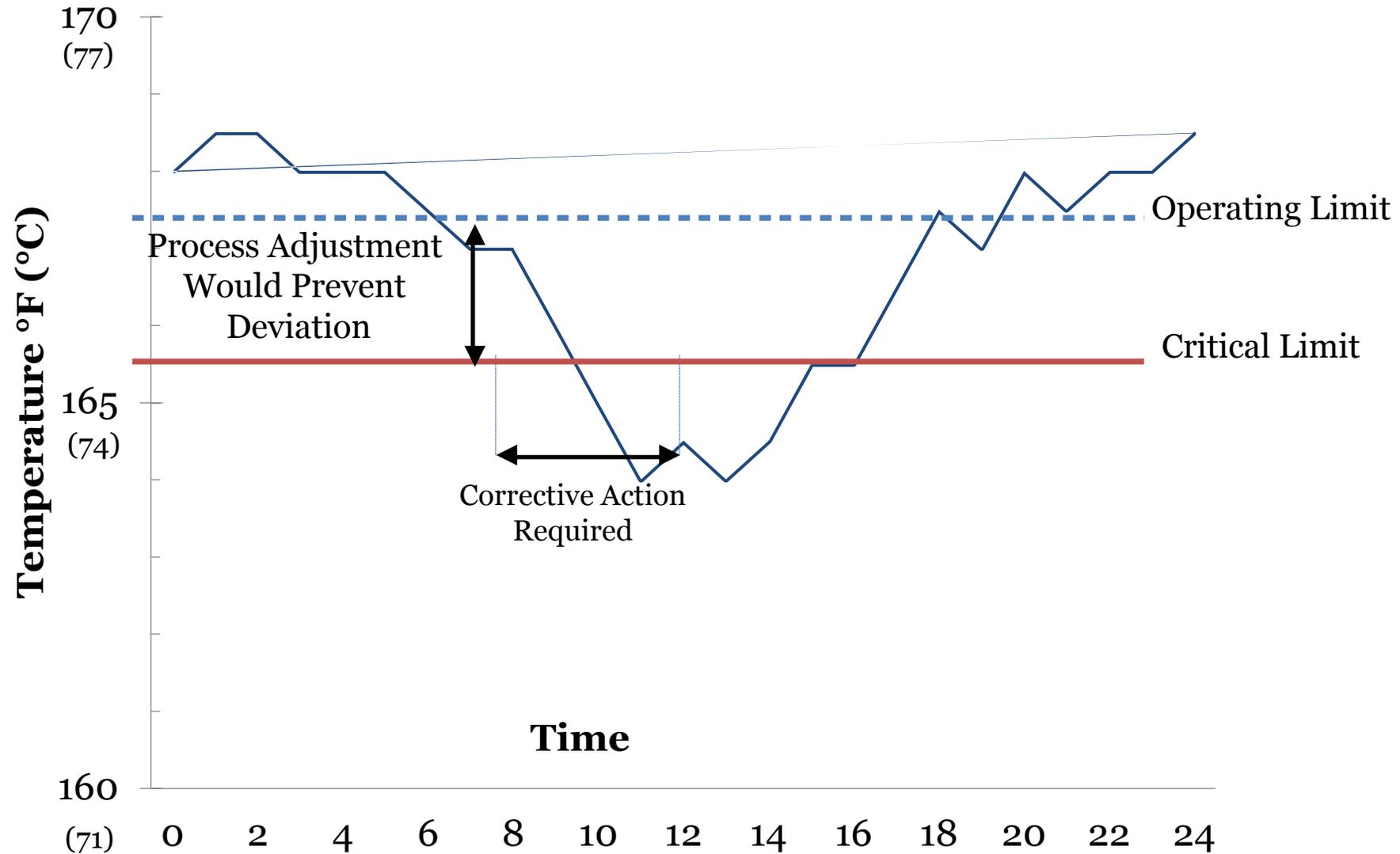
# Operating Limit Definition

- Criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation.
  - National Seafood HACCP Alliance. 2011

# Operating Limits Versus Critical Limits



# Operating Limits Versus Critical Limits



# Process Preventive Controls Summary

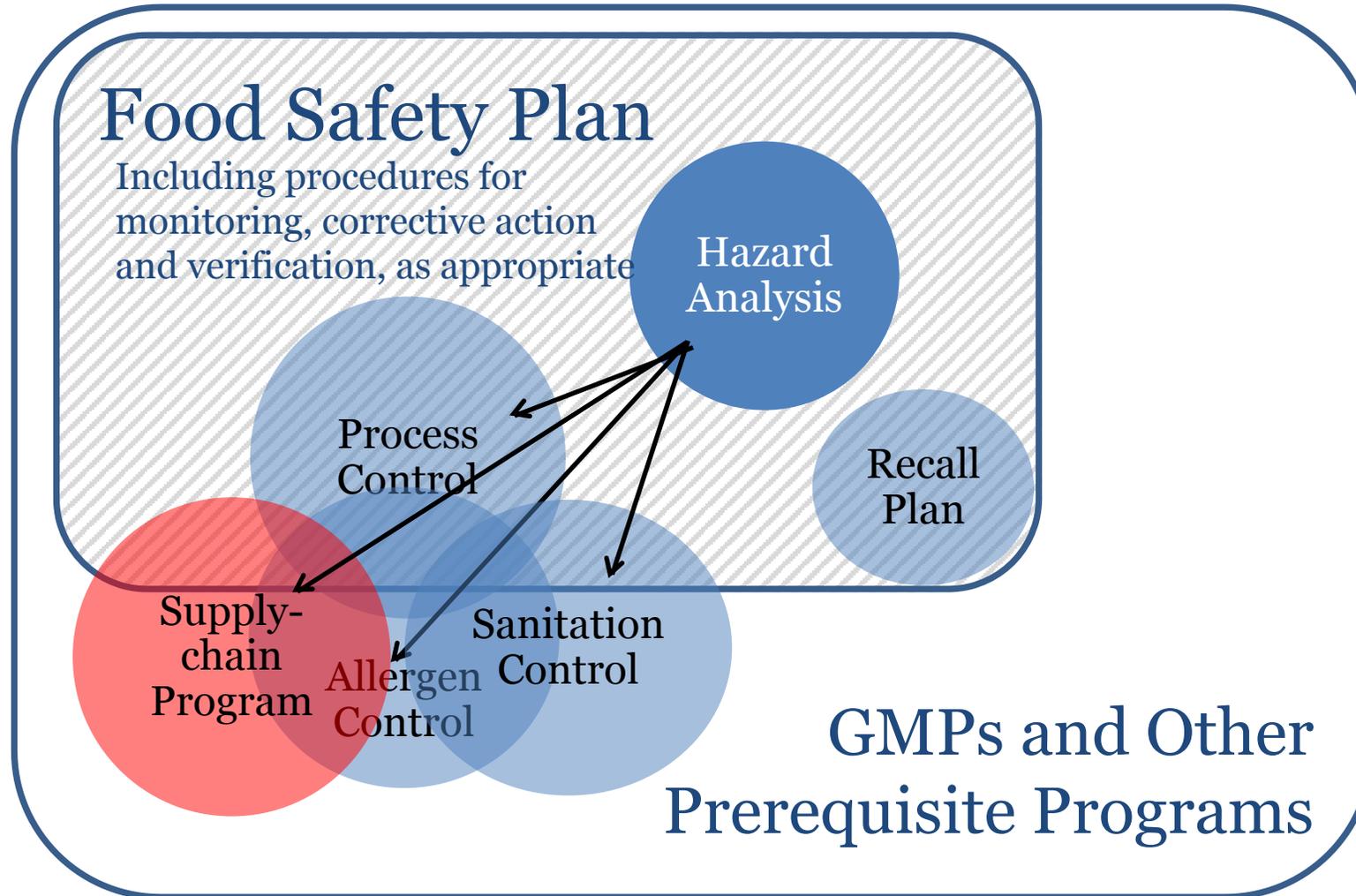
- Procedures must be documented for the process-related hazards requiring a preventive control identified through the hazard analysis process.
  - These controls are usually CCPs.
  - Specific controls depend on the nature of the hazard and the nature of the preventive control.

*continued*

# Process Preventive Controls Summary

- For each process-related preventive control identified, the following must be recorded, as appropriate:
  - Parameters and values (e.g., valid critical limits) that must be met
  - Monitoring procedures, including what, how, frequency and who
  - Corrective actions that identify the implicated product, determine its disposition, correct the cause and determine that the preventive controls are working again
    - Corrections may be appropriate in some situations
  - Verification and records (discussed in subsequent chapters)

# Preventive Controls



# Supply Chain Preventive Controls

- Supply-chain preventive controls are linked to the hazard analysis



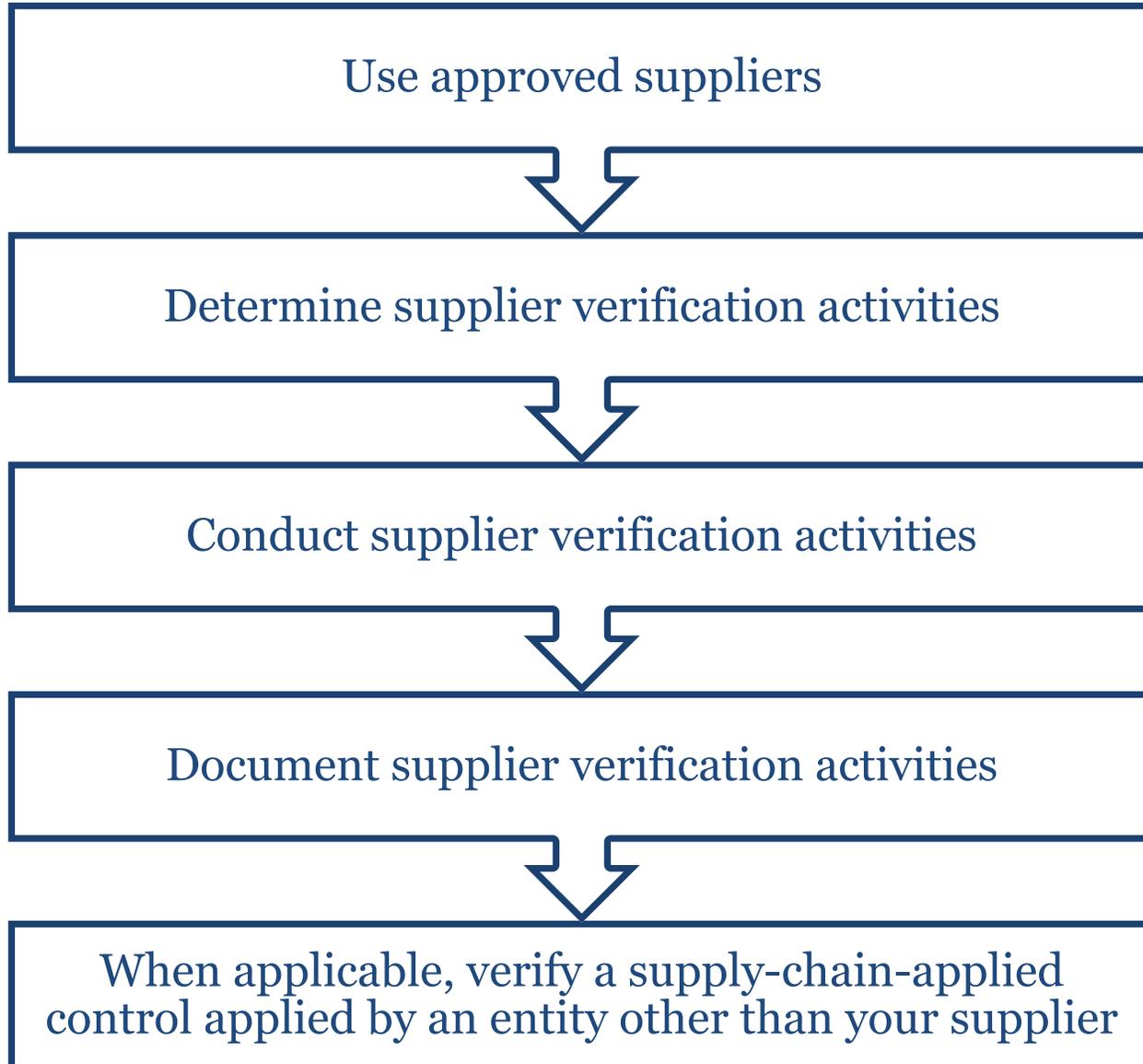
- Manufacturer, processor
- Raise the animal
- Grow the food

- Manufacturer, processor

- Manufacturer, processor or preparer

Source: Microsoft Office Clipart

# Supply-chain Program General Requirements



# Supply- chain Preventive Controls Summary

Supply-chain program must include:

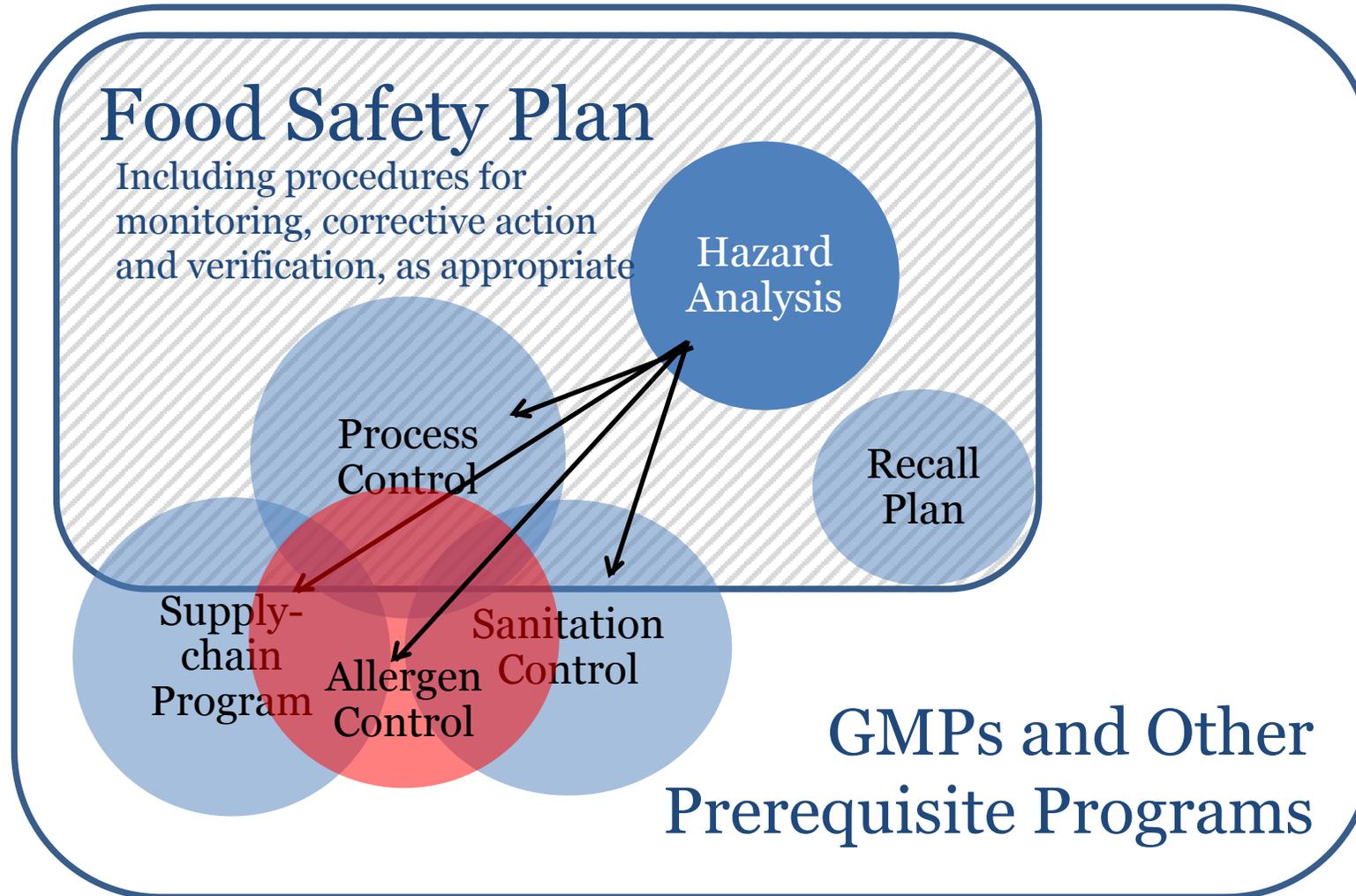
- Using approved suppliers
- Determining, conducting and documenting supply-chain verification activities

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

# Preventive Controls



# FALCPA\* Required Food Allergen Labeling

- Milk
- Egg
- Peanut
- Tree nuts (species specific)
- Fish (species specific)
- Crustacean shellfish (species specific)
- Wheat
- Soy

\* Food Allergen Labeling and Consumer Protection Act



Photo Sources: Microsoft Clip Art and KMJ Swanson (soybeans)

# Allergen Preventive Controls

Preventing allergen cross-contact

Clean shared equipment – potential sanitation controls

Properly manage rework

Avoid in-process or post-process allergen cross-contact

- Accurate allergen labeling of finished food

Ensure labels are correct – potential supply-chain program

Ensure the correct label or package is used

Human error can be involved – training is essential!

# Preventive Controls Rule: Summary

- FDA's *Preventive Controls for Human Food* regulation builds on existing food safety principles (GMPs, etc.)
- Preventive controls reduce risk for the business and for the public
- There are 4 main types of preventive controls:
  - Process Preventive Controls
  - Supply Chain Controls
  - Allergen Controls
  - Sanitation Controls (to be discussed later today)