

HACCP Principles 6 and 7

Verification and Validation

Record Keeping

HACCP Principle 6

- Establish Verification Procedures
- NACMCF 1997 Definition:
 - “Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.”

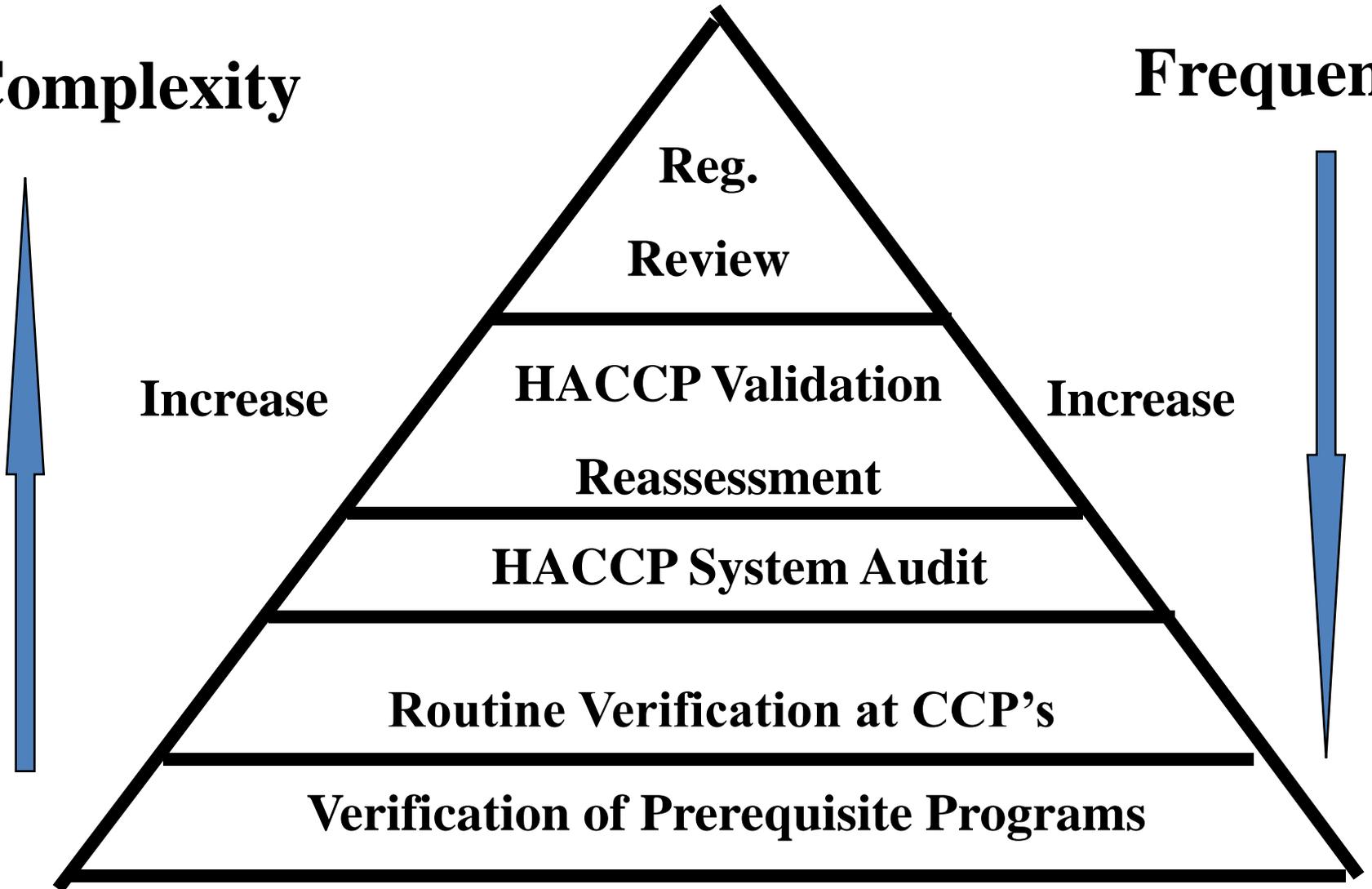
Verification

- HACCP Principle #6
 - Do we say what we do and do we do what we say?
 - Verify that we have implemented the HACCP system as it was designed

VERIFICATION PYRAMID

Complexity

Frequency



Increase

Increase

**Reg.
Review**

**HACCP Validation
Reassessment**

HACCP System Audit

Routine Verification at CCP's

Verification of Prerequisite Programs

FSIS 9CFR 417.4(a)

- Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and
- shall verify that the plan is being effectively implemented.

HACCP is NOT a Stand-Alone System

- ◆ **Prerequisite programs MUST be in place prior to HACCP**
- ◆ **Prerequisite programs are part of the formal HACCP system**
- ◆ **Prerequisite programs must be verified**

Three Aspects of Managing Prerequisite Programs

- ◆ **Written Standard Operating Procedures (SOPs)**
- ◆ **Training**
- ◆ **Verification of compliance with the written programs and of the program's adequacy**

Written Prerequisite Programs

- ➔ **Clearly communicate what is expected to be performed**
- ➔ **Identifies the frequency**
- ➔ **Identifies who is responsible**
- ➔ **Specifies actions taken if activity is not performed according to the procedure**

Training

- ☞ **Encompasses all employees**
- ☞ **Emphasizes importance of personal hygiene and hygienic handling of food**
- ☞ **Priority and frequency should be based on the food safety risks**

Verification of Prerequisite Programs

- ◆ **SOP should include procedures for routine verification**
- ◆ **Conducted by supervisor or other qualified position**
- ◆ **Periodically conducted by independent audit**

Verification of CCPs

In a perfect world all that is needed is

Hazard analysis

Critical control point(s)

Monitoring

In the real world

HACCP requires periodic independent checks

Verification of CCPs

Calibration of Processing and Monitoring Equipment:

Calibrated at a frequency sufficient to ensure that all measurements are accurate.

Frequency dependent on the likelihood that the instrument will go out of calibration.

Verification Task #2 – Records Review

Monitoring and Corrective Action Records Should be Reviewed:

By an individual other than the one preparing the record;

By a HACCP trained individual;

Corrective Action Records must verify that:

**The report was prepared correctly; and
the nature and extent of the deviation was
clearly recorded;**

Verification Task #2 – Records Review

**Review of Monitoring /Corrective Action
Records should ensure that:**

All entries have been made in pen

There are no erasures, white-outs

There is no evidence of falsification

**Person making the entries signs or initials
the record**

Verification Task #3 – Direct Observation

- **Verification must include direct observations or checks of those conducting monitoring and taking corrective actions**
- **Actual results of checks and observations must be recorded**

Verification of CCPs

- **For each verification task:**
 - **Identify the person responsible (by title)**
 - **Identify the frequency**
 - **Identify where the results are recorded**

Pre Shipment Reviews

FSIS Directive 74-13

Each plant must determine which records that are associated with the HACCP food safety system are reviewed before shipping the designated lot of product.

Records should indicate the safety of the product that was produced and that adulterated product was not shipped.

Verification of CCPs

Targeted Sampling and Testing

- It may be necessary to perform a periodic observation or measurement independent of the monitoring activity.
- Periodic samples may be collected for analysis.
- The frequency of sampling and testing may be specified in the HACCP plan.

Verification of CCPs

Verification by Microbiological Testing

Testing rarely recommended for HACCP monitoring

Can be used as a tool in verification

Microbiological test results are only as good as the sampling and analytical methods

Verification of CCPs

Collecting 60 samples per lot yields a 30% or greater risk of not detecting a pathogen if the pathogen is present at a frequency of 2% or lower in the lot.

One would need to test 3,000 samples from a lot in order to detect – at a 95% confidence level – a defect that occurs at a 0.1 % rate.

Verification of CCPs

Records:

Verifications must be documented and should include:

- Who
- What
- Results
- Date and time

Example:

I, Bob Smith, performed a record review and the record was acceptable
Signature, Date, and Time

Other Verifications

Other verifications include:

- **Reassessments**
- **Validation**
- **Internal Audits**
- **Additional Checks of your Systems**

Validation and Reassessment

Validation

NACMCF 1997 Validation – That element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the hazards.

- FSIS - §417.4(a)
 - Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis and shall verify that the plan is being effectively implemented.
- FDA FSMA - Proposed §117.150(a) (Validation)
 - Require the owner, operator, or agent in charge of a facility validate that the preventive controls identified and implemented in accordance with §17.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so.

- FSIS §417.4(a)(1)
 - “ Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended.” Implementation through the **first 90 days** of the plan.
- FDA Proposed §117.150(a)(1)(i)
 - would require that validation occur prior to implementation of the food safety plan or, when necessary, during the **first six weeks** of production.

FSIS - Validation

- Based on the results of FSIS, Food Safety Assessments (FSAs) FSIS has found that in-plant validation may not be consistently implemented by industry or enforced by inspection personnel.
- Specific concerns:
 - Not addressing and implementing all critical factors from scientific support into in-plant control processes

FSIS - Validation

- Specific concerns:
 - Need to measure parameters (time, pressure, concentration, etc., of a study to ensure they are being met.
 - If a critical factor is the reduction of a pathogen, measuring the outcome after applying the process may be needed.
 - May not be necessary to measure the pathogen. Surrogates and/or indicators found within the supporting documentation could be utilized.

FSIS - Validation

- Specific concerns:
 - Increased use of prerequisite programs to support a hazard is not reasonably likely to occur.
 - Prerequisite programs provide a foundation for the HACCP plan to operate effectively and consequently become part of the HACCP system and validation activities.

FSIS Compliance Guideline

HACCP Systems Validation

May 2013

This guidance document is designed to help very small meat and poultry establishments meet the initial validation requirements in 9 CFR 417.4. In particular, the guidance covers:

The difference between initial validation and ongoing verification;

How to identify scientific support documents;

What are critical operational parameters and how to identify them in the scientific support;

FSIS Guidance: HACCP System Validation

- Specific concerns:
 - Does the prerequisite program consistently prevent the occurrence of the hazard?
 - It does not if the establishment has not validated the prerequisite program and the establishment's supporting documents lack on-going, meaningful verification of the prerequisite program.

FSIS Guidance: HACCP System Validation

- Validation has two parts
 - Scientific and technical support for the HACCP system.
 - The initial practical in-plant demonstration proving the HACCP system can perform as expected.

FSIS Guidance: HACCP System Validation

- Scientific support is theoretical principles, expert advice from processing authorities, scientific data, peer reviewed journal articles, regulatory requirements, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately address specific hazards.
- FSIS does not advocate the introduction of pathogens in the plant environment.

Supporting Documentation

- **Supporting Documentation Identifies**
 - the hazard
 - the reduction of the hazard
 - the critical operational parameters
 - the steps in the process where the reduction occurs
 - how those steps will be monitored

Supporting Documentation

A challenge or inoculated pack study

The documentation on file should specify:

- the level of pathogen reduction, elimination or growth control,
- describe the process, including all critical parameters affecting the reduction or elimination, and
- the source of the documentation

Data gathered in-house

- Used if the establishment could not implement the process as documented in the literature within its processing environment
- Documentation used for in-plant validation should contain information from all the tests performed and results

Corporations and Design & Execution

In a corporation, one plant may gather data to validate a process and share the validation data with other plants in the company.

The plant where the data was gathered meets both the Design and Execution parts of validation

The other plants still need to demonstrate that the results of the validation studies will function in their facilities.

Regulatory performance standards

- Defined in the Code of Federal Regulations
 - 381.150(a)(1) Lethality – A 7-log reduction of Salmonella
 - 318.150(a)(2) Stabilization – No more than 1-log increase in the growth of Clostridium perfringens and no multiplication of toxigenic microorganisms such as Clostridium botulinum

Regulatory performance standards

- Incomplete validation would include:
 - Documentation of a specified log reduction but does not include information about critical parameter to achieve the reduction
 - Having a validated process on file but not following the process
 - Validating a process for a specific log reduction in a product other than meat and poultry

Initial In-Plant Validation

In-plant observations, measurements, microbiological test results, or other information demonstrating that the control measures, as written into the HACCP system, can be implemented with a particular establishment to achieve the process's intended result.

Initial In-Plant Validation

- First is to identify critical operational parameters
- Establishment should gather operational data during the initial 90 validation period to demonstrate the establishment can achieve the values set forth in the scientific supporting documentation.
- The establishment needs to collect enough data to support that the process can operate effectively on a daily basis and
- demonstrate that the collection of interventions (CCPs) and process steps together, in sequence, produce a safe, wholesome and unadulterated product.

Demonstrating Effectiveness of HACCP System

- Micro data can provide information that the various interventions can achieve the desired log reduction,
- The plant may also map data at each intervention.
- An establishment must also support why microbiological testing data is not needed to demonstrate the effectiveness of its HACCP system.

Validation Records

- The scientific support and initial in-plant validation data should be kept on file as part of 9 CFR 417.5(a)(2) for supporting documentation records.
- Establishments using existing HACCP Systems developed prior to the 2013 Guidelines that do not have the documents from their initial validation will need to gather data according to the timelines FSIS will set out in the Federal Register. (e.g., 90 days of data)

Validation Record Example

Validation Summary Document					
				Validation	
Product	Hazard	Process	Critical Operational Parameters	Supporting Documents	In Plant Supporting Documents
Chicken	Salmonella	Wash System with antimicrobial	PSI Temperature Nozzle Performance	<ul style="list-style-type: none"> • FSIS Guidelines • FSIS Directive on Fecal • FSIS Directive on Sanitary Dressing • Supplier Validation Study • Initial validation study by the plant • FSIS SIP Approval 	<ul style="list-style-type: none"> • Verification Documentation of plant performance • Zero Fecal CCP checks • Microbial mapping of generic E. coli in slaughter • Before and After Testing of birds using APC

Validation Record Example

		Validation Summary Document			
				Validation	
Product	Hazard	Process	Critical Operational Parameters	Supporting Documents	In Plant Supporting Documents
Turkey Deli Breast	Listeria	Hot Water Pasteurization	Belt Speed Water Temperature	Muriana et al, JFP, 2002, Post package Pasteurization of RTE Deli Meats by Submersion Heating for Reduction of Lm	Verification Documentation of plant performance CCP checks Product Testing

Reassessment 9 CFR 417.4(a)(3)(i).

- Annually or changes in:
 - raw materials or source of raw materials;
 - product formulation;
 - slaughter or processing methods or systems;
 - production volume;
 - personnel;
 - packaging;
 - finished product distribution systems; or,
 - the intended use or consumers of the finished product.

Resources

**FSIS Compliance Guideline
HACCP Systems Validation Draft
April, 2012**

**FSIS Compliance Guideline
HACCP Systems Validation
May 2013**

Principle 7

- Establish Record-Keeping and Documentation Procedures
- Records:
 - Written evidence through which an act is documented.

Records

- The record-keeping program should be viewed as a benefit rather than a burden.
 - Records are the only references available to trace the production history of a finished product.
 - Can be used as a tool to alert the operator to potential problems before they lead to the violation of a critical limit.
 - Records can serve as evidence that proper procedures are being followed.

Required HACCP Records

- Implementation of SSOPs
- Summary of the hazard analysis
- The HACCP plan
- Support documentation
 - Establishment of CCPs, CLs, monitoring procedures, corrective action procedures, and verification procedures
- Daily operational records
 - Monitoring records, corrective action records, verification records

Records Shall Include

- Name (& location) of the processor
- Date and time of the activity
- Signature of the person performing the operation or creating the record
- Where appropriate, the identity of the product and production code.
- The records shall contain the actual values and observations obtained during monitoring.

Retention of Records

- HACCP records must be retained for a specified time (USDA and FDA requirement)
 - One year
 - Perishable or refrigerated products
 - Two years (or shelf life of the product, if longer)
 - Frozen, preserved, or shelf-stable products

Regulatory Access to Records

- FDA regulators and inspectors have access to HACCP records.
- Proprietary non-HACCP information normally is not available to the regulatory agencies.