SAN BERNARDINO COUNTY

Public Health
Environmental Health Services

Manual for the Preparation of Hazard Analysis and Critical Control Point (HACCP) Plans

MANUAL FOR THE PREPARATION OF HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) PLANS

OVERVIEW

USDA

This manual was adapted from the United States Department of Agriculture (USDA) Guidebook for the Preparation of Hazard Analysis and Critical Control Point (HACCP) Plans. Specifically, from the Food Safety and Inspection Service (FSIS)

Purpose

This manual and the generic HACCP models are intended for new and prospective owners and operators of small and very small meat (including *Siluriformes* fish and fish products), poultry, and processed egg product establishments.

The guidebook:

- Clarifies the Code of Federal Regulations (CFR) 9 CFR Part 417 HACCP Systems requirements, and
- Provides guidance on how establishments might develop HACCP Plans that meet those requirements.

What is the law regarding this manual?

Establishments must comply with the 9 CFR Part 417 requirements. These regulations are included as text in this document and are available via govinfo.gov. No new requirements are presented in this manual.

The guidance provided on how to develop a HACCP Plan represents practices that the Food Safety and Inspection Service (FSIS) recommends based on scientific and practical considerations. The methods, practices and forms used to demonstrate HACCP Plan development are not required.

Establishments may choose to use approaches not demonstrated in the guidebook and the guidance does not have the force and effect of law.

Questions

For questions, use the search field in the USDA Food Safety and Inspection Service website.

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Contents

The following topics are in this guide.

INTRODUCTION TO HACCP

What is HACCP?

Hazard Analysis and Critical Control Point (HACCP) is a scientific system for process control that has long been used in food production. It prevents food safety problems by applying controls at identified points in a food production process at which hazards can be:

- Prevented,
- Controlled,
- Eliminated, or
- Reduced to acceptable levels.

Note: HACCP requirements for poultry and meat products can be found in Code of Federal Regulations (CFR) 9 CFR Part 417.

Components of an HACCP system

An effective HACCP system includes:

- A HACCP Plan,
- A hazard analysis,
- Supporting scientific documentation,
- Sanitation Standard Operating Procedures (Sanitation SOPs), and
- Any prerequisite programs that comply with regulatory requirements and prevent adulteration of a product.

Why HACCP is important

Preventing contamination by these hazards is key in reducing the number of:

- Deaths,
- Illnesses,
- Recalls, and
- Injuries linked to meat and poultry products.

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The PR/HACCP rule

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) published its final rule on Pathogen Reduction; HACCP Systems (PR/HACCP) (Federal Register Code 61 FR 38806) on July 25, 1996.

The PR/HACCP rule requires meat and poultry establishments to prevent or:

- Eliminate contamination of meat and poultry products with disease-causing, that is, pathogenic bacteria, and
- Reduce to an acceptable level, contamination with other biological, chemical, and physical hazards.

Sanitation SOPs

The PR/HACCP rule requires each establishment to develop and implement written sanitation standard operating procedures (SOPs).

In the appendices to the PR/HACCP rule, the Agency provided guidance on how individual establishments may develop their Sanitation SOPs.

Definitions

Corrective Action - Action to be taken when a deviation or unforeseen hazard occurs.

Critical Control Point (CCP) - A step in a food production process at which a control can be applied to prevent, eliminate, or reduce a food safety hazard to acceptable levels.

Critical Limits - Parameters that indicate whether the control measure at a CCP is in or out of control. Physical, biological, or chemical hazards must be controlled at a CCP within a maximum or minimum value or range, i.e., limit, to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Deviation - Failure to meet a critical limit.

Flowchart - A flow chart is a simple schematic, graphical, or text representation of the process that an establishment uses to produce the product.

Food Safety - Handling, preparing, and storing food in a way that best reduces the risk of individuals becoming sick from foodborne illnesses.

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Definitions, continued

Food Safety Hazard - Any biological, chemical, or physical property that may cause food to be unsafe for human consumption.

Good Manufacturing Practices (GMPs) - A written prerequisite program addressing minimum operational conditions and providing the foundation of a HACCP system.

HACCP System - The HACCP system is defined as the HACCP Plan in operation, including the HACCP Plan itself. The HACCP Plan in operation includes hazard analysis, any supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records.

Hazard - (see Food Safety Hazard)

Initial Validation - (design) is the scientific or technical support for the HACCP system design. It includes the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen-modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards (9 CFR 417.4 (a)(1) and 9 CFR 417.5(a)(1)).

In-Plant Validation - Execution is the in-plant observations, measurements, microbiological test results or other information demonstrating that the control measures in the HACCP system can perform as expected to achieve the intended food safety objective (9 CFR 417.4 (a)(1).

On-Going Verification - Activities such as calibration, direct observation, and review of records as well as other independent checks such as testing designed to ensure the HACCP system is functioning as intended on an ongoing basis.

Prerequisite Programs - Specific activities and procedures that are part of the HACCP system and chosen/developed during a hazard analysis to prevent a hazard from occurring in the production process. An establishment may determine that a hazard is not reasonably likely to occur because the implementation of a prerequisite program prevents the hazard from occurring.

Preventive Measure - Physical, chemical, or other means that the establishment can use to control food safety hazards reasonably likely to occur in the production process.

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Definitions, continued

Reassessment - A re-evaluation of the HACCP system in response to situations that may affect either the effectiveness of the HACCP system or the establishment's ability to carry it out. HACCP Plans must be reassessed annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP Plan, including but not limited to change of equipment, ingredients, or process.

Responsible Establishment Official - An individual with overall authority onsite at an establishment or a higher-level official there.

Step - A step is a point or activity in an operation within the production process that is essential to the proper production of the finished product.

Validation - This is the process of demonstrating that the HACCP system as designed can adequately control potential hazards to produce a safe, unadulterated product.

DEVELOPING A HACCP PLAN

Introduction

FSIS developed generic HACCP models for each process category which establishments can reference when developing their HACCP Plans.

An establishment must tailor the plan to suit the specific circumstances of its own products and production processes and meet the FSIS validation and verification requirements.

Resources

FSIS has several resources about HACCP development and implementation available to establishments:

1. askFSIS has an online search tool for establishments to research questions or ask their own questions about HACCP development and implementation. Submitted questions are directed to expert personnel in accordance with FSIS Directive 5620.1.2
2. FSIS has established HACCP contacts in each of the states, to which establishments can direct specific questions. State HACCP Contacts and Coordinators provide technical advice, assistance, resources, and conduct activities to support HACCP implementation in small and very small plants.
3. FSIS Compliance Guideline HACCP Systems Validation: This guidance document is designed to help very small meat and poultry establishments meet the initial validation requirements in the Code of Federal Regulations (CFR) 9 CFR 417.4
4. Small and Very Small Plants resource webpage and the Small Plant Help Desk: 1-877-374-7435
5. FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products
6. FSIS Guideline for Label Approval: this general site for FSIS labeling has information on generic versus special approval, standards of identity, label submission and approval system, etc.

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DEVELOPING A HACCP PLAN, Continued

Preliminary steps

Examples of Preliminary Steps to create an HACCP Plan are:

- Develop Fundamental Prerequisite Programs,
- Assemble the HACCP Team, including at least one person who is trained in HACCP,
- Describe the food and methods of producing and distributing the product,
- Develop and verify process flow charts, and
- Decide how products can be grouped using the process categories in 9 CFR 417.2(b)(1).

Develop fundamental prerequisite programs

Fundamental prerequisite programs in a food safety system describe the specific activities of an establishment used to support decisions made in the hazard analysis. These programs become part of the HACCP system.

Prerequisite programs may be:

- Regulatory requirements known prior to starting a HACCP Plan, or
- Developed as an establishment conducts its hazard analysis and determines that added controls are needed to ensure food safety parameters.

Examples of programs

Examples of fundamental prerequisite programs may include:

- Good Manufacturing Practices (GMPs),
- Standard Operating Procedures (SOPs),
- Raw material controls such as:
  - Receiving and storage,
  - Certificates of analysis from suppliers,
  - Purchase specifications, and
  - Residue control sampling, etc.
- Rework control,
- Sanitation SOPs (9 CFR 416.12-17),
- Preventive maintenance, such as:
  - Employee hygiene,
  - Chemical control and storage,
  - Allergen control,
  - Pest control,
- Traceability and recall, and
- Listeria monocytogenes (Lm).

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DEVELOPING A HACCP PLAN, Continued

Food safety culture

Prior to assembling a HACCP Team, the establishment must fully embrace a food safety culture that places value on:

- Attitudes,
- Practices, and
- Education of its employees.

Encouraging a food safety culture

Establishments can encourage a food safety culture by:

- Engaging employees in food safety practices,
- Empowering employees to speak up when they observe food safety issues,
- Reinforcing food safety during work meetings, and
- Offering continuous food safety training.

Questions to ask

To assess the food safety culture in an establishment, ask questions like:

- What would employees do if a CCP monitoring check fails?
- Are employees empowered to speak up?
- Are all employees trained in food safety?
- Are employees rewarded for positive food safety behaviors?
- Do employees feel food safety is part of the work environment?

HACCP Team expertise.

FSIS encourages establishments to assign more than one person to develop a HACCP system. The HACCP Team will have different areas of expertise, such as:

- Production,
- Processing,
- Maintenance,
- Sanitation,
- Management,
- Quality,
- Safety, and
- Marketing, etc.

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DEVELOPING A HACCP PLAN, Continued

Assemble the HACCP Team

To assemble a HACCP, consider the following:

If an establishment has...	Then...
Only a few employees,	All of them may need to be on the HACCP Team because they have multiple roles and responsibilities in the establishment's operations.
Limited internal expertise	Consider using outside resources which have expertise in HACCP such as: • Experts from trade associations, • HACCP consultants, • State HACCP coordinators, or • Local college or university extension offices.

Team member trained in HACCP

One resource that **must be included** is someone trained in HACCP in accordance with the requirements of 9 CFR 417.7(b). This individual does:

- Not need to be a company employee, but
- Need to be available for HACCP Plan development and certain other functions such as reassessing the HACCP Plans.

Note: Staff may obtain HACCP training online, through local university extension offices or trade organizations.

HACCP Team responsibility

A HACCP Team's most important responsibility is to:

- Gain and maintain the support of management for developing a sound HACCP Plan and its ongoing commitment to food safety, and
- Commit to never waver from producing and distributing safe food and good manufacturing practices (GMPs) are an important part of that commitment).

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HACCP Team responsibility, continued

The food safety pyramid.

Describe the food and methods of producing and distributing

The next preliminary step is to have the HACCP Team describe:

- The establishment's products and ingredients, and
- Methods of production, distribution and intended use of the product.

Optional worksheets are found in the appendix to help ensure that all the information is included.

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Product description

Briefly describe the product, packaging, storage, distribution and intended use.

Answer the following questions in the description.

1. What are the products' common and usual names?
2. What is the product's composition, including water activity (a_w), pH, etc., if those apply? Is it ready-to-eat or not ready-to-eat?
3. Where will the product be sold? Who is the intended consumer (especially important if at-risk populations are involved, such as school children, nursing home residents, hospital patients, etc.)?
4. What is the finished product's intended use, for example: for further processing at USDA establishments, for institutional use only, for retail sale to end-use consumer, etc.?
5. What is the packaging's durability? What are the storage conditions, for example, temperature control?
6. What is the product's expected shelf life? At what temperature?
7. What special labeling statements are needed, e.g., allergen warning, animal production claims, or gluten free?
8. What special distribution controls are needed during distribution, for example temperature control?

Product ingredients

It is necessary to list the products:

- Ingredients,
- Packaging material, and
- Incoming raw materials (see optional worksheet List of Product Ingredients and Incoming Material).

After staff has identified the products as described in Product Description and List of Product Ingredients and Incoming Material, they can continue to the next preliminary step.

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DEVELOPING A HACCP PLAN, Continued

What to consider

The establishment is to consider whether any biological, chemical, or physical food safety hazards are related to the activities at each step (9 CFR 417.2(a)(2)).

Develop and verify process flow charts

Each establishment must:

- Identify the steps that are essential to their operation, and
- Include each step on the flow chart.
  - The flow chart needs to be an:
    - ✓ Accurate,
    - ✓ Detailed, and
    - ✓ Clear sketch of the steps and processes involved in production.

Developing a flow chart

When the flow chart is developed:

- Observe how the establishment operates,
- Draft the flow chart,
- Walk the operation to verify the flow chart is correct, and
- Adjust the flow chart as needed.

Note: Multiple activities may be incorporated into one step as long as the **essential steps remain separated** to ensure a proper hazard analysis.

Verifying the flow chart

Verification is how inspection personnel and third-party auditors confirm a flow chart. To verify the flow chart is correct and includes all the steps in the correct order, staff must walk through the establishment's process.

Changes to the flow chart

If any part of the process changes after a HACCP Plan is completed, the flow chart must be adjusted, and the HACCP Plan is reassessed. Changes may include additional:

- Interventions,
- Processes,
- Steps, or
- Changes in raw material suppliers, ingredients, or equipment.

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Group products into process categories

9 CFR 417.2(b)(1) lists examples of nine process categories into which meat and poultry products can be grouped:

1. **Slaughter** – All species slaughtered: beef, swine, lamb, goat, and poultry.
2. **Raw product – non-intac**t; Examples include ground products, mechanically tenderized steaks.
3. **Raw product – intact**; Examples include sub-primal, whole muscle steaks, roasts, and chops.
4. **Thermally processed** – Commercially sterile in cans, jars, or pouches; examples include canned meat or poultry and prepared foods or entrees with meat or poultry.
5. **Not heat treated – shelf stable**; Examples include summer sausage and dry salami.
6. **Heat treated – shelf stable**; Examples include meat/poultry jerky and snack sticks.
7. **Fully cooked – not shelf stable**; Examples include hot dogs, roast beef, cooked ham, frozen entrees, and cooked chicken nuggets.
8. **Heat treated but not fully cooked – not shelf stable**; Examples include partially cooked patties and bacon.
9. **Product with secondary inhibitor – not shelf stable**; Examples include corned beef and cured beef tongue.

Products in the same process category

The HACCP system may control all the products in the same process category using a single HACCP Plan, if the processes are essentially the same.

The products in the same process category may be covered by the same HACCP Plan (9 CFR 417.2 (b)(2)), if the:

- Products differ only in characteristics that would not affect safety e.g. the amount or kind of seasoning used (hot vs. mild), and
- Food safety hazards, critical control points, critical limits and procedures listed in 9 CFR 417.2 (c) are the same,

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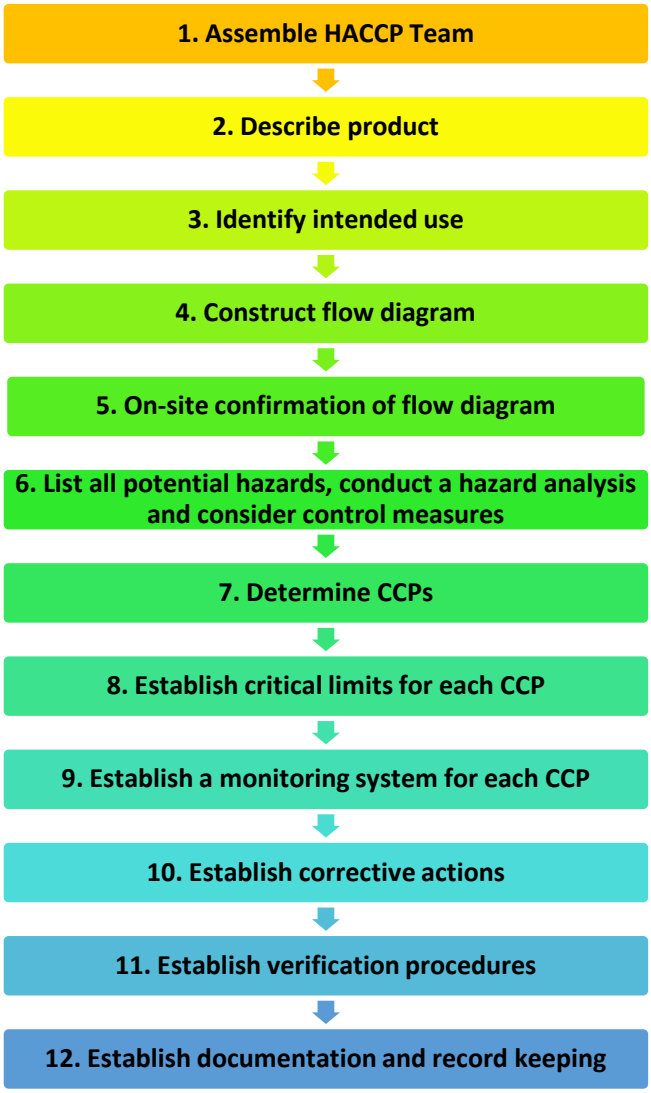
DEVELOPING A HACCP PLAN, Continued

Steps to completing a HACCP Plan

Staff applies the seven principles of HACCP (steps 6 through 12) and develops a HACCP Plan specific to the establishment.

The next seven sections of the guidebook cover the seven principles and the process of developing a HACCP Plan.



APPLYING THE SEVEN HACCP PRINCIPLES

The seven HACCP principles

The seven Hazard Analysis Critical Control Point (HACCP) principles are listed below and described in Code of Federal Regulations (CFR) 9 CFR 417.2 (c) and (d):

1. Conduct a Hazard Analysis,
2. Identify the Critical Control Points,
3. Establish Critical Limits for each Critical Control Point,
4. Establish Monitoring Procedures,
5. Establish Corrective Actions,
6. Establish Verification Procedures, and
7. Establish Recordkeeping Procedures.

Preparing a hazard analysis

9 CFR Part 417 contains definitions as well as specific provisions that affect how a HACCP Team must go about conducting its hazard analysis.

Before beginning the process, the HACCP Team reviews the definitions of **food safety hazard** and **preventive measure**, specifically the requirements in 9 CFR 417.2(a).

Conducting a hazard analysis

Conducting a hazard analysis is a two-step process.

Step One

- Identify the potential hazards to human health, which might be introduced before, during, and after production.
- To ensure a safe product, include “before” and “after” production when conducting a hazard analysis.
- These potential **hazards** are grouped into three categories:
  - Biological (including microbiological),
  - Chemical, and
  - Physical.

Step Two

Identify existing controls for those hazards. Helpful tools and resources are the FSIS:

- Meat and Poultry Hazards and Controls Guide,
- Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants, and
- Compliance Guidelines for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products.

BIOLOGICAL HAZARDS

What is a biological hazard?

Biological hazards are living organisms that can make food unsafe to eat which include:

- Bacteria,
- Parasites, and
- Viruses.

Proteinaceous infectious particles or prions, such as those associated with Bovine Spongiform Encephalopathy (BSE), may be included in this category.

Beef hazards

Depending on how beef slaughter/processing establishments deal with Specified Risk Material (SRM), establishments may refer to prions as biological or physical hazards.

Meat and poultry hazards

There is a great deal of concern about microbial hazards associated with meat and poultry products because they have been implicated in several disease outbreaks.

Biological hazards are frequently associated with livestock/birds and may be introduced to food (contamination):

- By people during processing of meat and poultry products,
- Through equipment, other ingredients, and/or
- Through the processes themselves.

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BIOLOGICAL HAZARDS, Continued

Pathogens

Major pathogens that may be associated with meat and poultry products include:

- Salmonella,
- Campylobacter,
- Shiga Toxin-Producing Escherichia coli (STEC)
  - Including the seven major STEC serogroups O157:H7, O26, O45, O103, O111, O121 and O145,
- Listeria monocytogenes,
- Clostridium botulinum, and
- Yersinia enterocolitica.

The sources for these pathogens are:

- Healthy animals that may shed these bacteria in their feces, and
- While dressing the carcasses during the slaughter process, bacteria may be transferred from the hide and offal to the carcass causing contamination.

Potential hazards of raw products

When producing raw products, the potential hazards are the:

- Cross-contamination of contaminated parts with non-contaminated parts, and
- Outgrowth of pathogens as they may be present in very small numbers.

Cross-contamination

Cross-contamination and pathogen outgrowth must be considered in the hazard analysis for:

- Processing,
- Storage,
- Thawing, and
- Any step where conditions may allow proliferation of pathogens.

Common biological hazards

Common biological hazards associated with certain meat and poultry products:

- Listeria monocytogenes – Post-lethality exposed Ready-to-Eat products. Examples are hot dogs and cold cuts.
- E. coli O157:H7 and STECS – **R**aw product, ground or intact, intended for non-intact use
- Salmonella – Raw and RTE poultry, beef, Siluriformes fish, and pork
- Campylobacter – Raw poultry
- Staphylococcus aureus enterotoxin – Dry sausage, jerky

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BIOLOGICAL HAZARDS, Continued

Controls for biological hazards

Controls for biological hazards include:

- Good manufacturing practices,
- Sanitation procedures,
- Employee hygiene, separation of not-ready-to-eat spaces and ready-to-eat spaces,
- Microbial interventions, and
- Post lethality pasteurization techniques.

Ready-to-eat products

Ready-to-eat products are not cooked before they are consumed. Therefore, the presence of a few pathogens may cause illness including:

- Salmonella,
- E. coli O157:H7, and
- Listeria monocytogenes.

Swine slaughter establishments

To demonstrate effectiveness of written procedures to prevent contamination using the Hazard Analysis Critical Control Point (HACCP) system, swine slaughter establishments are required to:

- Sample for microbial organisms, and
- Analyze results at prescribed locations and frequencies to assess the establishment's ability to maintain process control.

NSIS

Establishments operating under the New Swine Slaughter Inspection System (NSIS) must ensure that market hogs are sorted from swine going to slaughter which exhibit signs of:

- Moribundity (near death),
- Central nervous system disorders, or
- Pyrexia (high body temperature).

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Contamination prevention

To prevent contamination throughout the slaughter and dressing operation (9 CFR 381.65(g)), all poultry slaughter establishments, except for establishments that slaughter ratites, are required to:

- Develop,
- Implement, and
- Maintain written procedures.

At a minimum, these procedures must include:

- Sampling and analysis for microbial organisms at prescribed locations, and
- Frequencies to monitor the establishment's ability to maintain process control for prevention of contamination with:
  - Enteric pathogens (e.g., Salmonella and Campylobacter), and
  - Fecal material.

NPIS

Establishments operating under the New Poultry Inspection System (NPIS) are responsible for removing poultry carcasses from production exhibiting conditions that may carry pathogens capable of causing human illness, such as:

- Septicemia/Toxemia (Sep/Tox),
- Tumors, and
- Airsacculitis.

The spread of pathogens

Pathogens may reside in fecal material, both in the gastrointestinal tract and on the exterior surfaces of the animal going to slaughter. In livestock slaughter establishments, the primary avenues for the spread of pathogens are:

- Contamination of carcasses and parts from feces,
- Ingesta, and
- Milk.

Contamination through mammary glands

Lactating mammary glands and diseased mammary glands of livestock may contain pus or other objectionable material.

- When milk comes in contact with the carcass, the contaminated parts must be trimmed off.
- The edible portions can become contaminated with bacteria; the organisms may be spread from carcass to carcass or by other means.

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Zero tolerance

FSIS enforces a “zero tolerance” standard for:

- Visible fecal material,
- Ingesta, or
- Milk on livestock carcasses and parts at the time of inspection.

Note: The hazards above must be addressed in the hazard analysis (9 CFR 310.18(a)).

CHEMICAL HAZARDS

Introduction

Chemical and drug residues outside of limits established by the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) also represent food safety hazards.

Chemical hazards may also be the result of something:

- Naturally occurring in foods,
- Used,
- Added during the processing of foods, or
- Administered to live animals.

Naturally occurring chemical hazards

Naturally occurring chemical hazards can occur as the result of storage conditions for some products, for example, the mycotoxins produced by certain types of molds (fungi).

Molds that can produce mycotoxin grow on numerous foodstuffs. Aflatoxins are a mycotoxin and are produced by the fungi *Aspergillus. Aspergillus* can affect:

- Corn,
- Wheat,
- Soybeans,
- Spices, and
- Tree nuts.

Note: Other chemical hazards are sometimes associated with the product itself, such as mercury in fish.

Chemicals during processing

Food ingredients or chemicals used during processing can become a source of chemical hazards. This includes the unapproved use or amounts of preservatives such as:

- Sulfites,
- Nitrites/nitrates,
- Certain processing aids, such as antimicrobial interventions,
- Colors,
- Dyes, or
- Water additives.

Note: For more information on substances and usage levels during production refer to the FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat , Poultry and Egg Products webpage.

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Allergens

Certain foods, or food ingredients which cause allergic reactions in some people are to be considered as potential chemical hazards.

Proteins in these foods or food ingredients have been shown to cause and adverse immunologic reaction in some sensitive individuals.

Common ingredients with allergens

Eight of the most common foods that contain allergens causing allergic reactions include:

- Peanuts,
- Soybeans,
- Tree nuts,
- Eggs,
- Milk,
- Crustacea (shellfish),
- Fin fish, and
- Wheat.

Labels

Establishments are required to declare all ingredients on the label if they are included in the product formulation (Per Code of Federal Regulations (CFR) 9 CFR 317.2 and 381.118).

If allergens are not declared, the product is considered adulterated and misbranded.

Note: For detailed guidance related to control of allergens, refer to the FSIS Compliance Guidelines Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling.

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Other chemical hazards

Other chemical hazards are those which are sometimes unintentionally added to food during the:

- Growing,
- Harvesting,
- Storage,
- Processing,
- Packaging, or
- Distribution phases of production.

This group of chemical hazards is very broad and might include:

- Components of animal feed or drinking water,
- Animal drugs,
- Pesticides, or
- Chemicals used in the processing establishment such as:
  - Lubricants,
  - Cleaners,
  - Sanitizers,
  - Paints, and
  - Coatings.

PHYSICAL HAZARDS

What is a physical hazard?

A physical hazard is a physical component of a food that is unexpected and may cause injury to the person consuming the product, such as choking or cuts to the mouth or throat. These include:

- Glass,
- Metal,
- Bone in a boneless product, or
- Plastics.

On occasion, the potential physical hazards below can be found in meat and poultry because:

- A process or a piece of equipment was not properly maintained/controlled.
- Poor food-handling practices such as below falling into products while an employee is troubleshooting equipment:
  - Jewelry,
  - Gloves,
  - Packaging material/plastic,
  - Tools, or
  - Machine parts.

Contributors

There are several situations that can contribute to physical hazards in foods, including:

- Contaminated raw materials,
- Poorly designed or poorly maintained facilities and equipment,
- Contaminated packaging,
- Materials, and
- Poor food handler hygienic practices.

Controls

Controls of physical hazards include:

- Procedures for visual observations,
- Sanitation,
- Product handling SOP,
- Good manufacturing practices for maintenance and inspection, and
- Foreign material detection.

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Food defense plans

FSIS strongly encourages establishments to develop Food Defense Plans in the event an employee *intentionally* Contaminates a product to do harm to a company, its employees or the public.

Reference: FSIS Food Defense and Emergency Response and FSIS Developing a Food Defense Plan for Meat and Poultry Slaughter and Processing Plants.

PRINCIPLE 1: HAZARD ANALYSIS PROCESS

Introduction

To identify hazards associated with the production process at each step, the Hazard Analysis Critical Control Point (HACCP) team may:

- Conduct a brainstorming session.
- Use the flow diagram and product description created during the preliminary steps.

Worksheet

Attachment four is an optional worksheet with questions that could help staff consider hazards associated with the process and identify appropriate control measures.

Consider each process step in the flow chart. List any:

- Biological,
- Chemical, or
- Physical hazards introduced, controlled or enhanced at that step.

For example, if there are no hazards identified at the increased pathogen growth step, write “none”.

Hazard identified

If there is a biological, chemical or physical hazard identified, decide whether those hazards are reasonably likely to occur (RLTO) in the product or process and indicate “yes” or “no”.

For either answer, briefly write a justification for the decision and refer to any relevant supporting documents.

RLTO

When determining whether a hazard is RLTO, it is recommended but not required to list the actual hazard or organism of concern.

Examples of hazards include:

- Physical: metal contamination from equipment,
- Chemical: allergen (soy), and
- Biological: salmonella, Escherichia coli O157:H7 or other specific pathogenic hazards or a specific residue that is known to occur in a similar product.

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Control measures

List the control measures that can be used to:

- Control,
- Reduce to acceptable levels, or
- Eliminate the hazard.

If a hazard is RLTO, a critical control point is required at that step or a later step in the process. More than one:

- Preventive measure may be needed to control a food safety hazard, and
- Food safety hazards may be controlled by a specific preventive measure.

Documentation

Supporting documentation for the HACCP Team's decisions and justifications during the Hazard Analysis are an important part of the regulatory requirement of documentation in Code of Federal Regulations (CFR) 9 CFR 417.5(a)(1).

The following must be physically maintained as part of the decision-making process as supporting documentation:

- Historical records,
- Documentation,
- Other information about the process, or
- A summary of the information collected during the process known as initial validation.

The process described in the supporting technical and scientific documentation must closely match the establishment's actual process.

Decisions

Decisions for the HACCP system design can be made using scientific or technical support, such as:

- Theoretical principles,
- Expert advice from processing authorities,
- Scientific or technical data,
- Peer-reviewed journal articles,
- Pathogen modeling programs, or
- Other information demonstrating that process control measures can adequately:
  - Prevent,
  - Reduce, or
  - Eliminate specific hazards.

Continued on next page

Validating decisions

The process described in the supporting technical and scientific documentation must closely match the establishment's actual process.

A summary of the information collected during the process known as initial validation is part of the supporting documentation for the team's decisions.

Historical data

Historical data from the prerequisite program must show that the identified hazard is prevented from occurring or reduced to an acceptable level on an ongoing basis when the program is followed.

For example, an establishment may conclude that:

- Pathogen growth is not reasonably likely to occur in its raw intact products because it maintains and documents a prerequisite program for temperature control, or
- Producing cooked, ready-to-eat chicken nuggets means *Listeria monocytogenes* is not reasonably likely to occur because it follows well-designed Sanitation SOPs that include environmental and product testing programs (9 CFR Part 430).

Validation of prerequisite programs

When relying on data from prerequisite programs as a basis for determining that an identified hazard is not RLTO then:

- The prerequisite program itself must be validated, and
- Staff must maintain records that the programs are consistently and continuously implemented as designed.

PRINCIPLE 2: IDENTIFYING CRITICAL CONTROL POINTS

What is a CCP?

A Critical Control Point (CCP) is a point, step or procedure in a food production process at which control can be applied and, as a result, food safety hazards can be:

- Prevented,
- Eliminated, or
- Reduced to acceptable levels.

Note: CCPs are to address food safety hazards only, not quality parameters.

Identifying CCPs

For each food safety hazard that is reasonably likely to occur, staff must identify a CCP to control the hazard either at:

- The step at which the hazard is identified, or
- A later step in the process.

For every decision made about whether to identify a CCP, staff must support the decision in the Hazard Analysis Critical Control Point (HACCP) plan by providing:

- Credible,
- Documented,
- Scientific, or
- Technical justification.

Applying CCPs

Subsequently, staff must find the critical points in the process at which those preventive measures must be applied using Attachment 4 (optional worksheet).

For each "yes" listed in the RTLO column in Attachment 4, a CCP must be identified. The CCP must address the hazard at:

- That specific processing step, or
- A step later in the process.

Scientific support

All critical operational parameters should be incorporated into the prerequisite program when an establishment selects scientific support for its decision that a hazard is NOT RLTO (Code of Federal Regulations (CFR) 9 CFR 417.5(a)(1)).

Continued on next page

PRINCIPLE 2: IDENTIFYING CRITICAL CONTROL POINTS,
Continued

Common points of critical control

Common points at which critical control can be applied in the process include:

- Chilling to temperatures that minimize biological hazard (pathogen) growth,
- Cooking to specific temperatures for prescribed times to destroy pathogens,
- Cooling times and temperatures to prevent pathogen growth and toxin production,
- Product formulations, such as the addition of cultures or adjustment of pH or water activity to inhibit pathogen growth, and
- Sanitary dressing slaughter procedures and antimicrobial interventions to prevent or reduce the presence of pathogens.

Note: Different facilities preparing the same food can differ in the number and types of CCPs they choose to use.

Generic models

FSIS's generic HACCP models, as well as other generic models:

- Provide ideas about which CCPs might work in the various process categories, and
- Help the HACCP Team to think creatively and carefully about processes and how the HACCP system works.

Note: Attachment 5 is an optional worksheet that follows the NACMCF decision tree for making CCP determinations (Refer to the figure on next page).

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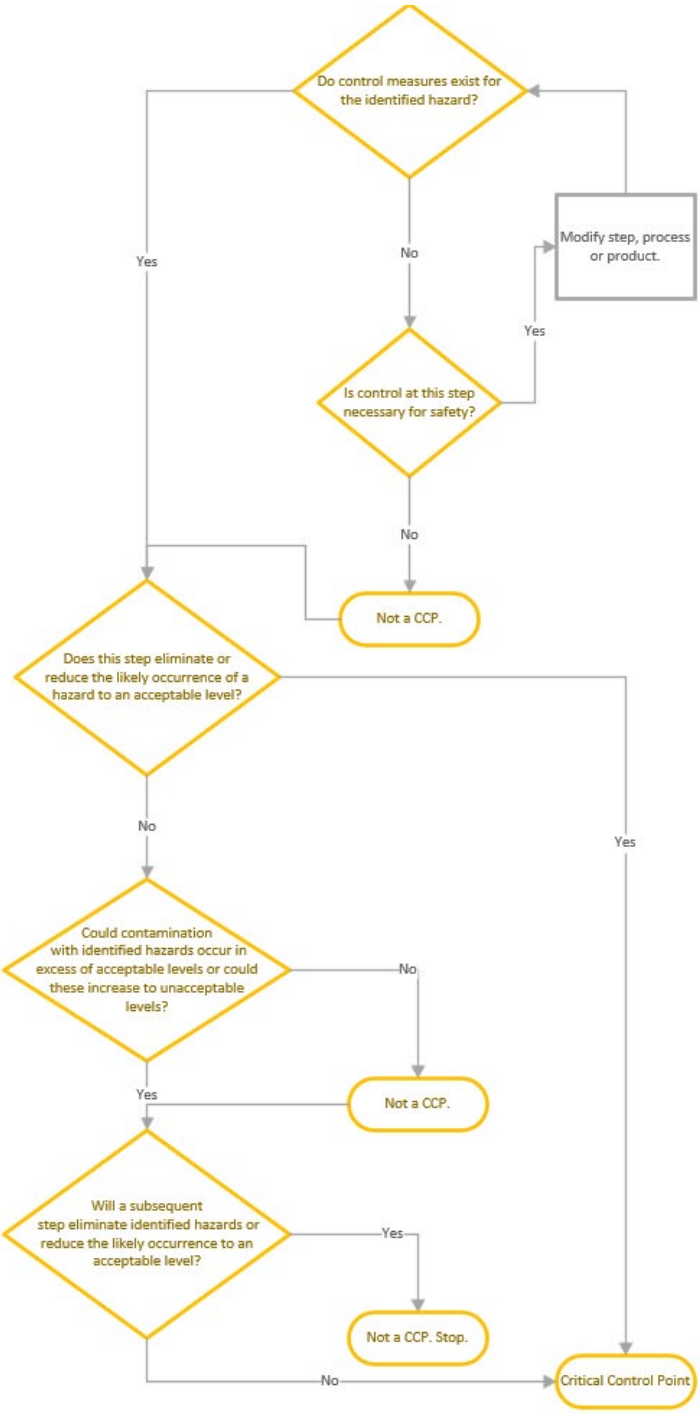
PRINCIPLE 2: IDENTIFYING CRITICAL CONTROL POINTS, Continued

Decision tree

The following is a decision tree for CCPs. Source: NACMCF, 1992.



PRINCIPLE 3: ESTABLISHING CRITCAL LIMITS

What is a critical limit?

The third Hazard Analysis and Critical Control Point (HACCP) Principle instructs staff to establish critical limits for each preventive measure carried out at each critical control point (CCP). This step involves establishing a criterion that must be met for each preventive measure associated with a CCP.

Some critical limits for identified CCPs have been established, either through regulatory requirements or through technical and scientific literature.

Examples of critical limits

Critical limits are safety boundaries for preventive measures and must be exact and specific when put in place at CCPs. Critical limit examples include:

- Reading or observation (e.g., temperature),
- Time (e.g. timeframe for cooking, cooling, etc),
- Product property (e.g., water activity), or
- Chemical property (e.g., available chlorine, salt concentration, or pH).

Guidance documents

Critical Limits **must be met** to maintain product safety.

The HACCP Team must become familiar with the guidance documents to help establish critical limits such as the:

- Minimum internal temperature and time to which products must be cooked, or
- Time elapsed while product is cooled to a specific temperature.

Continued on next page

PRINCIPLE 3: ESTABLISHING CRITCAL LIMITS, Continued

Determining critical limits

When deciding what the critical limits are, there are several sources to consider:

- The regulatory requirements that apply to the processes.
  - **These must be met** as required by Code of Federal Regulations (CFR) 9 CFR 417.2(c)(3) critical limits and 9 CFR 417.5(a)(3) recordkeeping.
  - For example, if producing cooked beef products, enact the critical limits that meet FSIS regulatory requirements for those products set out in 9 CFR 318.17.
- Scientific and technical information from studies or food processing textbooks.
- Specific research challenge studies or from recognized experts.
  - Staff are required to establish a critical limit for each preventive measure intended to apply at the CCPs, and
  - Adequately support the selection of the critical limit.

Upper and lower limits

A critical limit can be a(an)

- Upper limit, at which a set amount or level cannot be exceeded.
- Lower limit, at which a minimum amount is required to produce the safe effect.

Note: There may be instances in which there is both an upper and lower critical limit, that is, a range, such as nitrites that need to be above a specific limit to support a process, but do not exceed regulatory limits.

Examples of upper and lower limits

Below are examples of upper and lower limits:

- To address the hazard of pathogens in fecal material, the upper critical limit for a zero tolerance CCP is “no fecal material observed on the carcass.”
- An upper critical limit is a grinding room temperature of 50° F to control pathogen growth.
- A lower critical limit is the addition of an acidifier to inhibit bacterial growth; the acid concentration must reach a specific minimum level to be effective at inhibiting the pathogen.
- Antimicrobials often have an optimal effectiveness range for control of pathogens as described in scientific/technical research papers.
  - Antimicrobial usage *outside* of this optimal range – including above the range – may have a decreased effect on pathogens and not produce the desired effect.

Continued on next page

Stringency

Establishments may set target limits that are more stringent than the upper or lower limits set as “critical” limits.

For example, if a critical limit is to cook a product to an internal temperature of 155°F for 22 seconds, a higher target limit may be 160°F, this:

- Creates a safety margin as additional assurance that critical limits are met.
- Allows for the identification of trends that indicate potential deviations before an actual deviation occurs.

If an establishment uses a target limit, the establishment must be clear about which number is:

- The Critical Limit of the CCP, and
- A quality point.

Determining critical limits

When an establishment selects scientific support for:

- The development of its CCP and critical limits (9 CFR 417.5(a)(2)) then all of the critical operational parameters should be incorporated into the critical limits of the CCP to:
  - Prevent,
  - Reduce, or
  - Eliminate hazards.
- Its decision that a hazard is NOT reasonably likely to occur (9 CFR 417.5(a)(1)), then all of the critical operational parameters should be incorporated into the prerequisite program.

Time limited parameter

An establishment may determine that:

- Some of the parameters can be monitored on an ongoing basis as part of a prerequisite program.
- It only needs to ensure that *some* of the critical operational parameters are implemented – consistent with the support during the initial validation period.

Critical limits are included in a decision-making document but do not need to be monitored after the 90 days of initial validation unless there is a change to items such as:

- Spatial configuration,
- Equipment type, or
- Ingredient formulation.

PRINCIPLE 4: ESTABLISHING MONITORING PROCEDURES

What are monitoring procedures?

Monitoring procedures are procedures that are completed routinely, either by employees or mechanical means, to measure the process at any given Critical Control Point (CCP) and create a record for future use.

Monitoring procedures include observations or checks performed by:

- Employees (i.e. checking the documentation accompanying incoming materials), and
- Equipment (i.e. continuous recording thermometers).

Continuous and non-continuous monitoring

When continuous monitoring is not possible, the Hazard Analysis Critical Control Point (HACCP) team will determine:

- Non-continuous monitoring procedures,
  - Procedures must be performed often enough to reflect accurately that the process is under control,
- How frequently those procedures are performed, and
- What calibrated equipment is used for monitoring.

Note: Advice from experts in practical statistics and statistical process control is important in making decisions about monitoring frequency.

Corrective actions

When staff detect a deviation during monitoring, as set forth in the Code of Federal Regulations (CFR) 9 CFR 417.3, they must apply corrective actions to all the affected product. This includes all the product produced since the last recorded acceptable monitoring check.

For example, assume the monitoring procedure was to perform a cooking temperature check each hour, if the critical limit is not met, take corrective actions retroactively to the last acceptable check:

- The temperature check from an hour ago, or
- If the temperature was checked only once per shift, an entire shift's production would be held until corrective actions are taken.

Continued on next page

PRINCIPLE 4: ESTABLISHING MONITORING PROCEDURES,
Continued

Importance of monitoring

Due to the potentially serious consequences of loss of control, monitoring procedures must be:

- Well planned,
- Supportable, and
- Effective

Staff who monitor the CCPs must be trained in the techniques that are used to monitor each critical limit. They must fully understand:

- The purpose and importance of monitoring,
- How to accurately report monitoring activities and results as they occur, and
- The connection between their monitoring responsibilities and food safety.

Feedback

The HACCP Team must consider the need for rapid, real-time feedback when selecting the monitoring procedures and their frequency.

Physical and chemical procedures are preferred over microbial approaches.

Exact values

Staff performing monitoring must record exact values specified in code 9 CFR 417.2(c)(6).

For example, if the critical limit is a minimum internal temperature of 160°F, staff would record the exact temperature attained, rather than “yes/no” or “OK.”

Even when the monitoring procedure includes a sensory evaluation, such as a color change on litmus paper, the change must relate to a specific value.

Continued on next page

PRINCIPLE 4: ESTABLISHING MONITORING PROCEDURES,
Continued

Corrective actions

Staff are responsible for knowing which actions to take if critical limits are not met or if the results of their monitoring indicate that the process may be trending out of control.

The HACCP Team may use the Attachment 6 worksheet (optional) the to help decide:

- Monitoring procedures,
- The designated employee position to perform them, and
- How frequently they are performed.

Note: Employees who monitor a CCP will, whenever a Critical Limit is not met, immediately hold all affected product.

PRINCIPLE 5: ESTABLISHING CORRECTIVE ACTIONS

Establish corrective actions

Staff must establish which corrective actions to take when monitoring shows that there is a deviation from a critical limit. Section 9 CFR 417.3(a) of the Code of Federal Regulations (CFR) identifies the four features of corrective actions that FSIS regulators verify when a deviation from a critical limit occurs:

1. The cause of the deviation is identified and eliminated,
2. The Critical Control Point (CCP) is under control after the corrective action is taken,
3. Measures to prevent recurrence are established, and
4. No product that is injurious to health or otherwise adulterated due to the deviation enters commerce.

Deviations from critical limits

To ensure deviations do not lead to unsafe products in commerce a planned corrective action must be in place.

Questions to ask when developing corrective actions

For each CCP, staff are to create a standardized set of corrective actions that is followed when there is a deviation from a critical limit. Below are some questions to ask while creating the corrective actions:

- How are people informed when the deviation occurs?
  - If a person is performing the monitoring procedure, who do they contact?
- Who is responsible for controlling the product that may have been affected by the deviation?
  - How should the person who is controlling the product decide how much product needs to be controlled?
- Who is involved in deciding what to do about the product which might have been affected by the deviation?
- Who determines the cause of the deviation?
  - If technical experts outside the company are needed, how are they contacted?
- Once the cause of the deviation is found, who is involved in deciding how to get the process back in control and prevent the deviation from reoccurring?
- If the Hazard Analysis Critical Control Point HACCP-trained individual is not immediately available, how is HACCP expertise accessed to help decide if the plan needs modification?
  - Who in the company is required to sign off on any modifications to the plan?

Continued on next page

PRINCIPLE 5: ESTABLISH CORRECTIVE ACTIONS, Continued

Standardized actions for a deviation from a critical limit, continued

- Who is responsible for keeping the records of everything done in response to a deviation from a critical limit at this CCP?
  - If the individual(s) responsible in the corrective action plan is not available, who is the back-up?
  - Is this set of corrective actions feasible at all times?
- How will the reoccurrence be prevented in the future?

Note: Employees responsible for monitoring and other functions will be identified by title and not by name in the corrective actions to allow for appropriate substitutions when they are not available.

PRINICPLE 6: ESTABLISHING VERIFICATION PROCEDURES

Introduction to verification

To verify that the Hazard Analysis Critical Control Point (HACCP) system is working effectively and how often these actions are performed, decide which procedures the establishment performs.

The HACCP system is evaluated to confirm that it follows the HACCP Plan or if the HACCP Plan requires modification, verification uses:

- Methods,
- Procedures, or
- Tests in addition to those used in monitoring.

The three aspects of verification include:

1. Initial Validation,
2. Ongoing Verification, and
3. Reassessment.

Initial validation

Validation is the collection and evaluation of scientific and technical information to determine if the HACCP Plan, when properly implemented, will effectively control the hazards.

During this HACCP Plan validation period, the establishment repeatedly tests:

- The adequacy of the Critical Control Points (CCPs),
- Critical limits,
- Monitoring and recordkeeping procedures, and
- Corrective actions detailed in the HACCP Plan.

Continued on next page

PRINICPLE 6: ESTABLISHING VERIFICATION PROCEDURES,
Continued

2 step validation process

The FSIS Compliance Guideline HACCP Systems Validation April 2015 describes the process as two steps:

1. Design, and
2. Execution.

- **Design of the HACCP Plan** is scientific or technical support for the HACCP system design:
  - The theoretical principles,
  - Expert advice from processing authorities,
  - Scientific or technical data,
  - Peer-reviewed journal articles,
  - Pathogen modeling programs, or
  - Other information demonstrates that process control measures can adequately prevent, reduce, or eliminate specific hazards.
- **Execution of the HACCP Plan** is the:
  - In-plant validation data,
  - The in-plant observations,
  - Measurements,
  - Microbiological test results, or
  - Other information demonstrating the control measures in the HACCP system can perform as expected within a particular establishment to achieve the intended food safety objective.

Note: These supporting validation documents are critical to the success of the HACCP Plan and must be kept for the life of the plan.

Validation guidelines

Validation compliance guidelines recommend that establishments use the critical limits from the underlying study instead of using the university extension publications.

Extension publications:

- Often do not include all the critical operational parameters that establishments need to implement, and
- Use journal articles which must be referenced.

Continued on next page

PRINICPLE 6: ESTABLISHING VERIFICATION PROCEDURES, Continued

Ongoing verification

Ongoing verification ensures that the HACCP Plan is working effectively on a day-to-day basis after initial validation is completed.

This type of verification includes tasks such as:

- Calibrating monitoring instruments,
- Observing monitoring activities and corrective actions,
- Reviewing HACCP records to ensure they are used and kept according to the plan,
- Monitoring critical limits and parameters of prerequisite programs to ensure that the critical operational parameters in the scientific support continue to be met, and
- Testing for appropriate pathogens or other microorganisms.

Note: Title Code of Federal Regulations (CFR) 9 CFR 417.4(a)(2) includes specific regulatory requirements regarding ongoing verification:

Validation vs. verification

Often the concepts of verification and validation get confused. Ask the following questions to maintain a correct understanding of each of them when developing and operating a HACCP Plan**:**

- **Validation** asks: Are we doing the correct thing?
- **Verification** asks: Are we continuing to do those correct things correctly?

Attachment 7

Use Attachment 7 (an optional worksheet) to record ongoing verification procedures, including observing monitoring activities and calibration activities.

Example:
Verification (log/record) that a thermometer used for a temperature control CCP was calibrated. A documented program should detail the frequency of calibration and the thermometer calibration procedure.

Continued on next page

PRINICPLE 6: ESTABLISHING VERIFICATION PROCEDURES,
Continued

Reassessment

Reassessment is similar to validation in that it considers, in general, whether the plan is adequate, rather than focusing on the plan's daily operations. It is an overall review of the plan that must be performed:

- At least annually,
  - For annual reassessments, if the establishment determines that no changes are needed to its HACCP Plan, it is not required to document the basis for this determination.
- Whenever any changes occur that could affect the hazard analysis or alter the HACCP Plan.
- In response to a deviation not covered by a specific corrective action (unforeseen hazard).

Additionally, meat and poultry establishments must document each reassessment and based on the reassessment, the reasons for:

- Changing the HACCP Plan, or
- Not changing the HACCP Plan.

Note: Refer to title 9 CFR 417.4(a)(3) Reassessment of the HACCP Plan.

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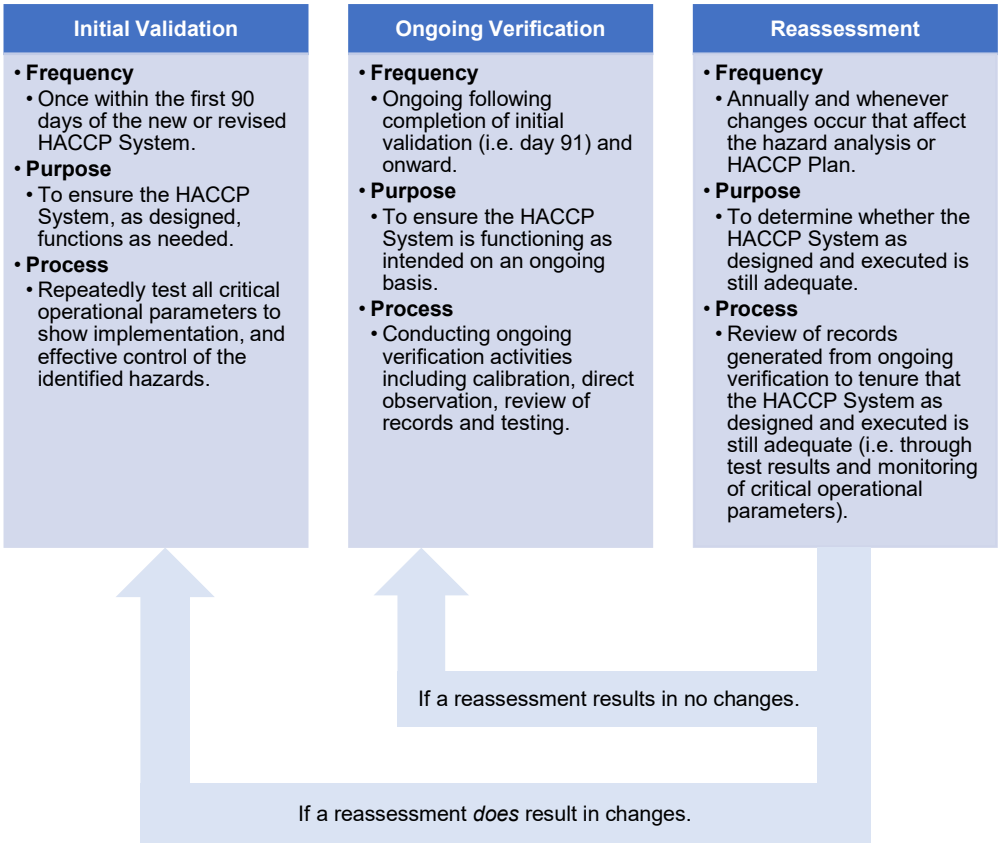
PRINICPLE 6: ESTABLISHING VERIFICATION PROCEDURES, Continued

Purpose and process overview

The guidelines for the Initial Validation, Ongoing Verification, and Reassessment Process are described below.



PRINCIPLE 7: ESTABLISHING RECORDKEEPING PROCEDURES

Recordkeeping

Hazard Analysis and Critical Control Points (HACCP) Principle 7 establishes effective recordkeeping procedures that document the HACCP system.

Recordkeeping is an essential feature of a HACCP system that must be planned and carried out as carefully as any other element. Records are kept of both the:

- Development of the HACCP Plan, and
- Operation of the HACCP system.

Note: Regulatory recordkeeping requirements for meat and poultry establishments are found in the Code of Federal Regulations (CFR) 9 CFR 417.5 and are comprehensive.

Records are proof

The most important aspect of recordkeeping is that, if an event was not documented, there is no evidence that the event occurred. Accurate HACCP records provide FSIS with the data it needs to make the determination that: are the establishment's best proof that it has produced a safe product.

- The product is safe, or
- Only a fraction of the suspected product should be recalled.
- FSIS reviews:
  - Monitoring records routinely to verify that an establishment is operating according to its HACCP Plan and is producing safe food.
  - HACCP records if an establishment's product in commerce is suspected of being adulterated and therefore potentially should be recalled.

Note: The document on which the designee has recorded results of monitoring at the time of observation is the actual record.

Keep it simple

The best recordkeeping system is usually the simplest one that is easily integrated into an existing operation; consider using simple, understandable forms that work well for the situation.

Ensure employees know exactly what is expected if they are responsible for making a record entry, they must:

- Sign/initial,
- Timestamp, and
- Date the records at the time the specific event occurs (9 CFR 417.5(b)).

Continued on next page

PRINCIPLE 7: ESTABLISHING RECORDKEEPING PROCEDURES, Continued

Records storage

Establishments will be cited for noncompliance due to failing to keep original records/documentation. Per 9 CFR 417.5(e), HACCP records must be maintained and stored as follows.

Activities or Products	Keep the records for at least:
Slaughter activities	One year
Refrigerated products	
Frozen product	Two years
Shelf stable products	

Note: After six months, HACCP records may be stored off-site, provided they can be retrieved for review by FSIS within 24 hours of a request.

Pre-shipment review

A complete pre-shipment review indicates that the product is free from food safety hazards, as well as other causes of adulteration and is ready for commerce.

The authorized staff must sign the review only after the following is reviewed:

- All of the lot specific documentation,
- All establishment and FSIS testing for adulterants such as *E. coli* O157:H7, drug residues, etc., are completed and negative,
- CCP monitoring and verification,
- Testing results in a prerequisite program,
- Letters of guarantee, and
- Other records associated with the production of that lot.

Note: 9 CFR 417.5(c) describes a pre-shipment review which can assure that everything in the HACCP system has been completed before shipping a product.

Continued on next page

PRINCIPLE 7: ESTABLISHING RECORDKEEPING PROCEDURES, Continued

Forms

The HACCP forms used for recordkeeping should include:

- Form Title,
- Date,
- Name of Product Involved,
- Production Code,
- Specific Measurement recorded,
- Monitors' Initials or Signatures,
- Time,
- Verification activity result and signature (Record Review or Direct Observation), and
- Pre-Shipment Reviewer's Signature and date when performed on a date different from the Critical Control Points (CCP) monitoring.

Writing a HACCP Plan

The records and the HACCP Plan are not required to be in any specific format. Attachment 8 is an optional example of a blank HACCP Plan.

Staff can transfer the information from the worksheets to create a completed initial HACCP Plan.

Small and very small establishments may need assistance specific to their individual HACCP Plans, products, and processes. In these cases they can:

- Use the **askFSIS** feature at https://www.fsis.usda.gov/(see References) to:
  - Research inspection-related policies,
  - Programs,
  - Systems, and
  - Procedures.
- FSIS's Small Plant Help Desk is a valuable source of guidance in achieving and maintaining regulatory compliance.

FOOD SAFETY AND INSPECTION SERVICE (FSIS) HELP DESK

Small Plant Help Desk	To find answers to common questions from various plant owners and operators across the country or to submit a question to the technical experts at the Small Plant Help Desk: • Email InfoSource@fsis.usda.gov, or • call 1-877-FSIS-HELP (1-877-374-7435)
Ask FSIS	The ask FSIS website provides answers to many frequently asked questions as well as a portal to submit specific questions.

ATTACHMENT 1: PRODUCT DESCRIPTION

Product description

PROCESS/PRODUCT TYPE NAME: Beef Slaughter/Intact Beef Primals, Sub-Primals

Process/Product Type Name	Description
Important Product Characteristics (Aw, pH, Preservatives, Ready-to-Eat, etc.)	
What is the intended use?*	
Packaging (Durability and storage conditions?)	
Shelf life and at what temperature?	
Where it will be sold (Specify intended consumers, especially at-risk populations**)	
Labeling instructions	
What special distribution controls are required?	

*Intended use of finished product. For beef establishments, the establishments must be able to demonstrate intended use (intact or non-intact) to the end consumer and support their intended use.

**At-risk populations include young children, elderly and persons with compromised immunity systems.

APPROVED BY: _____ DATE: _____

ATTACHMENT 2: LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL

List of product ingredients and incoming material

Process/Product Name

Meat and Meat-by-Products	Non-Meat Food Ingredients	Restricted Ingredients and Allergens
Processing Aids [6]	**Packaging Material**	**Other**

APPROVED BY: _____ DATE: _____

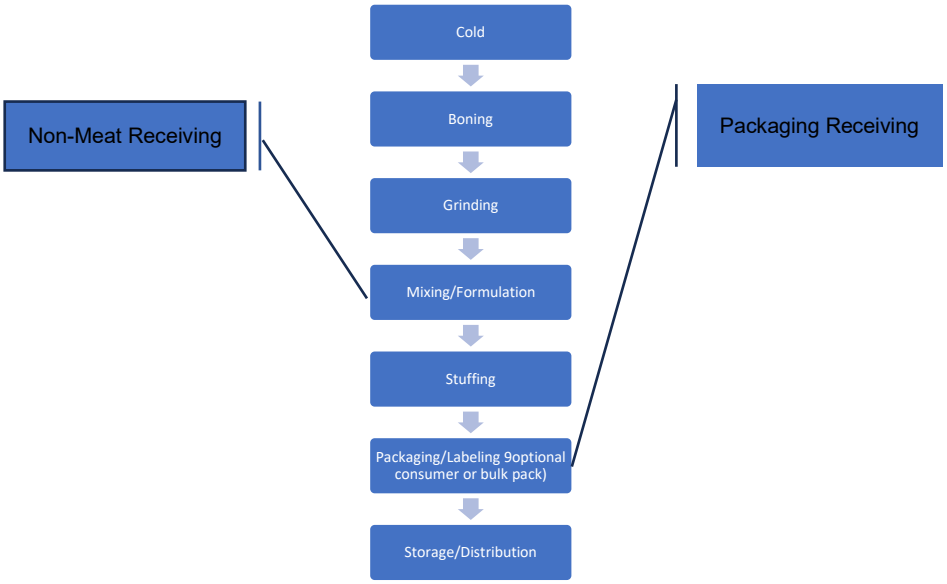
[6] Per FSIS Directive 7120.1, *Safe and Suitable Ingredients Used in Meat and Poultry Products*

ATTACHMENT 3: PROCESS FLOW DIAGRAM

Process flow diagram

Process/Product Names/HACCP Category: Fresh Pork Sausage/Raw non-intact

(Some fresh sausage is made from hot-boned carcasses; there is no chill step before boning. Chilling occurs after stuffing, not up front.)



APPROVED BY: _____ DATE: _____

ATTACHMENT 4: HAZARD ANALYSIS AND PREVENTIVE MEASURES

Product type: _____

1 **Ingredient / Process Step**	2 **Potential Hazards (Introduced or controlled at this step)**	3 **Is the potential food safety hazard reasonably likely to Occur (RLTO)?** **(Yes or No)[7]**	4 **Justification/Basis for decision[8]**	5 **If "yes" in column 3 (hazard RLTO), what control measures can be applied to prevent, eliminate or reduce the hazard to acceptable levels?**	6 **Is this step a Critical Control Point (CCP)?[9]**
Step 1	B: C: P:				
Step 2	B: C: P:				

[7] If "yes", then a CCP to control this hazard must be addressed at either this step or a later step.

[8] Scientific references are important in making decisions/justifications. If scientific references are used for decisions, the referenced article must be part of the HACCP records.

[9] To determine a CCP, see decision tree in row 1 of Attachment 5 and brainstorm to evaluate the areas of control (column 6) to determine the best CCP to control, reduce or eliminate a hazard.

ATTACHMENT 5: CCP DETERMINATION

CCP determination

1	2	3	4	5	6	7
Process Step	Hazard	Q1. Do preventative measures exist at this step for the identified hazard? • If "yes", move to the next question. • If "no", is control at this step necessary for safety? – If "yes", modify step, process or product and return to Q1. – If "no", stop; it is not a CCP. Identify how and where this hazard will be controlled.	Q2. Does this step eliminate the hazard or reduce the likelihood of its occurrence to an acceptable level? • If "no", move to the next question. • If "yes", this is a CCP.	Q3. Could contamination with the identified hazard occur in excess of acceptable levels or increase to unacceptable levels? • If "no", stop, not a CCP. • If "yes", proceed to the next question.	Q4. Will a subsequent step eliminate the hazard or reduce the likelihood of its occurrence to an acceptable level? • If "no", this is a CCP. • If "yes", stop, not a CCP.	CCP#

APPROVED BY: _____ DATE: _____

ATTACHMENT 6: CRITICAL LIMITS, MONITORING AND CORRECTIVE ACTIONS

Critical limits, monitoring and corrective actions

Process Step/CCP	Critical Limits[10]	Monitoring Procedures				Corrective Actions
		What	How	Frequency	Who[11]	

APPROVED BY: _____ DATE: _____

[10] Scientific documentation is required for critical limits decisions
[11] Refers to position title not employee name

ATTACHMENT 7: VERIFICATION AND RECORD KEEPING

Verification and record keeping

Process Step/CCP	Verification Procedures (What, How, Who, Frequency)	Records

APPROVED BY: _____ DATE: _____

ATTACHMENT 8: HACCP MASTER SHEET

Master sheet

Critical Control Point (CCP)	Significant Hazards	Critical Limits for Each Control Measure	Monitoring Procedures				Corrective Action	Verification Procedure (What, How, Frequency, Who)	Records
			What	How	Frequency	Who			

APPROVED BY: _____ DATE: _____