

Guidebook for the Preparation of HACCP Plans

Food Safety and
Inspection Service



Purpose

This guidebook is intended for small and very small establishments. The guidebook clarifies the 9 Code of Federal Regulations (CFR) Part 417 Hazard Analysis and Critical Control Point (HACCP) Systems requirements and provides guidance on how establishments might develop HACCP plans that meet those requirements.

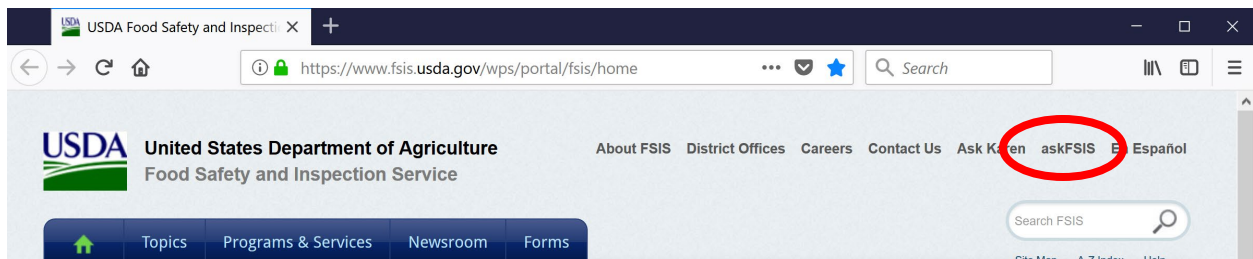
Establishments must comply with the 9 CFR Part 417 requirements. These regulations are included as text in this document and are available via active links (govinfo.gov). No new requirements are presented in this guidebook.

The guidance provided on how to develop a HACCP plan represents practices that 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. The methods, practices and forms used throughout this document do not represent requirements that must be met, and the guidance does not have the force and effect of law.

What if I still have questions after I read this guidebook?

You can search public Questions & Answers (Q&As) on the [askFSIS](#) page of the FSIS website or submit your own questions.



To submit a question, click Ask a Question, and type in the following information in these boxes:

Subject: HACCP Systems Validation Guideline

Question: *(type a detailed question)*

Product: Click **General Inspection Policy** from the drop-down menu.

Category: Click **HACCP – General HACCP** from the drop-down menu.

Policy Arena: Click **Domestic (U.S.) Only** from the drop-down menu.

Additional electronic copies of the Guidebook for Preparation of HACCP Plans and the Generic HACCP Models are available on the FSIS website at

<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/guidelines>



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The Food Safety and Inspection Service (FSIS) published the Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (PR/HACCP) final regulation on July 25, 1996. Since that time, HACCP has been used broadly for process control throughout the food processing industry. This guidebook and the associated generic HACCP models will be revised and updated periodically to reflect changes in FSIS policy and lessons learned about implementing HACCP since their inception.

This **Guidebook for the Preparation of HACCP Plans** presents the foundation of HACCP and the seven principles of HACCP as set forth by the National Advisory Committee for the Microbiological Criteria for Foods (NACMCF).

The guidebook 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 product¹ establishments. More complex options can be found in compliance guides on the USDA FSIS website in the [Compliance Guide Index](#). These guidance documents are specific to products and processes and offer more details regarding regulations and best practices to meet regulatory requirements.

The PR/HACCP rule also required each establishment to develop and implement written sanitation standard operating procedures (Sanitation SOPs). In the appendices to the PR/HACCP rule, the Agency provided guidance on how individual establishments may develop their Sanitation SOPs. That sanitation guidance has been revised. The new [Sanitation Standard Operating Procedure Model](#) provides an overview of the Sanitation Standard Operating Procedures (Sanitation SOPs) requirements, and a Sanitation SOP model.

¹ FSIS proposed to amend the egg products inspection regulations on February 13, 2018. The proposed rule requires official plants that process egg products to develop and implement HACCP Systems and Sanitation Standard Operating Procedures (Sanitation SOPs) and to meet other sanitation requirements consistent with the meat and poultry regulations. This guidebook and the HACCP models are consistent with the proposed rule.

A future revision of these documents will provide more specific information regarding processed egg products and associated HACCP plans once the final rule is in effect. See [FSIS Food Safety Guideline for Egg Products](#).

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Guidebook for the Preparation of HACCP Plans

Introduction

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) published its final rule on **Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems** (PR/HACCP) ([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, as well as to prevent, or to reduce to an acceptable level, contamination with other biological, chemical, and physical hazards.

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. 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 product.

[9 CFR Part 417](#) sets forth the HACCP requirements for poultry and meat products.

Preventing contamination by these hazards is key in reducing the number of deaths, illnesses, recalls, and injuries linked to meat and poultry products. The preamble to the final rule, based on seven HACCP principles set forth by NACMCF, describes an overall system in which preventive and corrective measures are instituted at each stage of the food production process where food safety hazards are deemed reasonably likely to occur.

Definitions

For the purpose of this document, the following definitions apply.

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.

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

Deviation: Failure to meet a critical limit.

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

Food safety hazard: Any biological, chemical, or physical property that may cause a 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 the hazard analysis, any supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records.

Hazard: (see Food Safety Hazard)

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 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.

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. You must reassess your HACCP plans at least 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.

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

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.

Developing a HACCP Plan

This **Guidebook for the Preparation of HACCP Plans** provides information that may be useful to establishments when developing plans specific to their food production processes and when implementing a food safety system. FSIS developed generic HACCP models for each process category which establishments can reference when developing their HACCP plans. Each of the fully developed generic models contains detailed information about one or more products. Establishment HACCP teams can study the models as they develop their HACCP plans.

An establishment must still tailor the plan to suit the specific circumstances of its own products and production processes. In addition, HACCP plans specific to an establishment's products still must meet the validation and verification requirements as described in the [FSIS Compliance Guideline HACCP Systems Validation](#). Even though the generic models have more detailed information, they are not designed to be used as is.

Resources

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

1. [askFSIS](#) is an online 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 9 CFR 417.4

² FSIS directives are instructions to FSIS personnel, but establishments may find the information helpful.

4. Other compliance guidelines for establishments during preparation of a HACCP system can be found at: [Guidelines](#)
5. [Small and Very Small Plants](#) resource webpage and the [Small Plant Help Desk](#): 1-877-374-7435
6. [FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants](#)
7. [FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products](#)
8. [Labeling and Label Approval](#) references: this general site for FSIS labeling has information on generic versus special approval, standards of identity, label submission approval system, etc.

Preliminary Steps

FSIS and most HACCP experts agree that, if an establishment takes **preliminary steps**, it will do a better job developing its HACCP plans.

Examples of Preliminary Steps

- 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
- Decide how products can be grouped using the process categories in [9 CFR 417.2\(b\)\(1\)](#)

1. Develop Fundamental Prerequisite Programs.

Fundamental prerequisite programs in a food safety system describe the specific activities of an establishment that can be used to support decisions made in the hazard analysis, and these programs become part of the HACCP system.

Some prerequisite programs are regulatory requirements, such as Sanitation SOPs, and are known prior to starting a HACCP plan. Most other prerequisite programs, however, are developed as an establishment conducts its hazard analysis and determines that added controls are needed to ensure practical and applied food safety parameters for their establishment so the HACCP plan can operate effectively.

The use of such programs creates the establishment-wide environment aimed at preventing any potential hazards from becoming reasonably likely to occur. These prerequisite programs in a HACCP system will be discussed in more detail later in this document.

Examples of fundamental prerequisite programs may include:

1. Good Manufacturing Practices (GMPs);
2. Standard Operating Procedures (SOPs);
3. Raw material control such as receiving and storage, Certificates of Analysis from suppliers, purchase specifications, residue control sampling, etc.;
4. Rework control;
5. Sanitation SOPs ([9 CFR 416.12-17](#));
6. Preventive maintenance;
7. Employee hygiene;
8. Chemical control and storage;
9. Allergen control;
10. Pest control;
11. Traceability and recall; and
12. *Listeria monocytogenes (Lm)* programs.

FSIS has published other guidance documents that offer more detail on the above topics. See the [Guidelines](#) page.

2. Assemble the HACCP team, including at least one person who is trained in HACCP.

Prior to assembling the HACCP team, ensure your establishment has fully embraced a food safety culture. Food safety culture includes the value an establishment places on attitudes, practices, and education of its employees about food safety practices. It is well documented that unsafe employee behaviors can produce unsafe food. You can encourage a food safety culture by engaging your 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.

To assess the food safety culture in your establishment, ask questions such as these.

- What would your employee do if a CCP monitoring check fails?

- Would this employee be empowered to speak up?
- Are all your employees trained in food safety?
- Are your employees rewarded for positive food safety behaviors?
- Do your employees feel food safety is part of the work environment?

FSIS encourages establishments to assign more than one person to develop a HACCP system. A variety of knowledge and experience is required to develop a sound HACCP system, so put people on the HACCP team who have different areas of expertise, such as production, processing, maintenance, sanitation, management, quality, safety, marketing, etc. If an establishment has only a few people involved, they all may need to be on the HACCP team because they likely have multiple roles and responsibilities in the establishment's operations.

Furthermore, if the establishment's internal expertise is limited, then consider using outside resources such as experts from trade associations, HACCP consultants, state HACCP coordinators (see the Resource section), or local college or university extension offices, which all have people with expertise in HACCP process control systems.

One resource you **must include** is someone trained in HACCP in accordance with the requirements of 9 CFR 417.7(b):

- (b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.*

This individual does not need to be a company employee but does need to be available to you for HACCP plan development and certain other functions such as reassessing your HACCP plans. FSIS does not certify or provide HACCP training for establishment employees. You may obtain HACCP training that includes the seven HACCP principles online or through local university extension offices or trade organizations.

A HACCP team's most important responsibility is to gain and maintain the support of the establishment's management for developing a sound HACCP plan and its ongoing commitment to food safety.

Picture an establishment's food safety system as a pyramid (see below). The HACCP plan is at the top. Below that, SOPs and other prerequisite programs support the HACCP plan and provide a food safety environment establishment-wide.

The foundation of any HACCP system – shown at the bottom of the pyramid – is the establishment's commitment never to waver from producing and distributing safe food.

Good Manufacturing Practices (GMPs) are an important part of that commitment.



Food Safety Pyramid

3. Describe the food and methods of producing and distributing it; identify the intended use and consumers of the products.

The next preliminary step is to have the HACCP team describe the establishment's products and its methods of production, distribution, and intended use of the product. If your team includes multiple people from different parts of the operation who know how things work, they can develop this description together. They need to include **every step** in the process.

These optional worksheets can help you ensure that all the information is included:

1. [Product Description](#)
2. [List of Product Ingredients and Incoming Material](#)
3. [Process Flow Diagram](#)
4. [Hazard Analysis and Preventative Measures](#)
5. [CCP Determination](#)
6. [Critical Limits, Monitoring and Corrective Actions](#)
7. [Verification and Record Keeping](#)
8. [HACCP Master Sheet](#)

Worksheet 1 ([Product Description](#)): Briefly describe the product, packaging, storage, distribution, and intended use. Answer the following questions in your 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?

List the products' ingredients, packaging material, and incoming raw materials (see optional worksheet ([List of Product Ingredients and Incoming Material](#))). After your team has identified the products as described in Product Description and List of Product Ingredients and Incoming Material, the team can continue to the next preliminary step.

4. Develop and verify process flow charts.

A flow chart is a simple schematic, graphical, or text representation of the process that your establishment uses to produce the product. The flow chart needs to be an accurate, detailed, and clear sketch of the steps and processes involved in production. 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.

Remember, you are responsible for ensuring that good hygienic practices are followed by all persons you invite inside your food production areas.

Each establishment must identify the steps that are essential to their operation. Include each step on the flow chart. You may incorporate multiple activities into one step as long as the **essential steps remain separated** to ensure a proper hazard analysis. The establishment needs to consider whether any biological, chemical, or physical food safety hazards are associated with the collective activities at the processing step (per [9 CFR 417.2\(a\)\(2\)](#)).

The Process Flow Diagram ([Attachment 3](#)) optional worksheet is a simple flow chart illustrating a relatively simple, fresh ground sausage process. As you develop your HACCP flow chart, include the process flow and any flow of packaging material, raw ingredients, interventions, and rework that occurs in the process.

To ensure that your flow chart is accurate, have the HACCP team verify it. Have them walk through the establishment to make sure the flow chart includes all the steps in the process and in the correct order.

Verification also is a means by which inspection personnel and third-party auditors verify that a flow chart is correct and complete. An accurate flow chart is essential to ensure that any potential hazards associated with the process are adequately evaluated.

If any part of the process changes after your HACCP plan is completed, you must adjust the flow chart and reassess the HACCP plan. Examples of changes may include additional interventions, processes, steps, or changes in raw material suppliers, ingredients, or equipment.

When you make a flow chart:

- Observe the operation
- Draft a flow chart
- Walk the operation to verify the flow chart
- Adjust the flow chart as needed

When you are certain that your flow chart is accurate and your team has verified that the steps are correct, it is time to move to the final preliminary step.

5. Decide how products can be grouped using the process categories in 9 CFR 417.2(b)(1).

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

- (i) *Slaughter – all species slaughtered: beef, swine, lamb, goat, and poultry³*
- (ii) *Raw product⁴ – non-intact; examples include ground products, mechanically tenderized steaks*
- (iii) *Raw product – intact; examples include sub-primal, whole muscle steaks, roasts, and chops*
- (iv) *Thermally processed – commercially sterile in cans, jars, or pouches; examples include canned meat or poultry and prepared foods or entrees with meat or poultry*
- (v) *Not heat treated – shelf stable; examples include summer sausage and dry salami*
- (vi) *Heat treated – shelf stable; examples include meat/poultry jerky and snack sticks*
- (vii) *Fully cooked – not shelf stable; examples include hot dogs, roast beef, cooked ham, frozen entrees, and cooked chicken nuggets*
- (viii) *Heat treated but not fully cooked – not shelf stable; examples include*

³Siluriformes fish should not be included in the slaughter category because FSIS found that the typical fish slaughter operation is a streamlined, automated process that combines slaughter with processing in the same continuous operation, more like meat processing-only operations than like slaughter operations for other species amenable to the FMIA (see [Changes to the Inspection Coverage in Official Establishments That Slaughter Fish of the Order Siluriformes](#)).

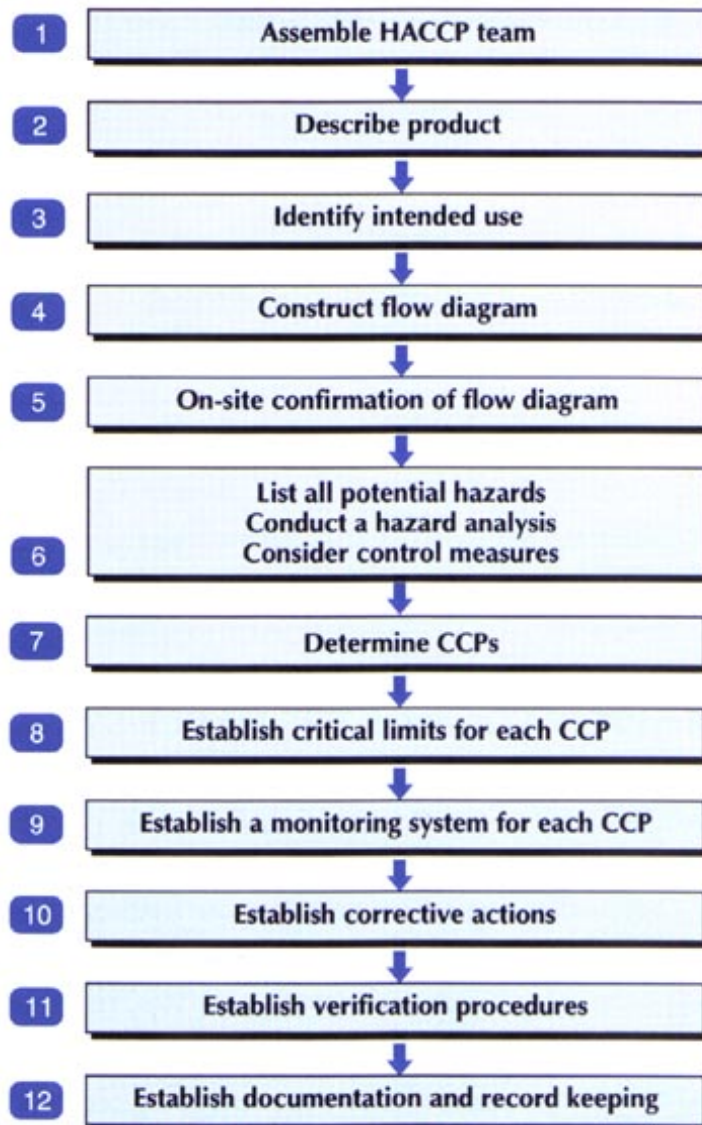
⁴9 CFR 417.2(b)(1) lists “Raw product-ground” instead of “Raw Product-non-intact” and “Raw product-not ground” instead of “Raw Product-intact.” The categories are the same. However, FSIS clarified the terms to include mechanically tenderized and vacuum marinated products in the non-intact category. Also see [Federal Register / Vol. 64, No. 11 / Tuesday, January 19, 1999](#).

partially cooked patties and bacon

- (ix) *Product with secondary inhibitor – not shelf stable; examples include corned beef and cured beef tongue*

The HACCP system may control all products in the same process category using a single HACCP plan, if the processes are essentially the same. That is advantageous for very small establishments that produce several different products. If those products differ only in characteristics that would not affect safety – such as the amount or kind of seasoning used, such as, hot vs. mild – and if the food safety hazards, critical control points, critical limits, and procedures listed in [9 CFR 417.2 \(c\)](#) are the same, then those products are in the same process category and may be covered by the same HACCP plan ([9 CFR 417.2 \(b\)\(2\)](#)).

The decision about process categories completes the preliminary steps that prepare you to develop a HACCP system. You have completed steps 1 through 5 in the following diagram. Now your team applies the seven principles of HACCP (steps 6 through 12) and develops a HACCP plan specific to your establishment. The next seven sections of the guidebook cover the seven principles and take you through the process of developing a HACCP plan.



Applying the Seven HACCP Principles

The Seven HACCP Principles:

- Principle 1: Conduct a Hazard Analysis
- Principle 2: Identify the Critical Control Points
- Principle 3: Establish Critical Limits for Each Critical Control Point
- Principle 4: Establish Monitoring Procedures
- Principle 5: Establish Corrective Actions
- Principle 6: Establish Verification Procedures
- Principle 7: Establish Recordkeeping Procedures

The seven HACCP Principles are described in the regulations. The following italicized text quotes the regulations from [9 CFR 417.2 \(c\) and \(d\)](#).

(c) *The contents of the HACCP plan. The HACCP plan shall, at a minimum:*

(1) *List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.*

(2) *List the CCPs for each of the identified food safety hazards, including, as appropriate:*

(i) *CCPs designed to control food safety hazards that could be introduced in the establishment, and*

(ii) *CCPs designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;*

(3) *List the critical limits that must be met at each of the CCPs. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;*

This guidebook explains how to meet the regulatory requirements of 9 CFR Part 417, as well as how to apply the seven HACCP principles correctly.

- (4) *List the procedures, and the frequency at which those procedures will be performed, that will be used to monitor each of the CCPs to ensure critical limits are met;*
 - (5) *Include all corrective actions that have been developed in accordance with § 417.3(a), to be followed in response to any deviation from a critical limit at a critical control point; and*
 - (6) *Provide for a recordkeeping system that documents the monitoring of the CCPs. The records shall contain the actual values and observations obtained during monitoring.*
 - (7) *List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4.*
- (d) *Signing and dating the HACCP plan.*
- (1) *The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.*
 - (2) *The HACCP plan shall be dated and signed:*
 - (i) *Upon initial acceptance;*
 - (ii) *Upon any modification; and*
 - (iii) *At least annually, upon reassessment, as required under § 417.4(a)(3).*

Principle 1: Conduct a Hazard Analysis

9 CFR Part 417 contains definitions as well as specific provisions that affect how your HACCP team must go about conducting its hazard analysis. Before beginning the process, your team should review the definitions of **food safety hazard** and **preventive measure** and look specifically at the requirements in 9 CFR 417.2(a).

§ 417.2 Hazard Analysis and HACCP Plan.

- (a) *Hazard analysis.*
 - (1) *Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the*

establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

- (2) *A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.*

Conducting a hazard analysis is generally a two-step process. The first step is to identify the potential hazards to human health, which might be introduced before, during, and after production. Establishments often focus on “during production” hazards. To ensure a safe product, however, you must include “before” and “after” production when you conduct a hazard analysis. These potential **hazards** are grouped into three categories: Biological (including microbiological), Chemical, and Physical.

The hazard categories biological, chemical and physical are abbreviated to B, C and P in column 2 (Potential Hazards) of the hazard analysis form.

Once those hazards are identified, the second step is to identify existing controls for those hazards. The [FSIS Meat and Poultry Hazards and Controls Guide](#), [FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants](#), and the [FSIS Compliance Guidelines for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products](#) are helpful tools for identifying potential hazards related to your process. Both also provide examples of procedures to control these hazards.

1. Biological Hazards

Biological hazards are living organisms that can make food unsafe to eat. Biological hazards 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. Depending on how beef slaughter/processing establishments deal with Specified Risk Material (SRM), establishments may refer to prions as biological or physical hazards.

Biological hazards are frequently associated with livestock and birds. Biological hazards also may be introduced during processing of meat and poultry products. In addition, biological hazards may be introduced by people involved in the processing, the environment in which the foods are processed, the equipment, other ingredients in the products, and/or the processes themselves.

Some of the 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 slaughter of livestock and poultry may introduce biological hazards such as *Salmonella*, *Campylobacter* and *E. coli* O157:H7. The ultimate source for all of these pathogens is apparently healthy animals that may shed these bacteria in their feces. While dressing the carcasses during the slaughter process, these bacteria may be transferred from the hide and offal to the carcass causing contamination. The [Meat and Poultry Hazards and Controls Guide](#) provides frequently used controls to address the incoming pathogen load at slaughter.

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 and pathogen outgrowth must be considered in the hazard analysis for processing, storage, thawing and any step where conditions may allow proliferation of pathogens.

When producing ready-to-eat products, it is the presence of pathogens that defines the hazard. Pathogens of concern include *Salmonella*, *E. coli* O157:H7 and *Listeria monocytogenes*. Generally, ready-to-eat products are not cooked before eaten. Therefore, the presence of a few pathogens may cause illness.

Identifying the specific biological hazards within your production processes is the most important task, one that requires all the expertise from your HACCP team. Because meat and poultry products have been implicated in several disease outbreaks, there is a great deal of concern about microbial hazards associated with such products.

All swine slaughter establishments are required to develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal material throughout the slaughter and dressing operation. To demonstrate effectiveness of such procedures using their HACCP system, 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.

Establishments operating under the New Swine Slaughter Inspection System (NSIS) have the added responsibility of ensuring that market hogs exhibiting signs of moribundity (near death), central nervous system disorders, or pyrexia (high body temperature) are sorted from those swine going to slaughter. Unhealthy swine may carry pathogens capable of causing human illness.

All poultry slaughter establishments, except for establishments that slaughter ratites, are required to develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal material throughout the slaughter and dressing operation ([9 CFR 381.65\(g\)](#)). 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.

Establishments operating under the New Poultry Inspection System (NPIS) have the added responsibility of ensuring that poultry carcasses exhibiting conditions such as Septicemia/Toxemia (Sep/Tox), tumors, and airsacculitis are removed from production before the carcasses are presented to the FSIS online carcass inspector. Poultry carcasses with these conditions may carry pathogens capable of causing human illness.

In livestock slaughter establishments, contamination of carcasses and parts from feces, ingesta, and milk are primary avenues for 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. Lactating mammary glands and diseased mammary glands of cattle, sheep, swine, and goats may contain pus or other objectionable material. When milk comes in contact with the carcass, the parts of the carcass contaminated shall be trimmed free of the contamination.

The edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans. Once introduced into the establishment environment, the organisms may be spread from carcass to carcass or by other means. FSIS enforces a "zero tolerance" standard for visible fecal material, ingesta, or milk on livestock carcasses and parts at the time of inspection. Therefore, such hazards must be addressed in the hazard analysis.

9 CFR 310.18(a) states: Carcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter; however, if contamination occurs, it shall be promptly removed in a manner satisfactory to the inspector.

All establishments that slaughter poultry other than ratites are required to maintain written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller ([9 CFR 381.65\(f\)](#)). The regulations require the written procedures be incorporated into the "HACCP System". The HACCP System includes the HACCP plan or Sanitation SOP or other prerequisite program.

9 CFR 381.65(f) states: Procedures for controlling visible fecal contamination. Official poultry slaughter establishments must develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs.

Controls for biological hazards include good manufacturing practices, sanitation procedures, employee hygiene, separation of not-ready-to-eat spaces and ready-to-eat

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 – raw 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

spaces, microbial interventions, or post lethality pasteurization techniques. For more details, refer to the hazard identification guides provided at the beginning of this section.

2. Chemical Hazards

Chemical hazards may be the result of something naturally occurring in foods, used, or added during the processing of foods, or administered to live animals.

Harmful chemicals have been associated with acute cases of foodborne illness as well as injury and chronic illness. In addition, chemical and drug residues outside of limits established by the Environmental Protection Agency and the Food and Drug Administration also represent food safety hazards.

Reference:
Seafood
HACCP and
the FDA
Food Safety
Modernization
Act

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm569796.htm>

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

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,

and colors, dyes, or water additives. The related documents for [FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products](#) webpage lists the substances and usage levels in the production of meat, poultry, and egg products.

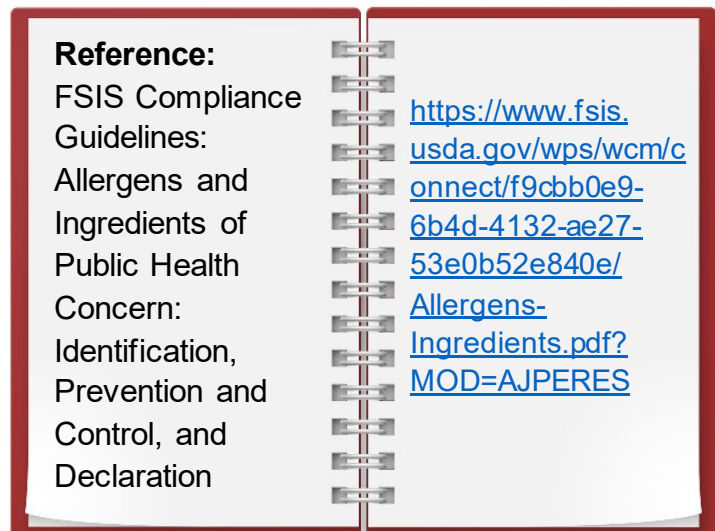
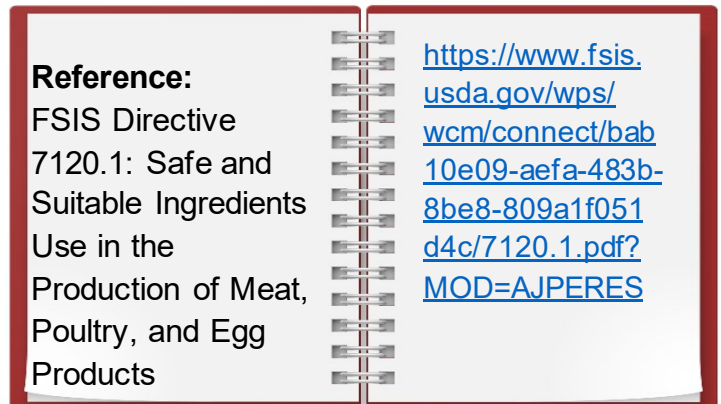
One of the most overlooked categories of chemical hazards in hazard analysis are allergens. Certain foods – or food ingredients themselves – which cause allergic reactions in some people need to be considered as potential chemical hazards. Proteins in these foods or food ingredients have been shown to cause an adverse immunologic reaction in some sensitive individuals. Eight of the most common foods that cause allergic reactions include peanuts, soybeans, tree nuts, eggs, milk, crustacea (shellfish), fin fish, and wheat.

Ingredients that can cause adverse reactions are controlled to prevent cross-contamination and are declared on labels. Establishments are required to declare all ingredients on the label if they are included in the product formulation (per [9 CFR 317.2](#) and [381.118](#)).

If allergens are not declared, the product is considered adulterated and misbranded. For detailed guidance related to control of allergens, refer to [FSIS Compliance Guidelines Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling](#).

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.

3. Physical Hazards



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. Foreign materials such as glass, metal, or bone in a boneless product, or plastics are potential physical hazards in meat and poultry products. They are sometimes found because a process or a piece of equipment was not properly maintained or controlled while the food was being produced. For example, jewelry, gloves, packaging material/plastic, tools, or machine parts may fall into products while a maintenance employee is troubleshooting equipment. Food contaminants can also occur through poor food-handling practices.

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 for physical hazards include procedures for visual observations, sanitation, product handling SOP, good manufacturing practices for maintenance and inspection, and foreign material detection.

4. Hazard Analysis Process

Identifying hazards associated with your production process could be a brainstorming session. Your HACCP team can use the flow diagram and product description that you created during your preliminary steps to consider systematically what could occur at each step in the process.

[Attachment 4](#) is an optional worksheet with questions that could help your team thoroughly consider hazards that might be associated with your process and identify appropriate control measures. First, consider each process step in your flow chart. List any biological, chemical, or physical hazards that could be introduced, controlled, or enhanced at that step, for example, increased pathogen growth. If there are no hazards you can identify at that step, write “none.”

If there is a biological, chemical, or physical hazard identified, decide whether those

Consider the possibility that someone may *intentionally* contaminate a product to do harm to a company, its employees, or the general public. FSIS strongly encourages establishments develop Food Defense Plans. See [FSIS Food Defense and Emergency Response](#) and [FSIS Developing a Food Defense Plan for Meat and Poultry Slaughter and Processing Plants](#).

hazards are reasonably likely to occur (RLTO)⁵ in the product or process and indicate “yes” or “no.” For either a “yes” or “no” answer, briefly write a justification for your decision and refer to any relevant supporting documents.

Finally, list the control measures that can be used to control, reduce to acceptable levels, or eliminate the hazard. If your team answers that, yes, a hazard is reasonably likely to occur, then there needs to be a critical control point at that step or some later step in the process.

More than one preventive measure may be needed to control a food safety hazard, and more than one food safety hazard may be controlled by a specific preventive measure.

When determining whether a hazard is reasonably likely to occur, it is recommended but not required that you list the actual hazard or organism of concern. For example:

- Physical: metal contamination from equipment;
- Chemical: allergen (soy); and
- Biological: *Salmonella*, *Escherichia coli* O157:H7, *STEC*, *Campylobacter jejuni*, *Listeria monocytogenes* or other specific pathogenic hazards, or a specific residue that is known to occur in a similar product.

You will find this list of hazards information helpful in finding adequate supporting documentation while conducting yearly reassessments or when a deviation or unforeseen hazard occurs.

For all “yes” answers in column 3 “reasonably likely to occur,” you must provide supporting, scientific and technical documentation that shows that the selected control measure can be applied to prevent, eliminate, or reduce the hazard to an acceptable level. Your justification or basis for your decision is recorded in column 4. Your control measures are recorded in column 5. For all “no” answers in column 3, record your prerequisite programs or other measures in column 4.

Supporting documentation for the HACCP team’s decisions and justifications during the Hazard Analysis are an important part of the regulatory requirement of recordkeeping ([9 CFR 417.5\(a\)\(1\)](#)).

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

⁵ A food safety hazard that is reasonably likely to occur is one which a prudent establishment would establish controls because it historically has occurred in any establishment (not just your establishment) producing this type of process or product, or there is a reasonable possibility that it will occur in the particular type of product being processed in the absence of those controls.

demonstrating that particular process control measure can adequately prevent, reduce, or eliminate specific hazards.

Establishment historical records, documentation, or other information about the process can also be used in the decision-making process, but it must be physically maintained as part of the supporting documentation. 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. [FSIS Compliance Guideline HACCP Systems Validation](#) has more detailed information regarding initial validation and supporting documentation.

Sometimes foundational prerequisite programs are used in a hazard analysis to justify that a potential hazard is not reasonably likely to occur (NRLTO). Prerequisite programs (such as Sanitation SOP, sanitary dressing procedures, purchase specifications, microbial interventions, allergen programs, *Listeria monocytogenes* programs, etc. listed in the *Preliminary Steps: Develop Prerequisite Programs* section, above) can help prevent conditions that make the potential hazard likely to occur. Therefore, the prerequisite program, used as justification that a hazard is not likely to occur, becomes part of the HACCP system and must be validated (see HACCP Principle 6 of the [FSIS Compliance Guideline HACCP System Validation](#)).

When establishments use prerequisite programs as justification for a hazard not reasonably likely to occur, establishments must maintain scientific evidence or technical support for the design of the prerequisite programs, including historical data to support the decisions used in the hazard analysis (see Principle 6 Element 1). Establishments must also collect validation data to ensure that the prerequisite programs are implemented as designed to prevent the hazard (see Principle 6 Element 2).

Historical data from the prerequisite program needs to show that the identified hazard is prevented from occurring or reduced to an acceptable level on an ongoing basis when the program is followed within the environment of the establishment. 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 throughout the establishment. Likewise, an establishment producing cooked, RTE chicken nuggets may conclude that *Listeria monocytogenes* is not reasonably likely to occur in its process because it follows well-designed Sanitation SOPs that include environmental and product testing programs (per [9 CFR Part 430](#)).

We cannot emphasize enough how important it is for your team to brainstorm potential hazards thoroughly during its hazard analysis. This often is a difficult and time-consuming step and one that requires all the technical and scientific resources you can obtain. Taking the necessary time is well worth the effort. You cannot expect to develop an effective HACCP system if you have not been careful and thorough in the hazard analysis. The [FSIS Meat and Poultry Hazards Guide \(Revised 2018\)](#) and the [FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of](#)

[Products Produced by Very Small Plants](#) can be helpful resources during this process.

Principle 2: Identify Critical Control Points

The second HACCP principle is to identify the CCPs in the food production process. A

Conducting a thorough Hazard Analysis is the heart of developing a sound HACCP System and plan, and its implementation will ensure the production of safe food.

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

In developing the HACCP plan, your HACCP team so far has identified potential biological, chemical, and physical hazards in the raw materials and the ingredients you use, as well as in the steps of your process. For each food safety hazard that is reasonably likely to occur, you must identify a CCP to control that hazard either at the step at which the hazard is identified or at a later step in the process.

Your next step is to find the critical points in the process at which those preventive measures must be applied. You can use [Attachment 4](#), an optional worksheet.

For each “yes” listed in the ‘reasonably likely to occur’ column in [Attachment 4](#), a CCP must be identified. The CCP may address the hazard at that specific processing step or at a step later in the process, but there must be a CCP in the process to control the hazard.

For every decision you make about whether to identify a CCP, you must provide credible, documented, scientific or technical justification to support the decision in your HACCP plan.

Fortunately, a great deal of work has already been done in identifying those points at which critical control can be applied during a process. Many points are commonly recognized in various food processing and production systems.

Common points at which critical control can be applied in your 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;

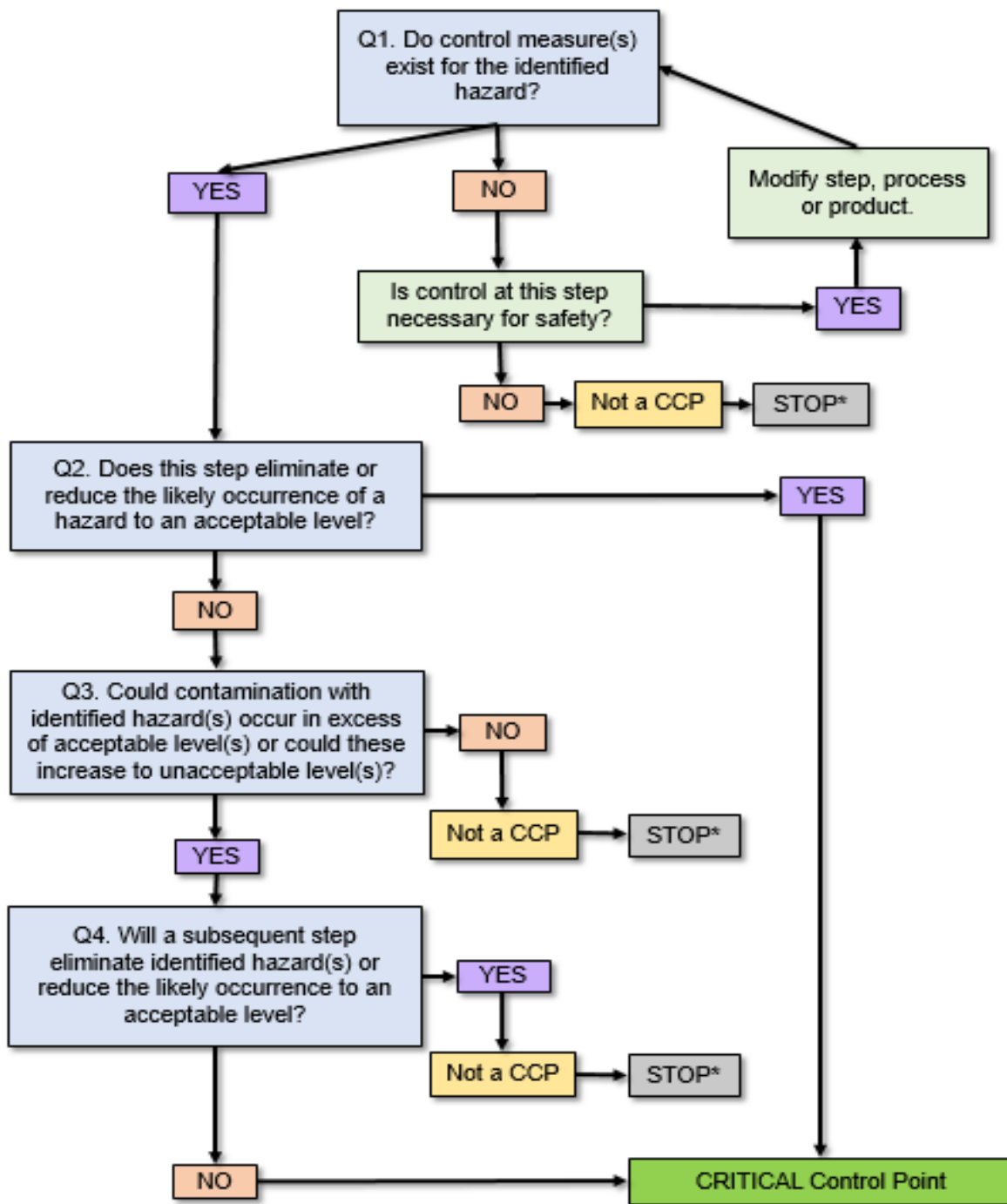
- Product formulations, such as the addition of cultures or adjustment of pH or water activity to inhibit pathogen growth; and
- Sanitary dressing slaughter procedures and antimicrobial interventions to prevent or reduce the presence of pathogens.

Those are just a few examples of measures that may be CCPs; there are many more possibilities. Different facilities preparing the same food can differ in the number and types of CCPs they choose to use. This is to be expected when preparing establishment specific HACCP plans.

FSIS's generic HACCP models, as well as other generic models, give you some ideas about which CCPs might work in the various process categories that are discussed. FSIS's generic models are to help your team to think creatively and carefully about *your* processes and how you want your HACCP system to work.

[Attachment 5](#) is an optional worksheet that follows the NACMCF decision tree for making CCP determinations (see figure on next page). This decision tree developed by the NACMCF will be helpful to your HACCP team when determining which points in the process are in fact CCPs.

[9 CFR 417.5 \(a\)\(1\)](#) requires that establishments maintain the written hazard analysis and all records, including the supporting documentation for the hazard analysis. In addition, 9 CFR 417.5 (a)(2) says that establishments must maintain their written HACCP plans, including all decision-making documents associated with the selection and development of CCPs.



**Proceed to next step in the described process*

CCP Decision Tree
 Source: NACMCF, 1992

Principle 3: Establish Critical Limits for Each Critical Control Point

The third HACCP Principle instructs your team to establish critical limits for each preventive measure you will carry out at each CCP. This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. 9 CFR 417.1 defines a critical limit as: *the maximum or minimum value or range to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.*

Critical limits are the boundaries of safety for preventive measures put in place at CCPs. A critical limit usually is a reading or observation (e.g., a temperature), a time, a product property (e.g., water activity), or a chemical property (e.g., available chlorine, salt concentration, or pH). Critical limits need to be exact and specific.

Some critical limits for identified CCPs have been established, either through regulatory requirements, such as zero tolerance for fecal contamination on poultry entering the chiller, or through the technical and scientific literature.

FSIS has also published many guidance documents to help establishments decide on its CCPs and critical limits. Your HACCP team should become familiar with those guides to help establish critical limits such as the minimum internal temperature and time to which products must be cooked (Appendix A – see box at the right), or the time which may elapse while product is being cooled to a specific temperature (Appendix B – see box at the right). Critical Limits **must be met** to maintain product safety.



When you are deciding what your critical limits must be, there are several sources to consider. The first of these sources are the regulatory requirements that apply to your processes. **These must be met** as required by [9 CFR 417.2\(c\)\(3\)](#) critical limits and [9 CFR 417.5\(3\)](#) recordkeeping. For example, if you produce cooked beef products, you must have critical limits that meet FSIS regulatory requirements for those products set out in [9 CFR 318.17](#). There may be other sources of critical limits; they may be based on scientific and technical information from studies or food processing textbooks. Critical limits may also be determined from specific research challenge studies or from recognized experts. In any case, you need to establish a critical limit for each preventive measure you intend to apply at your CCPs and adequately support the selection of the critical limit.

A critical limit can be an *upper limit*, at which a set amount or level cannot be exceeded. Conversely, a critical limit can also be a *lower limit*, at which a minimum amount is

required to produce the safe effect. 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. For example, 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.” Another example of an *upper* critical limit is a grinding room temperature of 50° F to control pathogen growth. An example of 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.

Critical limits fall under the “too much of a good thing is not always better” adage. For example, 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.

Establishments may also wish to 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 (see Appendix A link on previous page), a higher target limit may be 160°F. That creates a safety margin as additional assurance that critical limits are met. Moreover, it allows for the identification of trends

When an establishment selects scientific support for the development of its CCP and critical limits (9 CFR 417.5(a)(2)) to prevent, reduce, or eliminate a hazard, then all of the critical operational parameters should be incorporated into the critical limits of the CCP.

An establishment may determine, however, that some of the parameters can be monitored on an ongoing basis as part of a prerequisite program. An establishment may also determine that it only needs to ensure that *some* of the critical operational parameters are implemented – consistent with the support during the initial validation period. For example, spatial configuration, equipment type to the extent that it affects other parameters, or ingredient formulation, provided it does not change should be 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.

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

When an establishment selects scientific support for its decision that a hazard is NOT reasonably likely to occur (9 CFR 417.5(a)(1)) because implementing a prerequisite program prevents conditions that make the potential hazard likely, then all of the critical operational parameters should be incorporated into the prerequisite program.

Limit of the CCP and which number is a quality point.

Principle 4: Establish Monitoring Procedures

For HACCP Principle 4, your team needs to establish monitoring procedures. Monitoring procedures are those that are done routinely, either by employees or mechanical means, to measure the process at any given CCP and create a record for future use. Monitoring procedures include observations or checks performed by employees (for example, checking the documentation accompanying incoming materials) and by equipment (for example, continuous recording thermometers).

Continuous monitoring is always preferred. When continuous monitoring is not possible, your HACCP team needs to determine its non-continuous monitoring procedures, how frequently those will be performed, and what calibrated equipment will be used for monitoring.

There are several issues to consider when deciding the frequency of non-continuous monitoring checks. The most important is that procedures must be performed often enough to reflect accurately whether the process is under control. Advice from experts in practical statistics and statistical process control is important in making your decisions about monitoring frequency.

Another consideration for your HACCP team is the capacity of the establishment to take corrective actions if monitoring reveals deviations from critical limits. When your monitoring detects a deviation, as set forth in 9 CFR 417.3, you need to apply corrective actions to all the affected product. This usually includes all the product produced since the last recorded acceptable monitoring check. For example, assume your monitoring procedure was to perform a cooking temperature check each hour; if the critical limit is not met you would take corrective actions retroactively to the last acceptable check – ideally, the one an hour ago. Conversely, if the temperature were checked only once per shift, an entire shift's production would be held until corrective actions were taken.

When your HACCP team selects the monitoring procedures and their frequency, it must consider the need for rapid, real-time feedback. Generally, physical, and chemical procedures are preferred over microbial approaches for monitoring because those procedures provide more rapid feedback.

Monitoring procedures need to be well planned, supportable, and effective because of the potentially serious consequences of loss of control. Employees monitoring CCPs must be trained in the techniques that will be used to monitor each critical limit. They must fully understand the purpose and importance of monitoring and accurately report monitoring activities and results as they occur.

As [9 CFR 417.2\(c\)\(6\)](#) requires, the person performing monitoring must record exact values. That means that if the critical limit is a minimum internal temperature of, say, 160°F, the person would record his or her observations as 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.

Train your employees who are assigned to conduct and record the results of monitoring. Make sure they know how to do their jobs and understand the connection between their monitoring responsibilities and food safety, so they will record results accurately.

Per 9 CFR 417.5 (b), Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurred and include the date and time recorded and shall be signed or initialed by the establishment employee making the entry.

Moreover, they must know what to do if critical limits are not met or if the results of their monitoring indicate that the process may be trending out of control.

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

[Attachment 6](#) is a simple optional worksheet your HACCP team might use to help it decide on monitoring procedures, the designated employee position to perform them, and how frequently they will be performed. The worksheet can be used to list corrective actions if deviations occur.

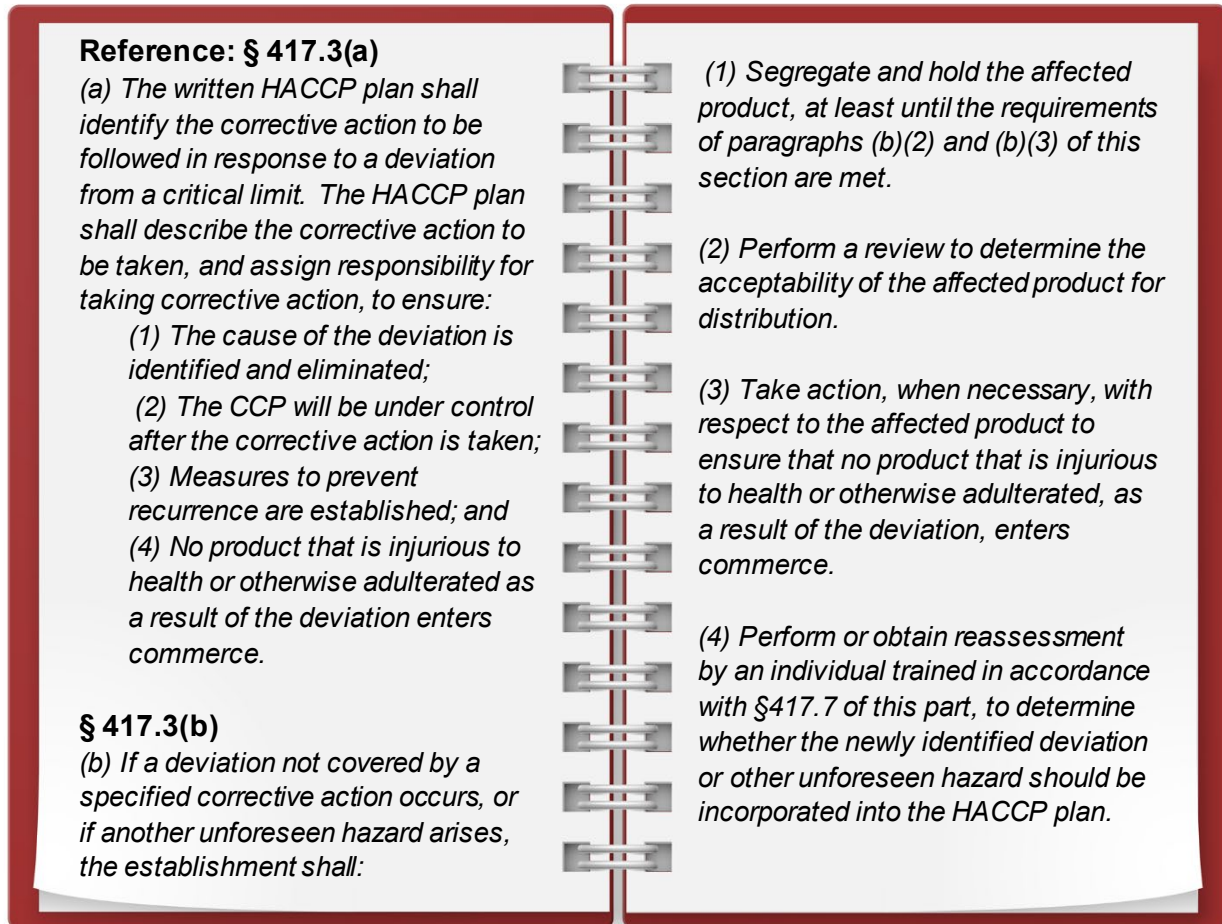
Principle 5: Establish Corrective Actions

For HACCP Principle 5, your team needs to establish corrective actions to be taken when monitoring shows that there is a deviation from a critical limit. In addition, [9 CFR 417.3\(a\)](#) identifies the four features of corrective actions that FSIS regulators will verify when a deviation from a critical limit occurs:

- (1) The cause of the deviation is identified and eliminated;
- (2) The CCP will be 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.

HACCP is a preventive system intended to correct problems before they affect the safety of the food products people will consume. Deviations from critical limits may occur; therefore, you need to have a plan to make sure those deviations do not lead to unsafe products in commerce. Planned corrective actions are the way to do this: your HACCP team needs to understand how important it is to carry out that principle.



For each CCP, your team needs to devise a standardized set of actions that company employees will follow when there is a deviation from a critical limit. These are some questions they might ask in developing corrective actions:

- How will people be informed when the deviation occurs? If a person is performing the monitoring procedure, who will that person contact?
- Who will be responsible for controlling the product that may have been affected by the deviation? How should that person decide how much product needs to be controlled?
- Who will be involved in deciding what to do about the product which might have been affected by the deviation?

- How will we determine the cause of the deviation? If we need technical experts outside the company, how do we get them?
- Once we have figured out the cause of the deviation, who will be involved in deciding how to get the process back in control and prevent recurrence of the deviation?
- If our HACCP-trained individual is not available in the establishment immediately, how can we get HACCP expertise to help decide if our plan needs to be modified?
- Who in the company needs to sign off on any modifications to our plan?
- Who will be responsible for keeping the records of everything we do in response to a deviation from a critical limit at this CCP?
- If any person, who has a responsibility in our corrective action plan, is not available, who will be the back-up?
- Is this set of corrective actions feasible at all times?
- How will the reoccurrence be prevented in the future?

Employees responsible for monitoring and other functions of the HACCP plan should be identified by title and not by name. This allows for appropriate substitutions when those individuals are not available.

Continue with the optional worksheet in [Attachment 6](#) to help your HACCP team make sure they have developed appropriate corrective actions for each CCP. 9 CFR Part 417 includes regulatory requirements which must be followed when a deviation not covered by a specific corrective action (unforeseen hazard) occurs. Your team should study [9 CFR 417.3\(b\)](#) so that you know what to do when this happens. In many ways, the actions to be taken will be similar to what you plan to do at any specific CCP, i.e., get control of the product, figure out the cause, decide how to keep it from happening again, decide whether to modify your HACCP plan, etc. However, if you have not addressed a hazard in your HACCP plan, you will also have to reassess your plan. Your team should consider how to handle those situations before they occur. Be proactive, not reactive, in your approach to HACCP development.

Principle 6: Establish Verification Procedures

§ 417.4 Validation, Verification, Reassessment.

(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 Principle 6 is to establish verification procedures to make sure the plan is working correctly. Verification is those activities, other than monitoring, that determine

the validity of the HACCP plan and that the system is operating according to the plan. Validation is part of verification. 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.

Your team needs to decide what procedures the establishment will perform to verify that the HACCP system is working effectively *and* how often these actions will be performed. Verification uses methods, procedures, or tests in addition to those used in monitoring to see whether the HACCP system follows the HACCP plan or whether the HACCP plan needs modification.

There are three aspects of verification:

1. Initial Validation
2. Ongoing Verification
3. Reassessment

1. Initial Validation.

That is the initial phase in which the HACCP plan is tested and reviewed. You must repeatedly test the decisions made while you are working through the preliminary steps and HACCP principles. During this phase, microbial or residue testing can be used to verify whether the process is in control and producing safe product. Such testing provides clear evidence that the techniques and methods adopted by the establishment to control hazards will work in *your* specific establishment and are not just effective in theory.

- (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. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

The [FSIS Compliance Guideline HACCP Systems Validation April 2015](#) describes the process as two steps: 1) Design and 2) Execution.

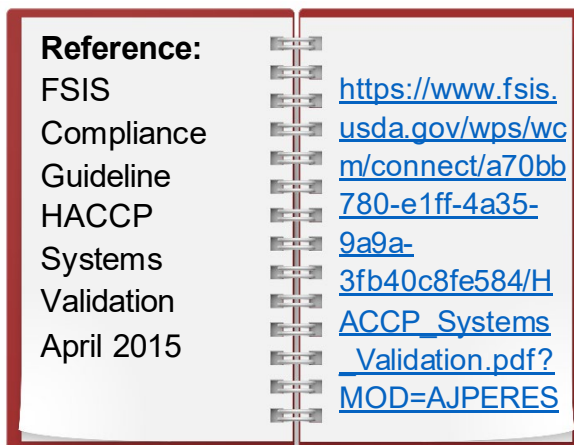
Design of the HACCP plan is the scientific or technical support for the HACCP system design – that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards.

Execution of the HACCP plan is the in-plant validation data or 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. These supporting validation documents are critical to the success of the HACCP plan and must be kept for the life of the plan.

Validation compliance guidelines recommend that establishments use the critical limits from the underlying study instead of just using the critical limits from the University extension service document.

University extension publications may also be cited as scientific support; however, extension publications often reference the original journal articles that were used to develop the support. In those cases, establishments should have the original journal articles on file referenced in the extension publication because the extension publications often do not include all the critical operational parameters that establishments would need to implement. Establishments need information on all the critical operational parameters to determine whether the process in the publication matches their actual process.



2. 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 such tasks as calibrating monitoring instruments, observing monitoring activities and corrective actions, reviewing HACCP records to see that they are being made and kept according to the plan, the monitoring of 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.

If you rely on data from your prerequisite programs as a basis for determining that an identified hazard is not reasonably likely to occur, then the prerequisite program *itself* must be validated and you must maintain records that the programs are consistently and continuously implemented as designed.

Title 9 CFR 417.4(a)(2) includes specific regulatory requirements regarding ongoing verification:

(2) *Ongoing verification activities. Ongoing verification activities include, but are not limited to:*

- (i) *The calibration of process-monitoring instruments*
- (ii) *Direct observations of monitoring activities and corrective action*
- (iii) *The review of records generated and maintained in accordance with §417.5(a)(3) of this part*

Often the concepts of verification and validation get confused. Here is a way to maintain a correct understanding of each of them when you are 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?

Use [Attachment 7](#) (an optional worksheet) to record ongoing verification procedures, including observing monitoring activities and calibration activities. An example of verification for Attachment 7 is calibrating a thermometer which is used for a temperature control CCP. Along with a thermometer calibration log/record, a documented program should detail the frequency of calibration and the thermometer calibration procedure (see [Thermometer Calibration Guide](#)). You can also use the worksheet to detail your HACCP records.

3. Reassessment:

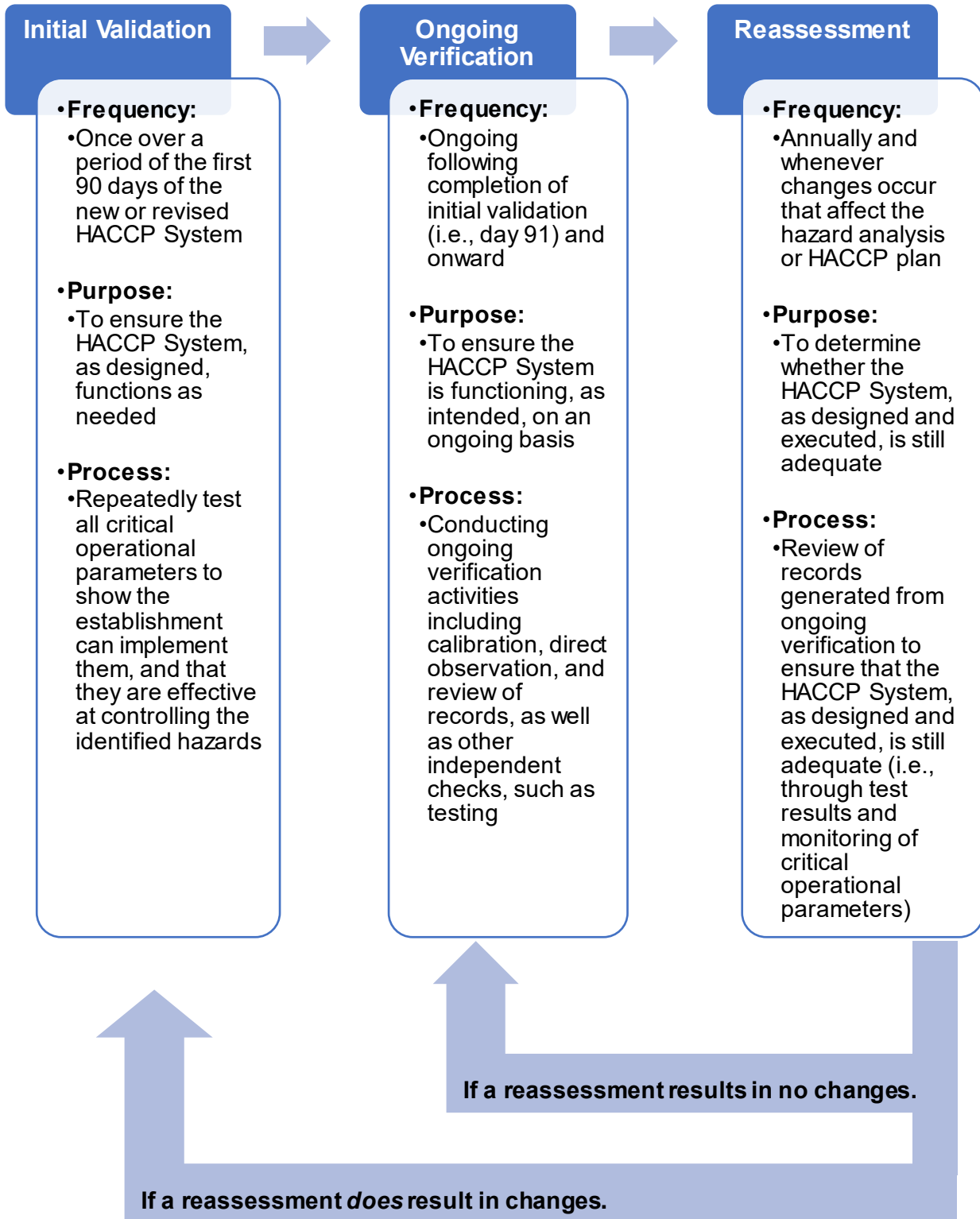
Reassessment is an overall review of the plan that must be performed at least annually, whenever any changes occur that could affect the hazard analysis or alter the HACCP plan and in response to a deviation not covered by a specific corrective action (unforeseen hazard). Reassessment is similar to validation in that it considers, in general, whether the plan is adequate, rather than focusing on the plan's daily operations.

CFR 417.4(a)(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, 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. The reassessment shall be performed by an individual trained in accordance with §

417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

Meat and poultry establishments must document each reassessment and the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment ([9 CFR 417.4\(a\)\(3\)](#)). 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.

Initial Validation, Ongoing Verification, and Reassessment Frequency, Purpose, & Process



Principle 7: Establish Recordkeeping Procedures

HACCP Principle 7 is to establish effective recordkeeping procedures that document your HACCP system. Regulatory recordkeeping requirements for meat and poultry establishments are found in 9 CFR 417.5 and are comprehensive. Have your team review those carefully.

§ 417.5 Records.

- (a) The establishment shall maintain the following records documenting the establishment's HACCP plan:*
 - (1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation.*
 - (2) The written HACCP plan, including decision making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.*
 - (3) Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product codes, product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.*
- (b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded and shall be signed or initialed by the establishment employee making the entry.*

HACCP records are an establishment's best proof that it has produced a safe product. The document on which your designee has recorded results of monitoring at the time of observation is the actual record. FSIS reviews those records routinely to verify that an establishment is operating according to its HACCP plan and is producing safe food.

FSIS also reviews HACCP records if establishment's product in commerce is suspected of being adulterated and therefore potentially should be recalled. Often, accurate HACCP records can provide FSIS with the data it needs to make the determination that a company's product is indeed safe, or that only a fraction of the suspected product should be recalled. FSIS requests that establishments recall product when necessary.

Recordkeeping is an essential feature of a HACCP system that must be planned and carried out as carefully as any other element. Keep records of both the development of your HACCP plan *and* the operation of the HACCP system.

The best recordkeeping system is usually the simplest one that you can easily integrate into an existing operation; consider using simple, understandable forms that will work well in your situation. Make sure your 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\(b\)](#)). Also consider the best place to store the records.

Historically, small, and very small plants have been cited for noncompliance because they failed to keep the original record when they had to document or “re-create” the record for whatever reason. Therefore, you must maintain and store the following HACCP records per [9 CFR 417.5\(e\)](#).

- Slaughter activities: keep for at least one (1) year
- Refrigerated products: keep for at least one (1) year
- Frozen product: keep for at least two (2) years
- Shelf stable products: keep at least two (2) years

After six (6) months, HACCP records may be stored off-site, provided that they can be retrieved for review by FSIS within 24 hours of a request.

In addition, there is one final verification/recordkeeping requirement which the company must perform found at 9 CFR 417.5(c):

- (a) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the records, preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.*

That is commonly referred to as **pre-shipment review**. It can assure that you have done everything in your HACCP system before you ship a product. A completed 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. Sign the review only after someone has reviewed all lot specific documentation and all establishment and FSIS testing for adulterants such as *E. coli* O157:H7, drug residues, etc., are completed and negative. That includes CCP monitoring and verification but may also include testing

Records

Management: Per 9 CFR 417.5 (b), *Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurred and include the date and time recorded and shall be signed or initialed by the establishment employee making the entry.*

results in a prerequisite program, letters of guarantee, or other records associated with the production of that lot.

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 CCP monitoring.

The most important aspect of recordkeeping is that, if you have not documented an event, you have no evidence that the event ever occurred.

HACCP System records also include records associated with prerequisite programs, certificates of analysis, letters of guarantee, supporting data, studies, documents, etc.

Records and the HACCP plan itself are not required to be in any particular format. [Attachment 8](#) is an optional example of a blank HACCP Plan. You can transfer information from the worksheets your team has prepared to create your completed initial HACCP plan.

A HACCP plan is never 'final.' You must assess it at least annually and whenever changes occur in your process and/or previously unforeseen hazards occur.

Small and very small establishments may need assistance specific to their individual HACCP plans, products, and processes. In that case:

- Use the **askFSIS** feature at www.fsis.usda.gov (see References) to research and ask questions about inspection-related policies, programs, systems, and procedures; and
- FSIS's Small Plant Help Desk (see References) is a valuable source of guidance in achieving and maintaining regulatory compliance.

Small Plant Help Desk



Find answers to common questions from small and very small plant owners and operators across the country or submit a question to the technical experts on the Small Plant Help Desk.

You can email us at InfoSource@fsis.usda.gov or call 1-877-FSIS-HELP (1-877-374-7435).

This **Guidebook for the Preparation of HACCP Plans** and updated HACCP models reflect the knowledge gained in the years since the earlier versions of these publications were developed. As with those early editions, these current HACCP models are not guaranteed to meet all the regulatory requirements for the establishment's own specific HACCP system. They can, however, provide HACCP teams within the small and very small establishments a foundation on which to build a HACCP system.

We hope you find this information useful.

Attachments:

- 1 Product Description
- 2 List of Product Ingredients and Incoming Material
- 3 Process Flow Diagram
- 4 Hazard Analysis and Preventative Measures
- 5 CCP Determination
- 6 Critical Limits, Monitoring and Corrective Actions
- 7 Verification and Record Keeping
- 8 HACCP Master Sheet

Attachment 1: Product Description

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

Process / Product Type Name	
Important Product Characteristics (A_w , pH, Preservatives, Ready-to-Eat, etc.)	
How It Is to Be Used/ 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 (reference: [FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli](#)).

**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

Process/Product Name:

MEAT and MEAT-BY-PRODUCTS	NON-MEAT FOOD INGREDIENTS	RESTRICTED INGREDIENTS and Allergens
PROCESSING AIDS ⁶	PACKAGING MATERIAL	OTHER

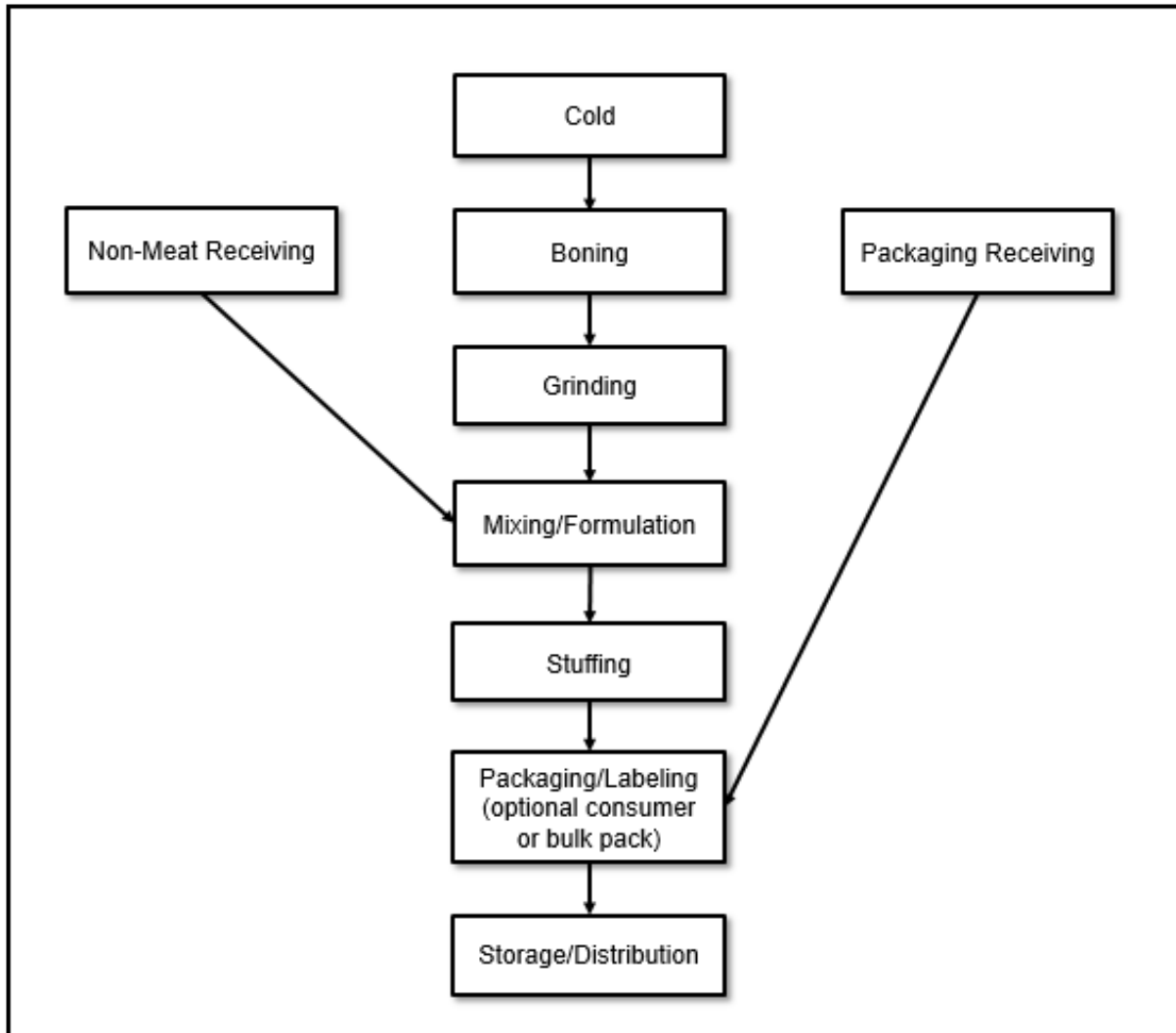
APPROVED BY: _____ DATE: _____

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

Attachment 3: Process Flow Diagram

Process / 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: _____

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Ingredient/ Process Step	Potential Hazards (Introduced or controlled at this step)	Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No)⁷	Justification/Basis for Decision⁸	If “yes” in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels	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

<p>Process Step</p> <p>(1)</p>	<p>Hazard</p> <p>(2)</p>	<p>Q1. Do preventative measures exist at this step for the identified hazard? *If yes, move to the next questions. *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.</p> <p>(3)</p>	<p>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.</p> <p>(4)</p>	<p>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.</p> <p>(5)</p>	<p>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.</p> <p>(6)</p>	<p>CCP#</p> <p>(7)</p>

APPROVED BY: _____ DATE: _____

Attachment 6: 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

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

APPROVED BY: _____ DATE: _____

Attachment 8: HACCP 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: _____