

Meeting the Requirements for Federal or State Meat Inspection: SSOP and HACCP Basics

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| Produced by: Minnesota Department of Agriculture Dairy and Food Inspection Division | In Partnership with: United States Department of Agriculture Food Safety Inspection Service |
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For additional information on how to develop SSOP's and a HACCP plan, contact:
The Minnesota Department of Agriculture Meat & Poultry Inspection Division at:
651-201-6027 or visit the MDA website at www.mda.state.mn.us.
FSIS Strategic Initiatives Partnerships and Outreach Staff at:
202-690-6520 or visit the FSIS website: <http://www.fsis.usda.gov>

Developing Sanitation Standard Operating Procedures (SSOP)



SANITATION STANDARD OPERATING PROCEDURES

Sanitation Standard Operating Procedures (SSOPs) are written descriptions of the procedures that a meat or poultry processor uses to prevent contamination or adulteration of their product. These include the actual procedures they perform to clean their equipment, utensils and facilities and other procedures they use to insure their product is not contaminated. Meat and poultry processors under Federal or State inspection must meet the specific requirements for SSOP's outlined in Federal Law. These requirements can be found in the Code of Federal Regulations at 9 CFR 416.11 through 416.17 (See regulations found at the end of this section).

Basic Requirements

All SSOP's must meet certain basic requirements. The written procedures must:

- Contain all of the procedures the establishment will use daily to prevent product contamination before they begin producing product (preoperational procedures) and address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils
- Contain all of the procedures they use daily to prevent product contamination while they are producing product (operational procedures)
- Specify the frequency with which each procedure is to be performed and identify the employee or position responsible for insuring the procedures are performed correctly and at the correct frequency.
- Be signed and dated by the individual with overall authority on-site or a higher-level official of the establishment. This signature means that the establishment will implement the SSOP's as written and will maintain the SSOP's to meet regulatory requirements.

These written procedures must cover the entire establishment and all shifts of operation. Before a meat or poultry processor can begin processing under inspection, they must have SSOP's that meet the basic regulatory requirements. More details on the basic requirements are described below.

1. **Preoperational procedures:** The document must identify which of their procedures are performed *before operations begin*. In other words, it must be clear in the written description of the procedures which ones will be performed daily before operations. These are the procedures the establishment will use on a daily basis to prevent product contamination or adulteration *before* they start processing. These procedures must be described and address the cleaning of food contact surfaces of facilities, equipment, and utensils.



Examples of pre-operational procedures:

- *Cleaning and sanitizing the meat slicer before using it*
- *Daily monitoring of cleanliness by observing each piece of equipment to be used that day before it is used in operations to ensure it is clean*

2. **Operational procedures:** The document must identify which procedures are performed *during operations* on a daily basis to prevent product contamination or adulteration.

Examples of operational procedures:

- *Employees will wash their hands during production as necessary to prevent product contamination.*
- *Pest and rodent controls will be in place each day.*

3. The written document must also identify *WHO* is responsible for making sure that these procedures are performed as stated in the document. This may be one or more than one person.

Example: Joe Green, the owner of Green's Meat Shop, is responsible for insuring the SSOP's are implemented as stated.

4. **Recordkeeping:** The establishment must identify and maintain records that document the implementation and monitoring of the SSOP and any corrective actions taken. This is commonly done in the form of a chart used to record monitoring of each procedure on a daily basis.
5. **Dated Signature:** The individual with overall authority on-site or a higher level official of the establishment must sign and date the SSOP (a) When they first begin using it and (b) anytime changes are made to it. Many facilities use signature log pages to meet this requirement.

Examples of good questions to ask to determine if your SSOPs meet the basic requirements!

- Have I identified and described the procedures I will use to ensure product is not contaminated before I operate each day?
- Have I identified and described the procedures I will use to ensure that product is not contaminated during operations each day?
- Have I identified who is responsible for ensuring that the SSOPs are implemented as they should be?
- Have I identified a frequency for performing each procedure described in my SSOP?
- Do I have an adequate recordkeeping system to document that I have implemented and monitored these procedures?
- Have I signed and dated the SSOP? If I make changes, have I signed and dated the SSOP to reflect that changes have been made?

Because no system is perfect, sanitation problems can occur. If a problem occurs, product may become contaminated or adulterated. Any time product has been contaminated or adulterated or direct product contact surfaces are unclean, the establishment *must take appropriate corrective actions and document them!*



These actions must include:

1. Ensuring the appropriate handling of affected product (if necessary)
 - a. If product has been contaminated, it may need to be disposed of. In some situations, it may be reprocessed.
 - b. In some cases, product has not been affected. For instance, if a monitor checks a piece of equipment for cleanliness before it is used for processing and finds a dirty spot, no product has been affected as the equipment had not been used yet.
2. Restoring sanitary conditions
 - a. The operation must take any measures necessary to correct the problem.
3. Preventing recurrence
 - a. The operation must identify actions they will take to prevent it from happening in the future.

There are many ways to document corrective actions; however, any documentation needs to include the three items identified above. A written corrective action might look like:

| Date | Problem identified | Handling of product | How sanitary conditions have been restored | Preventive measures | Initials of employee responsible |
|-------------|--------------------------------------------------------|-----------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------------|-----------------------------------------|
| 1/15/05 | Rust on the saw blade during preoperational monitoring | No product affected, equipment not in use yet | The rusty saw blade was removed and replaced with a new one | Blades will be inspected for rust and changed on a regular basis. | JG |

Implementing and Monitoring the Written SSOP



The establishment is responsible for developing written procedures that are adequate to prevent direct contamination of product during their operations. They must also perform these procedures as written. Monitoring of these procedures is also required to ensure that the procedures are adequate and performed as written. If the establishment writes a procedure in its SSOP, it must implement that procedure and **monitor it at least daily**. They must document their monitoring procedures as a means of providing evidence that the procedures were adequate and performed as written.

In short, the establishment must do what they say they are going to do, then monitor and document it!

Many facilities use daily sanitation logs to record the results of their daily monitoring procedures. There are many acceptable forms of documenting the monitoring procedures. All records must be initialed and dated daily by the employee responsible for implementing and monitoring the SSOP's. Each facility should use a form of documentation that accurately represents the monitoring procedures they use in their operation.

Evaluating the Effectiveness of the SSOP



To meet the regulatory requirements, the establishment must routinely evaluate the effectiveness of the SSOPs in preventing direct contamination of product. This means that the establishment must review their procedures on a regular basis to be certain that they are effective.

The establishment should also routinely review their SSOP monitoring records to determine if there are trends occurring that may indicate the SSOP needs revising. If monitoring records indicate certain pieces of equipment are found to be dirty frequently or certain personnel are not following procedures correctly, the procedures in the SSOP need to be changed to address these issues. Also, if changes are made in the facilities, equipment, utensils, operations, or personnel, the SSOP must be revised to keep it effective. Remember, the SSOP must be signed and dated when any modification is made.

Records Retention

The daily SSOP records and corrective actions must be kept on-site for 48 hours and must be maintained for at least 6 months. After the initial 48 hours, records may be kept off-site provided that they can be retrieved for inspection personnel within 24 hours of the request.



EXAMPLE OF A BASIC WRITTEN SSOP

Annie Oakley's Wild Meats-Establishment 22M Sanitation Standard Operating Procedures

Owner: Annie Oakley

This SSOP is for a very small plant that slaughters and processes beef for wholesale distribution.

Pre-operational:

All food contact surfaces of the facility, equipment, and utensils on the kill floor and processing room will be cleaned daily after production by rinsing, soaping, and sanitizing. All cleaning will be monitored daily by the owner or designee before production begins the next day. Records will be kept on the SSOP Checklist.

Operational

Every day, all equipment and surfaces on the kill floor and processing room will be kept as sanitary as necessary to prevent contamination or adulteration of the carcasses/product.

Every day, all employees will follow hygienic practices to keep themselves from contaminating or adulterating the carcasses/products. These actions will be monitored by the owner or designee once per day and recorded on the SSOP checklist.

Corrective actions taken during pre-operational sanitation inspection or during operations will be written on the back of the SSOP checklist as necessary.

(Signature & Date of Annie Oakley)

*****Note: This is a very basic example of a written SSOP that meets the regulatory requirements. Depending on the operation, other things may need to be added to the SSOP to adequately describe the appropriate procedures. These documents must be tailored specifically for each operation as each business operates differently.***

Example of a Sanitation Checklist

Processing Department Sanitation Checklist

| | | Mon | Tues | Wed | Thurs | Fri. |
|----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|--------------------------------------|------|-----|-------|------|
| Preoperational Sanitation Check | | Date: | | | | |
| 1. Stuffing tables | | Note: The date is recorded each day. | | | | |
| 2. Wrapping table | Each area or piece of equipment is monitored for cleanliness before operations each day. | | | | | |
| 3. Cutting table with boards | | | | | | |
| 4. Grinder plates and knives | | | | | | |
| 5. Meat lugs and tubs | | | | | | |
| 6. Mixer | | | | | | |
| 7. Stuffer, stuffing horns | | | | | | |
| 8. Tumbler | | | | | | |
| 9. Product sink | | | | | | |
| 10. Smokehouse racks | | | | | | |
| 11. Smokesticks | | | | | | |
| 12. Smokehouses | | | | | | |
| 13. Hand tools | Note: Initials of person implementing preoperational SSOP's are recorded in this row each day | | | | | |
| Initials | | | | | | |
| Operational Sanitation Check | | | | | | |
| 1. Employees washed hands as necessary and used gloves when required. | Each operational sanitation item is monitored and documented at least once per day during operations. | | | | | |
| 2. All persons are wearing a clean apron and hair cover. Gloves worn as needed. | | | | | | |
| 3. Condemned containers are emptied when necessary. | | | | | | |
| 4. All meat dropped on the floor is condemned or trimmed and reconditioned prior to its use if feasible. | Note: Initials of person implementing operational SSOP's are recorded in this row each day | | | | | |
| Initials | | | | | | |

Corrective Actions are to be noted on the back of this form

The establishment has provided for a recordkeeping system to record corrective actions by writing them on the back of the form.

Note: The results of daily monitoring are indicated for each section each day using the symbols in the key.

Key:
 √ = Found acceptable
 - = Not in use
 X = Not acceptable



SSOP Questions and Answers



What are preoperational procedures?

These are the procedures a processor performs before they begin production each day to ensure that their product will not be contaminated by equipment, utensils or facilities that have not been cleaned adequately.

What are operational procedures?

These are the procedures a processor performs during operations each day to ensure that their product will not be contaminated. Contamination or adulteration can occur when people handle the meat products or any equipment, utensils or facilities in contact with the meat product.

How frequently do these procedures need to be monitored?

The performance of these procedures needs to be monitored on a daily basis at a minimum.

Do SSOP monitoring records need to be signed?

No, but the monitoring records need to be initialed and dated by the person responsible for implementing and monitoring the SSOP's for that establishment.

Who needs to sign and date the SSOP's?

The individual with overall authority on-site or a higher level official must sign and date the SSOP's. This needs to be done at the time they are first put into action and anytime modifications are made after that.

Can SSOP's be maintained on a computer?

Yes, SSOP's may be maintained on computers as long as the establishment has adequate controls in place to ensure the integrity of the electronic data. This may include passwords, electronic signatures or other means of securing the data entered for SSOP monitoring.

How long do I need to keep my SSOP records around?

All SSOP records must be kept on-site for at least 48 hours following their completion. After 48 hours, they may be kept off-site; however, the establishment needs to keep them for at least 6 months. Off-site records need to be made available to inspection personnel within 24 hours of a request.

Can I just use the procedures from a sample plan to write my SSOP?

Every operation is different and the procedures for each operation's SSOP need to accurately reflect the actual procedures performed in the plant. Remember, each operation is responsible for doing what they said they would do in their written procedures. Some procedures from other SSOP's may be similar and can easily be tailored to your operation but many are different. Sample plans can be good examples for how to write procedures but each plant needs to write their procedures to accurately reflect their operation!

Code of Federal Regulations

TITLE 9--ANIMALS AND ANIMAL PRODUCTS CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 416--SANITATION

Sec. 416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

Sec. 416.12 Development of Sanitation SOP's.

- (a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).
- (b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.
- (c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.
- (d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

Sec. 416.13 Implementation of SOP's.

- (a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.
- (b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.
- (c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

Sec. 416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

Sec. 416.15 Corrective Actions.

- (a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).
- (b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

Sec. 416.16 Recordkeeping requirements.

- (a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.
- (b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.
- (c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

Sec. 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

- (a) Reviewing the Sanitation SOP's;
- (b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;
- (c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and
- (d) Direct observation or testing to assess the sanitary conditions in the establishment.

HACCP Basics

What is HACCP?

HACCP is a technical term that stands for **Hazard Analysis & Critical Control Points**. This is a system that meat and poultry processors use to put a business's food safety practices into action. The system focuses on preventing potential food safety hazards to ensure the production of food products that are safe to consume. It applies scientifically-based and technical information to practical situations in the meat and poultry production process. As of January 2000, all meat and poultry processors under Federal or State inspection, regardless of size, are required by the Federal Regulations to have a HACCP system in place.

HACCP can be a confusing and challenging concept for many meat and poultry processors. It is important to focus on learning the basic concepts of HACCP prior to designing and implementing your own HACCP plan. Using model plans can be helpful for learning these concepts. However, each individual processor has a unique process and their plan needs to accurately reflect that process and their food safety procedures.

Many different manufacturing and food processing industries use HACCP to control food safety problems in their processes. It can be a very effective tool for improving food safety procedures and processes. Note that each industry has some specific requirements for their HACCP plans that differ from other industries or manufacturing processes. The specific requirements for meat and poultry HACCP plans are found in 9 CFR 417 (the Code of Federal Regulations, see Appendix A).

How do I get started?

Before you get started with the actual plans, use the following simple steps to help you get a good foundation for building an effective plan. Some of the specific information developed with these steps is required by the HACCP regulations. In addition, HACCP training is required for at least one person involved in your operation.

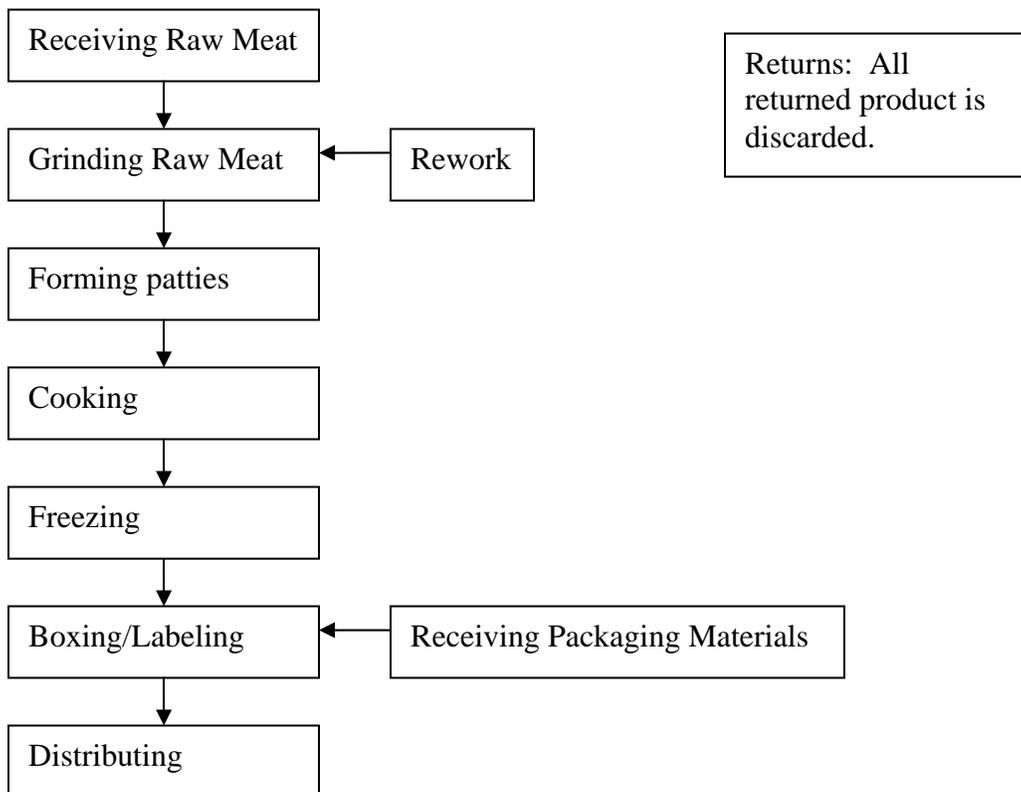


- **Assemble your HACCP team:** This team should consist of people who have specific knowledge and expertise appropriate to your product and process. While a team approach is helpful, some operations may only have one person working with the HACCP plan. The team should include people who are (or will be) directly involved in the operation as they are most familiar with the product and production processes. Depending on their level of knowledge, they need to be trained in the basic concepts of HACCP to effectively participate in the development process. Some processors also include a specially trained HACCP

consultant in the process to help them develop the plan. When consultants are used, they need to be familiar with your specific process.

- **Describe the product and its distribution:** The HACCP team should develop a basic description of the product or products being produced, including ingredients and processing methods. The method for distributing the product should also be described along with information on whether the product is to be distributed frozen, refrigerated, or at ambient (room) temperature. This step is important for determining which HACCP category a specific product will fall in.
- **Describe the intended use and consumers of the product:** In addition, the HACCP team must describe the normal expected use of the product. The intended consumers may be the general public or a particular segment of the population (i.e. infants, elderly, etc.). This is important for determining which food safety hazards are significant for the product.
- **Develop a flow diagram which shows the process steps:** For each type of process, the team must develop a flow diagram to represent their process. The purpose of the flow diagram is to provide a clear, simple outline of the steps involved in the process. It must cover all of the “action” steps in the process which are directly under the control of the plant. This step is required and serves as the basis for the future development of a hazard analysis.

Example of a Simplified Flow Diagram for a Cooked Hamburger Patty Process



HACCP Basics

After completing the introductory steps, you are ready to move on to the development of your HACCP system. The HACCP system is the basic food safety plan for the establishment and their processes. HACCP systems are science-based process controls that work to eliminate, prevent or reduce to an acceptable level food safety hazards that are likely to occur in an establishment's processes. In this system, the establishment has full responsibility for producing products that are safe for consumers. The system is based on seven principles that are described in this material. Understanding and implementing these principles is essential to creating and implementing an effective HACCP plan.

HACCP Definitions

The terminology used to describe HACCP can seem strange and confusing. The following list includes definitions of some commonly used terms used to describe and implement HACCP in meat and poultry production.

Control Measure: Any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective Action: An action that is taken when the maximum or minimum values or results for a critical control point are not met.

Critical Control Point (CCP): A step at which a control can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Limit (CL): A measurable or observable value that is used to judge whether certain food safety standards have been met.

Deviation from a Critical Limit: Failure to meet the value for a critical limit.

Flow Diagram: A symbolic and logical representation of the series of steps or operations used in the production of a particular food item.

Hazard: A biological, chemical, or physical agent that may be present in or added to a product during the production process with the potential to cause a harmful health effect.

Monitor: A planned sequence of observations or measurements designed to assess whether target values for a CCP have been met.

Step: A procedure or operation performed in the production of a food product.

Verification: Procedures performed to ensure that the HACCP plan is functioning as it was intended.

HACCP Categories

The regulations in 9 CFR 417 also describe several HACCP categories that can be used to describe an establishment's processes. These categories, and examples of products that might fall in these categories, are shown on the following table.

| HACCP Category | Product Examples |
|------------------------------------------------------|---------------------------------------------------|
| Slaughter | Beef slaughter, pork slaughter, poultry slaughter |
| Raw product – ground | Ground beef, ground turkey, fresh pork sausage |
| Raw product – not ground | Steaks, chops, roasts |
| Thermally processed – commercially sterile | Canned beef stew, canned pasta with meat |
| Not heat treated – shelf stable | Summer sausage, dry salami |
| Heat treated – shelf stable | Meat and poultry jerky, snack sticks |
| Fully cooked – not shelf stable | Wieners, roast beef, ham |
| Heat treated but not fully cooked – not shelf stable | Bacon, partially cooked patties |
| Product with secondary inhibitors – not shelf stable | Corned beef, cured beef tongue |

****Note:** An establishment may produce different products that fall under the same category. These products may be included in the same HACCP plan provided the steps for making each product are substantially similar and all steps for each product are covered in the plan.

The 7 HACCP Principles

The National Advisory Committee on Microbiological Criteria for Food (NACMCF) working group created guidelines for the seven basic principles of HACCP. These are not regulatory requirements, however they provide the regulatory framework for HACCP as it is applied to meat and poultry production. Understanding the principles of HACCP is critical to developing a HACCP plan that is not only effective, but meets the regulatory requirements. These principles can be systematically used to create an effective HACCP plan.

The seven principles of HACCP include:

- 1. Conduct a Hazard Analysis**
- 2. Determine Critical Control Points**
- 3. Establish Critical Limits**
- 4. Establish Monitoring Procedures**
- 5. Establish Corrective Actions**
- 6. Establish Recordkeeping and Documentation Procedures**
- 7. Establish Verification Procedures**

Principle 1: Conduct a Hazard Analysis

The purpose of the hazard analysis is to identify a list of potential food safety hazards in a production process that are reasonably likely to cause injury or illness if they are not effectively controlled. A thorough hazard analysis examines all of the steps in a process, including steps such as receiving ingredients and raw materials, product storage, and transporting and distributing the product.

A food safety hazard that is reasonably likely to occur is one for which a prudent plant would establish a control because the hazard has occurred in the product/process in the past or because there is a reasonable chance that the hazard would occur without these controls.

There are four goals for performing the hazard analysis:

1. Identify potential food safety hazards and associated control measures
2. Identify changes to a process or product that would improve product safety
3. Provide a foundation for determining which steps in the process are critical for controlling or preventing potential food safety problems
4. Assemble documents to support your decisions

Hazards identified as being significant in one operation may or may not be significant in another operation producing the same or similar product. Different establishments may identify different hazards likely to occur and different control measures for them, even though their processes may appear to be similar. Important differences may exist in the type of equipment used, incoming products, product formulas, employee training or production practices. A summary of the HACCP team decisions and their reasons for making them should be kept for future reference. After the hazard analysis has been completed, the hazards associated with each step in the process should be listed along with any measure(s) that are used to control them. Examples of potential hazards in meat and poultry production processes can be seen in Appendix B.

The term control measure is used instead of preventive measure because not all hazards can be prevented, but virtually all can be controlled. Control measures prevent, eliminate or reduce the hazard to an acceptable level. More than one control measure may be required for a specific hazard or a specific control measure may address more than one hazard. Also, the control point for a hazard may not be at that step but may be farther along in the process. For example, the cooking step is a common control for biological hazards that have been introduced into the product at previous steps.

Some hazards identified can be adequately controlled through the standard operating procedures (SOP's) the plant uses on a daily basis. A plant may determine that some hazards are not likely to occur because they have certain measures in place that minimize the chances that these hazards will occur. These procedures also need to be documented and available for review.

When completed, the hazard analysis should have:

- Identified the hazards reasonably likely to occur
- Identified the associated preventive measures that can be applied to control these hazards.
- Decision-making documents available to support the decisions made

This is the basis for determining which points are critical for ensuring food safety standards are met!

Examples of the Decision Making Process for a Hazard Analysis

| Process Step | Potential Hazards? | Reasonably Likely to Occur? | Reasoning |
|-------------------------------|-----------------------------|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| Receiving packaging materials | Biological – none | | All packaging material is visually examined upon receipt, letters of guarantee are available for all packaging materials used |
| | Chemical – none | | |
| | Physical – foreign material | No ☆ | |

This hazard has been determined to be not likely to occur because the plant has a standard operating procedure in place – visual examination of all packaging products on receipt. They also can support this decision with the letters of guarantee that they receive from their suppliers.

Or for a step further in the process...

| | | | |
|---------|----------------------------------------------------------------|-------|-------------------------------------------------|
| Cooking | Biological - Pathogens: E. coli O157:H7, Salmonella and others | Yes ☆ | Pathogens are naturally present on raw products |
| | Chemical - None | | |
| | Physical – None | | |

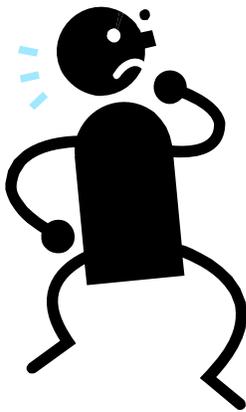
This operation has identified biological pathogens as likely to occur because they are naturally present in raw products. There are no standard operating procedures they can use to adequately control the presence of this hazard.

Principle 2: Determine the Critical Control Points

The hazards that were identified as being reasonably likely to occur in the hazard analysis must be addressed in the HACCP plan. **Any hazard reasonably likely to occur must be controlled by one or more critical control points (CCP's)!**

What is a Critical Control Point?

This is a point, step or procedure in a production process where a control can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level.



The CCP is a step that is essential for controlling a food safety hazard. Examples of steps which are commonly identified to be CCP's include cooking, product formulation, a product spray or rinse, product chilling or cooling, or an intervention to remove contamination with fecal material at slaughter. Remember, the step at which the critical control point is located does not necessarily have to be at the point where the hazard is introduced into the system. It can be later in the process. For instance, pathogens introduced into the process on raw meat may be controlled by a cooking step later in the process.

Again, different plants preparing similar products may find that they have identified different hazards and therefore, have identified different CCPs. This may be due to the differences in the plant's layout, equipment, personnel, processes used, or the selection of their ingredients.

An Example of the Identification of a Critical Control Point in a Hazard Analysis

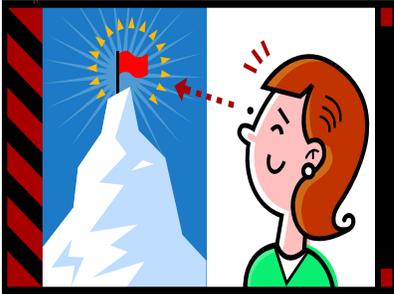
| Process Step | Potential Hazards? | Reasonably Likely to Occur? | Reasoning | Critical Control Point? |
|--------------|----------------------------------------------------------------|-----------------------------|--------------------------------------------------|-------------------------|
| Cooking | Biological - Pathogens: E. coli O157:H7, Salmonella and others | Yes | Pathogens are inherently present on raw products | Yes – CCP #1 |
| | Chemical - None | | | |
| | Physical – None | | | |

Cooking is a critical control point because it is essential for food safety: most common pathogens are killed if appropriate cooking temperatures are used. By ensuring that proper cooking temperatures have been met, the plant can ensure the product is meeting a high level of food safety.

Principle 3: Establish Critical Limits

At each critical control point, the establishment must identify corresponding critical limits.

Critical limits are measurable or observable values that can be used to judge whether specific food safety standards have been met.



When developing the critical limits, the HACCP team must consider the food safety standard or regulatory requirement that must be met. If a process can meet specific food safety standards, the resulting product will meet a certain food safety level. The critical limits are designed to ensure that the process meets specific goals or standards for food safety which have been scientifically determined through validated research studies.

Critical limits may be based on FSIS regulations or guidelines, FDA tolerances and action levels, scientific and technical literature, surveys, experimental studies or the recommendations of recognized experts in the industry, academia, trade associations or processing authorities. Most often, critical limits are parameters such as temperature, time, pH, physical dimensions, or the absence of target pathogens. They must be actual values that can be measured. Each establishment must be able to provide a basis for their decision regarding how they selected and developed their critical limits. This supporting documentation needs to be available for the inspector to review. A production process that has not met the critical limits may have produced an unsafe product.

An Example of a Critical Limit for a Process Step

| CPP (Critical Control Point) | Process Step | Critical Limit |
|------------------------------|--------------|-------------------------------------------------------|
| CCP #1 | Cooking | 158 °F or greater; ☆ Source: FSIS Appendix A |

The critical limit is the measurable value for a specific step in the process. It must have a specific value that must be met, not just a range of values. This is the minimum cooking temperature that must be met to ensure product safety! This goal is based on a FSIS guideline for cooking temperatures.

Principle 4: Establish Monitoring Procedures

Once critical limits are set for each CCP, procedures must be developed to monitor the CCP's. Monitoring is performed to determine whether the critical limits are being met.

Monitoring is a planned sequence of observations or measurements designed to assess whether the values for a CCP have been met. Monitoring procedures must be documented to provide evidence that the critical limits were met.

Every CCP in a HACCP plan must be monitored to ensure that the critical limits have been met. Each establishment is responsible for determining what procedure they will use to monitor each CCP. Usually these procedures are assessments or observations. If the critical limit is a numerical value, then monitoring usually involves taking a measurement. For critical limits defined as the presence or absence of something, the procedure usually involves direct observation.

Establishments must determine *how often* they need to monitor CCP's. Ideally, monitoring is done continuously; however, this may not be possible in many situations. An example of continuous monitoring is the continual recording of cooking temperatures on temperature recording charts. For intermittent monitoring, a frequency must be chosen. This frequency needs to be adequate to determine that a CCP is under control. An example of intermittent monitoring is the recording of the highest cooking temperature once per batch.

Any establishment employee may perform monitoring tasks. However, this is a very important task so it is necessary for this person to have proper training and understand the importance of monitoring. ***The HACCP plan needs to state the procedure being performed and the frequency at which it is being performed.*** It does not need to state *who* is performing the task but the task needs to be performed at the stated frequency by someone in the establishment.

The main goal of monitoring is to determine when specific food safety goals have not been met. If the critical limits have not been met, appropriate corrective actions need to be taken to ensure the product is safe.

Monitoring activities and their results must be documented on an official HACCP record. This provides written confirmation that the critical limits for each step were met for each batch of product produced in the establishment. The failure to monitor and/or document results could result in enforcement actions or a product recall!

An Example of a Monitoring Procedure for a Process Step

| CPP (Critical Control Point) | Process Step | Critical Limit | Monitoring Procedures |
|------------------------------|--------------|-------------------|-----------------------------------------------------------|
| CCP #1 | Cooking | 158 °F or greater | The product temperature will be recorded once per batch ☆ |

The monitoring procedure and frequency must be listed. Documents must be available to support how this frequency was determined and that they are using an acceptable method for measuring the temperature.

Principle 5: Establish Corrective Actions

For the next step, the establishment must determine what corrective actions they will take for each CCP in cases where the critical limit has not been met. This is called a “deviation from a critical limit”. When a CCP is not met, an actual or potential food safety hazard exists for consumers. The corrective actions that will need to be taken depend on the critical limit and the type of food being produced. For deviations from a critical limit, the corrective actions must consist of the following four actions:

- Identify and eliminate the cause of the deviation
- Ensure that the CCP is under control after the corrective action is taken
- Ensure that measures are taken to prevent the recurrence of the problem
- Ensure appropriate handling of any affected product. Unsafe product cannot be shipped or used for human consumption.

The HACCP plan should specify what action is to take place when a deviation occurs, who is responsible for implementing corrective actions, and that corrective actions will be documented as part of the HACCP records. When writing their HACCP plan, the establishment can list specific corrective actions they will take or they can simply state that they will address the regulatory requirements as stated in 9 CFR Section 417.3. In either case, the plant needs to think about what their corrective actions might be. *When a plant needs to take corrective actions, they must also document what these corrective actions were.*

An Example of a Corrective Action for a Process Step

| CPP (Critical Control Point) | Process Step | Critical Limit | Monitoring Procedures | Corrective Actions |
|------------------------------|--------------|-------------------|---------------------------------------------------------|--------------------------------------------------------------|
| CCP #1 | Cooking | 158 °F or greater | The product temperature will be recorded once per batch | Corrective actions will be taken as stated in 9 CFR 417.3. ☆ |

The corrective actions may be generically stated or specifically listed. Either way, the plant must meet the 4 requirements for corrective actions.

If a hazard occurs that hadn't been considered in the hazard analysis, different corrective actions are also required:

- Affected product needs to be segregated and held until a proper decision can be made regarding appropriate disposition
- Perform a review of the product to determine whether it is safe to distribute
- Prevent unsafe or otherwise adulterated product from entering commerce
- Perform a reassessment of the establishment's HACCP plan to determine if the new hazard should be routinely considered.

These corrective actions also need to be documented!

Principle 6: Establish Verification Procedures

Verification procedures are used to ensure that the HACCP plan is operating as intended. Doing these procedures confirms that the monitoring of the critical control points has been conducted as it was intended. Ongoing verification requirements include at a minimum, three types of procedures:

- **Calibration procedures:** Calibration is used to ensure that measuring devices are consistent and accurate. Measurements can only be as accurate as the instruments used to take the measurements. Routine instrument calibrations need to be done as part of the HACCP plan. If a device is found to be inaccurate, the establishment needs to determine if this resulted in the production of product that did not meet the critical limit.
- **Direct observation:** These procedures involve visual observation of the person performing the monitoring procedures. This is often confused with having the person doing verification performing the monitoring procedures periodically – it is important to remember that the verifier must actually observe the person performing the monitoring activities to do this procedure correctly.
- **Records review:** This procedure involves review of the HACCP records generated to ensure that all records were correctly completed, all activities were performed as per the HACCP plan and all results were within the critical limits.

All three verification procedures may not apply to every CCP. For instance, not all CCP's require calibration procedures because they do not use process monitoring equipment (like a thermometer). Each HACCP plan needs to contain each of these procedures at least once (if they apply). The written verification procedures must include the frequency that the procedures will be performed and the results of those procedures.



Types of Verification:

Internal verification (plant's do this!): Includes the daily review of HACCP records, revisions to the HACCP plans, spot checks or samples, calibration of equipment

External verification (regulatory officials/inspectors do this!): Includes review of written HACCP plans, review of records, review of corrective actions taken, visual observations of operations, random sample collection and review of plant's verification audits and corrective actions taken.

An Example of Verification Procedures for a Process Step

| CPP (Critical Control Point) | Process Step | Critical Limit | Monitoring Procedures | Corrective Actions | Verification Procedures |
|------------------------------|--------------|-------------------|---------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CCP #1 | Cooking | 158 °F or greater | The product temperature will be recorded once per batch | Corrective actions will be taken as stated in 9 CFR 417.3. | <p>The manager will observe the monitor taking product cooking temperatures once per week.</p> <p>All thermometers used to take product temperatures will be calibrated daily.</p> <p>Records review will be performed by the monitor once per week. ☆</p> |

Verification procedures must include calibration of instruments, direct observation and records review.

****CALIBRATION OF MONITORING EQUIPMENT****

The goal of calibrating monitoring equipment is to keep all measurements as accurate as possible. HACCP relies on accurate measurements of the critical limit parameters for food safety, so, it is important to use properly calibrated equipment for measuring the limits established for the Critical Control Points identified in the HACCP plan.



Each measuring device used in the monitoring process should be able to be calibrated. Often, the manufacturer of such equipment will include instructions on how to calibrate the specific equipment as well as how often it should be done. Whether you are using automatic smokehouses with internal thermometers or continuous recording devices, hand held thermometers, pH meters, or other equipment, it is important to keep them accurate and have written procedures that accurately document how they are calibrated and who is responsible for this task.

Regulations require that the calibration of all detection and measurement equipment should be included in the written HACCP plan under verification. The frequency of these calibrations must be stated in the plan as well. Calibration procedures and their results must also be documented in HACCP records.

Preshipment Reviews: This is another kind of verification activity that is specifically addressed in the HACCP regulations. Each establishment must review the records for each lot or batch or product before it leaves their control to be certain that all critical control points were met. They must verify that this has been completed by signing and dating the preshipment review records when they complete it.

Principle 7: Establish Recordkeeping and Documentation Procedures

Records are written evidence that document the operation of the HACCP system. These documents provide written evidence that the product made at the plant has met certain food safety standards. Every plant is required to have a recordkeeping system to document the implementation of their HACCP system. Measurements taken at CCP's, corrective actions and verification activities are examples of information that needs to be documented and kept on file.

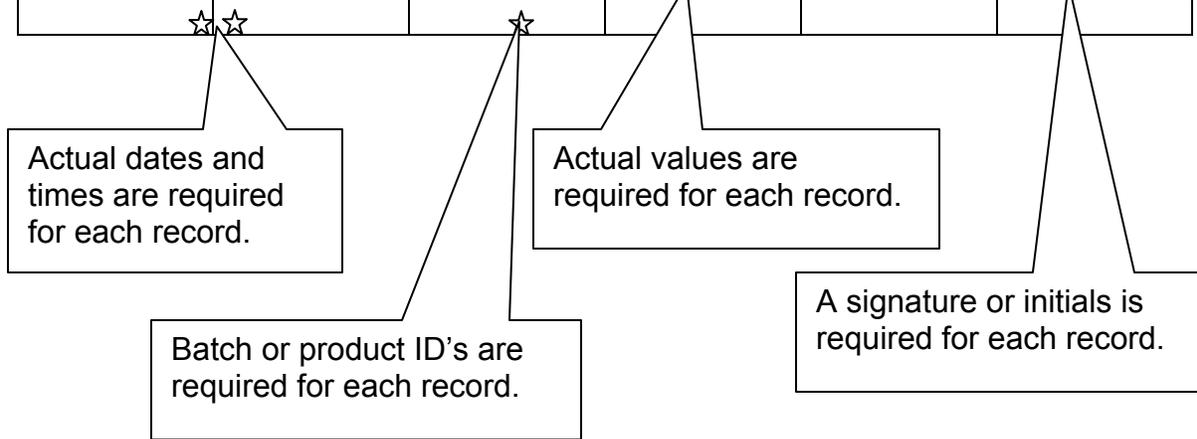
The HACCP regulation requires that all HACCP records:

- Contain the date and time of the activity;
- Contain the signature or initials of the employee making the entry;
- Have the information entered on the record at the time it is being observed;
- Contain actual observations or data values obtained; and
- Contain the product code or name

All establishments are also required to have appropriate supporting and decision making documentation as part of their records. Supporting documentation is any material used to support the rationale used to establish the CCP's, critical limits, monitoring procedures and frequencies, corrective action procedures and verification procedures and frequencies. This material may be scientific references, regulatory resources and materials from other sources. Historical data from the plant may also be used as supporting documentation in some situations.

Example HACCP Record

| Cooking Log | | | | | |
|-------------|----------|------------|---------------------|-----------------------------|------------------|
| Date | Time | Batch ID | Cooking Temp. (° F) | Met Critical Limit (Y or N) | Monitor Initials |
| 1/23/2006 | 12:07 PM | 012306-003 | 160 | Y | JL |



HACCP Summary

The development and implementation of a HACCP plan can be a challenging and sometimes, intimidating task. Often, it takes many adjustments and alterations to the plan before the plan can be practically implemented and maximize food safety practices for an establishment. Also, the HACCP system for an establishment needs to be reassessed each time the operation changes a procedure or process because the food safety hazards may also change. It is important to remember that HACCP is a fluid process and will continually need to be reassessed so it accurately reflects the plant's processes.

Remember that the HACCP plan needs to accurately reflect the actions of the establishment. In other words, the plant must do what the plan says they will do! This is a frequent problem identified by inspection personnel – the plan and the plant's actual procedures are not the same. If the plant's actual procedures are different than the plan, the safety of the product might be in jeopardy and the actual process may not be documented adequately.

**For HACCP, you must do what you say
you are going to do and document that
you did it!!**

Appendix A: 9 CFR 417

TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 417--HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Sec.

- 417.1 Definitions.
- 417.2 Hazard Analysis and HACCP plan.
- 417.3 Corrective actions.
- 417.4 Validation, Verification, Reassessment.
- 417.5 Records.
- 417.6 Inadequate HACCP Systems.
- 417.7 Training.
- 417.8 Agency verification.

Authority: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53.

Source: 61 FR 38868, July 25, 1996, unless otherwise noted.

Sec. 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action - Procedures to be followed when a deviation occurs.

Critical control point - A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit- The maximum or minimum value 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.

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

HACCP System- The HACCP plan in operation, including the HACCP plan itself.

Hazard - See Food Safety Hazard.

Preventive measure - Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument - An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official-The individual with overall authority on-site or a higher level official of the establishment.

Sec. 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. (3) Food safety hazards might be expected to arise from the following:

- (i) Natural toxins;
- (ii) Microbiological contamination;
- (iii) Chemical contamination;
- (iv) Pesticides;
- (v) Drug residues;
- (vi) Zoonotic diseases;
- (vii) Decomposition;
- (viii) Parasites;
- (ix) Unapproved use of direct or indirect food or color additives; and
- (x) Physical hazards.

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

- (i) Slaughter--all species.
- (ii) Raw product--ground.
- (iii) Raw product--not ground.
- (iv) Thermally processed--commercially sterile.
- (v) Not heat treated--shelf stable.
- (vi) Heat treated--shelf stable.
- (vii) Fully cooked--not shelf stable.
- (viii) Heat treated but not fully cooked--not shelf stable.
- (ix) Product with secondary inhibitors--not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(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 critical control points for each of the identified food safety hazards, including, as appropriate:

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

(ii) Critical control points 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 critical control points. 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;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with Sec. 417.3(a) of this part, 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 critical control points. 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 Sec. 417.4 of this part.

(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 Sec. 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this

section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

Sec. 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

- (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 as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with Sec. 417.4(a)(2)(iii) and the recordkeeping requirements of Sec. 417.5 of this part.

Sec. 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.

(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.

(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 actions; and
- (iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

(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 Sec. 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 Sec. 417.2(c) of this part.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. 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; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Sec. 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

- (1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;
- (2) The written HACCP plan, including decisionmaking 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 code(s), 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.

(c) 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 record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

Sec. 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;

(d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or

(e) Adulterated product is produced or shipped.

Sec. 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with Sec. 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with Sec. 417.3 of this part.

(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.

Sec. 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

- (a) Reviewing the HACCP plan;
- (b) Reviewing the CCP records;
- (c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
- (d) Reviewing the critical limits;
- (e) Reviewing other records pertaining to the HACCP plan or system;
- (f) Direct observation or measurement at a CCP;
- (g) Sample collection and analysis to determine the product meets all safety standards; and
- (h) On-site observations and record review.

Appendix B: Examples of Common Foodborne Hazards

Foodborne hazards are frequently separated into three types: **biological, chemical and physical**. Each step in the production process needs to be examined for the presence of each type of hazard. More information on common hazards is found below.

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Biological Hazards

The greatest risk for illness from food comes from biological hazards. Biological hazards are most commonly in the forms of bacteria, viruses, or parasites. These agents are called pathogens when they cause disease. Important factors in the production process such as improper storage/holding temperatures, inadequate cooking, poor personal hygiene, cross-contamination between raw and cooked foods, or improper cooling can impact the presence and growth of these agents.



In order for a foodborne illness to occur, the pathogen or its toxin (poison) must be present in the food. In some cases, only very small amounts of a pathogen can cause disease. In other cases, low numbers of a pathogen are not enough to cause foodborne disease. These pathogens must grow to high enough numbers to cause an infection or to produce a toxin (poison). For this to occur, the food must be capable of allowing the growth of the pathogen and the food must remain in the growth temperature range long enough for the organism to multiply and/or produce toxins. Lastly, enough of the contaminated food must be ingested to exceed the threshold of what a person can tolerate before showing signs of sickness.

Some examples of common pathogens of concern in meat and poultry include:

- Beef: *Salmonella*, *E. coli* O157:H7, *Clostridium perfringens*, *Listeria monocytogenes*.
- Pork: *Salmonella*, *Yersinia enterocolitica*, *Clostridium perfringens*, *Trichinella spiralis*, *Listeria monocytogenes*
- Poultry: *Salmonella*, *Campylobacter*, *Clostridium perfringens*, *Listeria monocytogenes*.

This is not an all-inclusive list; however, it gives an idea of the major pathogens associated with food. More information on these pathogens can be found on the following pages.



Escherichia coli O157:H7 (E. coli): These bacteria come from the intestinal tract of humans and animals. They are usually associated with the contamination of food or water with the ingesta or feces of cattle. It may also be transmitted from human to human through cross-contamination from an infected person with poor hygiene.

These bacteria can grow with or without oxygen. It grows best at body temperatures between 80-100 °F. It is killed with proper cooking/heating or low pH and low water activity of foods.

In humans, the main symptom of this pathogen is bloody diarrhea. This may lead to kidney damage, especially in young children, and/or blood clots which may lead to a stroke. This pathogen can be very serious and has been shown to be fatal in certain cases.

Methods of control: Thorough cooking of foods, proper refrigeration, good sanitation and personal hygiene of food handlers.

Campylobacter: These bacteria usually come from the intestines of animals and are associated with the consumption of milk, meat, or water. This pathogen can also be transmitted by direct contact with animals. Many outbreaks are associated with consumption of undercooked poultry, raw milk or contaminated nonchlorinated water.



Campylobacter grows best between 110-120°F. It can survive long term in freezing temperatures, but is easily killed by heat and drying.

The symptoms of infection with this pathogen are mild to moderate diarrhea. It may last from days to several weeks. Its effects are not usually fatal but can be more severe in immune compromised individuals.

Methods of control: Chlorination of water, pasteurization of milk, thorough cooking of poultry, avoiding cross-contamination of other foods from raw poultry, good sanitation and personal hygiene of food handlers.

Salmonella: Many different strains of these bacteria can cause illness in humans and animals. They come from the intestinal tract of animals and humans. It is commonly associated with poultry and other livestock. The primary method of ingestion is from eating raw or undercooked eggs, or contaminated milk, meat, and poultry.



The symptoms of this infection include diarrhea and vomiting and may last from days to weeks. In some cases, the disease can become very severe, with the infection spreading to all organs of the body.

Methods of control: Thorough cooking of foods, avoiding cross-contamination of other foods with contaminated food, low pH, good sanitation and proper hygiene of food handlers.



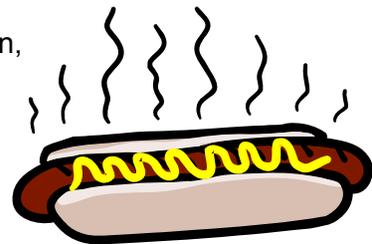
Staphylococcus aureus: These bacteria produce an enterotoxin (poison) that is the usual cause of foodborne illness associated with it. The toxin is heat resistant and can grow in certain foods if they are improperly stored under refrigeration. Foods like custards, salad dressings, sandwiches or meats are examples of foods that can be risks for pathogen growth if not stored properly. Many humans harbor the bacteria in their nasal passages and skin. Infected skin lesions are important sources of infection for food handlers.

Symptoms usually have a rapid onset and often occur within 2-4 hours of ingesting the toxin. They may include projectile vomiting and mild to severe diarrhea and usually last a day or two.

Methods of control: Proper hygiene of food handlers, proper refrigeration and cooling of foods, and holding of perishable foods at proper temperatures when hot.

Listeria monocytogenes: These bacteria come from the environment, animals, and humans. It can be found in water and soil as well as contaminated meats, dairy products, and even vegetables. It is also commonly found in ready-to-eat products with extended shelf life (Deli-meats, hotdogs, soft cheeses, etc.)

This infection is most serious in the fetuses of pregnant women, young children, and the elderly. It often appears with flu-like symptoms with varying severity (fever, headache, nausea, vomiting, delirium, and coma) within days to several weeks after ingestion and may from last days to weeks. This infection can cause abortions in pregnant women or be fatal in some cases, especially in the elderly.



This organism can grow at refrigerated temperatures, but also grows well at room temperatures. It is extremely hardy in comparison to most other pathogens. It can survive long drying periods and thrives in moist environments. It does not compete well with other organisms.

Methods of control: Proper heat treatment, low pH, avoiding cross-contamination of cooked products with raw products, maintaining proper temperature controls, and low water activity.

Clostridium perfringens: These bacteria also produce a toxin. It lives in the soil and intestinal tracts of people and animals. It produces spores that can survive heating and regrow during slow cooling of a food or improper refrigeration temperature. It then produces a toxin which can cause illness.

The most common symptom is diarrhea that usually occurs within 24 hours after ingestion and lasts about one day. It is often not reported to doctors due to the speed of the symptoms and its short duration.

Methods of control: Proper heating, reheating, and cooling of foods.

Yersinia enterocolitica: These bacteria may be found in contaminated pork. It lives in the mouth, tonsils, and nasal cavities of hogs and may be found in meat by cross-contamination with feces or ingesta during the slaughter process. It is not as common as some of the other bacteria mentioned; however it is responsible for some foodborne illness in humans each year.



Symptoms can be similar to appendix problems in humans including severe abdominal cramping and flu-like symptoms.

Methods of control: Proper heating of foods and avoiding cross-contamination of raw pork with other products

Trichinella spiralis: This is a roundworm (a type of parasite) often associated with pork. It can also be found in other meats like horse meat, deer/venison meat and bear meat. This organism penetrates the muscle tissue of infected species and can survive there indefinitely. Animals and humans become infected by eating raw or insufficiently cooked meat that has the parasite in it. Symptoms in infected people can range from muscle soreness and pain, fever or other flu-like signs.

Although relatively uncommon today in pork grown in conventional farming systems, all pork must still undergo heat treatment (or other process such as drying or freezing) to kill any potential parasites in the muscle tissues. This is also referred to as a “*Trichinae Treatment*” step. The parasite is very sensitive to hot and cold temperatures so control methods are very effective if performed properly.

Methods of control: Appropriate cooking of potentially infected meat, handling potentially infected meat such as pork separately from other meat, freezing meat.

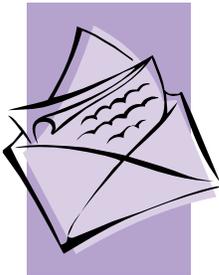
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Chemical Hazards

A wide variety of chemicals are routinely used in the production and processing of foods. They may be used for equipment lubricants, sanitizers, pest control and additives for treating water used in processing. Chemicals are also commonly used as antimicrobial agents in the slaughter process and some chemicals, like nitrites, are common in the formulation of sausages and cured meats. If used appropriately, these chemicals pose little hazard, but some of them are capable of causing severe health effects or even death if misused.



Chemicals can find their way into our foods in one of three ways: they can occur naturally in one or more of the product ingredients, they can be intentionally added during processing, or they can be added unintentionally. A letter of guarantee should be obtained from all suppliers of chemicals used in the processing facility. The letter should state that every item shipped to the establishment meets the specifications for its use and that they comply with all applicable laws and regulations.



Storage of chemicals is also very important. They must be labeled appropriately and stored in tightly sealed containers. All chemicals must be stored separately from food ingredients and packaging materials should also be covered and stored separately to avoid cross-contamination of food products with unapproved substances.

Allergens: Allergens have become an important consideration in the production of foods. They may pose significant health problems for a small percentage of people who have shown sensitivity to them. Foods that are commonly associated with allergic reactions include: peanuts, tree nuts (walnuts, pecans, etc.), eggs, dairy/milk products, soy, wheat, fish, and shellfish.



Because of the potentially serious impact allergens can have in certain people, they **must** be addressed as chemical hazards if they are used in the production of foods. Meat and poultry products containing allergens must contain appropriate labeling to inform consumers about potential risks. Cross-contamination of products with these allergens must also be considered throughout all stages of production.

Chemical Additives: Chemicals are commonly used to improve a product's appearance, flavor, shelf life, and safety. The levels of these chemicals must be closely monitored to ensure they are used safely. The Food and Drug Administration has established regulations to control which chemicals are allowed and at what level they can be safely used in food products. All chemicals added in the production process must also be listed on the ingredient statement.



Antibiotics and Hormones: The use of antibiotics and hormones is also closely controlled by regulations. Specific rules prevent the presence of these chemicals in animals which are used for human consumption. Drug Residue Testing is routinely done to ensure that meat and poultry products are free from illegal drug residues. While there is a low overall incidence of such chemical residues reported, these residues are of higher risk in certain types of animals, such as adult cows or veal calves.

Pesticides: Pesticides used in establishments include chemicals such as insecticides (insect control), rodenticides (rodent control), and fungicides (controlling molds). These are all required to have approval for use in food production areas from the Environmental Protection Agency (EPA). This approval includes specific instructions for their use and application. Always follow the manufacturer's directions when using these products.



Physical Hazards

Physical hazards are the least common of the three types, but may still pose significant problems. Physical hazards result most often in personal injuries such as a broken tooth, cut mouth, choking, or other non-life threatening problem. Glass, metal, wood and plastic are examples of some common materials associated with physical hazards. Some potential sources of physical hazards include:

- Contaminated raw materials
- Poorly designed equipment or facilities
- Improper maintenance of equipment
- Poor employee practices
- Processing procedure failure



Prevention of physical hazards begins at the receipt of the raw materials. All incoming materials and ingredients should be inspected upon receipt for any foreign materials or damage to the integrity of the package or box. A letter of guarantee from the supplier as well as material specifications should be collected to ensure the materials received are processed in a sanitary and proper manner.

All facilities should use good manufacturing practices (GMPs) in their day to day production. This will help ensure that their facility does not become a source of potential physical hazards in the foods they make. Proper installation of light fixtures, appropriate use of equipment, and adequate maintenance of the establishment and equipment is important.

Most physical hazards are introduced by employee practices. The most common types of contaminants are: jewelry, hairpins, pens, pencils, and paper clips. Following strict employee hygiene practices including proper attire, hair restraints, and absence of jewelry will help prevent many of these problems. Proper training of employees is also crucial to the success of preventing physical hazards in products.

For More Information

For additional information on HACCP or SSOP plan development, please refer to the following resources:

United States Department of Agriculture/Food Safety Inspection Service:

Contact Mary K. Cutshall at:
Small and Very Small Plant Outreach
USDA/FSIS
Aerospace Bldg., 3rd Floor, Room 405
14th and Independence Avenue SW.
Washington, DC 20250
202-690-6520

To obtain free copies of the models or materials, write to the above address or FAX requests to 202-690-6519.

HACCP models and most materials are available on the FSIS Website: <http://www.fsis.usda.gov>.
Many materials are also available in Spanish.

More specific information for businesses is available at:
<http://www.fsis.usda.gov/Business/index.asp>

FSIS Technical Service Center
1-800-233-3935

USDA Meat and Poultry Hotline
1-800-535-4555

USDA/FDA Food Safety Information Center
National Agriculture Library/USDA
301-504-5840; FAX: 301-504-6644
Email: fsic@nal.usda.gov
Website: <http://www.nal.usda.gov/foodborne/>

USDA Agriculture Research Service
(for a Pathogen Modeling Program on its website: <http://www.arserrc.gov/mfs/>)

International Meat and Poultry HACCP Alliance
979-862-3643
Website: <http://www.haccpalliance.org>