HACCP FOR RAW PROCESSES

CONTENTS

INTRODUCTION

This session will begin with a review of the raw processes, slaughter, raw product-not ground, and raw product-ground. We will briefly discuss common processing procedures from an industry perspective, including antimicrobial interventions. Then we will discuss establishment responsibilities, including the 7 HACCP (Hazard Analysis and Critical Control Points) principles, the regulations that establishments must follow, and common hazards. We will discuss the establishment's responsibilities for pathogen reduction, especially generic *E. coli* testing. Then we will examine the hazard analysis decision-making process that the establishment must perform, followed by demonstration of the inspection verification of the hazard analysis.

Next we will begin to examine the FSIS regulatory process, beginning with a discussion of the 01 and 02 procedures. We will conduct an in-depth review of the regulatory process for verifying compliance with the five regulatory requirements. We will continue with the regulatory process for verifying the slaughter food safety standards (commonly referred to as "zero tolerance"). Next we will examine how to perform the FSIS sampling programs and the pathogen reduction program for *Salmonella*.

We will continue with a discussion of the FSIS regulatory decision-making process, including: how to make noncompliance determinations, how to write NRs, how to use the noncompliance classification (trend) indicators, how to link NRs, and how to determine if an inadequate system exists. We will finish with a discussion of enforcement, including when to take immediate withholding, when to request an NOIE, and a brief review of further enforcement actions that FSIS might take.

OBJECTIVES

To demonstrate mastery of this module, the Consumer Safety Inspector will

1. Identify the regulatory processing categories.
2. Determine which of the regulatory processing categories are covered in the Raw products.
3. List the pathogens of concern in Raw products.
4. Identify biological/chemical/physical food safety hazards.
5. Identify the significance of performing the hazard analysis.
6. Identify the components of a HACCP plan and HACCP system.
7. Describe monitoring and verification activities.
8. State the difference between a HACCP noncompliance and a deviation.
9. Describe the plant's responsibility concerning a HACCP noncompliance and a deviation.
10. State where FSIS HACCP responsibilities are outlined.
11. List the 4 responsibilities for the CSI under the FSIS HACCP methodology.
12. Describe linkages and to what they may lead.
13. Describe the two components of a HACCP 01 and 02 procedure.
14. Describe a HACCP 01 and 02 procedure in relationship to the five regulatory requirements that will be verified.
15. Understand the difference between validation, verification, and pre-shipment review.
16. Identify the regulatory requirement for reassessment.
17. Identify the recordkeeping regulatory requirements.
18. Explain the pre-shipment review.

PROCESS FAMILIARIZATION

This section of training is about the nature of the regulated business. As regulators, we must have a general knowledge about the processes that the industry uses to produce products. Most of you are familiar with the slaughter processes (03J); therefore we will not cover the slaughter process steps other than information that pertains to food safety. Because some of you may not have experience with further processing, we will cover those operations in more detail. There are many different types of equipment, processes, and products that might be produced in processing plants. We are going to familiarize you with as much of this information as possible in this section. This information is important because it has an impact on some of the establishment's decisions when designing food safety systems. Having this knowledge will help you understand how to perform the verification procedures, which we will cover in later sections. We will cover some information about the technical aspects of the processes covered by this training. We will also cover some information about the science, especially as it applies to food safety.

Antimicrobial Interventions in the Slaughter Process

There are numerous antimicrobial interventions used today in slaughter processes. In this section, we will look at the most common and their effectiveness as shown in scientific studies. It should be noted that antimicrobial interventions are not a substitute for sanitary dressing procedures. In discussing the various interventions, we will use the beef slaughter process as our model for red meat and the young chicken slaughter process as our model for poultry. Let's begin by discussing beef slaughter interventions.

Beef Slaughter Interventions

Until recent years, knife trimming and carcass washing with plain water were the primary means by which the industry addressed meat contaminants. However, the occurrence of foodborne disease outbreaks and scientific advances over the years have shown that trimming and washing alone will not achieve the level of food safety that regulators and consumers expect from meat products. In response to food safety concerns, the industry and scientific community, with encouragement from FSIS, have introduced numerous antimicrobial interventions to the beef slaughter process.

• Steam Vacuum System

Steam vacuum systems are designed to remove small visible spots of contamination from carcass surfaces. The system is a hand-held apparatus that uses a hot water spray (185º F) in a vacuum nozzle, with steam sprayed above and below the vacuum head. The hot water sprayed onto a carcass kills 90% or more of the bacteria and detaches contamination such as ingesta or feces, which is then vacuumed off. Many establishments utilize the steam vacuum system at multiple points in the slaughter process. For example, there may be a steam vacuum location after each of the carcass parts is skinned.

The following items may be considered as guidelines for the use of the steam vacuum system. Establishments may develop alternate parameters and should have supporting documentation to validate the use of such parameters.

- Fecal and ingesta contamination *less than one inch* in its greatest dimension may be removed by the steam vacuum system; however, contamination *one inch or greater* in its greatest dimension should be trimmed by a knife.
- Accurate temperature and vacuum readings should be provided.
- Water or steam temperatures should be maintained at a minimum of 180º F.
- The vacuum pressure at the carcass surface should be sufficient to remove the steam and water from the vacuum area to prevent dripping.
- The outer surface of the vacuum head should be continuously sanitized by the 180º F minimum steam during its use.

• Carcass Washes Followed by Organic Acid Rinses

After hide removal, the carcass may be subjected to a pre-evisceration wash and subsequent organic acid rinse. The use of a carcass spray immediately after hide removal serves to remove bacteria before they have the opportunity to attach themselves to the carcass surface and begin growing. The subsequent organic acid rinse then provides a significant kill step for any bacteria that remain on the carcass surface. This intervention is also commonly applied after the slaughter process is complete and before the carcasses enter the cooler. The organic acids commonly used are *acetic* and *lactic*, although *citric* acid is also approved for this purpose. The concentration of the organic acid is between 1.5% and 2.5% and it may be applied as a mist, fog, or a small droplet rinse. (The establishment may use a concentration greater than 2.5% with supporting documentation.) Studies have shown that washing followed by an organic acid rinse is significantly more effective in reducing bacterial numbers than washing alone.

• Other Antimicrobial Chemicals

Some other chemicals utilized as an antimicrobial rinse in beef slaughter include the following:

Acidified Sodium Chlorite (Sanova®)—has been shown to have a significant kill rate for *E. coli* O157:H7*, Listeria, Campylobacter, Salmonella*, and other bacteria. Applied at ambient temperature by spray at 500-1200 ppm, it is being used in several establishments across the country.

Lactoferrin—Applied up to 2% of a water-based antimicrobial spray in the beef slaughter process, lactoferrin has been shown to be effective against more than 30 foodborne pathogens, including *E. coli* O157:H7*, Salmonella,* and *Listeria.*

• Hot Water Rinses

High temperature water (>160º F) sprayed on the carcass as the last step prior to chilling has been shown to be effective in substantially reducing the numbers of *E. coli* O157:H7 and *Salmonella.*

• Steam Pasteurization

Steam pasteurization is a process in which the carcasses are placed in a slightly pressurized, closed chamber at room temperature and sprayed with steam that blankets and condenses over the entire carcass, raising the surface temperature to 185º F and killing 95-99% of all bacteria. Carcasses are then sprayed with cold water.

Poultry Slaughter Interventions

The poultry industry has historically depended upon knife trimming, chlorine, and water washing to address carcass contaminants. In recent years, scientific research has brought new interventions to the young chicken slaughter process, which we will look at now.

• Antimicrobial Sprays or Dips

Many establishments have added antimicrobial carcass treatments after the final carcass wash and prior to chilling. Some chemicals commonly used include the following:

Trisodium Phosphate—This compound is being used in many establishments as a drench, spray, or dip and has been shown effective in preventing the attachment of bacteria to the skin. Used in concentrations of 8-12%, it has been shown capable of reducing *Salmonella* incidence 27-47%. TSP has been approved for use in establishments using online reprocessing of contaminated birds.

Acidified Sodium Chlorite (Sanova®)—Applied at ambient temperature by spray at 500-1200 ppm, this compound has been shown to achieve an average reduction in *Salmonella* prevalence of 27% and an average reduction of *Campylobacter* prevalence of 25%. Applied as a spray or dip, Sanova has also been approved for use in establishments using online reprocessing of contaminated birds.

Chlorine—Used at 20 ppm as a spray, it has been shown to produce a significant reduction in bacterial numbers.

• Hot Water Sprays

Hot water sprays (140º F), with or without chlorine, are being used on a trial basis to determine the effectiveness of reducing bacterial pathogens. Initial results showed a significant reduction in *Campylobacter* on the carcasses.

• Chiller Treatments

Several chemicals have been investigated as antimicrobial additives to the chiller water, but the most commonly used in practice are *chlorine* and *chlorine dioxide*. Chlorine is the most widely used sanitizer in poultry processing and levels up to 50 ppm at the fresh water intake may be used in the chillers. Chlorine dioxide may be used in chillers at a level not to exceed 3 ppm. Both have been shown to control cross-contamination by killing bacteria in the water and preventing their transfer from one carcass to another. Some poultry slaughter establishments are using a system which injects ozone into the chill water tank in order to reduce the numbers of bacteria in the water.

Multiple Hurdle Approach

Studies have shown that, rather than rely on any one intervention, it is more effective to use the "multiple hurdle" approach to pathogen control. In using this approach, an establishment will utilize multiple interventions at various steps of the process to achieve the maximum reduction in bacterial numbers on the carcass. For example, a beef slaughter establishment may utilize the steam vacuum at multiple locations as the carcass is dehided, rinse the carcass at pre-evisceration with water followed by an antimicrobial spray, then wash with water, steam pasteurize, and rinse again with an antimicrobial spray prior to chilling. A poultry slaughter establishment, as another example, may utilize a TSP rinse followed by chorine treatment in the chill water.

Some commercial applications have combined these different interventions to provide an enhanced antibacterial effect. For example, a beef slaughter establishment may use a process called Thermal Organic Rinse (TOR) which utilizes organic acid heated to 131º F to provide greater bacterial reductions. Other systems utilize a hot water wash followed immediately by an organic acid spray.

Process Familiarization for Raw Product—Not Ground

The raw product—not ground processing category (03C) includes all raw products that are not ground in their final form. Some examples are beef trimmings, tenderized cuts (e.g., injected or marinated), steaks, roasts, chops, poultry parts, fabricated products, and edible byproducts (e.g., livers, gizzards).

Receiving

The first step in these processes is receiving. Carcasses or parts are received either from other establishments, or from the slaughter department. After meat ingredients are received, they are stored in freezers or coolers until use. Any packaging materials or ingredients, if used, are also received and stored prior to use.

Written purchase specifications are developed by some establishments to ensure that a consistent product is received. Specifications are formal agreements between the supplier and the purchaser, and may include quality aspects, such as portions of lean and fat, and safety factors such as laboratory testing for pathogens.

Refrigeration achieves several purposes. Carcasses are chilled after slaughter for a specified period, allowing them to become firm enough to cut. Refrigeration reduces moisture loss from the product. It slows down metabolic and enzymatic activities within the meat tissues that would lead to product deterioration.

Refrigeration is also an important food safety factor. It slows the growth of microorganisms, including spoilage bacteria and pathogens. Continuous refrigeration is essential to control microbial growth. The temperature and the holding time of the raw materials affects the multiplication of microorganisms. Meat products must be maintained at refrigeration temperatures adequate to control spoilage and growth of pathogens.

Chiller or cooler temperatures substantially retard most pathogen growth. Chiller storage is temporary, however, because even at these temperatures, the spoilage organisms will continue to grow, although at a very slow rate. Freezers halt the growth of all bacteria. Product kept frozen will maintain safety and quality for longer periods of time.

Sanitation

Sanitation procedures are essential in processing raw products. Any contaminated product contact surface could transfer bacteria, potentially including pathogens, to product. Sanitation procedures should prevent cross-contamination from equipment, personnel, traffic, air flow, tables, and floors. Establishments that process more than one species should implement controls to prevent cross-contamination between different species.

Fabrication

Fabrication refers to creating the various cuts from the carcass to produce particular types of product. Primal or wholesale cuts are made first. Their names usually identify where the meat comes from on the animal, such as the loin, the shoulder, etc. The plant typically uses large mechanized saws to fabricate the carcass into primal cuts.

Retail cut names tell what part of the primal cut the meat comes from, for example, rib roast or round steak. Retail cuts may be made with a saw, especially if they include bone. Primal parts are often boned before cutting into retail cuts, in order to produce boneless items. Establishments that produce portion-controlled retail cuts for hotels, restaurants, and institutions are often called HRI operations.

Tenderization

Tenderization is another procedure used in some plants. All cuts can be tenderized, but this is typically applied to cuts from lower quality grades and less tender cuts of higher graded carcasses. There are several methods for tenderizing meat. They include aging, use of enzyme solutions, and use of mechanical tenderizers. Mechanical tenderizers typically press many thin blades through the meat pieces, cutting the muscle fibers. Whenever cuts are made into a piece of meat, any bacteria on the surface of the meat, or on the equipment, will be spread onto the cut surfaces. This is particularly significant during mechanical tenderization, when many cutting blades are inserted into the center of the meat, potentially drawing bacteria down from the surface.

Marination

Marination is the process of soaking, massaging, tumbling, injecting, or otherwise combining a liquid solution with the meat or poultry product. Products are marinated to improve taste, tenderness, color, juiciness, or other sensory attributes. Some examples of ready-to-cook marinated products include lemon-herb flavored boneless chicken breast, beef strips for fajitas, or seasoned pork roast.

Curing

There are also some uncooked cured products. Curing refers to the addition of certain additives to preserve the product and stabilize the color, most commonly salt and/or nitrite. The amounts of nitrite and the less commonly used nitrate are restricted by FSIS regulations; thus they are often referred to as “restricted ingredients.” These cure ingredients are sometimes mixed with water to form a curing solution, or “pickle,” before adding them to the meat or poultry products. Some examples of uncooked, cured products include corned beef briskets, cured beef tongues, or cured pork tails packed in brine.

Byproducts

Establishments may deal with edible byproducts in either the slaughter or the raw—not ground process category. They may be sold as fresh or frozen items, or used to make other processed foods. Here are a few examples of edible byproducts.

- **Casings** for sausages are sometimes made from sheep, hog, or beef intestines (distal portion of ileum removed as specified risk material (SRM) for beef).
- **Blood** is used as an ingredient of certain specialty products.
- **Sweetbreads** are thymus glands obtained from the ventral side of the neck and inside the chest cavity of young cattle.
- **Hearts, livers, and tongues** are sometimes used in the production of processed products.

Mechanically Separated Product

The mechanical separation process is a way to obtain more usable product from bones from which the muscle has been removed. Often, you will see these products referred to as **"mechanically separated product."** The species that can be used are lamb, pork, chicken, or turkey. Mechanically separated beef is **not** allowed.

Bones for this process have usually already had most of the muscle tissues removed by hand boning, or they are bones, like neck bones, which are difficult to process. The bones are ground up, and the resulting mass is forced through a sieve. The softer muscle particles are thus separated from the hard bone particles, which remain behind the sieve. The resulting product has a paste-like consistency.

Great pressure is used to force the product through the sieve, which results in a temperature rise in the product. Therefore, product must be processed quickly and the temperature immediately reduced in order to prevent oxidation and microbial degradation of the product. Even with these precautions, this product will deteriorate quickly.

Although mechanically separated product has many of the characteristics of meat and may be used as a meat ingredient in the formulation of quality meat food products, it is not "meat" as defined in the regulations. In particular, the consistency of mechanically separated livestock product and its mineral content are materially different from those of meat. A certain amount of fine bone particles and bone marrow are incorporated as part of the process, increasing the calcium and iron content of the product. There are specific limits on the quantity and size of the bone particles included in the final product.

A similar process is called **advanced meat recovery (AMR).** This process obtains the meat tissues from the bones without including materials that are not normally expected in meat. The resulting product consists of distinct particles of meat, with the typical color and texture of the species used. There are no special limits on the use of this product. FSIS has established and enforced regulations that prohibit spinal cord from being included in products labeled "meat."

Because the vertebral column and skull in cattle 30 months and older is considered inedible (SRM), these cannot be used for AMR (§ 318.24).

Packaging

Packaging materials protect the product from damage during refrigerated or frozen storage. Product may be packaged into retail size packages, into larger containers for institutional use, or into bulk containers for sale to other establishments for further processing. Although there are many different combinations of packaging materials in use, plastic films and cardboard boxes are some of the materials commonly used.

Distribution

The final step is distribution, either to other departments in the same plant, or to other plants or retail markets.

Process Familiarization for Raw Product—Ground

This processing category includes all raw products that are ground. Beef, pork, veal, lamb, chicken, and turkey can all be ground and sold or used in other products. Some of the common products are ground beef, hamburger, ground beef patties, ground pork, fresh sausage, Italian sausage, and ground poultry products.

Raw Materials

Raw materials for ground products include boneless meat, trimmings of different fat content, meat from older animals, head meat, cheek meat, diaphragm meat, esophagus, and advanced meat recovery products. Grinding is a way that establishments can use lower quality products that would not be saleable to a retail consumer. In addition to beef trimmings, ground beef is also commonly made from flanks, short plates, shank meat, briskets, and chucks. Meat ingredients used may be fresh or frozen, or a combination.

Some of these raw materials have undergone several processing steps already and have the potential to have become contaminated. Grinders are dependent on their suppliers to eliminate or reduce microbial hazards because antimicrobial treatments and interventions are most practical when the product is still intact.

Nonmeat Ingredients

Sometimes ground products contain nonmeat ingredients. Ground products are often seasoned with salt, sugar, spices, or other flavorings. Depending on the product being made, water may be added, and some product formulations include binders and extenders such as soy flour or nonfat dry milk.

Establishments use a formula to create a consistent product batch after batch. The formula lists the weights or percentages of ingredients to be used. Meats and other ingredients are weighed before use to ensure that the proper amount of each is added to the batch.

Reduction of Particle Size

Comminution is the process of reducing the particle size of meats. Several different machines are used, including the flaker, the grinder, and the bowl chopper. Some producers use a combination of several of these in the production of a product.

The **flaker** is used on large frozen blocks of meat or meat trimmings. Product is pressed against the knife blades, which shave off pieces of the still-frozen meat, enabling it to be used in formulation without thawing.

The **grinder** consists of a hopper into which the meat chunks are placed. The meat then moves along an auger or screw, through a cylinder, at the end of which is a grinding plate and a knife.

As the meat is pressed up against the plate, the knife turns and cuts off small bits of the meat. The size of meat particle produced is determined by the size of the holes in the grinding plate.

Another method of reducing particle size is the **bowl chopper**. This machine consists of a metal bowl that revolves and a metal knife that rotates, cutting through the meat pieces in the bowl. The bowl chopper also mixes product as it chops it.

Sometimes meat ingredients go through several grinding processes. Often, fat and lean meat ingredients are ground separately and then combined.

Mixing

After comminuting, products are mixed thoroughly. Product is often transferred to a separate piece of equipment, called a mixer or blender, in order to mix it. The mixer consists of a chamber that the ingredients are placed into, and blades or paddles that turn and mix the product, resulting in a uniform distribution of fat and lean particles. Non-meat ingredients, if used, are added at this stage.

Shaping/Forming

After being comminuted and mixed, the ground meat mixture is often shaped into different forms. Fresh sausage may be extruded into a casing. Hamburger or ground beef is often shaped into patties using a patty machine. After formation, the patties may be frozen.

Metal Detection

Because of the moving parts and high mechanical forces common in these operations, there is a possibility of metal chipping or breaking. Proper maintenance of equipment is essential to reduce this possibility. Some establishments use a metal detector to identify product that may be contaminated with metal fragments.

Trace Back and Trace Forward

Although the grinding establishment may not have access to records of the farm sources of their raw material, or records maintained by the plants that slaughter, dress, and bone their raw materials, they should purchase raw materials from suppliers that maintain such records. Establishments should also maintain records of distribution of products. These records can facilitate trace back and trace forward in the case of a recall or of an outbreak of foodborne illness.

Some establishments have developed a production coding system for tracking purposes. These systems enable the establishment to track the product from the raw material source up to the finished product. Some establishments use the period of time between clean-ups as a

production lot. This is because all product produced between clean-ups would be implicated in a recall.

Rework

Rework is sound finished product that is reincorporated into a batch of fresh ingredients prepared to make similar finished product. Establishments also sometimes choose to develop a rework tracking system to reduce the amount of product that would be implicated in a recall. Some establishments include all rework at the end of the production day, or divert it to cooked product processing departments.

There have been instances where a product recall was greatly affected by the establishment's ability to track the use of rework. In one example, an establishment recalled a large amount of product due to the presence of *E. coli* O157:H7, found during the investigation of an outbreak of foodborne illness. Review of the establishment's production practices revealed that some of the production lot that was recalled had been used as rework in subsequent days' production. As a result, the recall was expanded to include the entire amount of production that may have included the rework. This recall eventually involved over 25 million pounds of product.

Antimicrobial Interventions for Raw—Not Ground and Raw—Ground Products

Acidified Sodium Chlorite

Acidified sodium chlorite (Sanova®) is an antimicrobial agent, effective against most of the pathogens of concern. Acidified sodium chlorite solutions are typically applied at ambient temperature as either sprays or immersion dips, directly to the surfaces to be treated, at 500-1200 ppm. Although it is most commonly used in slaughter operations, it is permitted for use on parts or trimmings post-chill with no requirements for treated product labeling. Products treated with acidified sodium chlorite that retain water would need to reflect this on the label. Use of acidified sodium chlorite results in significant reduction of all microbial species, for example, 2-$\log_{10}$ reduction for *Escherichia coli* and 1-$\log_{10}$ reduction for total aerobics.

Milk-Derived Lactoferrin

Milk-derived lactoferrin is permitted for use as an antimicrobial spray that contains up to 2% lactoferrin, applied to uncooked beef parts. It must be declared on the label as “treated with lactoferrin from milk.”

Ozone

Ozone may be used in contact with food as a gas or liquid as an antimicrobial in meat and poultry products, including ground meats.

Irradiation

Food irradiation is the process of exposing food to radiant energy in order to reduce or eliminate bacteria. Ionizing radiation will reduce, and in some circumstances eliminate, pathogenic microorganisms in or on meat and poultry. FSIS has included ionizing radiation as an approved additive in pork carcasses and fresh, or previously frozen, cuts of pork that have not been cured or heat processed for the control of *Trichinella spiralis*, which causes trichinosis. Ionizing irradiation is also recognized as an approved additive in fresh or frozen, uncooked, packaged meat or poultry products for the purpose of reducing pathogenic microorganisms and extending shelf life.

Radiation is broadly defined as energy moving through space in invisible waves. Radiant energy has differing wavelengths and degrees of power. Forms of radiant energy include: microwave and infrared radiation, which heat food during cooking; visible light or ultraviolet light, which are used to dry food or kill surface microorganisms; and ionizing radiation, which penetrates deeply into food, killing microorganisms without raising the temperature of the food significantly.

Treating product with irradiation could result in the significant reduction or even the elimination of certain pathogens. Ionizing radiation has been shown to be effective at eliminating *Salmonella*, *E. coli* O157:H7, *Clostridium perfringens, Staphylococcus aureus, Listeria monocytogenes*, and *Campylobacter jejuni*.

Irradiation dose is measured in kiloGray (kGy); the maximum dose for use on meat products is 4.5 kGy. The radiation dose necessary to reduce the initial population of many of the bacterial pathogens by 90% (the D-value, or 1-$\log_{10}$) ranges from 0.1 kGy to just under 1 kGy. Higher radiation doses are needed to accomplish the same anti-microbial effect in a frozen food versus a nonfrozen food.

Irradiation does not significantly increase the temperature or change the physical, sensory, or nutritional characteristics of foods. Because irradiation does not raise product temperature, product is still raw and requires refrigeration.

The irradiation process requires a source of energy. The two types are radioisotopes (radioactive materials such as cobalt or cesium) or machines that produce high-energy beams.

The Food and Drug Administration (FDA) regulates all aspects of irradiation: what products it can be used on, what dose can be used, and how those products are labeled. The USDA is responsible for the inspection and monitoring of irradiated meat and poultry products and for the enforcement of FDA regulations concerning those products.

The “radura” is an internationally recognized symbol identifying irradiated food. The FDA requires that both this logo and a statement (“Treated with irradiation” or “Treated by irradiation”) must appear prominently on the label of packaged foods, and on bulk containers of unpackaged foods.

Processing Categories

9 CFR 417.2(b) requires establishments to 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. The regulation lists processing categories that group products by major processing parameters.

We will be discussing the three processing categories that deal with raw products. They correspond to the procedures in the Inspection System Procedure Guide (ISP).

- **Slaughter--all species, 03J,**
- **Raw product--ground, 03B and**
- **Raw product--not ground, 03C**

A single HACCP plan may be written for **multiple products** within a single processing category, as long as the hazards, critical control point, critical limits, and other HACCP regulatory requirements are essentially the same.

Some products can fall into more than one processing category. For example, one establishment may have a HACCP plan for beef carcasses, another for byproducts and a third for fabrication of primal parts. Another establishment might group all of these products into one HACCP plan. The important focus is not what processing category, but rather whether all of the regulatory requirements have been met.

Examples Of Products In Each Process Category		
Slaughter 03J01/02	**Raw--Not Ground 03C01/02**	**Raw—Ground 03B01/02**
Beef carcass	Beef forequarter	Ground beef
Veal carcass	Veal shanks	Ground beef patties
Pork carcass	Pork loin, boneless	Hamburger
Lamb carcass	Lamb rib chops	Beef patty mix
Goat carcass	Chicken parts	Ground pork
Chicken, whole	Turkey breast cutlets	Ground lamb
Turkey, whole	Beef trimmings	Ground chicken
Duck, whole	Mechanically separated pork	Ground Turkey
Squab	Beef liver	Italian sausage
Rock Cornish hen	Mechanically tenderized beef roasts	Fresh pork sausage
Ratite carcass (ostrich, rhea, emu)	Beef steaks, tenderized with enzyme solution	Breakfast sausage links
Equine carcass	Boneless skinless chicken breasts marinated in seasoning solution	Turkey bratwurst
Other exotic species carcass	Uncooked, corned beef brisket	Fresh chorizo

Establishment Responsibilities

Note: *This section is informational material to give you a basis for understanding what the establishment responsibilities are related to HACCP. It includes a review of the 7 HACCP Principles, hazards of concern for Raw products, and example flow charts and hazard analyses.*

FSIS has the overall authority and oversight to regulate meat/poultry products intended for distribution into commerce. The official establishment's responsibility is to produce safe wholesome meat/poultry products. When the Pathogen Reduction/HACCP System Final Rule was published in July 1996, and the regulation was first implemented in large establishments in January 1998, in small establishments in January 1999, and in very small establishments in January 2000, FSIS required all establishments that produce federally inspected meat and poultry products to design and operate HACCP systems. HACCP provides a framework for establishments to conduct science-based process controls that can be validated as effective in eliminating, preventing, or reducing to an acceptable level the food safety hazards that are reasonably likely to occur in an official establishment's particular production processes. Under the HACCP regulatory system, establishments assume full responsibility for producing products that are safe for consumers.

The 7 HACCP Principles

The National Advisory Committee on Microbiological Criteria for Food (NACMCF) Working group created guidelines and redefined the seven basic principles of HACCP as an effective and rational means of assuring food safety from harvest to consumption. The working group created the HACCP principles and application guideline document which was adopted in August 1997. This paper is not a regulatory document. However, it is a document that was utilized by FSIS when the HACCP regulation was developed and then published in the Federal Register. As regulators, you will be responsible for verifying compliance with the HACCP regulation. The HACCP guideline with the seven principles is not an enforceable document; however, it is helpful for inspection personnel to be familiar with the basis for the development of the HACCP plan which will be regulated under Title 9 Code of Federal Regulation (CFR) Part 417. The Inspection Methods and Regulatory Decision-making section later in this training will cover your regulatory responsibilities.

The 7 HACCP Principles

The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards 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.

A thorough hazard analysis is the key to preparing an effectively designed HACCP plan. The NACMCF[1] identified the purpose of the hazard analysis in the guidance document as a process used to develop a list of hazards which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. It is important to consider in the hazard analysis the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer. When conducting a hazard analysis, safety concerns must be differentiated from quality concerns.

A hazard is defined by NACMCF as a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. Establishments must consider all three types of hazards – biological, chemical, and physical – at each step of the production process. A food safety hazard that is reasonably likely to occur is one for which a prudent plant would establish controls because the hazard has historically occurred in the product/process or because there is a reasonable probability that the hazard would occur in the absence of these controls.

The hazard analysis and identification of associated control measures accomplish three objectives: (1) hazards and associated control measures are identified, (2) the analysis may identify needed modifications to a process or product so that product safety is further assured or improved, and (3) the analysis provides a basis for determining Critical Control Points (CCP) in Principle 2.

Hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product. A summary of the HACCP team decisions and the rationale developed during the hazard analysis should be kept for future reference. Upon completion of the hazard analysis, the hazards associated with each step in the production of the food should be listed along with any measure(s) that are used to control the hazard(s). The term control measure is used because not all hazards can be prevented, but virtually all can be controlled. More than one control measure may be required for a specific hazard. On the other hand, more than one hazard may be addressed by a specific control measure.

[1] The National Advisory Committee on Microbiological Criteria for Food (NACMCF) describes the seven principles in its HACCP document. The document and its revisions are currently on the NACMCF webpage, http://vm.cfsan.fda.gov/~comm/nacmcfp.html. Note Principle 6 and 7 above are switched from the document to meet the current FSIS regulation order for the HACCP principles.

Federally inspected establishments must conduct hazard analyses for their processes. The plant can either conduct the hazard analysis itself or have an outside source conduct it. This first principle is the key to a successful food safety system within the establishment. The identification of the food safety hazards in the hazard analysis must be thorough in order to ensure that the HACCP plan when executed will result in an adequate food safety system. When the hazard analysis is not well thought out, it results in a design flaw, and products may be produced and distributed into commerce that poses a food safety hazard to the consumer.

These concepts from the first principle will be discussed further in the next section.

Flow Charts

At each step, the establishment must determine what food safety hazards may be associated with that step, if that hazard is reasonably likely to occur in the process, and what controls will be used to prevent, eliminate, or reduce the hazard to an acceptable level. The control point for a hazard may be further along in the process than the point at which the hazard occurs. For example, the cooking step is the most common control for biological hazards that have been introduced into the product at previous steps.

Each establishment is responsible for identifying the hazards reasonably likely to occur in its process, and for determining how it will control those hazards to prevent, eliminate, or reduce them to an acceptable level. Different establishments may have identified different hazards as reasonably likely to occur and different control measures for them, even though their processes may appear to be similar. For example, differences may exist in the type of equipment, incoming product, employee training, or production practices.

When completed, the hazard analysis should have

- Identified hazards reasonably likely to occur, and

- Identified the associated preventive measures that can be applied to control these hazards.

The hazard analysis shall include hazards that can occur before, during and after entry into the plant.

This provides a basis for determining the critical control points (CCPs).

Principle 2: Determine critical control points

The hazards that were identified in the hazard analysis must be addressed in the HACCP plan. A hazard is controlled by one or more critical control points (CCPs).

A ***critical control point*** is defined as 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 control points are locations in a process at which some aspect of control can be applied to control food safety hazards that have been determined reasonably likely to occur.

Examples of CCPs include product temperature, certification of incoming product, microbiological testing, testing for foreign objects such as metal contamination, the chemical concentration of a carcass rinse or spray, and other such parameters.

The step of the process 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 is the plant's responsibility to determine the location of its CCPs. They may be placed at any location deemed adequate to prevent, eliminate, or effectively control the hazard in the meat/poultry product produced.

Control may actually be achieved as a cumulative effect. There may be several steps in the process that together attain sufficient control, but individually do so only partially. For example, an official establishment that slaughters cattle may have a pre-evisceration organic acid rinse, a post evisceration organic acid rinse, and a wash step followed by steam pasteurization.

For ***each*** hazard that is determined to be reasonably likely to occur, the establishment must identify critical control points and corresponding critical limits that are measurable or observable. Establishments must have documentation supporting all of these decisions, and they must be able to demonstrate that their plan designs are valid and effective in operation.

Principle 3: Establish critical limits

The next step in the development of a HACCP plan is to establish critical limits for each critical control point. ***Critical limits*** (CL) are the parameters that indicate whether the control measure at the CCP is in or out of control. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) states that a CL is **a maximum or minimum value** to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The HACCP team must consider the food safety standard that must be met at each CCP. Critical limits are designed to ensure applicable targets or performance standards pertaining to the specific process or product. Critical limit design should be based on applicable 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. Critical limits should not be confused with operational limits which are established for reasons other than food safety.

Critical limits are most often based on process parameters such as temperature, time, physical dimensions, or presence of target pathogens. Critical limits must be actual values that can be measured or quantified. Regardless of the parameter used, the critical limit must be sufficient to prevent, eliminate, or reduce to an acceptable level the occurrence of the food safety hazard it is designed to control. The establishment must be able to provide the basis for their decision documents regarding the selection and development of the critical limits. The HACCP team must develop CLs that work effectively given the capabilities and limitations of the plant's processes.

Principle 4: Establish monitoring procedures

Once critical limits are set for each CCP during the HACCP plan development, procedures must be established to monitor the CCPs to determine whether the critical limits are being met. ***Monitoring*** is a planned sequence of observations or measurements to assess whether a CCP

is under control and to produce an accurate record for future use in verification. Every CCP that is in the HACCP plan must be monitored to ensure that the critical limits are consistently met and that the process is producing safe product. Establishments are responsible for determining the procedure used to monitor each CCP. Monitoring procedures usually involve either a measurement or an observation. If the critical limit is a numerical value, then monitoring usually involves a measurement. If the critical limit is defined as the presence or absence of an attribute, then the monitoring procedure may involve observation. Monitoring procedures should be designed to determine when deviations from the critical limit occur so that appropriate corrective actions can be initiated.

Establishments must determine how often they need to monitor CCPs. Ideally, the monitoring frequency would be continuous whenever possible. An example is the continual recording of cooking temperatures on temperature recording charts. The advantage of continuous monitoring is that it allows a plant to see what is occurring at a CCP throughout the production process at any given time.

When it is not possible to monitor a CCP on a continuous basis then it is monitored intermittently and the frequency must be determined. The frequency selected should be adequate to determine that the CCP is under control. Statistically designed data collection or sampling systems are used to establish the frequency when monitoring is not on a continuous basis. Establishments can select any employee to conduct monitoring activities. Assigning monitoring responsibilities is an important consideration for establishment management. HACCP monitors are often production employees or quality control personnel. Employees selected to be HACCP monitors should be adequately trained and should understand the purpose and significance of monitoring. They should also be trained to immediately report unusual occurrences to the individual responsible for initiating corrective actions. The HACCP plan does not have to specify ***who*** will do the monitoring.

From a practical consideration, monitoring has three objectives:

- ***To track control of the process*****.**
  Monitoring the process allows the establishment to identify situations in which a trend is developing that may lead to loss of process control. If monitoring detects such a trend, plants can take appropriate measures to restore process control ***before*** a deviation occurs.

- ***To determine when there is a loss of control and a deviation occurs*****.** Monitoring serves to determine when the process has deviated from the critical limit. This information lets the establishment know appropriate corrective actions must be taken to restore process control and to effectively address all affected product.

- ***To provide a written document to be used in verification*****.**
  Monitoring results must be recorded on official HACCP records, and such records serve as the basis for verification activities.

Principle 5: Establish corrective actions

Next, the HACCP team determines corrective actions for each CCP that must be taken in cases where the CL is not met. The specific corrective actions depend upon the process used and type of food produced.

When there is a deviation from the critical limit, corrective actions are required to prevent potentially hazardous foods from reaching consumers. The HACCP plan must include corrective actions to be taken when a deviation from the critical limit occurs at a critical control point. The corrective actions consist of

- Identifying and eliminating the cause of the deviation,
- Ensuring that the CCP is under control after the corrective action is taken,
- Ensuring that measures are established to prevent recurrence, and
- Ensuring that no product affected by the deviation is shipped.

HACCP plans should specify what 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 designing their HACCP plans, establishments can either specify particular corrective actions they will take when a deviation occurs, or can simply state that they will address the regulatory requirements in Title 9 CFR Section 417.3 Corrective Action. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.

Principle 6: Establish recordkeeping and documentation procedures

When developing the HACCP plan, the HACCP team must ensure that the HACCP system has an effective recordkeeping system. ***Records*** are written evidence documenting the operation of the HACCP system. All measurements taken at a CCP, and any corrective actions taken, should be documented and kept on file. These records can be used to trace the production history of a finished product. If any questions arise about the product, a review of records may be the only way to determine whether the product was produced in a safe manner according to the HACCP plan.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1998) recommends that the establishment maintain four types of records. *Remember that these are recommendations which may be in addition to the regulatory requirements as outlined in 9 CFR Part 417.*

- Summary of the hazard analysis including the rationale
- HACCP plan
- Support documentation such as validation records
- Daily operational records generated during the operation of the HACCP plan

The **summary of the hazard analysis** covers the basis and justification for an establishment's HACCP plan. This includes information about decisions the HACCP team made during the hazard analysis process. It contains all the information about the hazard analysis, including justification for CCPs and critical limits.

The **HACCP plan** outlines the formal procedures the establishment will follow to meet the seven principles. The NACMCF recommends that the HACCP plan records a

- List of the HACCP team and assigned responsibilities
- Description of the food, its distribution, intended use, and consumer
- Verified flow chart for the entire manufacturing process with CCPs indicated
- HACCP Plan Summary Table that lists the following for each hazard of concern—the CCP, critical limit, the monitoring procedures and frequencies, the corrective actions, the verification procedures and frequencies, and the recordkeeping system.

The **supporting documentation** includes the rationale used to establish CCPs, critical limits, monitoring procedures and frequencies, corrective action procedures, and verification procedures and frequencies. This includes all scientific references, regulatory resources, and materials from other sources (e.g., extension services, academic experts, consultants, industry trade associations) that have been used in the development of the HACCP plan.

The **daily operational records** are what most of us think of when we think of HACCP records. These include the actual records from the implementation of the HACCP plan (monitoring, corrective actions, and verification).

The HACCP records should:

- Contain the date and time of the activity reflected on the record
- 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

Principle 7: Establish verification procedures

HACCP systems must be systematically verified. In the NACMCF explanation of the verification principle, which FSIS is following, four processes are involved in the verification of the establishment's HACCP system. The establishment is responsible for the first three; FSIS is responsible for the fourth. The first is the scientific and technical process, known as validation for determining that the CCP and associated critical limits are adequate and sufficient to control likely hazards. The second process is to ensure, initially and on an ongoing basis, that the entire HACCP system functions properly. The third process consists of documented, periodic, reassessment of the HACCP plan. The fourth process defines FSIS's responsibility for certain actions (government verification) to ensure that the establishment's HACCP system is functioning adequately.

Verification establishes the accuracy of, or confirms the monitoring of, the critical control points. The verification procedures demonstrate that the HACCP system is adequately controlling food safety hazards. After initial validation the system must be verified periodically. Periodic verification involves the use of methods, procedures, or tests in addition to those used for monitoring, to determine whether the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation to achieve its food safety objective. Establishments must also be able to provide supporting documentation for the verification procedures and frequencies specified in the HACCP plan.

Ongoing verification activities consist at a minimum of calibration procedures (if there are instruments that require calibration), direct observations of monitoring and corrective actions, and records review. All three of these will be described in the HACCP plan, as applicable.

The goal of **calibration procedures** is to ensure that all measurements are accurate. If the findings from the procedures show that the measuring device is incorrect, then the device must be recalibrated or replaced. The establishment should determine if the inaccurate process-monitoring instrument permitted the production of products that did not meet the critical limit. If it is determined that the critical limit was not met, the establishment would have to implement corrective actions.

The **direct observation** procedures and frequency for this type of verification procedure usually involve observing the monitor.

The purpose of **records review** is to ensure that the records were prepared correctly, that all activities were performed as required by the HACCP plan, that no activity was missed, and that all results were within the critical limits.

Not all CCPs require the calibration of process-monitoring equipment. Establishments are not limited to only these three types of verification activities. Other types of verification procedures that establishments may use include independent checks or measurements to verify the accuracy of monitoring and microbiological testing.

Let’s discuss in more detail the hazards of concern.

COMMON HAZARDS FOR RAW PROCESSES

During the development and design of the HACCP plan, the official establishment determines if there are any biological, chemical, or physical hazards that are reasonably likely to occur before, during, or after entry into the establishment. A food safety hazard is defined as any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. In this section we will introduce the food safety hazards that may be associated with raw processes. Most of the food safety hazards inherent in these processes originate with the live animals that enter the slaughter establishment and commonly include the ***biological*** hazards of bacterial pathogens, the ***chemical*** hazard of residues, and the ***physical*** hazards of foreign material. We will now address each of these three categories in more detail.

Biological Hazards

The biological hazards of meat and poultry products result from the presence of potentially pathogenic bacteria in and on the live animal or bird, including intestinal contents and exterior surfaces such as hide, hair, feathers, and hooves. In addition to bacterial hazards, per §310.22, plants that slaughter cattle and establishments that process the carcasses or parts of cattle must develop, implement and maintain written procedures for the removal, segregation and disposition of specified risk materials (SRM). Such procedures must be in the HACCP plan, SSOP or other prerequisite program. FSIS expects that plants which slaughter beef and process beef products would consider SRM in the hazard analysis. You need to verify that plants meet §310.22 and that they considered all potential hazards in the hazard analysis (§417.2(a)1).

Bacterial contamination of carcass surfaces is an unavoidable consequence of processing animals and birds into meat and poultry for human consumption. The types of bacteria present on the live animal or bird will largely determine the bacterial population that exists on the carcass surface. Consequently, products derived from carcasses will contain the same types of bacteria present on the carcass surfaces. The establishment faces a challenge, in that the raw processes do not commonly include a lethality step, a procedure that would eliminate the bacteria. These establishments must do their best to control or reduce the hazard, or to prevent it from entering the process.

The prevalence of the pathogen ***Salmonella*** in beef, lamb, pork, and poultry carcasses varies greatly. The overall contamination of meat and poultry carcasses with these pathogens depends not only on the numbers of the pathogens on the hair, feathers, skin, and in the intestinal tract of the animals, but is also significantly affected by the degree of cross-contamination occurring from these sources during slaughter and processing. Plant operators must adhere to pathogen reduction performance standards for *Salmonella*, as specified in 9 CFR 310.25 for livestock and in 9 CFR 381.94 for poultry.

Escherichia coli is commonly found as part of the normal bacteria of the intestinal tract of humans and animals. Some strains, including ***Escherichia coli* O157:H7,** can cause serious illness in humans. Cattle may carry *Escherichia coli* O157:H7 in the intestinal tract at the time of slaughter, although it is actually harmless to these animals. Beef has been implicated in a number of foodborne illnesses associated with this pathogen. Contamination with *Escherichia coli* O157:H7 can be reduced through the use of sanitary dressing procedures during slaughter (dehiding and evisceration) and pathogen reduction intervention treatments (organic acid rinses,

hot water rinses, and steam pasteurization). FSIS considers raw ground beef contaminated with *E. coli* O157:H7 to be adulterated, unless the ground beef is further processed to destroy this pathogen. FSIS samples and tests ground beef for *E. coli* O157:H7.

Raw poultry is the major source of ***Campylobacter***. Cross-contamination during preparation of raw chicken and the consumption of inadequately cooked poultry appear to be significant sources of this human illness. FSIS is conducting research about the prevalence of this organism. Current evidence is not conclusive about the risk, and FSIS does not regularly test for *Campylobacter*.
This chart summarizes the microbiological hazards in raw products, beef, lamb, pork, and poultry. Please note that an unusually high level of contamination or improper handling and storage may cause one or more of the pathogens to become a hazard in any species. Establishments may also choose to address other pathogens in their hazard analysis.

Process Categories	Species	Biological Hazards, reasonably likely to be present and cause foodborne illness, denoted by "+"		
		Salmonella	*E. coli* O157:H7	*Camplyobacter*
RAW- slaughter, not-ground, and ground	Beef	+	+	
	Lamb	+		
	Pork	+		
	Poultry	+		+

The following tables show examples for each of these biological hazards, the public health concerns associated with them, and some methods for controlling these biological hazards.

Salmonella

Disease symptoms	Causes infection (invasion of the lining of the intestine) with acute diarrhea, nausea, vomiting, abdominal cramps, chills, headache and fever. Occasionally, may cause blood stream infections and death. Frequency of death, 1-4%.
Source	Fecal contamination of meat and poultry.
Transmission	Primarily from consumption of raw or undercooked eggs, milk, meat and poultry. Infective dose can be as low as 15-20 organisms for immunocompromised individuals.
Controls	Sanitation, proper hygiene practices. Killed by mild heat, effective antimicrobial treatments are acetic and lactic acids, acidified sodium chlorite, trisodium phosphate, and hot water or steam.
Characteristics	• Grows at 41-115º F. • Grows with or without air. Optimum growth at human body temperature. Grows very poorly at refrigeration temperatures. • Survives well in frozen or dry foods.

Escherichia coli O157:H7

Disease symptoms	Causes infection with bloody diarrhea (hemorrhagic colitis). Produces a potent toxin in the intestinal tract of infected people. May lead to hemolytic uremic syndrome, resulting in kidney failure and death, especially in children. Mortality rate as high as 50% in elderly.
Source	Fecal contamination of beef.
Transmission	Consumption of raw or undercooked beef. Age and immunity status will impact infective dose. As few as 10 organisms may cause illness.
Controls	Prevention of cross-contamination. Killed by mild heat, effective antimicrobial treatments are acetic and lactic acids, acidified sodium chlorite, trisodium phosphate, and hot water or steam.
Characteristics	• Grows with or without air. • Grows at 45-121º F; optimum temperature for growth is human body temperature. • Grows in moist, low-acid foods.

Campylobacter

Disease symptoms	Causes a 2-5 day infection with diarrhea, fever, abdominal pain, nausea, headache, muscle pain. May lead to nerve damage. Rarely causes death.
Source	Fecal contamination of raw poultry
Transmission	Cross-contamination from poultry or consumption of undercooked food. Infective dose is 400-500 bacteria
Controls	Sanitation, proper hygienic practices, effective antimicrobial treatments are acetic and lactic acids, acidified sodium chlorite, trisodium phosphate, and hot water or steam.
Characteristics	• Sensitive to heating, drying, disinfection, acid, and air. • Grows only in reduced oxygen environments. • Grows at 86-113 º F

Chemical Hazards

Animals may be presented at slaughter with violative levels of chemical **residues**. This hazard includes chemical residues resulting from use of, or exposure to, drugs, pesticides, and other compounds. Bob veal (calves slaughtered at 21 days or less) and cull cow slaughter operations have historically had the highest rate of residue violations. For example, dairy cows may be given antibiotics by the producer to treat infections like mastitis, and failure to observe the required withdrawal time may result in violative residues. Some examples of environmental contaminants that may be consumed by animals include lead, cadmium, mercury, arsenic, dioxins, or polychlorinated biphenyls or PCBs.

The potential health consequences of exposures to chemicals in food can be serious, are often inadequately understood, and deserve serious consideration. The long-term and cumulative effects of exposure associated with chemicals in food pose special difficulties in identifying and addressing these risks. It is apparent that at least some of the identified chemical hazards are of concern because they exert particular effects. For example, **industrial chemicals** such as dioxins may be of concern because they have the potential to cause endocrine effects and/or interfere with the immune system. Some hazards such as lead contamination can affect a certain population- infants or young children causing toxic effects. Lead, in addition to being a chemical hazard, may be a physical hazard which will be discussed below. Chemical residues have been linked through research to various types of cancers. The public health concerns associated with the long-term effects of exposure to chemicals from ingestion of food is not well understood or well documented.

Food **additives** and non-meat ingredients must be safe for use, but even then, there are some consumers who have allergic reactions to certain ingredients. Food allergies are responses of the immune system to naturally occurring proteins in certain foods that most individuals can eat without any adverse effect. Frequently such reactions occur because the presence of the allergenic substances in the foods is not declared on the food label. Evidence indicates that some food allergens can cause serious reactions in sensitive individuals upon ingestion of very small amounts, therefore, the presence of an ingredient that contains an allergen must be declared on the product label. There is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies.

The “Big 8”, or top 8 foods that most people with food allergies are allergic to, are peanuts, soybeans, milk, eggs, fish, crustacean, tree nuts and wheat gluten.

Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), under which FSIS operates, all ingredients used to formulate a meat, poultry, or egg product must be declared in the ingredients statement on product labeling. A product is ***misbranded*** under the Acts when it contains ingredients that are permitted, but are not declared on product labeling.

Manufacturers are responsible for ensuring that food is not adulterated or misbranded as a result of the presence of undeclared allergens. There may be situations where these substances are added intentionally to food, but not declared on the label. Other situations involve substances unintentionally introduced into a food product and consequently not declared on the label. When an allergen, not formulated in the product, is identified as likely to occur in

the food due to the firms' practices (e.g., use of common equipment, production scheduling, rework practices), then you should determine if the establishment has identified and implemented controls to prevent potential allergen cross-contact, e.g., dedicated equipment, separation, production scheduling, sanitation, proper rework usage (like to like).

Some establishments may consider food allergens in their hazard analyses if there is a potential, but may address this issue through SSOP or other prerequisite programs (e.g., segregation and labeling).

Physical Hazards

A physical hazard is a physical component of a food that is unexpected and may cause illness or injury to the person consuming the food. Physical hazards, such as pieces of metal, sometimes occur because equipment has not been properly maintained. In some processes, such as raw—ground, product may be received that is contaminated by foreign material, which if not controlled, may subsequently become incorporated into the ground product. Foreign material would include non-animal objects such as metal, wood, rubber, glass, steel, lead, or other objects. For example, lead shot in a carcass may be considered by the establishment as a food safety hazard reasonably likely to occur in their operation, especially if the establishment historically receives animals containing such material. Another example might be a poultry operation that historically has a problem with metal shavings in its carcass chillers. Keep in mind that the foreign material we discuss here does not include things such as rail dust or rust, which would be covered by sanitation performance standards or SSOP requirements. The size, shape, and consistency of the foreign object should be considered in determining whether it is or is not a hazard.

Typical public health concerns associated with consuming products that contain physical hazards include broken teeth and damage, such as tears, to the mouth, esophagus, stomach, and intestines. These physical hazards may obstruct air passages or intestines. In some cases, death may result due to suffocation or infections (intestinal blockages). Small children are particularly susceptible to problems brought on by physical hazards since their body structures are smaller, and the physical objects may have a greater effect.

Methods that establishments use to control physical hazards include visual observation of product, sanitation procedures, SOP for product handling, GMP to ensure proper maintenance and inspections of facilities and equipment, and foreign materials detection equipment (inline magnets, screens, traps, filters, etc.) used during the production process.

Note: Biological, chemical, and physical food safety hazards although discussed separately, can share properties that span more than one hazard classification.

Workshop: Common Hazards

1. For each of the following biological hazards, list the temperature growth range from the information in the module. Looking over the list, what conclusion can you make about the value of refrigeration in the control of these hazards?

Organism	Temperature Growth Range
Salmonella	
E. coli O157:H7	
Campylobacter	

Conclusion:

2. Which biological hazard is regularly present in cattle, and therefore is often considered a food safety hazard in beef processes?

3. Which biological hazard is associated with all food animal species?

4. What are the sources of biological hazards in the slaughter process?

5. What are some examples of potential chemical hazards in the slaughter process and what type of animals are most often found to have violative chemical levels?

6. What are some examples of potential physical hazards in the slaughter process?

Slaughter Hazard Analysis

Next we will examine the slaughter process for beef, pork, and poultry from a food safety perspective to help you understand the thought process the establishment follows as the hazard analysis is performed. The hazard analysis is a two step procedure in which the establishment HACCP team:

- **identifies** hazards at each step.
- **evaluates** the hazards to determine if they are reasonably likely to occur.

Other Considerations

It is important to note that the slaughter establishment must also consider **regulatory requirements** related to food safety in its analysis. Under part 417, a HACCP plan must include, as appropriate, critical control points that are designed to control identified food safety hazards (§ 417.2(c)(2)). Because fecal material is a vehicle for pathogens, and microbiological contamination is a food safety hazard that is reasonably likely to occur in the slaughter production process, a slaughter establishment must adopt controls that it can demonstrate are effective in reducing the occurrence of pathogens. FSIS enforces a food safety standard for fecal, milk, and ingesta contamination on head meat, cheek meat, and weasand meat of beef at the end of the harvesting process for beef, and for livestock carcasses at or immediately after the rail inspection station. FSIS also enforces a food safety standard for fecal contamination at the prechill Finished Product Standards (FPS) station (or at the inspection station for AQL in establishments under traditional inspection) for poultry carcasses.

Prerequisite Program-GMP and SOP

A prerequisite program is a procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. The programs provide a foundation for the development and implementation of an effective HACCP system. They frequently function across product lines and are often managed as facility-wide programs rather than being process or product specific.

Some establishments may use prerequisite programs, such as **Good Manufacturing Practices** (GMP) and/or **Standard Operating Procedures** (SOP) to reduce the likelihood of certain hazards. GMP are minimum sanitary and processing requirements and SOP are step-by-step directions for completing important procedures. GMP are fairly broad and general and can be used to help guide the development of Standard Operating Procedures (SOP), which are very specific. GMP are not designed to control specific hazards, but are intended to provide guidelines to help establishments produce safe and wholesome products. SOP, on the other hand, are very specific instructions for performing a procedure and may address a specific hazard. Sanitation SOP (SSOP) may be considered by establishments to reduce the likelihood of occurrence of some

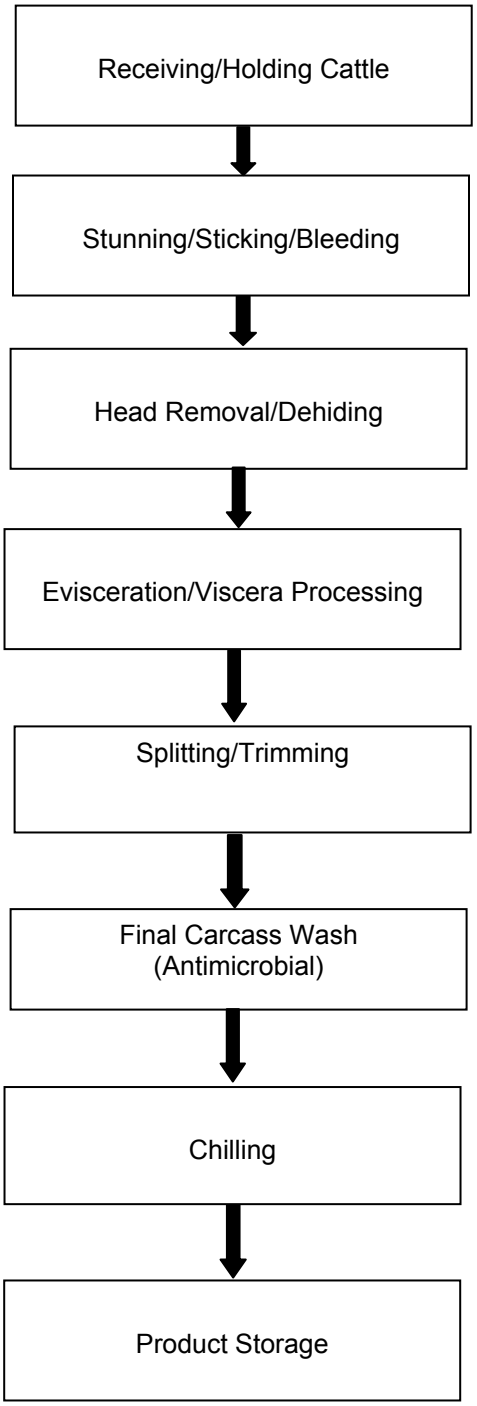
food safety hazards. For example, the SSOP may address washing and sanitizing of knife and hands between carcasses to reduce potential contamination with pathogens.

Based on the regulatory requirements of 9 CFR 417.2(a) and 9 CFR 417.5(a)(1), FSIS believes that the results of testing and monitoring activities related to the production of product that may have an impact on the establishment's hazard analysis are subject to FSIS review and must be available to FSIS personnel upon request, including records from prerequisite programs that are not referenced in the hazard analysis, HACCP plan, or Sanitation SOP. (Refer to FSIS Directive 5000.2).

If a hazard is judged reasonably likely to occur, the establishment must address the hazard with a CCP and **cannot** substitute a prerequisite program to control the hazard. Sometimes, however, an establishment determines that the hazard is not reasonably likely to occur, using the justification that a prerequisite program, properly implemented, is preventing the hazard from occurring. If the Consumer Safety Inspector determines that a prerequisite program is used as a justification for not addressing a hazard with a CCP in the HACCP plan, the CSI should notify the District Office. These programs must be evaluated by a specially trained individual, such as an EAIO.

We will use the **beef slaughter process as a model**. On the following page is an example of a flow chart of the process and a summary of the **potential food safety hazards** that the establishment could judge reasonably likely to occur. Potential food safety hazards are considered to exist at a step if the hazards could be **introduced** or **enhanced** at the step. There are certain steps in the slaughter process that inherently carry a high degree of risk. For these steps, it would be difficult for the establishment to support a decision that a hazard would be not likely to occur. Keep in mind that this flowchart is just an **example** and that **processes, hazards, and established CCPs will vary among establishments.**

Beef Slaughter Flow Diagram



Potential Food Safety Hazards

Receiving/Holding
- Biological—pathogens on the hide and in the feces: SRM
- Chemical—residues
- Physical—foreign materials (needles, shot)

Stunning/Sticking/Bleeding
- Biological—none
- Chemical—none
- Physical—none

Head Removal/Dehiding
- Biological—pathogens from the hide could be transferred to the carcass; SRM (spinal cord, tonsils)
- Chemical—none
- Physical—none

Evisceration/Viscera Processing
- Biological—pathogen contamination from the intestinal tract could occur; SRM (distal ileum)
- Chemical—none
- Physical—none

Splitting/Trimming
- Biological—pathogens may be spread; SRM
- Chemical—none
- Physical—none

This step is a potential CCP for visible contaminants

Final Carcass Wash (Antimicrobial)
- Biological—pathogens may be spread
- Chemical—none
- Physical—none

This step is a potential CCP for biological hazards

Chilling
- Biological—pathogens may multiply
- Chemical—none
- Physical—none

This step is a potential CCP for biological hazards

Product Storage
- Biological—pathogens may multiply
- Chemical—none
- Physical—none

This step is a potential CCP for biological hazards

Example: for training use only

Hazard Analysis of the Beef Slaughter Process

In this section, we want to discuss the hazard analysis in beef slaughter. Keep in mind that for every hazard identified in the previous flow chart, the establishment must determine if the hazard is **reasonably likely to occur** in its operation. If a hazard is identified as likely to occur in the operation, there must be a CCP **somewhere** in the process to address the hazard. The CCP does not have to be at the location at which the hazard is identified.

Now let's have a look at specific steps in the beef slaughter process and the food safety considerations the establishment could use in performing a thorough hazard analysis.

Receiving/Holding Cattle

Cattle under 30 months of age don't pose as great a risk for the SRM. But cattle 30 months or older do and need to be segregated. (All cattle, regardless of age, must have tonsils and the distal ileum removed from human food channels.)

Is this hazard reasonably likely to occur?

No—The establishment may judge that this hazard is not reasonably likely to occur because it does not purchase cattle over 29 months and removes all tonsils and distal ileum. Purchase specifications may be in place to certify the age of the animal. It may have a prerequisite program to check cattle to ensure there are no older animals.

Yes—The establishment may slaughter older animals and therefore needs a CCP to address the SRM. There could be a CCP here for segregating the animals and slaughtering the older ones at the end of the shift and keeping the carcasses as a group.

When cattle arrive at the slaughterhouse they carry mud, manure, bedding, and other materials that contain a load of microorganisms on their hides and hooves, and may carry microorganisms internally as well. Pathogens such as *E .coli* O157:H7 may be among the microorganisms; therefore, cattle may pose a **biological hazard** at this point.

Is this hazard reasonably likely to occur?

No—The establishment may judge that this hazard is not reasonably likely to occur because of sanitary procedures to address pathogens carried by animals during receiving and holding. The establishment should have supporting documentation to support this decision. The GMP or SOP could be written to include control measures applied to prevent a significant hazard at receiving (e.g., proper feed withdrawal, washing of animals).

Yes—If the answer is yes, there must be a CCP to address it. The CCP may be at this location or it may be further in the process. The establishment may choose to address this hazard here with a CCP if an intervention exists at receiving that would eliminate, prevent, or reduce the hazard to an acceptable level. For example, a chemical dehairing and wash methodology might be used as a CCP at receiving if it could be shown

effective in reducing pathogens. The establishment may choose to address the hazard with a CCP later in the process. For example, the establishment may address this hazard with a CCP at the pre-evisceration antimicrobial rinse.

Cattle may pose a **chemical hazard** if presented for slaughter with violative levels of chemical residues. The chemicals present in live animals may include antibiotics, pesticides, and environmental contaminants among others.

Is this hazard reasonably likely to occur?

No—The establishment may judge the chemical hazard is not likely to occur in its process because it has not been a problem historically in the type of cattle it slaughters. For example, FSIS monitoring has shown that feedlot animals have a very low incidence of residues. Establishments may confirm this with their own data from residue testing over a period of time. Establishments may judge that the chemical hazard is not likely because it requires producers to adhere to a quality assurance program, including strict controls for chemicals. Establishments should be able to provide supporting documentation for their decisions.

Yes—Establishments slaughtering classes of cattle that have historically had residue violations may judge that it is likely to occur in its process. For example, bob veal and cull cows have had a higher rate of violative chemical residues. If judged to be reasonably likely to occur, the hazard must be addressed in the HACCP plan.

Cattle may be received that pose a **physical hazard** due to the presence of foreign material, such as needles or shot.

Is this hazard reasonably likely to occur?

No—Establishments may judge that this hazard is not likely to occur in their process because it has not been a problem historically, or the establishment may choose to obtain animals from suppliers that adhere to a quality assurance program that prevents it. Again, the establishment must be able to support this decision with scientific or technical documentation.

Yes—If the establishment has a history of foreign material, such as lead shot, it may be prudent in choosing to address it with a CCP somewhere in the process. For example, the establishment may use a metal detector step in boning that is used to address this hazard.

Stunning/Sticking/Bleeding

If the potential for hide contaminants being introduced into tissues is judged negligible at **stunning, sticking, and bleeding**, the establishment may choose not to identify any hazards at this step. Some establishments may use SSOP to justify their decision.

Head Removal/Dehiding

The hide is one of the most significant sources of pathogens; therefore, the step of **dehiding** could be judged to pose a **biological hazard**. In addition, **head removal** may result in the spread of ingesta contamination if the esophagus is not closed properly.

Is this hazard reasonably likely to occur?

No—If the establishment judges this hazard is not likely to occur in its process, it should have documentation to support this decision. Some establishments may justify this decision based upon SOP that they have in place to prevent the transfer of hide contaminants to the carcass.

Yes—If judged to be a likely occurrence in its process, the establishment must address it with a CCP somewhere in the process. For example, the establishment may address it with a CCP at a steam pasteurization step prior to chilling.

Evisceration/Viscera Processing

Evisceration may result in carcass contamination with feces or ingesta containing pathogens, so this step may be judged to be a **biological hazard** by the establishment.

Is this hazard reasonably likely to occur?

No—The establishment may judge that it is not likely to occur in its process; however, there should be supporting documentation to justify the decision as well as demonstrate how the distal ileum is removed. Again, the establishment may choose to use SOP to justify this decision.

Yes—If judged likely to occur in its process, the establishment must address it with a CCP somewhere further in the process. For example, the establishment may address this hazard with a CCP at an antimicrobial rinse prior to chilling.

Splitting/Trimming

The splitting and trimming step may present a carcass with pathogens that could be spread by the processes, and therefore may pose a **biological hazard** at this point. Keep in mind that FSIS will enforce slaughter food safety standards for feces, ingesta, and milk at the rail inspection station just past the trimmers. Specified risk material (SRM) is of concern in beef.

Is this hazard reasonably likely to occur?

No—If no, the establishment should have supporting documentation to justify the decision. Operational SSOP may address prevention of cross-contamination by the splitting saw and trimmers. The establishment may be able to show support for the

determination that since all visible contaminants are trimmed at this point that it is not reasonably likely to occur.

To address SRM, the plant may have a procedure in the SSOP or another prerequisite program that requires the carcasses to be split on either side of the vertebral column and sanitize the splitting saw between each carcass. Therefore, the plant determines this is not a hazard reasonably likely to occur.

Yes—If yes, the establishment must address the hazard with a CCP somewhere in the process. For example, the establishment may designate the antimicrobial rinse prior to chilling as a CCP to address this hazard. If the plant determines that SRM are reasonably likely to occur, it must be addressed in a CCP.

Final Carcass Wash

The final wash step may spread pathogens on the carcass surface; therefore, this step may pose a **biological** hazard.

Is this hazard reasonably likely to occur?

No—If no, the establishment should have supporting documentation to justify the decision.

Yes—If yes, the establishment must address the hazard with a CCP somewhere in the process. For example, the establishment may designate the antimicrobial rinse prior to chilling as a CCP to address this hazard.

Chilling

At the **chilling** step, carcasses may still have pathogens on them that could multiply if not controlled and a **biological hazard** may result.

Is this hazard reasonably likely to occur?

No—If no, the establishment should have supporting documentation to justify the decision.

Yes—If yes, the establishment must address the hazard with a CCP somewhere in the process. For example, the establishment may elect to have a CCP at chilling to ensure the proper lowering of product temperatures immediately after slaughter to inhibit the growth of pathogens.

Product Storage

Product storage may pose a **biological hazard** since product may still contain some pathogens that could multiply.

Is this hazard reasonably likely to occur?

No—If no, the establishment should have supporting documentation to justify the decision.

Yes—If yes, the establishment must address the hazard with a CCP. For example, the establishment may have a CCP for finished product storage to maintain proper storage temperature to inhibit growth of pathogens.

The information we just covered should have given you an idea of the thought process the establishment uses in its hazard analysis. Keep in mind that this hazard analysis is only an **example** and it is not meant to represent what the hazard analysis in any particular establishment will look like.

Reassessment Requirement for *E. coli* O157:H7

FSIS requires that all establishments producing raw beef consider *E. coli* O157:H7 in the hazard analyses. If an establishment determines that *E. coli* O157:H7 is a hazard reasonably likely to occur in their production process, the establishment must address it in the HACCP plan. If the establishment determines that it is not a hazard reasonably likely to occur, there should be documentation that supports that decision.

Hazard Analysis of Swine and Poultry

The slaughter processes in swine and poultry have many similarities to beef slaughter. We will only highlight the differences in the processes that may have an impact on the hazard analysis for these species.

►Swine Slaughter

The major process difference in swine slaughter, in contrast to cattle, is the **scalding and dehairing** of the carcasses. The scalding and dehairing process can promote cross-contamination of carcasses with *Salmonella* and the establishment may address this as a **biological hazard**.

Is this hazard reasonably likely to occur?

No—If no, the establishment should have supporting documentation to justify the decision. For example, the scald temperature and subsequent singeing have been shown in some studies to reduce bacterial numbers.

Yes—If yes, the establishment must address the hazard with a CCP somewhere in the process. For example, the establishment may have an antimicrobial pre-evisceration rinse to address this hazard.

►Poultry Slaughter Process

Evisceration

One major difference in poultry slaughter, especially of young chickens, is the utilization of **highly automated equipment** that can have a significant impact on the degree of carcass fecal contamination. Equipment that is not properly adjusted can cause increased levels of contamination. For example, an improperly functioning evisceration machine can rupture the intestines, spreading fecal material inside the carcasses. Therefore, the fecal material on poultry carcasses may pose a **biological hazard**.
Is this hazard reasonably likely to occur?

No—If no, the establishment should have supporting documentation to justify the decision. Again, the establishment may choose to utilize SOP to prevent the hazard from being likely to occur. The poultry establishment may also consider in their analysis the FSIS **fecal slaughter food safety standard** regulation 381.65(e), which requires that establishments prevent visible fecal material from entering the chiller.

Yes—If yes, the establishment must address the hazard with a CCP somewhere in the process. For example, the establishment may have a CCP at the antimicrobial spray prior to chilling that addresses this hazard.

Chilling

Another procedure distinct to poultry processing is carcass **chilling,** which is usually done in a large tank of cold, circulating water called a chiller. Carcasses may have pathogens, such as *Salmonella*, which could cross-contaminate other carcasses in the chiller and they may pose a **biological hazard**.

Is this hazard reasonably likely to occur?

No—If no, the establishment should have supporting documentation to justify the decision.

Yes—If yes, the establishment must address it with a CCP. For example, the chiller step may be a CCP to ensure the proper lowering of product temperature to inhibit growth of pathogens. In addition, chlorine dioxide, chlorine, or ozone can be used as an antimicrobial treatment in the chiller.

Workshop: Hazard Analysis for Slaughter Processes

1. What are some hazards found at cattle receiving?

2. What is one way an establishment may address the chemical or physical hazard at receiving?

3. Name some antimicrobial interventions used in beef slaughter.

4. Based on the October 2002 Federal Register Notice, what must beef slaughter operations do if they have not done so already?

5. What is the hazard that may be associated with the scalding/dehairing of swine?

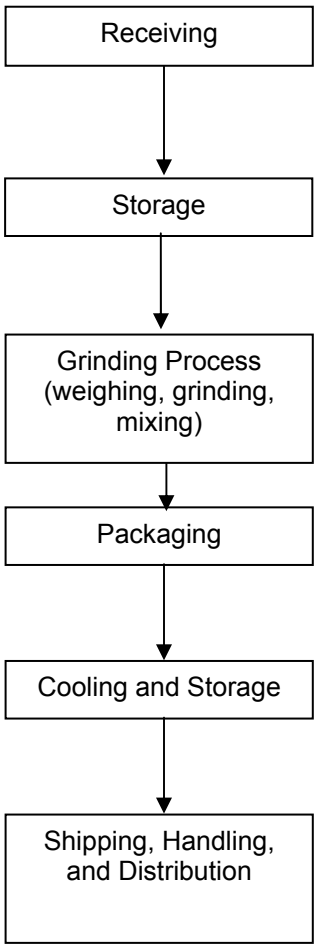
6. What is the hazard that may be associated with automated equipment in a poultry slaughter operation?

7. What is the hazard associated with poultry chillers? And what is a possible intervention?

Hazard Analysis of the Raw Ground Process

This section addresses the production of safe raw ground products and the thought process an establishment follows in its hazard analysis. We will use raw ground beef as our model. This is an example of a flow chart of the process and a summary of the food safety hazards that the establishment could judge reasonably likely to occur. Keep in mind that this flowchart is a simplified training example and that processes, hazards, and established CCPs will vary among establishments.

Raw Ground Beef Flow Diagram



Food Safety Hazards

Receiving
- Biological—Pathogens *E. coli* O157:H7 and *Salmonella* in trimmings or other raw meats used; SRM
- Chemical—None
- Physical—Foreign material contamination

Storage
- Biological—Growth of pathogens *E. coli* O157:H7 and *Salmonella*
- Chemical—None
- Physical—None

Grinding
- Biological—None
- Chemical—None
- Physical—Metal contamination

Packaging
- Biological—None
- Chemical—None
- Physical—None

Cooling and Storage
- Biological—Growth of pathogens *E. coli* O157:H7 and *Salmonella*
- Chemical—None
- Physical—None

Shipping
- Biological—None
- Chemical—None
- Physical—None

Example: for training use only

Let's take a look at specific steps in the raw ground process and the food safety considerations the establishment could use in performing a thorough hazard analysis. Keep in mind that for every hazard identified in the previous flow chart, the establishment must determine if the hazard is reasonably likely to occur in its operation. If a hazard is identified as likely to occur in the operation, there must be a CCP somewhere in the process to address the hazard. The CCP does not have to be at the location at which the hazard is identified.

Receiving Beef

When meat for grinding arrives at the establishment, it will carry a certain amount of bacteria, both spoilage and pathogenic organisms. The amount and types of bacteria present will vary, depending on the conditions at the slaughter or processing plant from which the meat is received. Grinders are dependent on their suppliers to eliminate or reduce any contamination. Therefore, raw meat may pose a **biological hazard** at this point.

The pathogen *E. coli* O157:H7 is of particular concern to grinding operations because it is considered an adulterant in ground beef. There is recent evidence that the prevalence of *E. coli* O157:H7 in cattle is higher than previously assumed. The presence of *Salmonella*, although not considered an adulterant, is also a public health risk. Establishments must demonstrate that they are able to control the occurrence of *Salmonella* in their product by producing products that meet the FSIS *Salmonella* Performance Standards. Raw ground products, by their very nature, do not have a lethality step to eliminate pathogens (except when processors choose to apply a lethal dose of irradiation). Decontamination interventions can significantly reduce the levels of pathogens when the control measures are effectively implemented and validated. These interventions, such as steam pasteurization, organic acid spray, hot water treatment, and steam vacuuming, are applied to intact carcasses at the slaughter establishment. Microbiological testing, when properly designed, can be used to verify that control measures are working. Microbiological testing should be used in combination with strict process controls that include intervention methods, in order to reduce the likelihood that the pathogen is present. Any ground beef found to be contaminated with *E. coli* O157:H7 must be treated to inactivate the pathogen: for example, by diverting it to a cooking operation.

Establishments should consider SRM for raw beef products.

Is this hazard reasonably likely to occur?

No—If no, the establishment should have supporting documentation to support the decision.

Yes—If yes, the establishment must address this with a CCP. In order to deal with the risk of pathogens entering the system with the starting materials, many establishments develop purchase specifications programs. Purchase specifications may specify that raw materials come from slaughter establishments that apply one or more intervention or antimicrobial treatment, validated to reduce or eliminate microorganisms on carcasses.

The grinding plant may have purchase specifications for the controls that the slaughter plant has in place to ensure that no SRM are in the products.

Purchase specifications may also include microbial testing specifications. Purchase specification programs for raw materials may be incorporated as a CCP in the HACCP plan. Establishments can also incorporate their purchase specifications in their Sanitation SOP or other programs such as prerequisite programs.

The grinding establishment may implement an examination step before accepting ingredients. The reduction of microorganisms resulting from the intervention method must be maintained in subsequent processing steps by control of temperature and cross-contamination. As a means of verifying this, the plant may establish a maximum product receiving temperature, or observation of other receiving condition. Other controls that may be utilized at receiving may include microbial testing as a verification procedure, to confirm results provided by the supplier. The establishment may also choose to verify records that facilitate trace back and trace forward, which are essential in case of an outbreak of foodborne illness. Grinding operators may establish recordkeeping requirements for their suppliers to trace products back to the farm of origin.

The establishment may determine that the potential for **chemical hazards** is negligible and if so may not address them.
.
There is also a risk that some foreign material has contaminated the product that is being received, thus posing a **physical hazard**.

Is this hazard reasonably likely to occur?

No—The establishment may judge that this is not likely to occur in its process because it has historically not been a problem. Establishments may also determine that this hazard is not reasonably likely to occur because of GMP or SOP that will be utilized in the process.

Yes—Establishments may determine that there is a risk that starting materials may be received with foreign material. If so, they may establish a CCP at receiving to detect contamination, such as visual inspection or use of detection technology such as an electronic metal detector or imaging system. Establishments may also choose to address this hazard with a CCP later in the process, for example, by using a metal detector on the finished product.

Storage

Continuous refrigeration is essential to prevent microbial growth. Inadequate holding temperatures can allow the bacteria present to multiply, which increases the risk from pathogens such as *E. coli* O157:H7 and *Salmonella*. Therefore, raw meat may pose a **biological hazard** at this point.

Is this hazard reasonably likely to occur?

No—If the establishment judges this hazard is not likely to occur in its process it should have supporting documentation to support this decision. For example, an establishment may justify this decision if it receives only frozen product, which does not remain at ambient temperatures long enough for product to thaw.
Yes—If the establishment judges this hazard is likely to occur, it must be addressed in the HACCP plan. Establishments commonly establish **room** temperature critical limits. It is advisable to control and monitor the **product** temperature as well as the room temperature. The establishment may have supporting documentation that demonstrates that control of room temperature correlates to control of product temperature. Establishments may also have a time or inventory control to ensure that product does not remain in storage for a time period that would allow bacterial growth at storage temperatures, either in the HACCP plan or addressed in GMP and SOP.

The establishment may determine that the potential for **chemical hazards** and **physical hazards** is negligible at this step. If not, the hazards must be addressed at a CCP in the HACCP plan.

Grinding Process

The establishment may determine that the potential for **biological hazards** and **chemical hazards** is negligible at this step.

The grinding process involves reducing the particle size of the raw meat ingredients, and mixing to distribute fat, lean, and any ingredients added. Because the equipment used produces high mechanical forces, and has moving metal-against-metal parts, there is a possibility of metal chipping or breaking. There is also the possibility that any foreign material in the product, such as lead shot, would be broken up and distributed throughout the product. Because of the risk that foreign material has contaminated the product received, or that the grinding/mixing process added metal to the product, the establishment may determine that this step constitutes a **physical hazard**.

Is this hazard reasonably likely to occur?

No—If no, the establishment should have supporting documentation to justify the decision. For example, the establishment may determine the foreign material contamination does not constitute a food safety hazard.

Yes—If yes, the establishment must address the hazard with a CCP, either here or at a subsequent step in the process. Some establishments use a metal detector to identify product that may be contaminated with metal fragments. The metal detector may be here or located further in the process, such as at packaging.

Packaging

The establishment may determine that the potential for **biological, chemical,** and **physical hazards** is negligible at this step. If not, the hazards must be addressed at a CCP in the HACCP plan.

Cooling and Storage

Establishments often freeze finished ground product, although some distribute the product refrigerated. Pathogens will grow in raw ground beef if temperature is not maintained at or below a level sufficient to prevent their growth. Since the product is now in a ground form, the small particles of meat provide a greatly increased surface area, which is ideal for bacterial growth. Any bacteria present on the meat pieces used, or present on the equipment surfaces, have been distributed throughout the product. Because of the risk of *E. coli* O157:H7 or *Salmonella* growth in the raw finished product, the establishment may address this as a **biological hazard**.

Is this hazard reasonably likely to occur?

No—If no, the establishment should have supporting documentation to justify the decision. It would be very difficult for an establishment to demonstrate this hazard was **not** reasonably likely to occur, but it is always possible that an establishment may be able to do so.

An establishment might justify this decision in the case of product that is individually quick frozen, and only remains at temperatures which would allow pathogen growth for a very short time.

Yes—If yes, the establishment must address the hazard with a CCP somewhere in the process. Continuous temperature control will prevent growth of bacteria that may have escaped the other control steps. Plants may establish one or a combination of control methods, such as monitoring the time/temperature profile during freezing, testing finished product for pathogens as a means of verifying process control, monitoring the temperature of finished product during storage, or monitoring the temperature of the refrigerator/freezer.

The establishment may determine that the potential for **chemical** and **physical hazards** is negligible at this step, and if so, may not address them.

Shipping, Handling, and Distribution

The establishment may determine that the potential for **biological, chemical,** and **physical hazards** is negligible at this step. If not, the hazards must be addressed at a CCP in the HACCP plan.

Reassessment Requirement for *E. coli* O157:H7

The reassessment requirement for *E. coli* O157:H7 that we discussed in beef slaughter also applies to raw—ground and raw—not ground operations. These establishments must reassess their plans to determine whether *E. coli* O157:H7 is a hazard reasonably likely to occur in their production processes. If reassessment results in a determination that *E. coli* O157:H7 **is** a food safety hazard reasonably likely to occur, the establishment **must** address it in the HACCP plan through one or more CCPs designed to control the pathogen. These CCPs may include purchase specifications for microbiological testing and supplier certification of validated interventions in the slaughter process. Additional CCPs may be established to prevent growth or contamination after product receipt. Establishments that determine that *E. coli* O157:H7 is **not** a hazard reasonably likely to occur may address this pathogen in their Sanitation SOP or through a prerequisite program; in this case FSIS would expect the establishment to maintain documents setting out the procedures of the prerequisite program and related records.

The information we just covered gave you an introduction to the thought process the establishment uses in its hazard analysis. Keep in mind that this hazard analysis is only a simplified training example and it is not meant to represent what the hazard analysis in any particular establishment will look like. The process in the establishment to which you are assigned might look different depending on whether the plant adds nonmeat ingredients, uses rework, stuffs product into casings, etc. The same thought process would apply to operations grinding poultry, pork, or other species. Processors would probably focus on the pathogens most prevalent for each species of meat processed: for example, *Salmonella* in pork, and *Salmonella* and *Camplyobacter* in poultry.

Hazard Analysis of the Raw—Not Ground Process

The food safety concerns for raw—not ground products are similar to the raw—ground products. The process flow is generally the same: product is received, stored before use, cut up, packaged, and held under refrigeration or frozen until shipped. The hazard analysis would reflect the same thought process described above for each step, considering whether biological, chemical, or physical hazards are reasonably likely to occur, and if so, establishing a CCP to control them somewhere in the HACCP plan. The species would generally have the same biological hazards as the raw ground products, that is, beef—*E. coli* O157:H7 and *Salmonella*, poultry—*Salmonella* and *Camplyobacter*, and pork and other meat species—*Salmonella*.

Reassessment Requirement for *E. coli* O157:H7

In May of 2005, FSIS published a notice in the Federal Register that requires all establishments producing injected or mechanically tenderized beef products to reassess their HACCP plans in light of new data that shows *E. coli* O157:H7 was the cause of three separate outbreaks associated with such beef products. FSIS believes that the new data could affect an establishment's hazard analysis, or alter its HACCP plans for such beef products. The reassessment must be for raw and cooked products.

Workshop: Raw—Not Ground and Raw—Ground Hazard Analysis

1. List processing steps that may introduce metal contamination.

2. Some establishments in their hazard analysis determine that *E. coli* O157:H7 in incoming raw products is not likely to occur. What's the typical support for this decision?

3. What is the food safety significance of grinding and mixing raw beef?

4. What controls are used to prevent the growth of bacteria in raw—ground and raw—not ground products?

INSPECTION VERIFICATION OF HAZARD ANALYSIS

03A01 Procedure

You should verify that an establishment has performed a hazard analysis as part of basic compliance with the regulations (9 CFR 417.2(a)) during the performance of the **03A01 procedure**. This is the only procedure that is used to verify the plant's hazard analysis. You should do this for any **new** establishment, or whenever an existing establishment adds a **new** HACCP plan. Procedure 03A01 is also conducted to verify the annual reassessment and establishment training requirements. We will cover the performance of the 03A01 procedure in more detail in the reassessment section.

Verification of the Hazard Analysis

You should use the thought process and methodology described below when verifying the hazard analysis. You will verify compliance by reviewing the flow chart, the hazard analysis, the HACCP plan, and HACCP records.

You must review hazard analysis records to determine if the analysis considered those properties that have a real chance of occurring in the food or in the processing of the food, and of causing the food to be unsafe. The hazards are those that would be identified by a reasonable consideration of the food, how it is processed, and where safety issues can arise. The fact that it is possible to imagine a hazard (e.g., a meteor may fall onto the plant) does not mean that the hazard is likely to occur or that the analysis must address that hazard. If you have concerns about whether the relevant hazards have been considered, you may decide to discuss issues with the Policy Development Division (formerly the TSC), your District Office, or with the establishment during the weekly meeting.

Use of Prerequisite Programs (SOPs and GMPs) to Prevent Hazards

There may be circumstances in which you find that the hazard analysis identifies a hazard, but determines that it is not reasonably likely to occur because of controls that the establishment has in place: for example, a standard operating procedure (SOP) for purchase specifications. If you determine that the establishment has used any prerequisite program, such as a good manufacturing procedure (GMP) or SOP, as justification for not addressing a hazard with a CCP in the HACCP plan, you should notify the District Office. The DO will assign a specially trained individual, such as an EIAO, to evaluate the program.

You should ask whether the establishment has considered and addressed the following questions when reviewing the hazard analysis.

1. Did the establishment conduct a hazard analysis or have one conducted for it?

2. Did the establishment's analysis start by identifying all hazards that may occur?

3. Does the hazard analysis identify preventive measures the establishment can apply to the food safety hazards?

4. Does the hazard analysis include a flow chart that describes (diagrams) the steps of each process and production flow in the establishment?

5. Does the hazard analysis identify the intended use or the consumers of the finished product?

6. Does the result of the establishment's hazard analysis reveal that one or more food safety hazards are reasonably likely to occur?

7. Does the establishment have a written HACCP plan for each of its products?

8. Has the establishment conducted validation activities to determine if a HACCP plan can function as intended?

9. Do the establishment's records include multiple results that verify the monitoring of CCPs and conformance with critical limits?

10. Does the establishment have subsequent results that support the adequacy of corrective actions in achieving control at a CCP after a deviation from a critical limit has occurred?

We will discuss what actions to take if you find a noncompliance in later sections.

Workshop: Hazard Analysis

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. When should you perform 03A01?

2. Review the flow diagram, product description, hazard analysis, and HACCP plan on the following pages, and answer the following questions:

    a. How did the establishment address biological hazards at receiving? (circle on form and mark “a”)

    b. How did the establishment address physical hazards at receiving? (circle on form and mark “b”)

    c. How did the establishment address biological hazards at storage? (circle on form and mark “c”)

3. What decisions in the hazard analysis would you request supporting documentation for, if any? Please explain your answer?

4. Are all steps in the flow diagram addressed in the hazard analysis? If not, please explain.

5. Are all hazards identified as reasonably likely to occur addressed by a CCP somewhere in the process? If not please explain.

6. At receiving, what would be a justification for deciding in the hazard analysis that the biological hazard is not reasonably likely to occur?

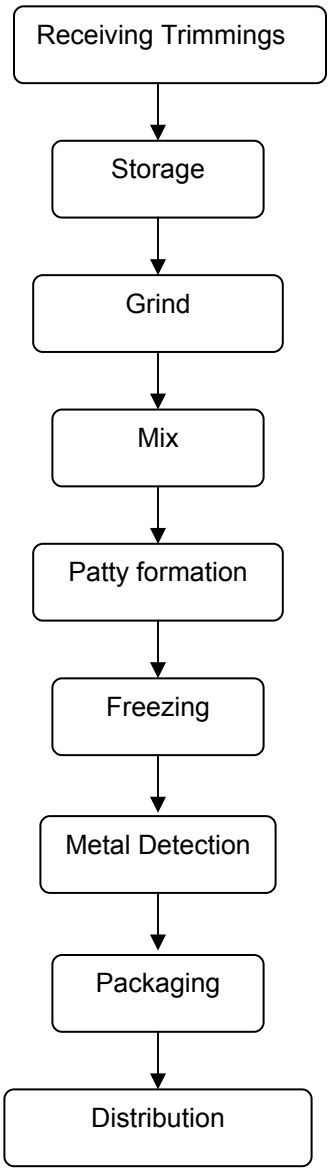
7. How does the establishment control the biological hazard – growth of pathogens- that was identified at storage?

8. How does the establishment monitor temperature control at storage?

9. Is the use of terms like “microbial growth” or “growth of pathogens” sufficient to identify hazards?

Raw ground beef patties

Process flow diagram



Product Description:

Process category: Raw ground

Product: Frozen ground beef patties

Name: Ground beef patties 6 per pound

Type of package: 10 pounds per box, in plastic bag with paper liners separating layers

Length of shelf life: 3-6 months if maintained frozen as recommended on label; 5 days if thawed and held refrigerated

Intended use: Fast food restaurant

Labeling instructions: Keep frozen, safe food handling label

Note: No rework used in this process

Example: for training use only

Hazard Analysis: raw ground beef patties					
Process Step	**Food Safety Hazards**	**Is hazard likely to occur?**	**Justification for decision**	**What control measures can be applied to prevent the significant hazards?**	**Is step a critical control point?**
Receiving trimmings	Biological: Pathogens *E. coli* O157:H7 and *Salmonella*	Yes	*E. coli* O157:H7 or *Salmonella* may be present on trimmings received	Purchase specifications for certification from all suppliers that trimmings are from carcasses that received validated interventions effective to eliminate or reduce *E. coli* O157:H7 to an undetectable level & negative microbiological test results for *E. coli* O157:H7 required from suppliers	Yes
	Chemical: none				
	Physical: foreign material	No	Plant records show that there has been no incidence of foreign material in products in past several years		No
Storage	Biological: Growth of pathogens	Yes	*E. coli* O157:H7 or *Salmonella* may grow if not maintained at proper refrigeration temperatures	Maintain product temperature at or below a level sufficient to prevent growth	Yes
	Chemical: none Physical: none				
Grind	Biological: none Chemical: none				
	Physical: metal contamination	Yes	Past history indicates that metal contamination has occurred during grinding	Proper maintenance of equipment, routine examination during cleaning, metal detector later in process	No

Example: for training use only

Hazard Analysis: raw ground beef patties					Continued
Process Step	**Food Safety Hazards**	**Is hazard likely to occur?**	**Justification for decision**	**What control measures can be applied to prevent the significant hazards?**	**Is step a critical control point?**
Mix	Biological: none Chemical: none Physical: none				
Patty formation	Biological: none Chemical: none Physical: metal contamination	Yes	Past history indicates that metal contamination has occurred during patty formation	Proper maintenance of equipment, routine examination during cleaning, metal detector later in process	No
Freezing	Biological: none Chemical: none Physical: none				
Metal Detection	Biological: none Chemical: none Physical: none		Past history indicates that metal contamination has occurred in previous process steps	Functioning metal detection equipment to identify and reject contaminated product	Yes
Packaging	Biological: none Chemical: none Physical: none				

Example: for training use only

HACCP plan: raw ground beef patties					
CCP	**Critical Limits**	**Monitoring Procedures & Frequencies**	**HACCP Records**	**Verification Procedures & Frequencies**	**Corrective Actions**
1 Receiving	Product not received without certification of interventions and micro testing	Receipt of certification letter for valid antimicrobial intervention and COA for *E. coli* O157:H7 for each load of product received	Receiving log Corrective Action Log	Every two months QA will request FSIS *Salmonella* data results and *E. coli* O157:H7 intervention validation results from at least two suppliers	Corrective actions shall meet all requirements of Part 417.3 (a)
2 Temperature control at storage	Product temperature ≤44 degrees F	QC personnel will record temperature of product exiting grinder every hour	Product Temperature Log Corrective Action Log Thermometer Calibration Log	HACCP Coordinator will verify accuracy of the Product Temperature Log once per shift and observe QC personnel performing monitoring HACCP Coordinator will verify temperature of raw materials cooler and freezer daily. QC will check all thermometers used for monitoring devices for accuracy by immersion in slush ice, and will verify to within 2 degrees F daily All thermometers found to be inaccurate will be calibrated using immersion in slush ice and re-evaluated	Corrective actions shall meet all requirements of Part 417.3 (a)
3 Metal Detection	Functional Metal Detector	Packaging line supervisor will check the metal detector using a seeded sample every two hours to determine limits are not exceeded	Metal Detection Log Corrective Action Log	QC personnel will verify that the metal detector is functioning as intended by running the seeded sample (2 mm) through the metal detector twice per shift. Functioning metal detector must identify and remove the seeded sample. HACCP Coordinator will verify accuracy of the Metal Detection Log and observe packaging line supervisor performing monitoring once per shift. Maintenance personnel will perform calibration procedure once per shift.	Corrective actions shall meet all requirements of Part 417.3 (a)

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