PROCESS CATEGORY INTRODUCTION

Objectives

To demonstrate mastery of this module, the Inspection Program Personnel (IPP) will:

1. Distinguish between the different HACCP processing categories.
2. Identify common hazards for all raw products.
3. Identify common hazards for other product categories.
4. Identify the raw product processing categories.
5. Identify common meat and poultry slaughter steps.
6. Identify common processing steps for intact and non-intact raw product.
7. Explain the food safety significance of non-intact product.
8. Identify common lethality for ready-to-eat product.
9. Identify amenable fish species and product types.

HACCP PROCESSING CATEGORIES

The HAACP regulations set out 9 processing categories in which finished product can be identified, 9 CFR 417.2(b)(1):

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

In PHIS, these Processing Categories are further divided into Finished Product Categories. Both categories are based on the process for the shipped finished product. We discussed these categories during the Establishment Profile presentation, and additional information can be found in Directive 5300.1. Remember, Processing Categories are considered critical profile information in PHIS. This information directs the system to provide the proper tasks for that establishment and, to some extent, the correct sampling projects and frequencies. The IPP is ultimately responsible for determining the correct HACCP Processing Category for the establishment’s product.
Slaughter Processing Category

This HACCP processing category applies to establishments that slaughter livestock or poultry. Slaughter is the process whereby healthy, live animals are humanely stunned, bled, dehided, dehaired and eviscerated. The slaughter process has inherent food safety hazards that originate with the live animal. Therefore, the slaughter process has heightened food safety significance. Slaughter establishments typically produce carcasses which are raw intact finished products. The food safety hazards identified for the slaughter process are also common to the Raw Product Intact and Raw Product Non-Intact processing categories.

Common Hazards

Most of the food safety hazards inherent in raw processes originate with the live animals that enter the slaughter establishment. These hazards are common in all raw processes. Common hazards include the biological hazards of bacterial pathogens, the chemical hazard of allergens and residues, and the physical hazards of foreign material. These hazards could be present in raw product in any step of the food process. We will now address each of these three categories of hazards in more detail.

Biological Hazards

The following chart summarizes the common microbiological hazards in slaughter products: beef, lamb, pork, and poultry.

<table>
<thead>
<tr>
<th>Process Category</th>
<th>Species</th>
<th>Biological Hazards, reasonably likely to be present and cause foodborne illness, denoted by “+”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slaughter</td>
<td></td>
<td>Salmonella, STEC, including E. coli O157:H7, Campylobacter, SRM</td>
</tr>
<tr>
<td>Beef</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Sheep, Goat</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Pork</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Poultry</td>
<td></td>
<td>+</td>
</tr>
</tbody>
</table>
Biological Hazards - Bacteria

The biological hazards of meat and poultry products result from the presence of pathogenic bacteria in and on the live animal or bird, including intestinal contents and exterior surfaces such as hide, hair, feathers, hooves and the gastrointestinal tract contents. Bacterial contamination of carcass surfaces is a detrimental 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 Slaughter, Raw Intact and Raw Non-intact processes do not include a lethality step. A lethality step is a procedure that would eliminate the bacteria or reduce the bacteria to an acceptable level. These establishments must control the hazard, or 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. Establishment 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, notably the *Shiga toxin-producing E. coli* (STEC) including *Escherichia coli* O157:H7, can cause serious illness in humans. Cattle may carry STEC 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 *Escherichia coli* O157:H7.

Contamination with this pathogen can be reduced through the use of effective sanitary dressing procedures during slaughter and pathogen reduction intervention treatments. FSIS considers raw, non-intact beef products and raw, intact beef used to produce raw, non-intact beef products contaminated with STEC to be adulterated, unless the beef is further processed to destroy these pathogens.

Raw poultry is the major source of *Campylobacter*. Cross-contamination during raw poultry preparation and the consumption of inadequately cooked poultry appear to be significant sources of the human illness - campylobacteriosis. FSIS has conducted research about the prevalence of this organism and, as of FSIS Notice 54-12, September 11, 2012, announced new performance standards for *Salmonella and Campylobacter*. 
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**

<table>
<thead>
<tr>
<th>Disease symptoms</th>
<th>Causes infection (invasion of the lining of the intestine) with acute diarrhea, nausea, vomiting, abdominal cramps, chills, headache and fever. Occasionally, may cause bloodstream infections and death. Frequency of death, 1-4%.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>Fecal contamination of meat and poultry.</td>
</tr>
<tr>
<td>Transmission</td>
<td>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.</td>
</tr>
<tr>
<td>Controls</td>
<td>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.</td>
</tr>
</tbody>
</table>
| Characteristics  | - Grows at 41-115°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. |

**STECs including *Escherichia coli* O157:H7**

<table>
<thead>
<tr>
<th>Disease symptoms</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>Fecal contamination of beef.</td>
</tr>
<tr>
<td>Transmission</td>
<td>Consumption of raw or undercooked beef. Age and immunity status will impact infective dose. As few as 10 organisms may cause illness.</td>
</tr>
<tr>
<td>Controls</td>
<td>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.</td>
</tr>
</tbody>
</table>
| Characteristics  | - Grows with or without air.  
- Grows at 45-121°F; optimum temperature for growth is human body temperature.  
- Grows in moist, low-acid foods. |

**Campylobacter**

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

In addition to bacterial hazards, FSIS has taken a number of steps to ensure that the public does not receive product from animals that could have the **Bovine Spongiform Encephalopathy (BSE)** disorder or “mad cow disease.” As we discussed in the Food Microbiology module, BSE is a progressive neurological disorder of **cattle** that results from infection by a protein, called a **prion**. The potential food safety hazard is the contamination of meat product by BSE, which is at highest risk in the **Central Nervous System (CNS)** of cattle. High-risk tissues for BSE contamination, known as **Specified Risk Materials (SRM)**, include tonsils and distal ileum for cattle of all ages. For cattle 30 months of age or older, additional SRMs include the cattle’s skull, brain, eyes, spinal cord, dorsal root ganglia, trigeminal ganglia, and sometimes the vertebral column. The direct or indirect intake of high-risk tissues may have been the source of human illness. SRM are inedible and prohibited for use as human food.

**Specified Risk Material (SRM)**

<table>
<thead>
<tr>
<th>Disease symptoms</th>
<th>Variant Creutzfeldt-Jakob disease (vCJD). Cases of vCJD present with psychiatric problems, such as depression. As the disease progresses, neurological signs appear including unpleasant sensations in the limbs/fac, problems with walking and muscle coordination, forgetfulness, among others. Late in the course of the disease, patients are hospitalized until death. Disease is rapidly progressing and fatal.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>Cattle Specified Risk Material (SRM)</td>
</tr>
<tr>
<td>Transmission</td>
<td>Not well understood. The direct or indirect intake of high-risk tissues may have been the source of human illness</td>
</tr>
<tr>
<td>Controls</td>
<td>§310.22 Removal of all SRM from cattle</td>
</tr>
<tr>
<td>Characteristics</td>
<td>• Some prion types can survive dry heat at 600˚C for 15 min.</td>
</tr>
<tr>
<td></td>
<td>• Found mostly in the Central Nervous System (CNS) tissue and brain.</td>
</tr>
<tr>
<td></td>
<td>• Incapable of replicating itself.</td>
</tr>
</tbody>
</table>

Common Controls for Slaughter - Biological Hazards

Establishments utilize a variety of controls to address bacterial hazards in the slaughter environment. Prerequisite programs and antimicrobial interventions are being used to control, eliminate or reduce microbial hazards in the slaughter process. While numerous antimicrobial interventions are used and effective, they are by no means to be used as a substitute for effective sanitary dressing procedures.

Let’s look at the most common controls, using the beef slaughter process as our example for common livestock and the young chicken slaughter process as our example for poultry.

**Beef Slaughter - Antimicrobial Interventions**

Knife trimming and carcass washing with plain water were historically 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 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 in a vacuum nozzle, with steam sprayed above and below the vacuum head. The hot water sprayed onto a carcass kills 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.

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 normally between 1.5% and 2.5% and it may be applied as a mist, fog, or a small droplet rinse. Studies have shown that washing followed by an organic acid rinse is significantly more effective in reducing bacterial numbers than washing alone.

**Acidified Sodium Chlorite** 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, it is being used in several establishments across the country.

High temperature water sprayed on the carcass (**Hot Water Rinse**) as the last step prior to chilling has been shown to be effective in substantially reducing the numbers of STEC and *Salmonella*.

**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 (generally to 185°F) and killing up to 95-99% of all bacteria. Carcasses are then sprayed with cold water.
Beef Slaughter – Other Biological Controls

According to §310.22, establishments 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 SRM. Such procedures must be in the HACCP plan, Sanitation SOP or other prerequisite program. FSIS expects that establishments which slaughter beef and process beef products would consider SRM in the hazard analysis. IPP will verify that establishments meet §310.22 and that they considered all potential hazards in the hazard analysis (§417.2(a)(1)).

In addition to the required SRM removal for cattle of all ages, establishments may also choose to reduce the risk of this hazard by only slaughtering and/or processing product from cattle younger than 30 months of age. Dentition programs may be used to determine or confirm the age of the cattle or certificates may be collected for establishments using carcasses and parts.

Poultry Slaughter – Antimicrobial Interventions

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

Many establishments have added antimicrobial carcass treatments in the form of sprays or dips, after the final carcass wash and prior to chilling. Some chemicals commonly used include the following:

**Trisodium Phosphate** (TSP) is used in many establishments as a drench, spray, or dip and has been shown effective in preventing the attachment of bacteria to the skin. It has been shown capable of reducing *Salmonella* incidence. TSP has been approved for use in establishments using online reprocessing of contaminated birds.

**Acidified Sodium Chlorite** applied at ambient temperature by spray has been shown to achieve an average reduction in *Salmonella* prevalence of 27% and an average reduction of *Campylobacter* prevalence of 25%. It can be applied as a spray or dip, and has also been approved for use in establishments using online reprocessing of contaminated birds.

**Chlorine** used as a spray has been shown to produce a significant reduction in bacterial numbers. **Hot water sprays**, with or without chlorine, show a significant reduction in *Campylobacter* on carcasses. Several other chemicals have been investigated as antimicrobial additives to the chiller water (**Chiller Treatments**), but the most commonly used in practice are chlorine and chlorine dioxide. Chlorine is the most widely used sanitizer in poultry processing. Chlorine dioxide may be used in chillers. 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 use a system which injects ozone into the chill water tank in order to reduce the numbers of bacteria in the water.

On August 21, 2014, FSIS published the Modernization of Poultry Slaughter Inspection final rule. FSIS Notice 50-14 addresses how IPP are to verify compliance with approved online and offline reprocessing antimicrobial intervention systems. Establishments that slaughter poultry other than ratites are allowed to use these approved systems to clean carcasses accidentally contaminated with digestive tract contents (9 CFR 381.91). A list of approved systems is included as an attachment to this notice.

Poultry Slaughter– Other Biological Controls

As mentioned in the above paragraph, FSIS published the Modernization of Poultry Slaughter Inspection final rule in August, 2014. This rule does away with the previous time and temperature regulatory requirements for all ready-to-cook poultry, except ratites. Establishments must develop, implement and maintain poultry chilling procedures and incorporate these procedures into one of the following written documents: the HACCP Plan, the Sanitation SOP’s or a prerequisite program (9 CFR 381.66(b)(3)). Refer to FSIS Notice 51-14.

Chemical Hazards - Residues

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.

The most commonly affected types of animals presented for slaughter with chemical residues are bob veal (calves slaughtered at 21 days or less) and cull cows. These 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.

Common Controls

The best available preventive practices for control of violative residues include: 1) Ensuring that all animals brought into an establishment for slaughter are identified so they can be traced back to their producers, with receiving as a Critical Control Point; 2) Notifying animal producers in writing of residue findings, with such notification including (a) a discussion of the issues involved; (b) the company’s future expectations; (c) an indication that repeat violators will not be future suppliers; 3) Exploring possibilities for the establishment of state-certified voluntary residue avoidance programs comparable to those developed by major
producer trade organizations and require suppliers to participate in such programs and supply certifications to that effect; and, 4) Exploring the possibilities of live-animal testing so slaughter establishments could have a rapid, convenient verification tool.

Chemical Hazards - Other

Other examples of environmental contaminants that may be consumed by animals include lead, cadmium, mercury, arsenic, dioxins, or polychlorinated biphenyls (PCBs). Industrial chemicals such as dioxins may be of concern because they have the potential to cause endocrine effects 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.

Common Controls

Establishments may pay special attention to cattle, carcasses and parts received to avoid environmental chemical contamination. Since these hazards can come into the process from a variety of sources, establishments should be vigilant to control and prevent them in the product. Establishments may use programs to ensure only food grade ingredients and chemicals are being used in their processes, and have procedures to ensure. They may use a visual examination program in which employees examine product at different points, remove effected product, and document any findings and concerns.

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. Product may be received that is contaminated by foreign material, which if not controlled, may subsequently become incorporated into the finished 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 Sanitation SOP 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.

Common Controls

Establishments may install metal detectors to identify and eliminate metal in product due to broken pieces of equipment or other metal items that enter with the live animal. Methods that establishments use to control physical hazards also include visual observation of product, sanitation procedures, standard operating procedures (SOP) for product handling, good manufacturing practices (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.
Common Steps in a Slaughter Process
- Beef Carcass as the example

We are now looking at an example of steps in the slaughter process using beef slaughter as an example. This is just to give you some familiarization to the slaughter process. This is only one example and is simplified from the flow diagram which follows. This process will vary from establishment to establishment. This example is more typical for highly mechanized, large. Smaller plants follow many of the same steps, but with fewer employees and less automated equipment.

Receiving

Cattle are received, unloaded from trucks, and held in pens. Prior to slaughter, packers will usually require that animals be kept off feed to facilitate the dressing procedures. The amount of time animals are kept off feed will vary by establishment. The animals must have access to water at all times.

Stunning

Stunning is the first step in the slaughter procedure. This must be done in a way that complies with the Humane Slaughter Act. You will learn more about this in your Humane Methods of Slaughter module. Most establishments use a mechanical method, such as a captive bolt, to render each animal completely unconscious with a minimum of excitement and discomfort.

Sticking/ Bleeding

Sticking causes death, resulting from the rapid loss of blood (exsanguination). A sharp blade is inserted into the neck, severing the carotid arteries and jugular vein. Typically, this is done while the animal is hanging head down from the rail. These overhead rails or tracks move at a controlled speed so that the carcass advances through the various slaughter processing steps.

Hide Removal

The next step is removing the hide. This may be achieved through various methods, either using mechanical equipment or by hand (at small operations). After the head and hide are removed, many establishments use anti-microbial interventions, as previously discussed.
Bunting

Bunting happens prior to evisceration. It entails severing the muscular attachments to the rectum so that it can be removed. It is important that it be secured to prevent contaminating the carcass with fecal material.

Evisceration

Evisceration is performed to separate the internal organs from the carcass. Even in highly mechanized plants, this is still done by hand. It is important that evisceration is done properly so as not to contaminate the carcass with the contents of organs such as the stomach or intestines. Fecal material or stomach contents (ingesta) will contain many bacteria, and may possibly harbor certain harmful pathogens.

Splitting

Next, the carcass is split with a saw. At the trim rail, an inspection reveals whether the carcass is free from contamination or quality concerns that can be removed by trimming.

Chill

In the next step, the carcasses are weighed and washed. They move to a chill box or cooler and chilled to a specified temperature. The chilling step helps inhibit the growth of microorganism. There are various methods and equipment used for chilling the carcass. Carcasses are typically stored in large refrigerated warehouses called coolers until they are shipped.
SLAUGHTER FLOW DIAGRAM
Example product: Beef (carcasses)
Raw Product - Non-Intact Processing Category

This HACCP processing category applies to establishments that further process product by comminuting product, injecting product with solutions, or mechanically tenderizing product by needling, cubing, pounding devices or other means of creating non-intact product. If the establishment produces bench trim or pieces of meat produced from non-intact meat, then the bench trim or pieces are also considered non-intact. It includes all raw products that are not intact in their final form.

It is very important to understand and properly identify a product's processing category both for FSIS sampling and PHIS establishment profile purposes. Understanding the way in which the establishment produces raw product will assist you in determining its appropriate processing category.

This processing category was previously referred to as Raw Product – Ground. It is important to note the changes from the old terminology. Products that formerly belonged to this category have changed as well. You may reference FSIS Directive 5300.1, April 11, 2011 Managing the Establishment Profile in the Public Health Information System (PHIS) for HACCP Processing Categories and Products as well as the 1999 Federal Register Notice 64 FR 2803.

Non-intact product presents an increased food safety concern due to the spreading of pathogens throughout the product and pathogen penetration from the surface into the interior of the product. Among the non-intact products, beef products pose a heightened public health concern. **Beef products pose increased risk of adulteration from Shiga-toxin producing *E. coli* (STEC), including *E. coli* O157:H7.** A very small dose of consumed *E. coli* O157:H7 can result in severe health consequences, and consumers frequently consume beef after preparations that do not destroy this pathogen.

Beef, pork, veal, lamb, chicken, and turkey can all be further processed into non-intact product, then sold or used in other products. Some of the common products are bone in and boneless meats that are mechanically tenderized or injected.

Mechanically Separated Product (MSP) is also considered raw non-intact product. The mechanical separation process is a way to obtain more usable product from bones from which the muscle has been removed. 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 may 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 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 that can be included in the final product. These limits can be found in 9 CFR 319.5 and 381.173 for meat and poultry, respectively.

A process similar to MSP 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. Regulations (9 CFR 318.24) require that meat derived from AMR systems meet iron and calcium requirements. FSIS has established and enforced regulations that prohibit spinal cord from being included in products labeled "meat." Because Specified Risk Material (SRM) is considered inedible, these parts cannot be used for AMR.

Remember, the distinction between intact and non-intact product depends on whether the meat interior remains protected from pathogens migrating below the exterior surface and whether or not the depth of pathogen penetration is significant.
Common Hazards

Establishments must address common **biological, chemical, and physical hazards** as they pertain to and affect their non-intact raw product.

Biological Hazards

The **biological hazards** in the non-intact raw product are mostly carried over from the slaughtered carcass. Establishments that further process raw products 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.

*Trichiniae* is a potential pathogen of concern in raw pork products. This pathogen is only of concern when the consumer doesn’t thoroughly cook pork products. Directive 7320.1 (8/6/2018) gives direction to IPP on how to verify the establishment is properly addressing *trichiniae* as a potential hazard in their hazard analysis. It is of greater concern in feral swine, and NRTE pork products that may not customarily be thoroughly cooked. For more information, see FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork (March 2016).

Chemical Hazards

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 “big 8” foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies. They 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), 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.

Establishments 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.

Physical Hazards

Establishments conducting processes such as needle injection or comminution of product regularly use equipment with numerous moving metal parts. If this equipment is not properly maintained, it can easily lead to metal contamination of product.

Common Controls

Other Biological Hazards

Establishments producing non-intact raw product may require certificates from their suppliers or institute programs that ensure the slaughtering establishment has removed any SRM. They may also purchase only carcasses and parts of cattle less than 30 months of age.

Chemical

Establishments producing non-intact product may use programs to ensure the safe handling, weighing, and use of ingredients of public health concern (allergens and ingredients that cause food sensitivities) in product and only antimicrobial agents listed in FSIS Directive 7120.1 are being used in their processes. They may also have procedures in place to ensure the safe handling and use of chemicals in processing areas. When an allergen is identified, the establishment should implement controls to prevent potential allergen cross contamination such as dedicated equipment, separation, labeling, production scheduling, sanitation, or proper rework usage.

Physical

For physical contaminants, they may use a visual examination program in which employees examine product at different points, remove affected product, and document any findings and concerns. They may incorporate an enhanced equipment maintenance program as well.
Common Steps in a Raw Non-Intact Process  
- Ground Beef Patties as the example

Now let’s look at an example of steps in the raw non-intact process, using Ground Beef Patties as the example. This is just to give you some familiarization to a raw non-intact process. This is only one example and is simplified from the flow diagram which follows. This process will vary from establishment to establishment.

Receiving

Establishments receive raw beef and other components at the receiving step to produce the ground product. Raw components for beef patties could include advanced meat recovery products, boneless meat, trimmings of different fat content, meat from older animals, head meat, cheek meat, diaphragm meat, and esophagus. Low temperature rendered products such as lean finely textured beef (LFTB) and boneless lean beef tissue (BLBT) are derived from beef trimmings and may be used as components in raw ground beef and beef patties. Partially defatted beef fatty tissue (PDBFT) and partially defatted chopped beef (PDCB) are also low temperature rendered products derived from beef trimmings but they may only be used as components in raw beef patties. Meat ingredients used may be fresh or frozen, or a combination. Some of these raw meat materials have undergone several processing steps already and have the potential to have become contaminated.

Sometimes non-intact products contain nonmeat ingredients. These 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.

Weighing

Establishments may use a formula to create a consistent product. 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.

Comminution

Comminution is the process of reducing the particle size of meats. 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.
Other equipment can be used to achieve comminution. In addition to the grinder, establishments commonly use the flaker and the bowl chopper. Some producers use a combination of several of these in the production of a ground 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. 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 processes. Often, fat and lean meat ingredients are ground separately and then combined.

Mixing

Non-intact product is often transferred to a separate piece of equipment, called a mixer or blender, for integration. 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 more uniform distribution. Non-meat ingredients, if used, are added at this stage.

Shaping/ Patty Formation

Non-intact meat mixtures are often shaped into different forms. Hamburger or ground beef is often shaped into patties using a patty machine.

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.

Packaging/ Labeling/ Distribution

After formation, and metal detection, the patties may be frozen. At this point the finished patties are packaged and labeled ready for storage and distribution.
Other steps and Considerations in Non-Intact Product

Tenderization

Tenderization is another procedure used in some establishments that produce non-intact products. All cuts can be tenderized, but this procedure is typically applied to less tender cuts of carcasses. There are several methods for tenderizing meat that produce non-intact product. These methods include the use of injected enzyme solutions and mechanical tenderization. Product that has been mechanically tenderized by needling, cubing, or pounding devices is considered non-intact.

Whenever such 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 when many cutting blades or needles are inserted into the center of the meat, potentially drawing bacteria down from the surface. Non-intact beef steaks, specifically, have been subjected to processes that cause significant pathogen penetration such that customary cooking practices would not attain a time and temperature combination sufficient to destroy any potential *E. coli* O157:H7 throughout the product.

Added Solutions

Non-intact meat and poultry products may have solutions added. The solutions may be added by injecting, also known as pumping, or by being tumbled with or without a vacuum. Any process which adds the solution using a process that could result in significant pathogen penetration from the surface of the product into the interior would be considered a non-intact product. Some of these products may be labeled as “marinated”, if they contain a maximum of 10% in red meat products and 3% for bone-in poultry/8% boneless poultry. If the solution is in excess of these percentages the term “% added solution” is required on the label. There are labeling policy memos available on the FSIS website if more detailed information is needed about product labeling. Some of these products have proteolytic enzymes applied for tenderization; these ingredients are listed in 9 CFR 424.21.

Trace Back and Trace Forward

Establishments must purchase raw materials from suppliers that maintain producer records representing the source of their raw material. Establishments must also maintain records of distribution of products and are required per 9 CFR 418.3 to maintain written recall procedures (See FSIS Notice 34-12). 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.
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.
RAW PRODUCT- NON-INTACT FLOW DIAGRAM
Example product: Ground beef patties

- Receiving - Packaging materials
- Receiving - Non-meat ingredients
- Receiving - Meat
- Storage - Packaging materials
- Storage - Non-meat ingredients
- Storage - Meat
- Weigh, Comminution of Meat
- Mix, Final grind
- Patty formation
- Metal Detection
- Freezing
- Packaging, Labeling
- Storage, Shipping, Distribution
Raw Product – Intact Processing Category

This HACCP processing category refers to product that receives further processing directly after the slaughter processing steps or after receiving raw products. It includes all raw products that are intact in their final form. This processing category was previously referred to as Raw Product – Not Ground. Again, it is important to note the changes from the old terminology. Products that formerly belonged to these categories have changed as well. As previously stated, it is important to understand and properly identify a product’s processing category both for FSIS sampling and PHIS establishment profile purposes. Understanding the way in which the establishment produces raw product will assist in determining its processing category. See FSIS Directive 5300.1, April 11, 2011 Managing the Establishment Profile in the Public Health Information System (PHIS) for HACCP Processing Categories and Products as well as the 1999 Federal Register Notice 64 FR 2803.

The processing steps at the establishment include the meat fabrication or poultry cut-up. If the establishment also slaughters, these steps are typically applied after the chilling requirements (9 CFR 381.66) are met for poultry carcasses, or after meat carcasses are cooled.

Finished products such as raw poultry (in whole or in part) or raw meat products such as primal or subprimals are part of the Raw Product-Intact processing category. Beef manufacturing trimmings (e.g., pieces of meat remaining after steaks, roasts, and other intact cuts) are also an example of intact raw beef product. FSIS considers raw products to be intact unless they have undergone any of the processes previously discussed, associated with the Raw Product Non-Intact HACCP processing category. The distinction between intact and non-intact product depends on whether the interior remains protected from pathogens migrating below the exterior surface and whether or not the depth of pathogen penetration is significant.

Common Hazards

The common hazards for raw intact product are the same as those identified in the Slaughter Processing Category. The common biological, chemical, and physical hazards in the intact raw product are mostly carried over from the slaughtered carcass. Establishments must address these hazards as they pertain to and affect their intact raw product.

Common Controls - Biological

In addition to the controls that may have already been used during the slaughter process, establishments commonly utilize additional antimicrobial interventions for pathogens of concern.
Acidified Sodium Chlorite

Acidified sodium chlorite 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-log10 reduction for *Escherichia coli* O157:H7 and 1-log10 reduction for total aerobics.

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. 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. Ionizing irradiation is recognized by FSIS 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. Irradiation does not significantly increase the temperature of food; product is still raw and requires refrigeration.

Ionizing radiation penetrates into food, killing microorganisms. 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*, *STEC*, *Clostridium perfringens*, *Staphylococcus aureus*, *Listeria monocytogenes*, and *Campylobacter jejuni*. 
The “radura” is an internationally recognized symbol identifying irradiated food. The FDA requires that both this logo and a statement “treated with irradiation” must appear prominently on the label of packaged foods, and on bulk containers of unpackaged foods.

Common Controls – Other Biological

Establishments producing intact raw product may require certificates from their suppliers or institute programs that ensure the slaughtering establishment has only sold them carcasses and parts of cattle with SRMs properly removed.

Common Controls – Chemical, Physical

Establishments may use programs to ensure the safe handling, weighing, and use of ingredients of public health concern (allergens and ingredients that cause food sensitivities) in product and only antimicrobial agents listed in FSIS Directive 7120.1 are being used in their processes. They may also have procedures in place to ensure the safe handling and use of chemicals in processing areas. They may also use a visual examination program in which employees examine product at different points, remove effected product, and document any findings and concerns.

When an allergen is identified, the establishment should implement controls to prevent potential allergen cross contamination such as dedicated equipment, separation, labeling, production scheduling, sanitation, or proper rework usage.
Common Steps in a Raw Intact Process  
- Beef Trimmings and Roasts as the example

Let's look at an example of steps in the raw intact process, using Beef Trimmings and Roasts as the example. This is just to give you some familiarization to a raw intact process. This is only one example and is simplified from the flow diagram which follows. This process will vary from establishment to establishment.

Receiving

The first step in these processes is typically receiving. Carcasses or primal and subprimal 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.

*Prerequisite Programs or Other Written Purchase Specifications* are developed by some establishments to ensure that a safe and 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 affect 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 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.

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 establishment 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.

*Image of Retail Cuts of Beef diagram*
Marination

Marination is the process of combining a liquid solution with the meat or poultry product. Products are marinated to improve taste, tenderness, color, juiciness, or other sensory attributes. Products that are "still" marinated are considered intact as long as the process does not cause significant pathogen penetration into the products' interior. Some examples of ready-to-cook marinated products include lemon-herb flavored boneless chicken breast, beef strips for fajitas, or seasoned pork roast.

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. Modified Atmospheric Packaging (MAP) systems are commonly utilized to maintain product wholesomeness. MAP systems introduce carbon monoxide into the package which also provides greater flexibility with distribution and reduces shrinkage of the meat. Sodium nitrite may be used inside packaging film at this step to maintain color. Intact cuts may also be sprayed with antimicrobials to aid in controlling bacteria. 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 establishment, or to other establishments or retail markets.

Other Common Steps not included in the Diagram

Aging

Some establishments age meat to tenderize it and improve taste and texture. This is generally done with higher quality cuts used for steaks. Aging is done in temperature and humidity controlled coolers for various lengths of time.

Curing

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. Beef products that are immersion cured or
have the cure solution massaged or tumbled into the product without a vacuum are considered intact because the actions of these processes do not typically cause significant pathogen penetration into the products’ interior. An example of uncooked, cured product may include corned beef briskets.

Edible offal

Edible offal is produced as a byproduct of the slaughter process. They may be sold as fresh or frozen items, or used to make other processed foods. Here are a few examples.

- **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.
RAW PRODUCT- INTACT FLOW DIAGRAM
Example product: Beef Trimmings and Roasts
Workshop: Common Hazards for Raw Product

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?

<table>
<thead>
<tr>
<th>Organism</th>
<th>Temperature Growth Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella</td>
<td></td>
</tr>
<tr>
<td><em>E. coli O157:H7, STEC</em></td>
<td></td>
</tr>
<tr>
<td><em>Campylobacter</em></td>
<td></td>
</tr>
</tbody>
</table>

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?
Thermally Processed-Commercially Sterile Processing Category

This processing category includes canned meat products, some products processed in pouches and semi-rigid containers. Common examples are stew, chili, soup, canned hams, Vienna sausage, hash, potted meat product, and pasta sauce with meat. Although there are several types of packaging options available, such as pouches, plastic cups and plastic trays, the metal can is still the most common package used. For this reason, these products are usually referred to as “canned”. These products undergo a heat treatment (thermal process) while inside a specially sealed container which makes them ready-to-eat.

Thermally processed product and its process are discussed in great detail in the 2-week Thermal Processing Course. If you are assigned to an establishment that produces this type of product, you will attend this special training.
Not Heat Treated - Shelf Stable Processing Category

This process category applies to products that are further processed by a curing, drying, or fermenting step as the sole means by which product achieves food safety. We will discuss the steps, products and hazards further in the Ready-to-Eat/ Shelf Stable (RTE/SS) module. A low-level heat treatment may be applied, as long as the heat treatment is not used as the sole means to achieve food safety. The finished products produced are shelf stable. Since these products are shelf stable, they don’t have to be frozen or refrigerated for food safety purposes. Several products (not all) in this HACCP category are considered ready to eat (9 CFR 430.1), meaning they can be consumed as packaged, safe for the consumer to eat without refrigeration or further processing.

Products in this category typically include dried sausage, such as salami and pepperoni. Semi-dry sausages may also be in this HACCP category, depending on the process steps. Dried whole muscle products which are mostly dry cured could also fall into this category. These products include dried hams, such as prosciutto, parma and country ham, and dried intact pieces of meat such as dried pork bellies (Pancetta), dried pork shoulders (coppa), and dried beef rounds (bresaola, beef prosciutto, basturma). Products in this category could sometimes also be categorized in the Heat Treated Shelf Stable processing category, due to the methods by which it is made.

Again, the primary consideration in determining the processing category for these products is how food safety is achieved.

Common Hazards and Controls

Biological hazards which are common to these products differ from raw products. The lethality step(s) in these products kills the pathogens (e.g., Salmonella, Campylobacter, Listeria monocytogenes, and E. coli O157:H7) which may otherwise be present in the raw materials. However, there are other biological hazards of concern as a result of the different ingredients and process steps these products may undergo.

Similar to a cooking step, these products undergo a step, multiple steps, or a process that eliminates or reduces biological hazards to an acceptable level. Such a step, steps or process is referred to as lethality. The lethality step(s) addresses the common biological hazards which would otherwise be present in the product in its raw state.

Listeria monocytogenes (Lm) is also a potential biological hazards that may re-contaminate the product. This could happen after lethality if products are exposed to food contact surfaces, raw products or contaminated ingredients prior to final packaging. The establishment may choose to control pathogenic...
recontamination in a number of ways. To address *Lm*, the establishment could apply treatments or processes after lethality to kill any surviving pathogens of concern, in addition to executing additional sanitation procedures in the processing environment.

While this product may undergo a mild heating step, this step would not include elevated temperatures. Stabilization (cooling) is not a concern because the combination of acid and reduced moisture controls *Staphylococcus aureus* and *Clostridium* spp.

Common **chemical hazards** include allergens, such as soy or milk byproducts which may be used as ingredients. Lactic acid or acetic acid may be used to speed acid formation. Nitrites are commonly used as part of the curing process and phosphates might also be used for binding, flavor and/or color. Allergens and nitrite could be hazardous if not handled properly and used in proper measurements. The establishment may utilize procedures and programs to help prevent and control these hazards.

There are no notable physical hazards unique to this process category.

Like non-intact raw products, metal contamination from equipment with small and moving parts could pose potential **physical hazards** as well. As mentioned previously, establishments may install metal detectors to identify and eliminate metal in product due to broken pieces of equipment or other metal items that enter with the live animal. Methods that establishments use to control physical hazards also include visual observation of product, sanitation procedures, standard operating procedures (SOP) for product handling, good manufacturing practices (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.
Common Steps for a Not Heat Treated Shelf Stable Process
   - Pepperoni as an example

Receiving/ Weighing/ Mixing/ Stuffing

Raw meat ingredients are received, ground and mixed with non-meat ingredients. An ingredient important to this process, but not previously discussed is the starter culture. The starter culture is important in ensuring a predictable and consistent lethality. It consists of a blend of non-pathogenic bacteria that help to increase the acidity of the product. The meat mixture is stuffed into casings.

Fermentation

This step is very important for pathogen control. During this step, the acidity of the product is increased by time, temperature and the starter culture activity. The product is held in an environment optimum for this process. Temperature and humidity are carefully monitored to ensure the starter culture bacteria actively reproduce, which produces acid and increases acidity. The acid needs to be produced quickly to inhibit pathogens, such as toxin-producing *Staphylococcus*. The pH is monitored to measure acidity and determine when the process is complete.

Drying

At this stage, the salami/pepperoni is hung in a dry room to dry. Temperature, humidity, and moisture which directly affect microbiological growth, is controlled. The product must be dried to the point at which harmful bacteria are inactivated or destroyed in order to create a safe, shelf stable product.

Slicing/Peeling

Some product is *sliced* so that it can be used for purposes such as sandwiches, pizza, or salads. This is a step where re-contamination can occur.

Packaging/Labeling

At this point the finished sausage sticks are dry and ready to be packed for storage and distribution.

This process category contains all products that are shelf stable, which may or may not have been heat treated. These products are rendered safe by a combination of processes, such as fermentation, heating, and drying.
NOT HEAT TREATED- SHELF STABLE FLOW DIAGRAM

Example product: Pepperoni

1. Receiving Packaging Materials
2. Receiving Raw Meat
3. Receiving Restricted Non-meat Ingredients
4. Receiving Unrestricted Non-meat Ingredients
5. Storage (Cold – Frozen/Refrigerated) Raw Meat
6. Storage
7. Weighing Raw Meat
8. Weighing
9. Tempering Frozen Meat
10. Weighing
11. Combining Ingredients/Processing:
   - Chopping
   - Grinding
   - Mixing
   - Stuffing
   - Forming
12. Preparing
13. Storage
14. Receiving Starter Cultures/Casings
15. Fermenting
16. Drying (optional)
17. Slicing/Peeling
18. Packaging/Labeling
19. Finished Product Storage
20. Shipping
Heat Treated- Shelf Stable Processing Category

This process category applies to product that receives further processing by using a heat treatment in combination with a curing, drying, or fermenting process step to achieve food safety. The heat treatment is the primary means of achieving lethality. Finished products produced under this processing category are safe to eat without refrigeration or further processing. This processing category typically includes popped pork skins, bacon bits, snack sticks or jerky, summer sausage, Lebanon bologna, thuringer, kippered beef, pickled sausages and rendered products. Rendering refers to the extraction of edible and inedible fats and oils from meat after slaughter. The rendering process can be either wet (usually through steam) or dry. It yields products such as tallow and lard.

These products are considered ready to eat (9 CFR 430.1), meaning they can be consumed as packaged. The finished products produced are shelf stable. Since these products are shelf stable, they don’t have to be frozen or refrigerated for food safety purposes. These products are considered ready-to-eat, meaning they can be consumed as packaged, safe for the consumer to eat without refrigeration or further processing. Products in this category could sometimes also be categorized in the Not Heat Treated Shelf Stable processing category, due to the methods by which the product is made.

Common Hazards and Controls

These ready-to-eat products, like the Not Heat Treated Shelf Stable products, undergo steps which achieve lethality in the product. Like those products, there are other biological hazards of concern as a result of the different process steps and procedures these products undergo. Potential biological hazards include *Listeria monocytogenes*, which may re-contaminate the product after lethality.

Although this product does undergo an elevated heating process (typically cooking), stabilization (cooling) is not a concern because the combination of acid and reduced moisture controls *Staphylococcus aureus* and *Clostridium* spp.

Common chemical hazards include allergens, such as soy or milk byproducts which may be used as ingredients. Chemical accelerants, acidifiers and antioxidants may be used as part of the fermentation process or assist in the quality. These could pose hazardous if not used in proper measurements.

There are no notable physical hazards unique to this process category. However, like non-intact raw products, metal contamination from equipment with small and moving parts could pose potential physical hazards as well. As mentioned previously, establishments may install metal detectors to identify and eliminate metal in product due to broken pieces of equipment or other metal items that enter with the live animal. Methods that establishments use to control physical hazards also include visual observation of product, sanitation.
procedures, standard operating procedures (SOP) for product handling, good manufacturing practices (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.
Common Steps for a Heat Treated Shelf Stable Product
- Jerky as an example

Receiving/ Weighing/ Mixing/Forming

Jerky may be made from solid pieces of whole muscle or chopped product at receiving. Many of the processing steps are similar to the processes we have already discussed. Raw meat ingredients may be sliced or ground, ground product is formed into strips.

Brine/Cure/Marinate

The strips may be mixed or tumbled with brine, cure and spices and/or marinated in a solution with salt, sugar and flavoring ingredients.

Cooking

Cooking the product for a specified time and temperature with relative humidity is designed to eliminate pathogens and control bacterial growth. The cooking process also helps to shorten the drying time.

Drying

The *drying* step helps to further reduce the moisture and water activity in the product to the safe and desired level. Reducing the moisture helps control harmful bacteria such as *Staphylococcus aureus*. Water activity (available moisture) of the product is the primary factor affecting shelf stability and safety.

Packaging/Labeling

These products may be stored and shipped at frozen, refrigerated, or at ambient temperatures. Storing product below ambient temperature is usually done for quality reasons.
HEAT TREATED- SHELF STABLE FLOW DIAGRAM
Example product: Jerky

- Receiving Packaging Materials
- Receiving Raw Meat
  - Storage (Cold – Frozen/Refrigerated) Raw Meat
  - Tempering Frozen Meat
  - Weighing and Slicing Meat
  - Combine Ingredients/Processing (Chopping Grinding Mixing Forming)
    - Marination/Cure
    - Cook/Heat Treatment
    - Drying
    - Packaging/Labeling
    - Finished Product Storage
      - Shipping

- Receiving Restricted Non-meat Ingredients
  - Storage
  - Weighing

- Receiving Unrestricted Non-meat Ingredients
  - Storage
  - Weighing
Fully Cooked - Not Shelf Stable Processing Category

This process category applies to establishments that further process products by using primarily a full lethality heat process step (e.g. cooking) to achieve food safety. These products have been processed in a manner that makes them safe to eat, with no further preparation required by the consumer. However, the finished products that establishments produce under this process category are not shelf stable. These products must be frozen or refrigerated throughout their shelf-life to maintain product safety. These products also meet the definition of Ready to Eat (RTE) product, as defined in 9 CFR 430.1.

Please note, however, that many of these products are customarily eaten hot, and the establishment may choose to include cooking or reheating instructions may on the label. (This does not affect how FSIS classifies these products into this processing category.)

There are many different types of products that fall under this category. Deli meats such as ham, roast beef, and smoked turkey breast all have very similar processes. These products are produced by adding a solution of ingredients to the raw meat ingredient. Cured products, like ham, turkey ham, and corned beef, have nitrite in the solution. Other products, like roast beef or chicken roll, may have only salt and seasonings used. The solution is often added with an injector, but products may also simply be immersed in the solution.

Another type of product in this category is the meat salad. Ham and chicken salad are some of the common salads produced. The establishment starts with fully cooked product. The fully cooked meat is chopped or ground, and mixed with other ready to eat ingredients such as mayonnaise, salt, spices, onions, celery, or pickle relish. The finished salad is packed into containers, and may be distributed fresh or frozen. These products are rarely reheated; most consumers eat them cold.

There are other products that we did not mention that you might encounter in the marketplace or being produced in an establishment. These products all have some things in common: they are fully cooked and ready-to-eat by the consumer; and they require refrigeration or freezing in order to maintain product safety and quality.

Common Hazards and Controls

The cooking step in these products kills the pathogens. However, there are other biological hazards of concern as a result of the different process steps and procedures these products undergo.

After the cooking process, the product is commonly cooled. The cooling process is also known as stabilization. Potential biological hazards during the
stabilization process include spore-forming bacteria *Clostridium perfringens* and *Clostridium botulinum*. These pathogens can survive cooking and establishments must be carefully control time and temperature in order to ensure that product does not remain at warm temperatures that would support the outgrowth of these pathogens. *Listeria monocytogenes* (LM) is also a potential biological hazard that may re-contaminate the product after cooking, if cooked products are exposed to the environment, food contact surfaces, or cross-contamination with raw products prior to final packaging.

The establishment must have procedures in place to ensure chilling and cold storage at acceptable time and temperature combinations during stabilization. These controls are essential to limit the growth of these bacteria.

The establishment may choose to control pathogenic microorganism recontamination in a number of ways. Spices that may contain *Salmonella* could be irradiated. To address LM, the establishment could apply treatments or processes after cooking to kill any surviving pathogens of concern, in addition to executing additional sanitation procedures in the processing environment.

Common **chemical hazards** include allergens, such as soy or milk byproducts which may be used as ingredients. Chemical accelerants, acidifiers and antioxidants may be used as part of the fermentation process or assist in the quality. These could pose hazardous if not used in proper measurements.

There are no notable physical hazards unique to this process category. However, like non-intact raw products, metal contamination from equipment with small and moving parts could pose potential **physical hazards** as well. As mentioned previously, establishments may install metal detectors to identify and eliminate metal in product due to broken pieces of equipment or other metal items that enter with the live animal. Methods that establishments use to control physical hazards also include visual observation of product, sanitation procedures, standard operating procedures (SOP) for product handling, good manufacturing practices (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.
Common Steps for a Fully Cooked – Not Shelf Stable Product  
- Hot Dog as an example

One of the major product groupings that fall under this category is the cooked and smoked sausage. There are many different types of these sausages made; some common examples are bologna, cooked salami, polish sausage, and hot dogs. Let’s take a closer look at hot dogs as an example of how these products are produced.

Receiving

The first steps are the same as we have previously covered: meat and/or poultry, other ingredients, and packaging materials are received and stored in the establishment until ready to use. Many establishments carefully control the quality of the incoming ingredients through purchasing specifications. Meat ingredients may have quality specifications such as percent fat, moisture, and protein. These are parameters that will affect the final quality of the product.

*Raw meat ingredients* used in these products will depend on the type of finished product desired. Many formulations include at least some *poultry* products, (turkey or chicken), and some products are made exclusively with poultry.

Weighing and Mixing

The first step in the formulation process is weighing or measuring the meat and/or poultry ingredients. They are ground and mixed or blended with the non-meat ingredients. Often establishments will *pre-blend*, that is, they will grind and mix the meats with water and salt, and sometimes with the nitrite, and let it stand for a period of time in a cooler.

We have already discussed the most common non-meat ingredients used in hot dogs: water, salt, curing agents like sodium nitrite, and sugar. Let’s take a look at some of the other ingredients that may be used, depending on the formulation.

*Binders and extenders*, such as dry milk powder, cereal flours, and soy protein, have a number of uses in a sausage formulation. They increase the overall yield, improve binding qualities, and add certain flavor characteristics.

*Cure accelerators* such as ascorbates and erythorbates are used to speed up the curing process. They also stabilize the color of the final product.

*Phosphates* are used to improve the water-binding capacity of the meat, and contribute to the flavor and color of the product.
Spices and flavorings are used to add flavor to the sausage. The wide range of available spices, seasonings, and flavorings is a primary reason for the variety available in sausages in the marketplace.

Emulsification

After the non-meat ingredients are blended with the ground meats, the mixture is emulsified. This is done in an emulsifier, and further reduces the size of the meat particles to achieve a very fine texture. Fat, protein, salt, and water are mixed and combined into a semi-fluid emulsion.

Stuffing

After emulsification, the mixture (or “batter”) is stuffed into casings, usually artificial plastic casings that allow moisture to cook out and smoke flavors to penetrate. Natural casings such as sheep small intestines may also be used.

Following stuffing, the product is linked by pinching and twisting the casing to form separate units of sausage. The sausages are still held together by the casing. These lengths of casings are then placed on racks or trees, and are ready to be loaded into the smokehouse. Some establishments load trees into individual smokehouses, however, some large volume establishments use continuous smokehouses.

Smoking

The smokehouse parameters that must be controlled are temperature, time, and humidity. The product must be exposed to a high enough temperature in order to produce a fully cooked, ready-to-eat product. Cooking is a very important step, because it is here that any pathogens that may be in the product will be eliminated.

Cooling

After product has reached the final temperature desired, the cooling process begins. This product is often showered with cold water inside the smokehouse. This removes some of the heat from the product, and immediately halts the cooking process. The shower is usually not sufficient to complete the cooling process. Usually product is moved to another chiller or cooler to finish cooling. Some establishments use very cold water as a chilling medium, sometimes with salt added to lower the temperature below the normal freezing point of water. This is called a brine chiller. Other establishments may use cold air, and some use a combination of methods. This is also referred to as the stabilization process, very important because this is also where biological hazards are potentially present.
Peeling

After product has been chilled to the desired temperature, it is removed from the artificial casings in a machine called a *peeler*. This equipment quickly runs the sausage through a tunnel that has a tiny blade that slices the casing. Steam or air is then used to blow the casing away from the sausage. The sausage links are now separate. If you closely examine the outside of a hotdog, you might see where the casing had been cut. This blade is a potential source of contamination, since it contacts every hot dog. This is a potential source for recontamination with biological hazards.

Packaging and Labeling

The final steps are packaging, labeling, and storage. The product is ready for distribution to retail stores, restaurants, or institutions.
FULLY COOKED- NOT SHELF STABLE FLOW DIAGRAM
Example product: Hot Dogs

- Receiving, Storage, Packaging materials
- Receiving, Storage - Non-meat ingredients
- Receiving & Storage - Meat
  - Purchase Specifications, Sampling
  - Weighing, Metering
  - Grinding
  - Blending
  - Emulsification
  - Stuffing, Linking
  - Smoking, Cooking
  - Showering
  - Cooling
  - Peeling
- Packaging, Labeling
- Storage, Shipping, Distribution
- Rework
Heat Treated But Not Fully Cooked - Not Shelf Stable Processing Category

This process category applies to further processed products that are either not ready-to-eat products (NRTE) or raw, otherwise processed products that are refrigerated or frozen throughout the product's shelf life. These products are produced using the criteria of one of the two following heat processing steps. The heat processing step is not adequate to achieve food safety; therefore, products may be partially cooked or heated to set batter on a raw product. The other criteria is that the heat processing step was adequate to achieve food safety; however, product is further processed, assembled, or packaged so that the cooked product contacts non-ready to-eat product ingredients. In this case, the final product is in a form that is not edible without additional preparing to achieve food safety.

The products included in this category vary quite a bit from each other. One well-known not ready to eat product is bacon. It is a cured and smoked pork product. Another product is cold smoked sausage, a product that has been smoked to add flavor, but is still raw. Partially cooked battered and breaded poultry is included in this category; it has been cooked only enough to “set” the breading. Char-marked patties are similar; they have been cooked only enough to add distinctive char marks on the meat surface, but are still essentially raw. Low temperature rendered products are heat treated to melt and remove some of the fat in the meat tissues, but again, they are not fully cooked. Chicken pot pie contains cooked chicken and raw dough, and so, falls into this category. As you can tell, there are many different types of products grouped into this category.

Cold smoked sausage is smoked primarily for appearance and flavor, but is still raw. The process is called “cold-smoked” because the smoking does not result in high enough temperatures to cook the product. The smoke used is not actually cold; it is usually 90 - 120°F. The product must be quickly cooled (stabilized) to prevent bacterial growth.

Partially cooked battered, breaded poultry products are another product in this category. The raw poultry pieces are coated with batter, a liquid mixture of flour, egg, milk, or water; or with breading, a powder or granular mixture of cereal products, like breadcrumbs; or they are both battered and breaded. The pieces are then heat treated to “set” or precook this coating, usually in hot oil. The poultry product inside is still uncooked. The products are cooled, usually in a special IQF (individually quick frozen) freezer, and packaged.

Char-marked patties are also included in this category. These products received a heat treatment on the outside surface that produces a “char-mark” which imitates the marks created from cooking product on a grill. The product is still essentially raw, and it is important that product labeling distinguish this product
from ready-to-eat products. It is crucial that this product be fully cooked by the final user, to ensure safety.

*Low temperature rendered products* are derived from the low temperature rendering of fresh meat. The products are usually ground, heated, then treated to a process that separates some of the fat from the lean portion. The temperature used must not exceed $120^\circ$ F. The product is then cooled quickly to limit potential growth of bacteria at these warm temperatures. The heat treatment is not sufficient to eliminate pathogens or to result in a cooked appearance. The rendered product is frozen and used in further processing operations. If the raw meat trimmings had at least 12% lean meat prior to rendering, the resulting product is called *Partially Defatted Chopped (species)*. If the fatty trimmings used as raw materials contain less that 12% lean meat, the resulting products are called *Partially Defatted (species) Fatty Tissue*.

There are many other products that you may encounter that would fall into this category. The most well-known product is not ready to eat bacon. It is a cured and smoked pork product. We will use bacon as an example to look at common steps in the process. The common characteristic is that these products receive some heat treatment, but not enough to result in a fully cooked, ready-to-eat product.

**Common Hazards and Controls**

The food safety hazards in this processing category are not unique. In general, you can refer to the common hazards and controls for Raw Intact and Raw Non-Intact products. Many hazards and common controls will be the same.

Common *biological* hazards and controls for these products will be similar to the hazards for raw products because these products have not undergone a lethality step to rid the product of harmful pathogens. Additionally, if the product undergoes a step or process using elevated heat, the establishment should consider pathogens associated with improper stabilization. See previous discussion in other processing categories about this.

See previous discussions about *chemical and physical hazards* and controls. Hazards and controls will vary based on the product and how it is processed.
Common Steps - Heat Treated But Not Fully Cooked – NSS Process
- Bacon as the example

Bacon is an example of a product that is cured and smoked. Let’s study the process flow diagram for this product. This is just to give you some familiarization to a Heat Treated but Not Fully Cooked, Not Shelf Stable process. This is only one example and is simplified from the flow diagram which follows. This process will vary from establishment to establishment.

Receiving

First, raw meat ingredients are received, either from another establishment, or from the fabrication department within a large establishment. In this case, the raw meat ingredient used is the pork belly.

Weighing and Mixing

The non-meat ingredients are weighed and combined. Bacon is a cured product, which means that additives are used to preserve the product and stabilize the color. Following are some of the most common additives:

- *Salt* is used for flavor and because it preserves the product by inhibiting bacterial growth.
- *Sugar* is sometimes used as a sweetener. It can counteract the harsh flavor of the high levels of salt used in some products.
- *Nitrite (or less commonly used nitrates)* stabilizes the color of the meat, contributes to the characteristic flavor of cured meat, inhibits the growth of both pathogens and spoilage microorganisms, and retards rancidity (deterioration of the fat).

The amounts of nitrite and nitrate allowed are restricted by FSIS regulations. Additives that have regulatory limits are known as restricted ingredients. Because nitrates are reduced to nitrites and is further converted to nitric oxide which react with amines present in muscle fibers to form nitrosamines (are known to cause cancer), the nitrite and nitrates levels must be closely monitored. Nitrite is most important because of its role in the developing the cured meat color. A series of chemical reactions results in the formation of the stable pink color of cured meat.

These are just some of the most common curing ingredients. Many other ingredients are used by industry, and will contribute to the variety of formulations that you may encounter.
Curing

These cure ingredients are sometimes mixed with water to form what is known as a *pickle*, or a curing solution. The solution is often injected into the meat using an *injector*. This equipment carries the meat past a series of needles that pierce it and force the pickle solution into the interior of the meat pieces. This process is called *pumping*. This results in a fast and even distribution of the pickle. There are many other means of introducing the pickle; sometimes meat pieces are simply placed into a barrel or vat of the pickle. This is a much slower process than injection.

Draining/Chilling

After injection, the meat pieces are hung onto racks called *trees* or *cages*, which hold the meat while it is further processed. The meat hangs in a cooler for a period of time to ensure that the cure ingredients have time to react with the meat, and to allow some of the solution to drain out, if necessary.

Smoking

The next step is the *smoking* process. The racks of meat are loaded into a smokehouse. The establishment operator carefully controls the smokehouse. Time, temperature, and humidity are parameters that effect product. These parameters are usually carefully monitored to ensure that the smoking step proceeds as designed by the establishment.

One common type of monitoring equipment used is the dry bulb/wet bulb thermometer. This device monitors the temperature inside the smokehouse with two thermometers set right next to each other, one dry, and one inside a moist piece of cloth. The difference between the two temperature readings is used to calculate the humidity of the environment.

The operator sets the smokehouse controls to run through a series of processes, in which the addition of steam and smoke will change the conditions inside the smokehouse. Although bacon receives some heat treatment in the smokehouse, it is not fully cooked. The smokehouse treatment is primarily designed to deposit the smoke onto the surface of the meat.

*Smoke* has several important effects on the meat product:

- It develops the characteristic smoke flavor.
- It results in a color change (browning effect), on the surface of the meat.
- It has some preservative effect.
- It protects the meat from *oxidation*, which is the development of off-flavors.
Smoke is a complex mix of chemical compounds, including phenols, alcohols, organic acids, carbonyls, hydrocarbons, and gases. The phenols and carbonyls produce the color and flavor of smoke. Smoke has a *bactericidal* action; that is, it kills some of the bacteria present. This is due to the combined effects of heating, drying, and depositing the chemical components of the smoke. Smoke is often produced from hardwood sawdust in a *smoke generator*. Liquid smoke is also used.

**Cooling**

After the product has been smoked according to the establishment's desired process standards, it must be cooled down to safe product storage temperatures. This is often done initially in a *blast cooler* for maximum cooling effect. This cooler forces cold air at a very high velocity around the bacon pieces, quickly cooling them.

**Shaping**

After the product is properly chilled, it may be sold in the bulk form. Most bacon, however, is sold as sliced product. The meat pieces are usually shaped in a press, or *blocked*, in order to produce uniform slices.

**Packaging and Labeling**

The product is sliced, and packaged. *Net weights* are checked by establishment personnel to ensure that the net weight statement on the label is accurate. Other quality checks are often performed by the establishment on the finished product. The product is now ready for final distribution.
HEAT TREATED BUT NOT FULLY COOKED - NSS
FLOW DIAGRAM
Example product: Bacon
Products with Secondary Inhibitors – Not Shelf Stable
Processing Category

This process category applies product that has been further processed by curing or using other ingredients that inhibit bacterial growth. These products are generally refrigerated or frozen throughout the product’s shelf life. Depending on the process and ingredients, these products may or may not meet the definition of ready to eat product as defined in 9 CFR 430.1.

Finished products in this regulatory processing category may or may not have had heat applied to the product. The finished products in this category are not shelf stable and require special handling to maintain safety.

Some examples of products that may fall into this processing category include products that are uncooked, cured, fermented, dried, salted, or brine treated, which are not shelf stable but can be ready to eat or not ready to eat, such as sliced country style ham, salt pork, and semi-dry fermented sausage. The product standards, processing methods, and labeling are all factors that must be considered in determining the regulatory processing category.

Secondary inhibitors are usually ingredients or processes such as fermentation or drying that when used, in combination or alone, assists in inhibiting, or slowing the growth of possibly harmful bacteria. Primary microbial growth inhibitors include lowered water activity (aw) and higher acidity. Salt or sugar in quantities that effectively lower the water activity of the finished product is an example of a secondary inhibitor. We will discuss each of the inhibitors and then concentrate on one product example - country-style ham.

Water activity (aw) - Microorganisms in food need water in order to live and grow. The water must be in a form that is available to the microorganisms. Water activity is a measurement of how much water is available in a product. The water activity can be reduced by removing water (drying) or by increasing the concentration of solutes dissolved in the water (adding salt or sugar).

Acidity - Most bacteria grow best in a medium that is neutral or slightly acidic, and the growth of most bacteria is significantly inhibited in very acidic foods. The ionic hydrogen concentration (pH) is measured on a scale from 1 to 14, with 7 being neutral; pH levels above 7 are basic, or alkaline, while those below 7 are acid. Foods that are highly acidic are seldom the vehicles for pathogens. Many foods are acidified to prevent the growth of undesirable microbes. This may be done by adding acidic ingredients, like tomatoes, or by adding the acid directly, like vinegar. The acidity of products may also be increased by the process of fermentation.
The process of using secondary inhibitors is a very complex system. Often several different inhibitors are used, each depending on the others in order to result in a safe product.

Common Hazards and Controls

**Biological hazards** which are common to these products depend mostly on if the product is still essentially raw; or, if the product undergoes a process that makes it shelf stable, or ready to eat. Common biological hazards for not ready to eat product would be consistent with common biological hazards for all raw products. Additional consideration for potential pathogens of concern for intact or non-intact product, respectively, depends on the species and the degree of meat surface penetration. If the product undergoes a step or process using elevated heat, the establishment should consider pathogens associated with improper stabilization. See previous discussion in other processing categories about this.

See previous discussions about **chemical and physical hazards** and controls. Hazards and controls will vary based on the product and how it is processed.
Common Steps - Products with Secondary Inhibitors – NSS Country-Style Ham (Not Ready to eat) as an example

Let’s look at the example of the perishable sliced country-style ham.

Receiving

Sliced country-style ham or shoulder is traditionally made from a single piece of raw meat from a pork shoulder.

Weighing/Mixing

All ingredients added are carefully weighed, in order to conform to the product formula. Ingredients include meat and non-meat ingredients, such as spices, flavorings and items for curing.

Dry Curing

Dried whole muscle products are mostly dry cured. An initial process for manufacturing whole muscle products consists of dry mixing the non-meat ingredients with the meat. Curing is the addition of salt, saltpeter, nitrites, sugars, spices, and flavorings. Nitrate and nitrite contribute to the characteristic cured flavor and reddish-pink color of the cured pork.

The entire exterior of the ham or pork shoulder is coated or rubbed by the dry application of salt combined with the other ingredients. The high salt level and the colder temperatures are the only measures protecting against the growth of pathogens.

Refrigeration

After the initial salting, the product is held for some period of time at refrigeration temperatures (at 40 °F) for the salt mix penetration and equilibration. This period often takes many weeks, with the goal of lowering the water activity sufficiently to inhibit microorganisms.

Maturation

The product undergoes a maturation period (during this stage, the product is held at elevated temperatures for drying and flavor development), air drying and smoking (if desired), and storage. During these periods at higher temperatures, the humidity and air circulation is lowered, with further moisture loss.
Packaging and Labeling

The final product is then sliced and vacuum packaged for sale.

This is an example of a system of inhibitors. The nitrite and the salt are both inhibitors, they work together to achieve a certain amount of preservation of the product. The lethality of the process for pathogens achieved in a salt-cured product will depend on the interaction of salt content, time and temperature of curing, drying, and aging.
PRODUCT WITH SECONDARY INHIBITORS – NSS
FLOW DIAGRAM
Example product: Sliced Country-Style Ham

- Receiving/Storage - Non-meat ingredients
  - Weighing of non-meat ingredients
  - Curing application
    - Cure diffusion/ additional application of Cure
      - Cure removal/ stock in net/hang
        - Salt equilibration/ Equalization/ drying
          - Dry aging/ Storage
            - Slicing, boning

- Packaging, Labeling

- Storage, Shipping, Distribution

- Receiving, Storage - Packaging
Inspection of Fish of the Order *Siluriformes*

**Background**

The program covers domestic slaughter and processing establishments and import reinspection. In 2008, Congress made amendments to the FMIA to transfer inspection of “catfish” from FDA to USDA/FSIS. Congress made further amendments to the FMIA in the 2014 Farm Bill to clarify that “all fish of the order *Siluriformes*” (which includes catfish) are subject to inspection by FSIS. This includes several fish species that are imported including Swai and Basa.

The Dec 2015 Final Rule created regulations 9 CFR 530-561 which requires mandatory inspection of official establishments that prepare or process fish. There was an initial 18 month transition period so that establishments could become familiar with FSIS regulatory requirements, develop HACCP plans, train staff, and make any necessary changes. The full FSIS enforcement period began on Sept 1, 2017 for both domestic and import inspection programs. The inspection program is similar to processing establishments, once daily. Recently several countries were approved to import *Siluriformes* fish and fish products to the U.S. (Vietnam, China, and Thailand)

**Amenable Fish Species**

Section 601(w)(2) was added to the FMIA and specified all fish of the order *Siluriformes* as amenable species under the act. FSIS has regulatory jurisdiction over all fish of the order *Siluriformes* produced for human food. The order Siluriformes includes the family *Ictaluridae* (e.g., channel catfish and blue catfish) (historically grown in United States) as well as other catfish-like fish species (historically imported.) Common names for some of these other catfish-like species are basa, tra, and swai.

Organisms are classified according to the following hierarchy: Domain, Kingdom, Phylum, Class, Order, Family, Genus, and Species.

*Siluriformes* is an order of bony fish that includes all catfish and catfish-like species. As you may know the name catfish refers to the long barbels, or feelers, which are present about the mouth of the fish and resemble cat whiskers. Altogether, the Order *Siluriformes* comprises nearly 2,900 species in about 35 Families. Several species within the families *Ictaluridae, Pangasiidae,* and Claridae are important food fish.
This table is a partial listing of various *Siluriformes* species along with common names.

<table>
<thead>
<tr>
<th>Order</th>
<th>Family</th>
<th>Acceptable Common/Usual Name</th>
<th>Genus species</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Blue Catfish, Catfish</td>
<td><em>Ictalurus furcatus</em></td>
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<td></td>
<td></td>
<td>Channel Catfish, Catfish</td>
<td><em>Ictalurus punctatus</em></td>
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<td></td>
<td>White Catfish, Catfish</td>
<td><em>Ameiurus catus</em></td>
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<td>Black Bullhead, Bullhead, Catfish</td>
<td><em>Ameiurus melas</em></td>
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<td>Yellow Bullhead, Bullhead, Catfish</td>
<td><em>Ameiurus natalis</em></td>
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<td></td>
<td>Brown Bullhead, Bullhead, Catfish</td>
<td><em>Ameiurus nebulosus</em></td>
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<td>Flat Bullhead, Bullhead, Catfish</td>
<td><em>Ameiurus platycephalus</em></td>
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<td>Whitespotted fish, Chinese fish</td>
<td><em>Clarias fuscus</em></td>
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<td>Sharptooth Clarias Fish</td>
<td><em>Clarias gariepinus</em></td>
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<td>Broadhead Clarias Fish</td>
<td><em>Clarias microcephalus</em></td>
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<td>Walking Clarias Fish</td>
<td><em>Clarius batrachus</em></td>
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<td></td>
<td></td>
<td>Swai, Sutchi, Striped Pangasius, Tra</td>
<td><em>Pangasianodon hypothalamus</em></td>
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<td></td>
<td></td>
<td>Basa</td>
<td><em>Pangasius bocourti</em></td>
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<td></td>
<td>Mekong Giant Pangasius</td>
<td><em>Pangasius gigas</em></td>
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<tr>
<td></td>
<td></td>
<td>Giant Pangasius</td>
<td><em>Pangasius sanitwongsei</em></td>
</tr>
</tbody>
</table>
Products labelled as “catfish” must be of the family *Ictaluridae*. Other species may only be labeled by their common or usual name. All of these fish are desirable food fish. Once a fish has been deheaded, eviscerated, and skinned or filleted, it is difficult to accurately distinguish one family or species from another on visual exam. The agency has genetic-based species testing for that purpose.

**Statutory Exclusions for Fish**

Siluriformes fish are excluded from the FMIA statutory provisions regarding antemortem inspection and humane handling. Siluriformes fish are excluded from the statutory provisions regarding the postmortem, carcass-by-carcass inspection of meat. FSIS did provide a regulatory exemption for retail stores and restaurants based on 21 U.S.C. 661(c)(2).
Inspection Methods
FSIS began to fully enforce the fish regulatory requirements (CFR 530-561) starting Sept 1, 2017. Many of the fish regulations mirror the regulations for livestock in parts 300 and 400.

**Sanitation Regulations, HACCP and Notifications – 9 CFR 537**

537.1 Basic Requirements  
537.2 Hazard analysis and HACCP plan  
537.3 Notification of adulterated product

**Fish Inspection Directives**

These directives cover inspection and sampling at domestic and import fish establishments.  
14,000.1 – CSI Responsibilities at Fish Establishments  
14,010.1 – Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes from Domestic Establishments  
14,100.1 - Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes at Official Import Inspection Establishments  
14950.1 – IPP Responsibilities at Official Import Inspection Establishments that Receive Shipments of Fish Products

**Fish Sampling**

In raw fish and fish products, the food safety hazards of concern are primarily chemical residues. FSIS considers fish products adulterated if they are contaminated with chemical residues.

Possible misbranding can occur if fish product is of a different species than labeled. Speciation testing will determine the species.

*Salmonella* testing initially will be used to collect baseline prevalence data. There is no regulatory control action taken for a positive *Salmonella* result.
Additional references

www.fsis.usda.gov/siluriformes

FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products (Mar 2017)


Fish Inspection Summary

1. Congress amended the FMIA to transfer jurisdiction of all fish of the order *Siluriformes* to FSIS
2. Products labelled as “catfish” must be of the family *Ictaluridae*
3. Congress excluded *Siluriformes* fish from certain statutory provisions