The Regulated Industries: Characteristics and Manufacturing Processes

OBJECTIVES

After completing this module, participants will be able to describe the characteristics of the regulated industry, the processes used, and manufacturing principles related to the meat and poultry industry.

INTRODUCTION

The purpose of this module is to give you a brief introduction to the meat and poultry industries. We will not be covering the details of how we regulate the industries; this is addressed in other modules. This module will give you an overview of the processes used and the products produced by the industries that we regulate. During the module, you'll see some video footage of different production processes. These are shown as examples, not as standards. Each establishment is unique, and the production processes used by establishments in your assignment are likely to differ in detail from the ones we present in this module. There are a wide variety of products produced and a number of different activities conducted by regulated establishments. The industry as a whole is dynamic, in that over time, production of products that are not favored by consumers are decreased or discontinued, and new products are created to meet consumer needs.

We have organized these materials by what FSIS calls processing categories. These processing categories are addressed and defined in the “Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP)” regulations, 417.2 (b). The 9 different processing categories that we will cover include the following:

- Slaughter
- Raw product – non-intact
- Raw product – intact
- Heat treated but not fully cooked - not shelf stable
- Heat treated – shelf stable
- Fully cooked - not shelf stable
- Product with secondary inhibitors - not shelf stable
- Not heat treated - shelf stable
- Thermally processed - commercially sterile

There are some processes and technologies that are not specifically addressed by a processing category in the HACCP regulations as listed below:

- Mechanically Separated and Advanced Meat Recovery
- Irradiation
- Egg Products
The Agency developed and distributed generic HACCP models that addressed most of these processing categories. We will be referring to some examples given in these models as we discuss the processing categories. Every product produced by an establishment (when the hazard analysis reveals any food safety hazard that is likely to occur) must be produced according to a written HACCP plan. Many different products may be grouped within a single processing category, as long as the food safety hazards, critical control points, and critical limits are essentially the same.

In this module, we will discuss both quality and safety issues. Both of these issues are important to both the agency and the industry. There are many quality issues, sometimes referred to as non-food safety consumer protection, which would render product adulterated. Some examples are products with low net weights or with water added above allowed limits. Safety or public health protection issues are given an extremely high priority because of the potential to cause food-borne disease outbreaks. The most common hazard to public health is the presence of harmful bacteria. Throughout this module, we will point out processes where quality or safety issues are important.

**Definition of terms:**

Before we go further, let's define a few terms:

- **Amenable** - accountable or liable to an order or regulation.
- **Product** - any carcass, meat, meat byproduct, or meat food product, poultry, or poultry food product capable of use as human food.
- **Process** - is a procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products.
- **Process flow diagram** - process flow diagrams provide a simple description of the steps involved in the process. The flow diagram covers all steps in the process which are directly under the control of an establishment. It may also include steps in the food chain which are before and after the processing occurs.

To give you an idea of the production volume of the meat and poultry industry, in FY 2008, there were 43.8 billion pounds of poultry slaughtered in federally inspected establishments. For the same period, there were 49.74 billion pounds of meat animals slaughtered.

**SLAUGHTER**

Slaughter is the process whereby healthy, live animals are humanely stunned, bled, dehided, dehaired and/or defeathered, and eviscerated. The resulting carcass may be split and/or fabricated in some fashion. During the process, inedible waste and products (e.g., products not used for human food such as the hides) are produced. Edible byproducts (e.g., livers and gizzards) are also produced. The establishment must keep
inedible materials separate from edible ones. We will cover byproducts when discussing another processing category.

SLAUGHTER - includes all amenable red meat species, and all poultry classes. Some examples are beef and pork carcasses, and ready-to-cook whole chickens and turkeys. Some of the products, such as whole poultry, will be distributed for sale following the slaughter process. However, most products go for further processing.

**Beef slaughter process**

Look at the *process flow diagram* (at the back of this handout) for the beef slaughter process. They are only examples of the slaughter process. These processes will vary from establishment to establishment. The examples we use are more typical of large establishments. Large establishments (large volume/many employees) are typically highly mechanized and may process thousands of carcasses daily. Smaller establishments follow many of the same steps, but with fewer employees and less automatic equipment.

Beef slaughter covers all market classes of cattle. Class is determined based on maturity and sex of the animal at the time of slaughter. The *classes* of beef carcasses are calves, steers, bulls, heifers and cows. There are a number of quality issues that are of concern to the producer, such as marbling, color, and texture of the meat, that do not affect the slaughter process.

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 in all holding pens. This is a requirement of the humane handling regulations.

A thorough inspection of the live animals before slaughter is called *ante mortem inspection*. The inspection is to identify any disease conditions in the cattle. Some disease conditions are unacceptable because they may affect human health. Others are unacceptable from an aesthetic standpoint.

*Stunning* is the first step in the slaughter procedure. This must be done in a way that complies with the Humane Slaughter Act. Most establishments use a mechanical method, such as a captive bolt, to render each animal completely unconscious with a minimum of excitement and discomfort. Because of the positive finding of Bovine Spongiform Encephalopathy (BSE) in the United States, the method of air injection stunning is prohibited.

*Sticking* is the second step in the process. A sharp blade is inserted into the neck, severing the carotid arteries and jugular vein, resulting in exsanguination and death. 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.

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*. Anti-microbial interventions include, but are not limited to, hot and/or ambient temperature water wash, organic acid wash, and steam vacuuming. The steam vacuuming system is used to remove contamination from the dehided carcass either before or after evisceration. Additionally, some of these interventions are used as a multi-hurdle methodology. These interventions can be done before or after evisceration of the carcass for the removal of visible contamination.

*Bunging*, when the rectum (bung) is secured to prevent contaminating the carcass with fecal material, happens prior to evisceration.

*Evisceration* is done to separate the internal organs from the carcass. Even in highly mechanized establishments, 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*) contain many bacteria, and may possibly harbor certain harmful bacteria (*pathogens*) such as *E. coli* O157:H7, *Salmonella*, *Campylobacter jejuni*, etc.

At this point the carcass receives *post mortem inspection*. Similar to ante mortem inspection, the carcass is examined for disease conditions that cause the carcass or parts to be unacceptable for human consumption.

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*.

In the next step, the carcasses are weighed, *marked* with an official USDA inspected and passed brand, and washed. They are then moved to a chill box or cooler and *chilled* to a specified temperature. The chilling step helps inhibit the growth of spoilage and harmful bacteria. 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. It is important that an appropriate temperature, humidity, and air flow be maintained in coolers. Generally, the colder the temperature in the cooler, the slower the bacteria grow. Proper temperature is essential for preserving the quality and maintaining the safety of the product.

From this point, the carcass halves are ready to be *fabricated*, which means cut into parts. This *further processing* may happen at the slaughter facility in a processing or fabrication department, or the carcasses may be shipped to another establishment.

Edible and inedible byproducts will be covered when we discuss the RAW PRODUCT – NON-INTACT processing category. Some establishments may include edible and inedible byproducts in their Slaughter HACCP plan.

**Pork slaughter process**

Now, let's look at the process flow diagram for pork slaughter (at the back of this handout). We will discuss the process for the skin-on pork carcass, which is most common. There are other pork slaughter processes, such as skinned, or hot boned.
Hog slaughter is somewhat similar to beef slaughter, but there are some major differences; we will highlight only the differences.

Hogs are usually stunned with an electrical shock or using CO₂ that renders them unconscious and insensible to pain.

Sometimes hogs will be hanging during the sticking and bleeding step. However, sticking and bleeding can also be done while the hog is lying on its side or being held on its back.

Instead of removing the hide, usually hogs are scalded and dehaired. Then, they are quickly singed with a flame to remove any remaining hairs.

The step called "gambrelling" refers to slicing the tendons on the back of the hock so that the carcass can be hung on a gambrel, or special type of hook.

**Poultry slaughter process**

In addition to the different species of poultry, such as chickens or turkeys, there are also different classes of poultry. Classes are groups based on physical characteristics like age or sex, such as fryers, roasters, or hens.

The process flow diagram (at the back of this handout) for the poultry slaughter process has many similarities to beef and pork slaughter. For example, there is holding, stunning (varies), bleeding, washing, evisceration, trimming, washing, and chilling. Some of the other steps are specific to poultry, such as picking, which removes feathers. The establishment may use a variety of methods and types of machinery to accomplish each of these steps, such as an automatic stunner, an automatic scalder, a picker, an outside bird washer, an eviscerating trough, oil sac cutter, etc., to allow it to process thousands of birds per hour.

The presentation step entails placing the carcass and its visceral organs in position to facilitate inspection for disease conditions.

The salvage and reprocessing steps refer to interventions the establishment employees would perform to remove contamination, bruises, or other unwholesome conditions from a carcass, so that the carcass is acceptable for human consumption and eligible for the marks of inspection.

Chilling for poultry is different than chilling for beef or swine. Poultry chilling is usually done in a large container of chilled water called a chiller, which holds a large number of poultry carcasses. It is very important that the chiller water does not become contaminated with fecal matter from any poultry carcass, because it could potentially contaminate all carcasses that enter the chiller. The amount of time birds spend in the chiller is a quality issue because the birds gain water weight.

The processing of byproducts may be covered either in the slaughter HACCP plan, or in another processing category.
RAW PRODUCT – INTACT

The RAW PRODUCT – INTACT processing category includes all raw products which are not ground in their final form. Some examples are beef trimmings, steaks, roasts, chops, poultry parts, fabricated products, and edible byproducts (e.g., livers, gizzards).

The process flow diagram (at the back of this handout) for this category uses the example products beef trimmings and beef tenderized cuts.

Notice that the first step is carcass receiving. Carcasses are chilled after slaughter for a specified period allowing them to become firm to facilitate a neat job of cutting.

Fabrication

Fabrication refers to creating the various cuts from the carcass to produce particular types of product. Primal or wholesale cuts are made first (refer to Figure 1, at the back of this handout). 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.

As denoted in Figure 1, retail cuts describe 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. Often, primal parts are boned before cutting into retail cuts, in order to produces boneless items. Establishments that produce portion controlled retail cuts for hotels, restaurants, and institutions are often called HRI (Hotel, Restaurant, and Institution) operations.

Packaging materials (such as wax treated paper or plastic film) protect the product from damage during refrigerated or frozen storage.

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

Tenderization

Tenderization is another procedure used in some establishments. All cuts can be tenderized, but this is typically used on cuts from lower quality grades and less tender cuts of higher graded carcasses. There are several methods for tenderizing meat. They include aging (natural chemical process), the use of enzyme solutions (artificial chemical process), and use of mechanical tenderizers. Mechanical tenderizers typically press many thin blades through the meat pieces, cutting the muscle fibers. Not all tenderized products fall into this category. Products in this category are those tenderized by natural aging, and marination or tumbling without vacuum.

Byproducts

The processing category of RAW PRODUCT - INTACT includes edible byproducts. Consumer demand has had an effect on production levels of various byproducts. For example, vegetable oils have replaced animal fats like lard and tallow in the frying industry. Technological developments have also had an impact on the demand for
inedible byproducts. Synthetic materials have been developed to make many items that were once made of animal products.

**Edible byproducts** - Some of the edible byproducts include tongues, brains, sweetbreads, hearts, livers, and kidneys. These are called variety meats. Because variety meats are more perishable than carcass meat, they must be chilled quickly after slaughter and processed or moved quickly into retail trade. They may be sold as fresh or frozen items, or used to make other processed foods. There are exceptions to the use of edible byproducts derived from cattle 30 months of age and older, including brain, skull, eyes, trigeminal ganglia, spinal cord tissue, and dorsal root ganglia. As of January 12, 2004, new regulations and policies prohibited the use of the aforementioned materials for human consumption as a result of a positive case of BSE.

Some descriptions of the sources and uses of various edible byproducts are as follows:

- **Casings** for sausages are sometimes made from sheep or hog intestines. (Note: the distal ileum of beef small intestines are prohibited regardless of age)
- **Chitterlings** are made from thoroughly cleaned and cooked intestines of pigs, and consumed as a variety meat.
- **Blood** is used as an ingredient of certain specialty products.
- **Tripe** is obtained from the first (rumen) and second (reticulum) stomach compartments of cattle. It is consumed as a variety meat and used in specialty products.
- **Sweetbreads** are thymus glands obtained from the ventral side of the neck and inside the chest cavity of young cattle. They are used fresh or frozen.

**Inedible byproducts** - The uses for inedible byproducts are constantly changing based on the available technology and consumer interests. Next are some examples of the ways in which inedible byproducts are used:

- **Hides, skins, and pelts** are used to make leather goods and glue.
- **Fats** are used to produce industrial oils, lubricants, soap, glycerin and other cosmetic ingredients. Most inedible fats are processed by dry rendering.
- **Bones** are used to produce animal feed (except ruminant bones to feed ruminants) and fertilizer.
- Some **glands** are used to produce pharmaceuticals. For example, bovine ovaries yield estrogen. The pancreas glands yield insulin, which is used to treat diabetes.
- **Lungs** are used to produce pet foods.

These lists are by no means complete, but give a few examples of the uses of edible and inedible byproducts.

**RAW PRODUCT – NON-INTACT**

This processing category includes all raw products that are raw ground, comminuted or otherwise non-intact. Some of the common products are ground beef, hamburger, ground beef patties, ground pork, fresh sausage, Italian sausage, and ground poultry products. Beef, pork, veal, lamb, chicken, and turkey can all be ground and sold or used in other products. One of the favorite products served in this country is the hamburger patty, which is the example we will use in this section (refer to flowchart at the back of
this handout). However, the processing steps that are used to produce hamburger patties are also used for other products. Establishments differ in how they design their production processes, and you may see many variations of the basic processes that we illustrate.

Meat for use in non-intact products may come into the establishment from outside suppliers, or it may be produced within the establishment during fabrication and boning operations. Non-meat ingredients and packaging materials will come from outside suppliers. Many establishments use a combination of suppliers, depending on the cost and type of product available from each.

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

After meat ingredients are received, they are stored in freezers or coolers until use. Meat products must be maintained at refrigeration temperatures adequate to prevent spoilage and growth of pathogens. *Refrigeration* achieves several purposes: it slows the growth of microorganisms, including spoilage bacteria and pathogens; slows the metabolic and enzymatic activities within the meat tissues that would lead to product deterioration; and also reduces moisture loss from the product.

Chiller or cooler temperatures in the range of 38° - 45°F will substantially retard most pathogen growth. However, certain types of bacteria, like *Yersinia* and *Listeria*, can grow at these temperatures and may be a significant hazard. Chiller storage is temporary because even at these temperatures, the spoilage organisms will continue to grow, although at a very slow rate. Freezers, generally maintained at -10° F or below, halt the growth of all bacteria. Product kept at these temperatures will maintain safety and quality for longer periods of time.

Dry ingredients and packaging materials are also received and stored prior to use.

Ground products are often made from *trimmings*. Trimmings are the pieces that are removed from carcasses while producing higher quality retail cuts of meat. Grinding is a way that establishments can use lower quality products that would not be saleable to a retail consumer. In addition to trimmings, ground beef is also commonly made from flanks, short plates, shank meat, briskets, chucks, rounds, or sirloins. Meat ingredients used may be fresh or frozen, or a combination.

Often products contain *non-meat ingredients*. Ground products are often seasoned with salt, sugar, spices, or other flavorings. Depending on the product being made, water may be added, and some product formulations include binders and extenders such as soy flour or non-fat dry milk.

Establishments use a specified recipe, called a *formulation*, to create a consistent product batch after batch. The formula lists the weights or percentages of ingredients to be used. Meats and other ingredients are weighed before use to ensure that the proper amount of each is added to the batch.
*Comminution* is the process of reducing the particle size of meats. Several different machines are used, including the grinder, the bowl chopper, and the flaker. Some producers use a combination of several of these in the production of a product.

The *grinder* consists of a hopper into which the meat chunks are placed. The meat then moves along an auger or screw, through a cylinder, at the end of which is a grinding plate and a knife. As the meat is pressed up against the plate the knife turns and cuts off small bits of the meat. The size of meat particle produced is determined by the size of the holes in the grinding plate.

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

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.

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

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

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

Because of the moving metal parts 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.

The final step for ground products at the processing establishment is *packaging and labeling*. Product may be packaged into retail size packages, into larger containers for institutional use, or into bulk containers for sale to other establishments for further processing. Although there are many different combinations of packaging materials in use, plastic liners and cardboard boxes are some of the materials commonly used. Labels must accurately reflect the product.

After packaging and labeling, products must be held at proper refrigeration temperature during storage, and throughout distribution to the customer.

Many variations of these steps are used to produce the different products available in the marketplace. Ground products may be marketed in bulk or in patty form. Fresh sausage products are also included in this category, and these products may be sold in bulk or in casings. Poultry products are common today, and ground poultry products are
available in bulk, packaged into chubs (short plastic casings), or formulated into a variety of sausage products.

**Mechanically Separated and Advanced Meat Recovery Product**

Often, the industry searches for ways to yield the maximum edible, wholesome product from the meat or poultry carcass. The mechanical separation process is a technology that industry uses to obtain more usable product from bones from which the muscle has been removed. Often, you will see these products referred to as “mechanically separated (species) or MS (species)”.

Any species, except beef, can be used: lamb, pork, chicken or turkey. Use of beef in MS product is prohibited. Mechanically separated product falls under the Raw Product Non-Intact category.

The process begins with bones (refer to flow chart at the back of this handout). 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, and this result in a temperature rise in the product. Therefore, product must be processed quickly and the temperature immediately reduced, in order to prevent oxidation and microbial degradation of the product. Even with these precautions, this product will deteriorate quickly.

Although mechanically separated product has many of the characteristics of meat and may be used as a meat ingredient in the formulation of quality meat food products, it is not meat, as defined in the regulations. In particular, the consistency of mechanically separated livestock product and its mineral content are different from those of meat. The bone marrow, spinal cord, and a certain amount of fine bone particles are included in the finished product. This actually provides a readily absorbed source of valuable nutrients like calcium and iron. However, there are specific limits on the quantity and size of the bone particles included in the final product. There are also limits on how much of the mechanically separated product that can be used in meat or poultry products, and it must be identified in the ingredients statement of the label. As per 9 CFR 319.5(b) mechanically separated beef is prohibited for use as human food.

A similar technology used by industry is called advanced meat recovery (AMR). This process obtains the meat tissues from the bones without incorporating significant amounts of bone and bone products into the final product. The resulting product consists of distinct particles of meat, with the typical color and texture of the species used. There are no special limits on the use of this product. Nevertheless, the presence of CNS-type tissue may be evident in product derived from AMR systems. Therefore, AMR derived products from cattle that contains central nervous system (CNS) tissue cannot be used as an ingredient of a meat food product. More specifically, Regulation 9 CFR 318.24 prohibits the use of skulls or vertebral columns (with exceptions) of cattle 30 months of age and older from use in AMR systems.
Irradiation

Food irradiation is a technology that exposes 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 (refer to flow diagram at the back of this handout). FSIS recognizes irradiation as an important technology for helping to ensure the safety of meat and poultry. FSIS has included ionizing radiation as an approved additive in pork carcasses and fresh, or previously frozen, cuts of pork that have not been cured or heat processed for the control of *Trichinella spiralis*, which causes trichinosis. Ionizing irradiation is also recognized as an approved additive in fresh or frozen, uncooked, packaged meat or poultry products for the purpose of reducing pathogenic microorganisms and extending shelf life.

*Radiation* is broadly defined as energy moving through space in invisible waves. Radiant energy has differing wavelengths and, hence, degrees of power. Forms of radiant energy include: microwave and infrared radiation, which heat food during cooking; visible light or ultraviolet light, which are used to dry food or kill surface microorganisms; and ionizing radiation, which penetrates deeply into food, killing microorganisms without raising the temperature of the food significantly. Food is most often irradiated commercially to reduce the numbers of pathogenic microorganisms, to extend shelf-life, or to prevent reproduction of insects. Food irradiation for these purposes is practiced in many countries, including the United States.

Treating product with irradiation could result in significant *reduction or even the elimination of pathogens*. Ionizing radiation has been shown to be effective at eliminating *Salmonella*, *E. coli* O157:H7, *Clostridium perfringens*, *Staphylococcus aureus*, *Listeria monocytogenes*, and *Campylobacter jejuni*, among others. Irradiation also can significantly extend the shelf-life of meat and poultry food products through the reduction of spoilage bacteria.

Irradiation *dose* is measured in kilo Gray (kGy); the maximum dose for use on meat products is 4.5 kGy. The radiation dose necessary to reduce the initial population of bacterial pathogens by 90 percent (the D-value, or 1-log) range from 0.1 kGy to 1 kGy. Higher radiation doses (above 1 kGy) are needed to accomplish the same anti-microbial effect in a frozen food versus a non-frozen food of the same type.

Irradiation does not significantly increase the temperature or change the physical, sensory, or nutritional characteristics of foods. Irradiation does not make food radioactive. During irradiation, the energy waves affect unwanted organisms but are not retained in the food. This is similar to the way that food cooked in a microwave oven does not retain those microwaves. Because irradiation does not raise product temperature, product is still raw and requires refrigeration.

The irradiation process requires a source of energy. The two types are radioisotopes (radioactive materials such as cobalt or cesium) or machines that produce high-energy beams. Specially constructed facilities are used to confine the beams so that personnel won’t be exposed.

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

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

Irradiation can be used within a HACCP system. Establishments that irradiate product probably would establish critical limits such as radiation dosage. By ensuring that specific limits for these parameters are met, establishments could be reasonably sure that a predetermined reduction in pathogens has been achieved within the irradiated product.

HEAT TREATED BUT NOT FULLY COOKED - NOT SHELF STABLE

Up to now, all of the processing categories that we discussed dealt with raw product - product that had not been heat treated. This section covers a group of products that receive a heat treatment, but they are not fully cooked. These products still need to be thoroughly cooked in order to be safely consumed.

The products included in this category vary quite a bit from each other. What they have in common is that they have received some type of heat treatment, but not sufficient heat treatment to result in ready-to-eat product. One well-known product is bacon, 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. As you can tell, there are many different types of products grouped into this category.

We are going to discuss the processes involved, focusing on some of the most common products. There will be many variations of these processes used by establishments, and this module will only provide an introduction to the procedures used.

Bacon

Bacon is an example of a product that is cured and smoked. Let’s study the process flow chart (at the back of this handout) for this product.
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.

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. Also, nitrites can be very toxic to humans therefore the use of these ingredients is carefully controlled. Supplies of nitrites and mixtures containing them are kept securely under the care of a responsible employee of the establishment. Often, the nitrite is purchased pre-mixed with salt and colored pink to prevent its accidental misuse.

Nitrite is most important because of its role in the developing the cured meat color. Nitric oxide (the chemical reaction product of nitrite) reacts with myoglobin, a complex protein present in meat. Myoglobin is the pigment that is responsible for the red color of muscle tissue. 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.

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.

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.

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.

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.

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. 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.

Other products in this category

Cold smoked sausage is similar to bacon, in that the product is smoked primarily for appearance and flavor. 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 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 uncooked, 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° 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, of course, many other products that you may encounter that would fall into this category. The common characteristic is that these products receive some heat treatment, but not enough to result in a fully cooked, ready-to-eat product.

FULLY COOKED - NOT SHELF STABLE

This processing category includes all food items that have been fully cooked, but are not shelf stable. Fully cooked means that these products have been sufficiently cooked so that they are safe to eat as they are, with no further preparation required by the consumer. This is also known as “ready-to-eat”. Please note, however, that many of these products are customarily eaten hot, and cooking instructions may be included on the label. This does not affect the classification of these products into this processing category. An example is the hot dog. This product receives sufficient heat treatment to be fully cooked, and does not necessarily need to be reheated by the customer. Most customers do, however, heat this product, and cooking instructions may be included on the label of the product. Another parameter that defines this category is that the products are not shelf stable. Shelf stable means that the product has received a treatment that renders it safe to store without refrigeration. This does not apply to this category. These products, although fully cooked, are not shelf stable, and must be kept refrigerated or frozen in order to maintain safety and quality. Again, the hot dog is a great example. It must be kept refrigerated by the consumer until it is eaten.

There are many different types of products that fall under this category. There are some major groups that we will closely examine, but there will be many other products that you will encounter in the industry. Keep in mind that what they all have in common is that
they are fully cooked, but they are not shelf stable. Some examples that we will discuss are the cooked and smoked sausages, cooked deli meats such as ham, roast beef, pastrami, corned beef, cooked chicken roll, and smoked turkey breast. Other meat and poultry products that fall under this classification are salads, such as chicken or ham salad, and frozen entrees.

**Cooked and smoked sausage**

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 (refer to flowchart at the back of this handout).

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. Not long ago, most hot dogs were either a combination of pork and beef, or they were all beef. Today, establishments still make these products, but many more combinations of ingredients are used. Many formulations include at least some poultry products, (turkey or chicken), and some products are made exclusively with poultry.

Many larger volume establishments use a system called *least cost formulation*. This is a computerized program that allows the processor to determine the specific allocation of ingredients required for a given product at a minimum cost. The product can be manufactured subject to ingredients available. These establishments carefully analyze samples of each batch of ingredients and enter the data into the computer program. The program determines how many pounds of each ingredient to use, in combination, to produce the desired product. Theoretically, each finished batch of product will then be identical to each other batch. Of course, the final retail label must have a list of ingredients in the correct *order of predominance*, despite any variations caused by the least cost formulation system.

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.

- **Spices** are any aromatic vegetable substance that is intended to function as contributing flavor to food, rather than as a nutritional substance. The active aromatic or pungent properties of spices that contribute the most to the flavoring effect are present in the volatile oils, resins, or oleoresins of the spice. Spices may be used whole or ground. White pepper, paprika, and nutmeg are common spices used to produce the characteristic flavor of the hot dog. Because paprika also adds color and makes meat look brighter red, it must be listed as “paprika” on labels.

- **Flavorings** are substances that are extracted from a food, and contribute flavoring, such as spice extracts.

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. The meat muscle protein, myosin, is solubilized, or released from the muscle fibers, by salt. The solubilized protein and water combine and surround the fat globules, and suspend the fat particles within the mixture.

Careful control of the amount of each ingredient is essential to the quality of the final product. The manufacturer must select a mix of raw meat materials with the appropriate binding characteristics. Different meats vary in their ability to bind. Lean beef, for example, bull, cow, and shank meat, has high binding ability. Regular pork or beef trimmings with more fat, and poultry, have medium binding ability. Low binding meats contain high levels of fat, such as jowls and briskets. Organ meats have no binding qualities. The binding capabilities are directly proportional to the myosin (red) in the muscles. Thus, the paler the muscle, the less bind it contributes to the mixture.

Control of the emulsification process is also essential. Product defects result from too much chopping or from an increase in temperature during the process. Over-chopping makes the protein fibers too short. It also creates heat from friction that melts fat. This results in product defects such as pockets of fat in the final product.

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.
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. The temperature inside the smokehouse and the internal temperature of the sausage, may be monitored by the establishment in order to verify that the critical limits are met. Cooking is a very important step, because it is here that any pathogens that may be in the product will be eliminated and the numbers of spoilage bacteria will be lowered to an acceptable level.

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.

The cooling process is also known as stabilization. There are two types of bacterial contamination that must be addressed by the stabilization process:

- Spore-forming bacteria (Clostridium perfringens and Clostridium botulinum) can survive cooking when in the heat-resistant spore form, and these organisms need to be considered as the products are chilled. Growth (sometimes referred to as “outgrowth”) of these bacteria is slowed by rapid cooling. Cooling rates, or time/temperature relationships, must be carefully controlled in order to ensure that product does not remain at warm temperatures that would support the outgrowth.

- Recontamination with bacteria (e.g., E. coli, Salmonella, L. monocytogenes) must be considered as cooked products are exposed to the environment, food contact surfaces, or cross-contamination with raw product prior to final packaging. Proper chilling and cold storage temperatures are essential to limit the growth of these bacteria.

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!

Sometimes a product that has partially or fully completed the production cycle is not sellable but is still wholesome, and can be used for food. For example, the casing of some sausages may split during the cooking or smoking cycle. Manufacturers may reuse these edible but unsalable products by removing the casing and adding the contents to the grinder to include in another run of the same product. This is called rework. Since the proteins are coagulated from cooking, rework has no bind capabilities. Of course, the ingredients of the rework must be compatible with the ingredients of the batch to which they are added.
The final steps are packaging, labeling, and storage. The product is ready for distribution to retail stores, restaurants, or institutions.

**Deli meats**

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.

Traditionally, these products were produced with whole muscle pieces, such as bone-in hams, pieces of beef round, whole briskets, or whole boneless turkey breasts. Today, many products are made with chunks of meats of various sizes, to make chopped and formed products.

Products may be *tumbled* or *massaged*, which increases both yield and tenderness. In this procedure, meat and solution are added to a chamber with baffles. The chamber or the baffles rotate, which subjects the meat pieces to a gentle beating process. This produces muscle fiber disruption, with a corresponding release of salt-soluble protein, which in turn coats the meat pieces. The protein is then coagulated by cooking to form a matrix between the individual pieces, thus giving the product an intact muscle appearance.

The meat pieces are often formed into uniform shapes. This can be done by stuffing them into nets, casings, or molds. The product takes on the shape of the mold when cooked. The cooking and cooling of these products is similar to the cooked sausage procedure. Some of these products, however, are cooked in a water bath or in a steam chamber.

After chilling, many of the products are packaged as whole roasts, for the retail deli market. Other products are sliced and packaged in retail consumer sized portions. Most are vacuum packed, which helps to protect the product quality and increases the shelf life.

**Salads**

Another type of product in the FULLY COOKED - NOT SHELF STABLE 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. Therefore, there is no chance that any pathogens present will be eliminated by consumer re-heating. Whatever bacteria are in the product when mixed, or contamination of the product during mixing, will remain in the product when eaten. The temperature of this product must be carefully controlled to ensure that bacteria in the mixture do not have a chance to grow.
Fresh or frozen entrees

Another group of products that fall within this category are the fresh and frozen entrées. These range from pre-cooked chicken pieces, barbecue beef, to prepared dinners with meat or poultry along with rice, pasta, sauce, and vegetables. There are many of these convenience type items produced today, and new products are introduced almost daily.

The processing procedure for all of these products is very similar. Fully cooked meat or poultry portions are combined with sauces, vegetables, pasta, or other ingredients. Each of the ingredients is individually weighed or portioned, to result in the desired finished proportions.

Most of these products are designed to be re-heated by the customer. Most packages will include instructions for re-heating. This does offer some degree of safety to the consumer, in that the re-heating may eliminate some bacteria if present. However, this re-heating must not be depended on, as consumers may vary greatly in how well they re-heat the product. These products are intended to be fully cooked and must be safe to eat without the re-heating step.

These are some of the major product groups that fall within the FULLY COOKED - NOT SHELF STABLE category. 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.

PRODUCT WITH SECONDARY INHIBITORS - NOT SHELF STABLE

Finished products produced under this regulatory processing category can be not-ready-to-eat (NRTE) or ready-to-eat (RTE) meat and poultry products that have been processed in a manner that utilizes strategies which produce results that will inhibit secondarily the growth of pathogenic bacteria. 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 products and require special handling to maintain their wholesome condition. In other words, the product may be heat treated, but not fully cooked, and a secondary inhibitor gives a cumulative effect (heat plus a food additive that affects the product) so that the product is RTE, yet it would not be ready-to-eat in the absence of the secondary inhibitor. The NRTE products must be kept refrigerated or frozen to maintain product quality and safety. Refrigeration, therefore, is still the primary inhibitor of the growth of pathogens and spoilage bacteria in NRTE products. RTE products need to be kept refrigerated to inhibit growth of spoilage organisms that are still present and capable of growth at ambient, non-refrigerated temperatures.

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* \( (a_w) \) - 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. You will learn more about this topic in the Inspection Methods (IM) training.

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 RTE or NRTE, 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 for the
03I products

Let’s look at the example of the perishable sliced country-style ham (refer to flowchart at
the back of this handout).

**Country-style Ham or Shoulder**

Sliced country-style ham or shoulder is a cured, dried product, traditionally made from a
single piece of raw meat from a pork shoulder. The example shown is for a NRTE,
cured product (refer to flowchart at the back of this handout).

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, salt peter, nitrates, sugars, spices, and flavorings. Nitrate
and nitrite contribute to the characteristic cured flavor and reddish-pink color of the cured
pork. All ingredients added are carefully weighed, in order to conform to the product
formula.

The entire exterior of the ham or pork shoulder is coated or rubbed by the dry application
of salt combined with the other ingredients. Additional salt or dry-cure mixture of salt
can be reapplied to the product as necessary to insure complete penetration. The high
salt level and the colder temperatures are the only measures protecting against the
growth of spoilage and pathogenic microorganisms.
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 ("burning" period). This period often takes many weeks (at least 28 days) to achieve uniform salt distribution to greater than 4.5% with a water activity below 0.96. The goal is to eventually lower the water activity sufficiently to inhibit microorganisms to a point at which the temperature can be elevated. 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. This final step in the process can be from 3 to 12 months in duration. 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. This also extends the shelf life of the product, because spoilage organisms are inhibited. 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. In addition, this product does not receive the amount of drying or reduction in water activity needed to make it shelf-stable. Therefore, the product is not completely preserved, and still requires refrigeration for safe storage. Products that are shelf stable will be covered in other sections.

**NOT HEAT TREATED - SHELF STABLE**

The NOT HEAT TREATED - SHELF STABLE processing category includes products controlled by water activity, pH, freeze dried, and dehydrated product, such as salami, pepperoni, or prosciutto. What defines this category is that the product is shelf stable, and while heat may be applied, it is not the primary means of achieving lethality. Many processors of products, such as pepperoni, include a low temperature heat treatment step in order to safely produce this type of product. We will examine the processing steps that are necessary for this type of product.

The process flow diagram (at the back of this handout) for this category represents salami/pepperoni. These are dry sausages that are ready-to-eat without any further cooking. Pepperoni was traditionally made with pork, while salami was made of pork along with some beef. Today, of course, many combinations of meat ingredients are used.

Many of the processing steps are similar to the processes we have already discussed. Raw meat ingredients are ground and mixed with non-meat ingredients. The meat mixture is stuffed into casings. Let's take a look at some of the unique aspects of these processes.

**Starter cultures** - Bacterial fermentation is used to produce the lactic acid that results in the tangy flavor associated with this type of sausage. The acid inhibits bacterial growth. The resulting lower pH causes the proteins to release water, which assists in the drying process, and further inhibits bacterial growth in the finished product. Producers typically use a commercial lactic acid bacteria starter culture. Commercial starter cultures consist of a blend of harmless bacteria strains such as *Lactobacillus*. Simple sugars, such as
dextrose or corn syrup, are added. They help promote lactic acid bacterial growth by serving as food to the bacteria during fermentation.

**Fermentation** - This step is an important one for pathogen control. During this step, the pH level of the product is reduced by the starter culture activity and by appropriate time/temperature factors. The starter culture is added to the meat mixture, along with the sugar. The mixture is stuffed, and held in an environment optimum for their growth. These rooms are sometimes called *green rooms*. The temperature and humidity are carefully monitored. The starter culture bacteria actively reproduce, and as they do they give off lactic acid, which decreases the pH of the product. It is important that lactic acid is produced quickly, because it inhibits undesirable bacteria, like the toxin-producing *Staphylococcus*. The pH is monitored over time to determine when the process is complete. During fermenting, the establishment will probably want to achieve a pH of 5.0 or less within a certain time.

Most microorganisms thrive on pH near neutral (7.0) although there are exceptions. Meat processors can control pH to limit microbial growth and give meat a longer shelf life. Muscle tissues are close to 7 in the live animal. At slaughter, lactic acid builds up and the pH is lowered. The pH of fresh meat ranges between 5.3 and 6.4. At pH between 6.0-6.4 meat spoils faster than meat in the lower pH range (5.3 to 5.7), because the spoilage bacteria are more active at the higher pH.

**Heating (optional)** - Both *Salmonella* and *E. coli* O157:H7 have been isolated from fermented sausage products. Consequently, many dry/semi-dry fermented sausages, particularly in the United States, have a significant “heat step” in the process to assure lethality of high numbers of bacterial pathogens.

**Drying** - At this stage, the salami/pepperoni is hung in a dry room to dry. Again, temperature and humidity are controlled. One of the factors that affect microbiological growth is moisture. Bacteria need moisture to survive and grow. Drying is the simple process of dehydration in which osmosis withdraws water from the cell of the spoilage organisms, shriveling or inactivating the cells. The product must be dried to the point at which bacteria are inactive or destroyed in order to create a safe, shelf stable product.

FSIS product standards state that dry sausage must have a *Moisture Protein Ratio (MPR)* of 1.9:1 or less, in order to qualify as a shelf stable product. This is a calculation that compares the percentage of moisture to the percentage of protein. For comparison, fresh meat has a MPR of about 4.0:1.

At this point, the finished sausage sticks are dry and ready to be packed for storage and distribution. Some product is sliced so that it can be used for purposes such as sandwiches, pizza, or salads. This step is another one where the potential for cross-contamination of product must be controlled by the establishment.

**Validation for E. coli** - In light of food-borne outbreaks of *E. coli* O157:H7 linked to dry fermented ready-to-eat beef sausage products, FSIS strongly recommends that all procedures for dry and semi-dry fermented sausages be validated to show a 5-log reduction of *E. coli* O157:H7. Full documentation is required.
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.

**HEAT TREATED - SHELF STABLE**

The HEAT TREATED - SHELF STABLE processing category includes rendered products, popped pork skins, bacon bits, snack sticks or jerky, summer sausage, kippered beef, and pickled sausages. These products are considered ready-to-eat, meaning they can be consumed as packaged. This category contains products that are shelf stable, and have received a full lethality treatment. Cooking is generally the primary method for achieving all or most of the lethality in these products.

**Rendering**

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.

**Summer sausage**

Summer sausage is a semi-dry sausage. It is not as dry as the “hard” sausages such as salami and pepperoni. This product is made ready-to-eat by a combination of fermentation (pH), smoking, cooking, and drying. Just one or two of these steps is not enough to produce a safe, shelf stable product.

The formulation for summer sausage typically includes lean beef, lean pork, sage or ground mustard seed, salt, sugar, pepper, and sodium nitrite. It may include a starter culture. The meat ingredients are ground, and seasonings and preservatives are added. Then the mixture is stuffed into casings. Next it is placed in a cooking chamber and heated at a low temperature (100° to 110° F) to quickly ferment the product. Often a smokehouse is used, although generally no smoke is applied. When the required pH is reached, the temperature is raised, and product is heated to a desired temperature for lethality. This also kills off the lactic acid bacteria and stops the fermentation. The product is then placed in a drying room until it dehydrates to the specified level. Sometimes a smokehouse is used as the drying room.

**Snack sticks and jerky**

Different types of snack sticks are made (refer to flow chart at the back of this handout). Some are fermented, with either a low or high moisture level. Some are not fermented, with a very low moisture level. They are usually ground, and are similar to a dry sausage. Jerky is not fermented; it is often beef, but turkey and other products are also found in the marketplace. Jerky may be made from either solid pieces of muscle or chopped product. Processing steps are similar to dry sausage and summer sausage:

- **Acidifiers** such as citric acid, lactic acid, and glucono delta-lactone may be used to reduce the pH of the product.
• **Antioxidants** such as butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), or propyl gallate may be used to prevent oxidation and rancidity.

• The *thermal processing* step, which involves cooking the product for a specified amount of time, is designed to control bacterial growth, both spoilage and pathogens. The cooking process also helps to shorten the drying time.

• The *drying* step helps reduce the moisture in the product to the desired level. Reducing the moisture helps control *Trichinae* and enteric pathogens such as *E. coli* O157:H7 and *Salmonella*.

FSIS has established **product standards** for certain dried products that specify a moisture protein ratio (MPR) needed to achieve shelf stability and ensure the product meets the standard established for that product. For example, a “dry sausage” must have a MPR of 1.9:1 or less, in order to be labeled as a “dry sausage” and also ensure shelf stability. Likewise, a non-refrigerated, semi-dry, shelf-stable sausage must have an MPR of 3.1:1 or less and a pH of 5.0 or less to ensure shelf stability. However, for most type of salt cured dried products, the water activity (available moisture) of the product is the primary factor affecting shelf stability and safety.

These products may be stored and shipped at frozen, refrigerated, or ambient temperatures. Storing product below ambient temperature is usually done for quality reasons.

**THERMALLY PROCESSED - COMMERCIALLY STERILE**

The THERMALLY PROCESSED - COMMERCIALLY STERILE processing category includes canned meat products, products in reportable 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 pans, the metal can is still the most common package used. For this reason, these products are usually referred to as “canned”.

This category contains all products that have been thermally processed in order to achieve commercial sterility. The term *commercially sterile* does not mean that the product is completely sterile. Complete sterility is not achievable with canned products, because the *thermal processing* required to assure absolute sterility is so severe that the quality of the product would suffer. Certain types of microorganisms survive the thermal processing, but remain dormant or are inhibited from growth by some other factor. Thermally processed, commercially sterile product is ready-to-eat. It can be eaten directly from the container, although most consumers heat the product as a matter of personal taste.

**Thermal process**

Our example product is pasta with meat sauce (refer to flow chart at the back of this handout). You’ll notice some familiar processing steps, such as receiving, storage, assembling ingredients, and formulation. Because we’ve covered steps very similar to these earlier, we will not cover them now. Let’s focus on some of the items that are unique to thermal processing:
• **Filling** - involves adding product, which has been mixed and formulated, to the product container. The typical container is a metal can. In most operations, filling is done with high-speed machines.

• **Types of cans** - there are several types of cans used most frequently in the meat industry. Three basic types of cans are round sanitary, drawn aluminum, and oblong. The *round sanitary* can holds a variety of meat-base products, such as pasta with meat sauce. *Drawn aluminum* cans are used most often for Vienna sausage and meat spreads. Their use is increasing, because they use less metal and are more economical. *Oblong* cans are used for canned luncheon meats.

To prevent an interaction between the meat product and the metal, cans are generally coated on the inside. The kind of coating that is typically used with meat products is sulfur-resistant. It prevents the sulfur released from meat proteins during retorting from staining the tinplate black.

• **Sealing** - lids are placed on the filled cans and a hermetic seal is formed. This seal prevents air from getting in or out. It is this seal which will preserve the integrity of the can after it has been thermally processed, so it is critical that the seal is formed correctly.

• **Thermal processing** - involves placing the filled and sealed cans in a retort so that they can be thermally processed. A retort is a steel tank in which metal crates or baskets containing the cans are placed for subsequent cooking and cooling. The retort operates under pressures of 12 to 15 pounds per square inch (psi). This pressure cooking raises the cooking medium (usually steam) to temperatures above the normal boiling point of water, 212°F. Three minutes at 250°F is an example of a minimum process. The retort subjects product to a high temperature for a sufficient duration to destroy the organisms that might adversely affect consumer health, as well as more resistant organisms that cause spoilage under normal storage conditions. These procedures are based on the destruction of all vegetative cells and all spores of the deadly, toxin-producing bacteria *Clostridium botulinum*.

• **Cooling** - after the heat process has been completed, all canned meat products should be cooled as quickly as possible to stop the cooking process and to lower the temperature below the range at which any heat tolerant bacteria can grow. Because the cans are wet, it is best to permit some heat to remain to evaporate any remaining moisture, in order to prevent rust. When cans are being cooled, they contract and even well-made seams may permit some inward leakage. Therefore, the water used for cooling must be as near sterile as possible. Canning cooling water is chlorinated, and rust inhibitors may be added.

• **Incubation** - after product is cooled, some establishments will hold it for 10 to 30 days before the cans leave the establishment. This holding time is used to test a sample of the retort load. A sample of each processing lot is held at a temperature that would promote bacterial growth. This is done in an incubator. At the end of this incubation period, cans are examined for evidence of spoilage. If none is found, canned products are shipped.
- **Storage** - canned meats should be stored in a cool, dry place because relative humidity and temperature influence their shelf life. Canned meat and poultry will maintain quality 2 to 5 years if the can remains in good condition and has been stored in a cool, dry place.

Here are some terms you commonly hear with regard to thermal processing:

- **Critical Factor** - any characteristic, condition, or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

- **Processing authority** - the person(s) or organization(s) having expert knowledge of thermal processing requirements of canned foods and utilizing procedures recognized by the scientific community as being adequate to properly calculate and assign thermal processes.

- **Process calculation** - scientifically defined procedures that determine the process time and temperature as adequate under specific conditions of manufacture for a given product.

- **Process deviation** - any change in a critical factor of the scheduled process that reduces the sterilizing value of the process.

- **Scheduled process** - the time, temperature, and critical factor controlled process, selected by the process authority and scientifically determined to yield commercial sterility under conditions of manufacture for a given product.

- **Sterilizing value** - this is normally expressed as “F₀” and is the number of minutes required to destroy a given number of microorganisms at a given temperature. The F₀ value is used to compare the sterilizing values of different processes.

- **Vacuum** - Removal of air from the can to prevent oxidation of the product.

This category contains many different types of canned product. Although we discussed metal cans, you will also see plastic cups and flexible pouches on the grocery shelf. These items are processed in a similar fashion. This category groups all products that are thermally processed in order to achieve commercial sterility.

**EGG PRODUCTS**

**What Are Egg Products?**

The term "egg products" refers to eggs that have been removed from their shells for processing. The processing of egg products includes breaking eggs, filtering, mixing, stabilizing, blending, pasteurizing, cooling, freezing or drying and packaging.

Basic egg products include whole eggs, whites, yolks and various blends with or without non-egg ingredients that are processed and pasteurized. These products may be available in liquid, frozen, and dried forms.
Who Inspects Egg Products?

On May 28, 1995, USDA's Food Safety and Inspection Service (FSIS) became responsible for the inspection of egg products. FSIS inspects all egg products, with the exception of those products exempted under the Act that are used by food manufacturers, food service, institutions, and retail markets.

Whole eggs in the shell are now regulated by FDA, not FSIS.

How Are Egg Products Made?

The initial step in making egg products is breaking the eggs followed by separating the yolks and whites from the shells. Eggs are processed by automated equipment which: moves the eggs from flats; washes and sanitizes the shells; breaks eggs and separates the whites and yolks and/or makes mixtures of them. The liquid egg product is filtered, mixed, and then chilled prior to additional processing.

Why and How are Egg Products Pasteurized?

The 1970 Egg Products Inspection Act requires that all egg products distributed for consumption be pasteurized. This means that they must be rapidly heated and held at a minimum required temperature for a specified time. This destroys Salmonella, but it does not cook the eggs or affect their color, flavor, nutritional value or use. Heating in the dried form pasteurizes dried whites, again for a specified time and at a minimum required temperature.

FSIS Egg Products Inspection

There are currently about 76 egg products processing plants under FSIS jurisdiction. Because of the EPIA requirement for continuous inspection, about 110 egg products inspectors oversee the day-to-day operations at these plants. In fiscal year 1998, the total of shell eggs produced was 79.7 billion. Of those, 20.3 billion were processed for egg products (25.5%). In 1999, the percent increased to 28%.

On the Horizon

Egg products are not currently covered under the Sanitation SOP (Sanitation Standard Operating Procedures) or HACCP (Hazard Analysis and Critical Control Point) regulations to which meat and poultry ascribe. A task group is reviewing egg products regulations and policies to move egg products toward the Sanitation SOP and HACCP requirements. Instructions and guidelines are slowly being revised and issued as either directives or notices within the standard FSIS issuance framework.
APPENDICES

Process Flow Diagrams

The following process flow diagrams are examples of the variety of formats that you will see in use by the industry. Please keep in mind that these are to be used as a classroom aid only.
Slaughter: Flow Chart
Example product: Beef (carcasses)

- Receiving Live Cattle
- Stunning/Bleeding
- Head/Shank Removal
- Skinning
- Evisceration
- Splitting
- Trim Rail
- Final Wash
- Chilling
- Packaging/Labeling
- Finished Product Storage (cold)
- Shipping
SLAUGHTER : FLOW CHART
Example product: Pork (carcasses)

1. Receiving Packaging Materials
2. Receiving Live Swine
3. Stunning/Bleeding/Scalding
4. Dehairing
5. Gambrelling/Singeing/Polishing/Shaving
6. Pre-evisceration Wash (Antimicrobial)
7. Head Drop/Head Removal
8. Bunging
9. Evisceration
10. Pluck/Viscera Disassemble & Process
11. Final Trim/Final Wash (Antimicrobial)
12. Chill/Cold Storage
13. Packaging/Labeling
14. Shipping
15. Wash (Antimicrobial)
16. Disassemble & Process
**SLAUGHTER : FLOW CHART**

Example product: *Young Chicken*

- Receiving Packaging Materials
- Receiving Live Poultry
  - Unloading/Hanging/Stunning/Killing/Bleeding
  - Scalding/Picking/Head Removal/Singeing/Washing/Hock Cutter/Transfer/Rehang/Pinning
  - Oil Gland Removal/Neck Breaking/Venting/Opening
  - Evisceration/Presentation
  - Lung/Crop Removal Neck Removal/Harvest
  - Reprocessing*
  - House Inspection/Trim
  - Final Wash*
  - Chilling*
  - Packaging/Labeling
  - Finished Product Storage (Cold)
  - Shipping
  - Liver/Heart Harvest Gizzard Harvest/Peel

* Steps in the process where antimicrobials may be used

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Entry Training for PHV
RAW PRODUCT- INTACT: FLOW CHART
Example product: **Beef Trimmings and Roasts**

- Receiving Packaging Materials
- Storage Packaging Materials
- Tenderizing
- Packaging/Labeling
- Finished Product Storage (Cold)
- Shipping
- Receiving Carcasses
- Storage (Cold) Carcasses
- Fabrication of Beef Cuts and/or Beef Trimmings
- Beef Trimmings
MECHANICALLY SEPARATED PRODUCT: FLOW CHART
Example product: Mechanically Separated Pork

FSIS as a Public Health Regulatory Agency: Regulated Industries
5/7/13

Entry Training for PHV
RAW PRODUCT- NOT-INTACT: FLOW CHART
Example product: Ground beef patties

1. Receiving - Packaging materials
   - Storage - Packaging materials

2. Receiving - Non-meat ingredients
   - Storage - Non-meat ingredients

3. Receiving - Meat
   - Storage - Meat
     - Weigh, Grind Meat
       - Mix, Final grind
         - Patty formation
           - Freezing
             - Packaging, Labeling
               - Storage, Shipping, Distribution
IRRADIATION: FLOW CHART
Example product: Poultry parts

Storing/transporting of packaged poultry parts (Refrigerated or frozen)

Irradiating of poultry parts (Refrigerated or frozen)

Storing
Transporting
Distribution
(Refrigerated or frozen)
HEAT TREATED BUT NOT FULLY COOKED- NOT SHELF STABLE:
FLOW CHART
Example product: Bacon
FULLY COOKED- NOT SHELF STABLE : FLOW CHART
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
- Packaging, Labeling
- Peeling
- Rework
- Storage, Shipping, Distribution
PRODUCT WITH SECONDARY INHIBITORS - NOT SHELF STABLE:
FLOW CHART
Example product: Sliced Country-Style Ham

1. Receiving/Storage - Non-meat ingredients
2. Weighing of non-meat ingredients
3. Curing application
4. Cure diffusion/additional application of Cure
5. Cure removal/stock in net/hang
6. Salt equilibration/Equalization/drying
7. Dry aging/Storage
8. Packaging, Labeling
9. Slicing, boning
NOT HEAT TREATED - SHELF STABLE: FLOW CHART
Example product: Pepperoni

Receiving Packaging Materials

Receiving Raw Meat

Receiving Restricted Non-meat Ingredients

Receiving Unrestricted Non-meat Ingredients

Storage (Cold – Frozen/Refrigerated) Raw Meat

Tempering Frozen Meat

Weighing Raw Meat

Combine Ingredients/Processing: Chopping Gridding Mixing Stuffing Forming

Preparing

Storage

Receiving Starter Cultures/Casings

Weighing

Storage

Weighing

Fermenting

Storage Packaging Materials

Drying

Heat (optional)

Slicing/Peeing

Packaging/Labeling

Finished Product Storage

Shipping
HEAT TREATED- SHELF STABLE : FLOW CHART
Example product: **Jerky or Snack sticks**

- Receiving Packaging Materials
- Receiving Raw Meat
  - Storage (Cold – Frozen/Refrigerated) Raw Meat
  - Tempering Frozen Meat
  - Weighing Raw Meat
  - Combine Ingredients/ Processing (Chopping Grinding Mixing Stuffing Forming)
    - Fermenting (some snack sticks only)
  - Heat Treatment
    - Drying
      - Cooling/Equilibration
      - Packaging/Labeling
      - Finished Product Storage
        - Shipping
- Receiving Restricted Non-meat Ingredients
  - Storage
  - Weighing
- Receiving Unrestricted Non-meat Ingredients
  - Storage
  - Weighing
THERMALLY PROCESSED - COMMERCIALLY STERILE: FLOW CHART
Example Product: Pasta Sauce with Meat
FIGURE 1: Wholesale cuts and Retail cuts

Retail Cuts of Beef: WHERE THEY COME FROM AND HOW TO COOK THEM

This chart approved by National Live Stock and Meat Board

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WORKSHOP

A. For each product listed below, identify the appropriate processing category.

<table>
<thead>
<tr>
<th>Product</th>
<th>Processing category</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Beef liver</td>
<td></td>
</tr>
<tr>
<td>2. Sliced Ham</td>
<td></td>
</tr>
<tr>
<td>3. Pork chops</td>
<td></td>
</tr>
<tr>
<td>4. Beef jerky</td>
<td></td>
</tr>
<tr>
<td>5. Canned Luncheon Meat</td>
<td></td>
</tr>
<tr>
<td>6. Ground beef patties</td>
<td></td>
</tr>
<tr>
<td>7. Bologna</td>
<td></td>
</tr>
<tr>
<td>8. Whole chicken</td>
<td></td>
</tr>
</tbody>
</table>

B. Define the following industry terms:

Stunning-

Pathogens-

Sticking-

Trimmings-

Comminution-

Formulation-
C. What is the food safety significance of the following procedures? (What is it about this step that must be controlled in order to ensure safety?)

Cooking-

Chilling-

Evisceration-

Grinding-

Drying-