

Safe Practices for Sausage Production

Distance Learning Course Manual



• Association of **AFDO** Food and Drug •
• Officials •

Sponsored by:

The U.S. Department of Agriculture (USDA),
Food Safety and Inspection Service (FSIS), and
The Association of Food and Drug Officials (AFDO)

In cooperation with the U.S. Food and Drug Administration (FDA)

Version 1 - September 1999

Index

Introduction	3
Producing Sausages	6
Fresh Sausages	6
Cooked and Smoked Sausages	10
Dry Sausages	15
Sausage Production Equipment	19
Ingredients in Sausages	20
Performing Sausage Formulation Calculations.....	24
Biological Hazards of Concern	28
Sanitation Issues	33
HACCP Plan Implementation	35
Summary	39
Glossary	42
Appendices.....	60

Introduction

"...even kids with chicken pox, love hotdogs..." (Armor hot dog jingle)

History of Sausages The process of preserving meats by stuffing salted, chopped meats flavored with spices into animal casings dates back thousands of years, to the ancient Greeks and Romans, and earlier. The word "sausage" is derived from the Latin word "salsus", which means salted, or preserved by salting. Sausages and sausage products have since evolved into a wide variety of flavors, textures, and shapes resulting from variations in ingredients and manufacturing processes.

In the United States, expansion in the meat packing industry during the Civil War, along with development of refrigeration for use in railroad cars and slaughtering facilities, provided an incentive for meat processors to create sausage products that could utilize cheaper, perishable cuts of meat, along with scrap trimmings and offal products. In addition, persons from various nationalities and ethnic groups immigrated to the U.S., bringing with them traditional recipes and manufacturing skills for creating a wide range of sausage types.

A series of scandals, including the publication of Upton Sinclair's *The Jungle*, exposed undesirable practices in the meat processing industry, including the practice of adding variety meats and offal products to a sausage product without identifying the ingredients to the consumer. The Federal Government responded in 1906 with the Federal Meat Inspection Act (FMIA).

Today, the sausage manufacturing industry must adhere to government standards for ingredients and processes. In addition, accurate labeling requirements ensure that the consumer is informed of the ingredients of a sausage product. The objective of these standards is to help ensure that sausage products maintain a consistent quality and are safe to consume.

Overview of the Safe Practices in Sausage Production Course and Manual

This manual is one component of a USDA FSIS tele-course on the safety issues associated with the production of sausage products. The manual is designed to supplement the information presented within the course, and provide you with a lasting reference that you can review at a later date.

What information is covered in this manual?

Throughout this manual, we will cover a range of issues related to sausage production, including;

- the sausage production process,
- safety and sanitation issues at each stage of the process, and
- pathogens of concern to sausage makers.

Course Objectives Once you have completed this course, you will be able to:

- Describe the stages of the sausage production process, along with the production, safety, and sanitation issues as appropriate to each stage of the process.
- Identify the range of pathogens of concern to sausage makers.

Purpose of this course and manual

This program is intended to provide the retail food inspector some insight into the processes used by food processors to produce the many products distributed for retail sale. Today, however, many grocery stores, meat markets, and other retail food establishments are producing their own sausage products. Many of the principles that apply to large food processors also apply to retail operations. Therefore, our primary purpose is to provide some background information to the retail inspector who encounters these sausage processes. This course will review the sausage production process, identify critical food safety areas within the process, and review the procedures that should be followed to ensure that only safe products are produced. We have attempted to target the information presented to the retail inspector.

Increasingly stringent food safety standards are driving food industries internationally, nationally, and at the state level to adopt HACCP. HACCP has been used for decades to increase product safety. HACCP is also good business: it results in decreased liability potential for the establishment, and increased consistency and consumer satisfaction in the products produced.

The U.S. FDA has identified recommended retail standards in the 1999 Food Code. HACCP plans are specifically required for retail facilities that use smoking, curing, acidifying, use food additives, use alternative cooking time/temperature combinations, or use reduced oxygen packaging (see sections 3-502.11, 3-401.11 (D)(3), 8-201.13 of the 1999 Food Code). The Food Code requires that a food establishment obtain a variance from the regulatory authority before conducting these operations.

State food laws often can not provide detailed proscriptive guidance for the diverse processes used in sausage manufacturing. Often State and local inspectors rely on compliance with general good manufacturing practices (GMP), which can cause conflicts because GMPs are open to subjective interpretation.

The FSIS technical staff has access to recognized meat safety standards that have been developed based on years of scientific study and practical experience. This program is presented in the hope that retail inspectors may find this information useful when they need to determine if a practice in one of their facilities is a safe one or not. This material presents detailed information regarding specialized processes that may not be specifically addressed in their state laws or the model Food Code. This information may be helpful, when used in conjunction with the FDA Food Code, for evaluation of requests for variances from establishments. The

information can also be useful when evaluating the scientific soundness of a retail establishment's HACCP plan. As with any type of guidance from outside agencies, inspectors should discuss with their supervisors how this information could appropriately be used in their regulatory programs.

Examples of Sausage Products

Several categories of sausage products are typically consumed in the U.S., each with specific production processes and storage requirements. These categories include fresh sausages, such as fresh pork sausages, cooked sausages, such as frankfurters, and dry sausages, such as meat sticks.

Fresh Pork Sausage Fresh pork sausages are produced from selected cuts of fresh and sometimes frozen pork, pork trimmings, and water, along with seasonings. Since fresh sausages do not contain curing agents, and are neither cooked nor smoked, they require refrigeration. These types of sausages must be thoroughly cooked before serving.

Frankfurter Frankfurters are examples of cooked and smoked sausages. They are produced from fresh meat that is fully cooked, and have flavors that are imparted through the addition of curing ingredients, and via various cooking and smoking processes. Although they are fully cooked they are not shelf-stable, and must be refrigerated until the time of consumption.

Meat Stick Meat snack sticks are produced using controlled, bacterially-induced fermentation to preserve the meat and impart a special flavor, along with a long drying period to cure and preserve the meat. These processes produce a shelf-stable product.

In this course, you will learn about the production process and production requirements for each of these categories of sausages.

Producing Sausages

In this section, you will go over the main steps that are utilized to produce standard sausage products, including Fresh Sausages, Cooked and Smoked Sausages, and Dry Sausages.

Fresh Sausages Fresh Sausages are made from selected cuts of fresh and sometimes frozen meats. Fresh sausages are not allowed to contain curing agents [i.e., sodium or potassium nitrites, nitrates, or salt in sufficient quantities to preserve the product] and are not cooked. Fresh sausages are usually seasoned, and have limited water content. These types of sausages require refrigerated storage, and must be thoroughly cooked before serving.

Fresh sausages are not as widely produced as cooked sausages, and are typically consumed as breakfast meals. Typical fresh sausages include products such as pork sausages, beef sausage,

breakfast sausage, Italian sausage, and fresh chorizo sausages.

This chart provides some of the FSIS established Standards of Identity for typical fresh sausages. [see 9 CFR 319.140-145] These FSIS standards are presented as guidelines for State and local inspection.

Standards of Identity for Fresh Sausages

Type	Fat Content	Characteristics
Fresh Pork Sausage	Up to 50%	No pork by-products, paprika, binders, or extenders allowed. Water/ice up to 3% permitted.
Country Style Pork Sausage	Up to 50%	All spices and flavorings must be natural.
Whole Hog Sausage	Up to 50%	Can use meat parts from entire hog, including muscle by-products like tongue and heart, in proportions consistent with the natural animal. Water/ice up to 3% permitted.
Breakfast Sausage	Up to 50%	Can contain mechanically-separated product up to 20% of the meat portion, and binders and extenders up to 3.5%. Can contain meat ingredients from multiple species. Water/ice up to 3% permitted. Paprika not permitted.
Fresh Beef Sausage	Up to 30%	Can contain mechanically-separated beef product up to 20%. Binders, extenders, and paprika are not permitted. Water/ice up to 3% permitted.
Bratwurst (fresh)	No fat limitation	Usually made from pork but can be made from poultry if properly identified on label. Can contain binders and extenders up to 3.5%. Water/ice up to 3% permitted.
Italian Sausage By standard is only pork, special labeling for others	Up to 35%	Must contain 85% meat/fat. Can contain mechanically-separated pork product up to 20% of the meat portion, approved condiments, and additional food ingredients. Water/ice up to 3% permitted. Paprika is permitted. Must have anise or fennel as spices, which provide product identity.

Of course, establishments may want to produce other types of sausage. Establishments have the flexibility to design their own particular sausage formulas. Many manufacturers are creating gourmet-type fresh sausage products that are acceptable as long as a truthful, descriptive product name and an accurate ingredients statement are included on the label.

The main processes used to produce Fresh Sausages are:



- Grinding meat ingredients
- Adding non-meat ingredients
- Blending
- Stuffing
- Packaging

Grinding Meat Ingredients

In this section we'll briefly review each stage of the production process for creating most types of fresh sausages. These steps are

also used to create other types of sausages.

The first step in sausage production is grinding the ingredients. The grinding stage reduces the meat ingredients into small, uniformly sized particles. Ground meat is the primary ingredient in a sausage formulation. The characteristics of the meat ingredients used to create the sausage define the type of sausage - the overall taste, texture, aroma, along with the protein and fat content.

A variety of raw meat ingredients are utilized in the sausage production process. Each ingredient contributes a specific property to the final sausage formulation.

Meats must be clean, sound, and wholesome. These products should be inspected when arriving at the facility, and just prior to use, to ensure that they were not contaminated during transit or handling.

The specific meats used in a sausage formulation must be correctly identified by type and quantity.

Prior to grinding, the meat is held in cold storage. Although the Food Code requires the meat to be held at 41°F or less, often processors prefer to chill the meat to below 30°F to minimize the potential for fat smearing. The grinder blades must be sharp and matched with the grinding plate to ensure an efficient grind without generating extra heat during the grinding process.

Grinding processes will vary according to the manufacturer and the nature of the product. Some sausage products use coarsely ground meats, others use more finely ground meat ingredients. Some manufacturers grind the lean and fat trimmings separately, grinding the lean trimmings to a finer consistency than the fat meats.

Adding Non-Meat Ingredients

There are many non-meat ingredients that are essential to the sausage making process. These non-meat ingredients stabilize the mixture, and add specific characteristics and flavors to the final product. Ingredients used in fresh sausage include water, salt, and antioxidants, along with traditional spices, seasonings, and flavorings.

It is important to note that the use of some non-meat ingredients is limited or prohibited. In fresh sausage, for example, water is limited to 3 percent of the total weight, and binders and extenders such as dry milk powder are limited to 3.5 percent of the total weight.

Paprika is a spice that is considered both a flavoring and a coloring agent, because of its strong red color. For this reason, paprika or oleoresin of paprika may not be used in any fresh meat product, except products that it is traditionally expected in, such as Italian sausage and chorizo.

The amount of non-meat ingredients, such as spices, is determined by the overall weight of the product mixture. Since the amounts of these ingredients must be carefully controlled, and measuring very small amounts of numerous specific ingredients within a manufacturing environment is often not practical, many manufacturers use a commercially pre-measured and packaged mix of these ingredients.

Blending Manufacturers carefully control the blending of the meat and non-meat ingredients to create the desired characteristics for a specific sausage formulation.

The meat and non-meat ingredients are placed in a mixer and thoroughly blended.

The manufacturer must monitor and control the blending process, since excessive mixing can cause the salts in the formulation to break down excessive amounts of protein, or friction created by the blending process can increase the product temperature and cause fats to partially render. Excessive handling also cuts protein fibers too short. All of these problems could result in product quality defects.

The blending process must also obtain a uniform distribution of any non-meat ingredients within the product formulation. For example, flavorings, salts, and other ingredients must be consistently mixed throughout a sausage formulation.

Stuffing After the blending is complete, the blended ingredients may be bulk packaged, or they may be extruded into a casing. This process is called stuffing. Fresh sausages are typically stuffed into natural animal casings. Natural casings used for fresh sausage are derived from the small intestines of sheep. To create the natural casings, the casing processor washes, scrapes, and treats the casings, grades the casings for size and condition, then salts, packages, and ships the casings in brine or propylene glycol (for preservation) to the sausage manufacturer.

Fresh sausages may also be stuffed into a small diameter artificial casing, or may be extruded into a short, large diameter plastic casing called a “chub” pack, usually containing 1 to 2 pounds of meat

The Stuffing Process The stuffing process can be accomplished in a number of ways. Natural casings are typically flushed with water, and the mixture is injected into the casing at a pressure that is sufficient to fill the casing without leaving any air pockets, and without tearing the casing. The stuffing process is also sometimes conducted at lower temperatures (<35-38⁰F) to minimize fat smearing on the casing.

Smaller volume or specialty producers may stuff the formulation into the casing by hand or from a screw feed. These small operations may also bypass choppers, mixers, and stuffers, and stuff the

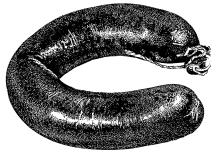
output of the grinder directly into the casing. Larger manufacturers may use air or water-piston type automatic stuffers.

The stuffed casings are then separated into uniform segments of equal length in a process called linking. These segments form the single sausage portions. The linking process is typically accomplished by twisting the casing.

Packaging

The fresh sausage product is sometimes packaged for sale to the customer. The product may be wrapped in a gas impermeable plastic, and placed into refrigerated storage or display. The specific packaging will vary according to the needs of the end user, however, the processor must follow hygienic standards when packaging any sausage product to avoid contaminating the product. Often retail fresh sausage is tray packed.

Cooked and Smoked Sausages



Cooked and smoked sausages account for approximately 85% of all sausages produced today. Typical cooked sausages, like frankfurters or bologna, are made from fresh or frozen meat that is cured during processing, fully cooked, and smoked. These types of sausages are perishable and must be refrigerated until time of consumption, or they expire. These sausages have additional flavors that are imparted through the addition of nitrites and nitrates, and via various cooking and smoking processes.

This category of sausages contains many process variations that result in the wide range of cooked and smoked sausages that can be seen in the retail trade. Although most are cooked and smoked, some are cooked without smoke, and there are many other process modifications. This manual does not cover all of the possible variations. We are only going to discuss a few of the most common processes for manufacturing cooked and smoked sausages.

One type of cooked and smoked sausage is made from emulsified (finely ground) meats. This type includes frankfurters (hot dogs), bologna, knockwurst, and vienna sausages. This class of sausage is allowed to contain a combination of fat and added water of up to 40%, with no more than 30% fat in the finished product. These product standards are found in FSIS regulation §319.180 (see appendix).

Some cooked and smoked sausages are more coarsely ground, such as Polish sausage, cotto salami, and smoked sausage. Fat is considered visible to the consumer in these types of sausages, so there is no fat limitation, however water is limited to 10% of the finished product weight. These product standards are found in FSIS regulation §319.140 (see appendix).

Other types of cooked sausage, such as braunschweiger, liver sausage, blood sausage, and tongue items, are cooked in water

inside of an impervious casing or steel mold, often inside a steam cabinet or water bath instead of a smokehouse. The impervious casing causes these types of cooked sausage to retain all moisture during cooking, so the manufacturer must closely control the amount of water during formulation to ensure that it does not exceed the 10% limit.

In addition to the standard production steps used to produce fresh sausages, cooked and smoked sausages have additional production stages, including:

- Smoking
- Cooking
- Showering
- Chilling
- Peeling

In this section we will briefly review each of these additional stages that are used to produce cooked and smoked sausages.

Cooked and smoked sausages start out very similar to the fresh sausages. Raw meat ingredients are ground and blended with non-meat ingredients. A bowl chopper (known in the industry as a silent cutter) is sometimes used to simultaneously blend and chop the mixture. The bowl chopper passes a series of knives through the mixture, usually resulting in an increase in temperature due to friction. A combination of ice and water is often added to the mixture to control the temperature and facilitate the grinding and blending process.

Cooked and smoked sausages are typically composed of a wide variety of meat ingredients. Each ingredient contributes a specific property to the final sausage formulation. For example, each meat ingredient will vary in overall content of protein, moisture, fat, collagen, and in its ability to encapsulate fats and hold the mixture in a stable suspension, called binding ability.

Meat Ingredients Binding Ability

Skeletal beef muscle tissue from bull, cow, and shank meat have the highest binding capabilities. Intermediate or medium binding meats include head meat, cheek meat, and lean pork trimmings. Low binding meats contain higher levels of fat, and are typically non-skeletal meats, such as jowls, fat, briskets, hearts, and tongue trimmings.

Some meat by-products have minimal binding ability, so the use of these products in sausage is generally avoided. These products include tripe, pork stomachs, lips, snouts, and skin.

Non-meat proteins, such as cereal flours and non-fat dry milk must also be uniformly distributed, however, these ingredients usually are added last, since they absorb water that is required for protein emulsification

Emulsification Some manufacturers run the mixture through an emulsifier after the blending stage to further reduce the size of the meat particles, to achieve a very fine texture. In the emulsification process, fat, protein, salt and water are mixed, and combined into a semi-fluid emulsion. The meat muscle protein, called "myosin", is solubilized or released from the muscle fibers by contact with salt. The solubilized protein and water combine and surround the fat globules, and hold the fat particles in a dispersed suspension within the mixture, along with spices and seasonings.

Careful control of the amount of each ingredient and the grinding process is essential. The manufacturer must select a mix of raw meat materials with the appropriate emulsifying and binding characteristics. Emulsifying properties are dependent on the hydrophobic (water repulsing) and hydrophilic (water attracting) characteristics of the specific protein. Myosin protein has the best emulsifying properties (possessing both hydrophobic and hydrophilic properties), while proteins such as collagen have little or no emulsifying properties, and tend to break down at higher temperatures during the cooking. Manufacturers typically limit the use of low binding materials to less than 15% of the product formulation to ensure finished product quality.

If too much fat is added, or overchopping of the ingredients exposes too much fat, there may not be sufficient protein to encapsulate the fat. This creates a condition called "shorting out", "greasing out", or "fat capping". In this case, fat droplets migrate to the product surface and form small pockets of fat called "fat caps". The emulsion can also break down when the mixture is chopped too long, causing too short protein fibers, or the product temperature is increased, causing some of the fats to partially render. In this condition, the protein is unable to hold liquid fat in suspension. In addition, emulsion breakdown can occur in products with a high acid content, or when heating coagulates protein before it has a chance to surround the fat and "set" the emulsion.

Stuffing Cooked and smoked sausages are stuffed into casings in a process similar to fresh sausages, however, manufacturers of these products utilize a wider range of casing materials.

Natural casings used for cooked and smoked sausages are derived from the stomach, and intestines of hogs, the intestines, bung and bladder of cattle, and the intestines of sheep. They are edible, and allow smoke and moisture to permeate the sausage during processing.

Hog middles are produced from the large intestine, and are used for Italian sausages and liver sausages. The small intestine is utilized to create small hog casings that are utilized for smaller diameter products, such as Polish sausage, smoked pork sausage, and bratwurst. And hog bladders are used as casings for minced luncheon meats.

Sheep casings are generally made from the small intestine. These small diameter casings are typically used for frankfurters and pork sausages.

Beef rounds are casings that are produced from the small intestine, and are used for products such as bologna and mettwurst. Beef middles are larger casings created from the large intestine, and are used to produce sausages such as bologna, cervelat and salami.

Sometimes manufacturers use casings that are not derived from the same type of meat as the main meat ingredients of the sausage. For example, a manufacturer can use a pork casing on a beef and lamb combination sausage. Currently, manufacturers are not required to disclose that the natural casing is not derived from the same livestock species as the sausage itself.

Regenerated Collagen Sausage Casings

Regenerated collagen sausage casings are made from collagen extracted from cattle hides and hog skins in a process called regeneration. The extracted collagen is dissolved, then hardened, washing, swelled with acid, and finally formed into the tubular casing shape in an extrusion process. This final shape is then fixed in an alkali bath.

These types of lower strength casings are typically used for smaller diameter products.

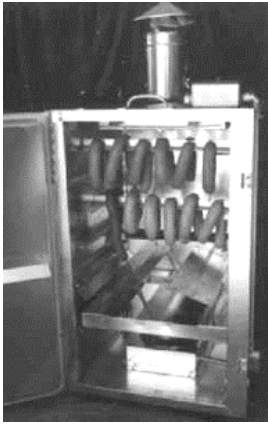
Synthetic and Cellulose Casings

Synthetic or artificial casings are made from special papers impregnated with cellulose, saran casings made from synthetic plastics, and hydro-cellulose casings made from regenerated cellulose. Cellulose casings are created from dissolved fibers extracted from cotton seeds or paper pulp. Each of these types of casings are available in a wide range of sizes and characteristics and are easy to handle, however, these types of casings are not edible and must be removed from the sausage prior to consumption. Artificial casings provide high strength and are available with excellent permeability to moisture and smoke, or as impermeable casings for use in producing water-cooked products such as braunschweiger.

Smoking

Smoking is used to dry and cure the meat, and impart flavors and aroma to the final product. Smoking was traditionally important because it inhibited bacterial growth on the finished product, however, in modern times we rely on refrigeration to inhibit bacteria. A smoke generator creates natural smoke via a carefully controlled burning of hardwood sawdust, wood chips, or logs. Hickory is the most popular wood used for smoking, but other hardwoods and fruitwoods are also used. Coniferous trees such as pine are unacceptable because they contain resins, smoke from that type of wood has a high tar content and imparts a bitter flavor.

The distinctive effects of smoking are imparted through absorption of the condensable phase of the smoke. This phase consists of



acids, carbonyls, phenolics, and polycyclic hydrocarbons. The amount of these materials that is deposited on the product surface is controlled by varying the density of the smoke, the duration of the smoking cycle, and the air velocity within the smoking chamber.

Sausage manufacturers also control the moisture level of the product before and during the smoking process in order to produce a high quality product. The surface of the product must be slightly moist in order for the smoke volatiles to properly adhere to the product. If the product surface is too moist, the smoke process will cause streaking. If the casing is too dry, the smoke will not properly adhere to and permeate the casing. Producers therefore ensure that the drying cycles are carefully controlled to ensure a consistent smoked product.

Artificial liquid smoke can be used to impart the smoke flavors. Liquid smoke is created by distilling and refining the condensable elements of natural wood smoke to create a liquid concentrate of the desired elements. Liquid smoke is applied by dipping or drenching the product in a bath of the liquid smoke product. It can also be applied within a smokehouse environment by atomizing the liquid smoke into a fine mist, or by superheating and evaporating the liquid smoke in a process called regeneration. It can also be in the formulation of the sausage; if so it must be included in the ingredients statement of the product.

The length of the smoking process varies according to the type of product and desired effect of the smoking process. An effective smoke application can be accomplished in as little as 30 minutes. Liquid smoke can be effectively applied in less than 5 minutes. This chart illustrates use of a smokehouse schedule.

Sample Smokehouse Schedule

Function	Time	Smokehouse Temperature	Relative Humidity	Damper
Drying	30 min.	125 ° F	25%	Open
Smoking	1 hour	140 ° F	35%	Closed
Cooking	1 hour	165 ° F	35%	Closed
Steam Cooking	10 min.	180 ° F	100%	Closed

As this chart indicates, the smokehouse may also serve as a controlled thermal processing chamber, and is used to dry, smoke, heat (cook), and add humidity to the product.

Cooking Manufacturers cook sausage products to enhance the flavor and color, produce the desired final product, and to inhibit the bacteria responsible for spoilage. In order to produce a safe product, cooking must also destroy parasites and pathogenic bacteria. Sausages can be cooked through immersion in a heated water bath, within a smokehouse environment, or within ovens.

The cooking process is carefully controlled to ensure that the product reaches a specific internal temperature for a defined period of time. Thermocouples are used to monitor the temperature during the cooking process.

Showering / Chilling

After the smoking and cooking phase, the sausage product undergoes a cold water shower. Showering maintains the product humidity and stops the cooking process by reducing the product temperature as quickly as possible. Showering also helps to prevent shrinkage and wrinkling of the product casing.

The cooling process is also carefully monitored and controlled. The temperature of the cooked product must be lowered to a specific temperature within a desired time. The FDA Food Code specifies that a product must be lowered from 140°F to 70°F within 2 hours, then from 70°F to 41°F or less within an additional 4 hours. To meet the FSIS stabilization requirements of no more than 1-log growth of *Clostridium perfringens* **uncured** product can be cooled from 130°F to 80°F with 1.5 hours and 80°F to 40°F in 5 hours. These guidelines are described in FSIS Directive 7110.3, "Time/ Temperature Guidelines For Cooling Heated Products."

Peeling

Peelers are used by the sausage manufacturer to remove non-edible casings from sausage products during the later stages of the production process.

Dry Sausages

Producers of dry sausages and semi-dry sausages utilize controlled, bacterially-induced fermentation to preserve the meat and impart flavor. The most common examples of dry sausages are salami and pepperoni. The dry category also includes shelf-stable non-fermented products such as beef jerky. Again, there are many variations of process steps and ingredients, resulting in the vast array of products available to the consumer. We are not going to deal with all possible products, rather, we will concentrate on the most common examples of these types of products.

In addition to the standard production stages identified for fresh, cooked and smoked sausages, dry sausages have additional production steps, including:

- Blending special curing ingredients
- Drying process

Let's briefly review each of these additional special production steps used to produce dry and semi-dry sausages.

Blending Special Curing Ingredients

The meats used in dry sausages are typically ground or chopped at low meat temperatures (20-25°F) to maintain the well defined fat and lean particles that are desired in this type of sausage. The ground meats and spices are then mixed with curing ingredients, such as nitrates, nitrites, antioxidants, and bacterial starter cultures.

Salts have traditionally been used to help preserve sausages. Eventually, producers learned that nitrates and nitrites in the salts were essential to the curing process. Manufacturers of dry and semi-dry sausages use a curing agent consisting of salt and nitrates and/or nitrites. Approved antioxidants may also be added to protect flavor and prevent rancidity, and are limited to .003% individually, or 0.006% in combination with other antioxidants. These ingredients must be uniformly distributed throughout the mixture to achieve the maximum microbiological stability.

Bacterial fermentation is then used to produce the lower pH (4.7 to 5.4) that results in the tangy flavor associated with this type of sausage. In earlier days of sausage making, the bacteria growth was uncontrolled, resulting from bacterial contamination of the meat or production equipment, producing unreliable results. Traditionally, sausage makers held the salted meat at low temperatures for a week or more allow plenty of time for the lactic acid bacteria coming from the environment to reproduce in the meat mixture. Unfortunately, this traditional method was not always reliable and subject to several errors such as cutting the time short, adding too much or too little salt, or growth of the wrong lactic acid bacteria. Therefore, modern producers of dry sausage use a commercial lactic bacteria starter culture and simple sugars, such as dextrose or corn sugar, that promote lactic acid bacterial growth by serving as food to fuel the bacteria during fermentation. The bacteria starters are harmless, and are limited to 0.5% in both dry and semi-dry sausage formulations. Commercial bacteria starter cultures typically consist of a blend of microorganisms such as *Pediococcus*, *Micrococcus*, and *Lactobacillus*, using specific species such as *P. cerevisiae*, *P. acidilactici*, *M. aurantiacus*, and *L. plantarum*. The bacterial fermentation lowers the sausage pH by producing lactic acid. This lower pH also causes the proteins to give up water, resulting in a drying effect that creates an environment that is unfavorable to spoilage organisms, which helps to preserve the product. However, mold may grow, and could become a problem

Some small producers may still allow the mixture to age in a refrigerator for several days to encourage the fermentation process, even though they are using starter cultures. However, most modern processors stuff the mixture directly into casings, which then undergoes a fermentation process at about 70°F to 110°F (depending on the starter type). This fermentation process is designed to allow the bacteria to continue to incubate. The fermentation occurs during a one to three day process that takes place in a “greening room” which provides a carefully controlled environment designed to obtain specific fermentation results. Temperatures are typically maintained at approximately 75°F, and relative humidity at 80%. Semi-dry sausages are usually fermented for shorter periods at slightly higher temperatures.

Cooking/Smoking

What happens after fermentation depends on the type of product being produced. Semi-dry sausages like summer sausage are

almost always smoked and cooked before drying. Dry sausages like pepperoni are rarely smoked, and may or may not be cooked. Today, some establishments choose to heat treat these dry sausages as a critical step designed to eliminate *E.coli*. A moist heat process may be used for some products. This process utilizes a sealed oven or steam injection to raise the heat and relative humidity to a meet a specific temperature/time requirement sufficient to eliminate pathogens (e.g., 130°F minimum internal temperature for 121 minutes, or 141°F minimum internal temperature for 10 minutes). [Processors should consult the FSIS regulations 9 CFR 318.10 and the Cattlemen’s Blue Ribbon book for processes designed to control *E. coli*.] The product is then sent on to the drying stage of the process.

Drying Process The drying process is a critical step in ensuring product safety. FSIS requires that these products undergo a carefully controlled and monitored air drying process that cures the product by removing moisture from the product. Pork-containing products must be treated to destroy trichinae (see 9 CFR 318.10). Sausages not containing pork have no such requirement.

Manufacturers are required to control the ratio of moisture to protein in the final product. The Moisture/Protein Ratio (MPR) is controlled by varying the amount of added water based on the overall product formulation, and, primarily by the drying procedure. In some products, the MPR can affect the final microbiological stability of the product. In other products the MPR is important to ensure elements of the overall product quality, such as the texture. The minimum requirement for all products produced in FSIS inspected facilities is that they must meet the FSIS policy standards for MPR (see chart below). However, these prescribed treatments have proved to be insufficiently lethal for some bacterial pathogens. Thus, most of the industry has volunteered to implement a more rigorous treatment.

The drying process consists of placing the product in a drying room under a relative humidity of 55-65%, in a process that can last from 10 days to as long as 120 days, depending on the product diameter, size, and type. The drying process is designed to produce a final product with approximately 30 – 40% moisture, and an MPR generally of 1.9:1 or less, to ensure proper drying and a safe product. Facilities must keep accurate records of the temperature and the number of days in the drying room for each product manufacturing run to help ensure product safety and consistency.

The drying environment is controlled to ensure that the drying rate is slightly higher than the rate required to remove moisture from the sausage surface as it migrates from the sausage center. Drying too quickly will produce a product with a hard and dry casing. Drying too slowly results in excessive mold and yeast growth, and excessive bacterial slime on the product surface.

The controlled drying process is designed to reduce moisture to the point where the final product has a specific MPR. This process will

vary depending on the specific facility operation and the specifications desired for the final product. For example, pepperoni is required to maintain an MPR of 1.6:1, indicating a requirement of 1.6 parts moisture to one part protein. Genoa salami should have an MPR of 2.3:1, and all other dry sausages an MPR of 1.9:1. Inspectors may sample the products to determine compliance with the specified MPR.

Semi-dry sausages are prepared in a similar manner, but undergo a shorter drying period, producing a product with a moisture level of about 50%. These products are often fermented and finished by cooking in a smokehouse, at first at a temperature of approximately 100°F and a relative humidity of 80%. The temperature is later increased to approximately 140 – 155°F to ensure that microbiological activity is halted. Since the moisture level of the final product is about 50%, semi-dry sausages must be refrigerated to prevent spoilage. Examples of semi-dry sausages include summer sausage, cervelat, chorizo, Lebanon bologna, and thuringer.

This chart identifies the FSIS MPR policy standards for some dry and semi-dry sausage products. These standards are not in the regulations, they are contained in the FSIS Food Standards and Labeling Policy Book.

FSIS Policy Standards, Moisture-Protein Ratio (MPR) for Dry and Semi-Dry Sausages

Sausage product	Maximum moisture to one part protein
Jerky, Pemmican	0.75 : 1
Pepperoni	1.6 : 1
Dry sausage (e.g., hard salami)	1.9 : 1
(line deleted)	
Summer sausage, shelf-stable	3.1 : 1 + pH 5.0
Dry salami	1.9 : 1
Genoa salami	2.3 : 1
Sicilian salami	2.3 : 1
Italian salami	1.9 : 1
Thuringer (semi dry sausage)	3.7 : 1
Ukrainian sausage	2.0 : 1
Farmer Summer sausage	1.9 : 1

Although these are the FSIS standards for dry and semi-dry sausages, they can provide a basis for State and local decisions about whether specific processes are adequately designed to ensure product safety.

To ensure that the fermentation and drying processes are sufficient to reduce or eliminate any pathogens present in the product, the procedures must be validated to demonstrate that they achieve a specific reduction in organisms (e.g., a 5-log reduction in *E. coli* 0157:H7).

Sausage Production Equipment

In this section we'll take a brief look at some of the standard equipment and processes that are used to produce sausages, along with the safety issues that should be addressed for each item. There are many different manufactures of equipment, and you will see many variations of these basic equipment types.

Grinders Grinders are used to chop the meat ingredients into small pieces. Meat is fed from a hopper, passed along a cylinder with an auger or worm, to a perforated plate where it is sliced away by a series of revolving blades. The friction produces a rise in temperature, which potentially could result in bacterial growth if not controlled.

Blenders Blenders use screw-like agitators to mix the solid ground meat mixture with any additional non-meat ingredients to create a consistent distribution of all ingredients within the formulation.

Bowl Choppers Bowl Choppers (silent cutters) utilize a series of knives that chop and mix the product formulation. The friction of the knives passing through the meat will raise the temperature of the meat mixture.

Stuffers Stuffers are used to extrude the sausage formulation into the casing. The ground mixture is fed from a hopper into a reservoir and forced through a nozzle into the casing.

Since grinders, blenders, choppers, and stuffers come into contact with the product formulation, they must be cleaned daily, cleaned every time that a new formulation is processed, and be kept free of excess product during the process. This will ensure that any contamination is not passed on to the product formulation.

Smokehouses Smokehouses are heated drying rooms into which the manufacturer injects smoke. The smoke adds specific flavors to the product, and helps dry and cure the product. The smokehouse may also serve as a controlled thermal processing chamber, and is used to dry, smoke, heat, cool, and add humidity to the product.

Smokehouse Recorders Smokehouse recorders are devices that monitor and track the smoking duration for each sausage production run. The smoking process must be carefully controlled to ensure a consistent level of product quality.

Temperature Monitoring The temperature of drying, smoking, and cooking chambers must be carefully monitored and controlled to ensure a consistent product, and to ensure that process temperatures/times are maintained at a sufficient level to eliminate pathogens.

Peelers Peelers are used by the sausage manufacturer to remove non-edible casings from sausage products during the later stages of the production process. Steam is generally used in the peeler to loosen the casings, creating a warm, moist environment. Peelers use a

blade that slices the casing, touching each sausage that goes by, this is an ideal environment for bacteria, especially *Listeria*. Peelers must be carefully monitored because of the potential for bacterial growth.

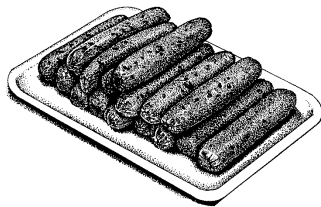
**Greenrooms /
Drying Rooms**

Greenrooms and drying rooms are used to cure and dry the sausage product. In some cases, the environment is designed to support controlled, bacterially-induced fermentation processes that are used to cure the product and impart special flavorings.

Coolers

Coolers use refrigeration to lower the temperature of the sausage product.

Packaging Equipment



The final sausage product is often packaged prior to sale. Packaging typically consists of wrapping the product in plastic film. The packaging protects the product from cross contamination, and helps to retard spoilage caused by contact with the air.

Ingredients in Sausages

In this section, we will go over the types of ingredients that are used to produce standard sausage products, including fresh sausages, cooked and smoked sausages, and dry sausages. Each type of sausage uses a different mix of ingredients.

“Variety Meats”

Sausage products provide the manufacturer with an opportunity to utilize various types of meat by-products, also known as “variety meats”, such as hearts, tongues, livers, tripe, and pork stomachs. The specific amount and type of variety meats used in a product depends on the formula designed by the processor. USDA regulations allow use of variety meats, only in cooked sausage like hot dogs, as long as the name of the product is modified to include the words “with by-products” or “with variety meats”, and the particular types of variety meats are included in the ingredients list in the order of predominance in the formulation. (see 9 CFR 319.180)

Manufacturers also often use specific types of variety meat to impart specific flavors or characteristics to the final product. For example, hearts may be used to help create the dark red color desired for summer sausages.

**Ensuring
Wholesomeness**

All meat and meat by-products used in sausage formulations must be clean, wholesome and properly labeled. Receiving of raw ingredients is an important step in ensuring food safety. The manufacturing facility should inspect all incoming meat to ensure that is not contaminated. Even previously

inspected meat should be re-inspected to ensure that it has not become contaminated during transit.

Properly Identifying Meat ingredients

FSIS regulations require that the manufacturer properly identify the types and amounts of meat and meat by-products present in the final product. The actual ingredients must match the ingredients listed on the label.

However, once the meat products are chopped or ground, they lose their visual identity, making it difficult to identify specific ingredients in a formulation. Sausage manufacturers are therefore required to carefully identify and track ingredients throughout the production process, and ensure that unlisted meat items are not accidentally or purposely substituted during the production process.

"Rework"

Sometimes a product that has partially or fully completed the production cycle is not sell-able but still wholesome, and can be used for food. For example, the casing of some sausages may split during the cooking or smoking cycle. Manufacturers are allowed to 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. Manufacturers are not allowed to use this "rework" in a product with a different list of ingredients. Rework has little binding ability since the proteins are coagulated, so the amounts added are self-limiting, in that it has a detrimental effect on product quality.

Non-Meat Ingredients

A number of non-meat ingredients are essential to the sausage making process. These non-meat ingredients stabilize the mixture and add specific characteristics and flavors. These typically include extenders and binders, water, salt, nitrite, nitrate, ascorbates, erythorbates, sugars, antioxidants, phosphates, mold inhibitors, extenders, along with traditional spices, seasonings and flavorings. In this section, we will look at the effect and use of each of these ingredients.

Binders and Extenders

Binders and extenders have a number of uses in a sausage formulation. Manufacturers use extenders such as dry milk powder, cereal flours, and soy protein as a lower cost method to increase the overall yield of the formulation, to improve binding qualities and slicing characteristics, and to add specific flavor characteristics. A sausage formulation can include up to 3.5% of these substances.

Water

While water is a naturally-occurring component of meat, manufacturers also add water to the formula in specific amounts to improve the consistency of the mixture and to substitute for fats. FSIS regulations permit manufacturers of fresh sausages to add water up to 3% of the total product weight.

Cooked sausage manufacturers are allowed to vary the amount of added water according to the amount of fat. The maximum fat content is limited to 30%, and the amount of fat and water combined is limited to 40%, so the manufacturer can increase water to substitute for reduced fat. Typically, the amount of naturally occurring water is determined by computing four times the protein content. Any moisture above that amount is considered added water.

Salt Salt is an essential ingredient of any sausage formulation. Salt is used to preserve the product, enhance the flavor, and to solubilize the meat proteins in order to improve the binding properties of the formulation.

Since the advent of refrigeration, the preservative properties are the least important use of salt, though dry sausages still use salt for preservation. A salt concentration of around 17% is necessary for preservation to be effective.

The most important use of salt in a sausage product is its ability to solubilize proteins. This enhances the product texture and improves water and fat binding.

Since sodium chloride (NaCl) salt has been linked to hypertension, other non-sodium salts, such as potassium and calcium chlorides, are sometimes substituted for a portion of the sodium chloride.

Curing Agents Curing agents such as nitrite and nitrate have traditionally been used in sausage formulations, originally as a contaminant present in salts, and later added intentionally in the form of saltpeter. Nitrites provide bacteriostatic and antioxidant properties, and improve the taste and color of the sausage. Nitrites help to control the growth of bacteria in vacuum-packed products, such as frankfurters and luncheon meats. Nitrites prevent the outgrowth of bacteria, such as the lethal *Clostridium botulinum* bacterium that causes botulism. Nitrites also inhibit the oxidation of fats in meats, reducing the development of oxidative rancidity. Nitrites produce the desired reactions much faster and are much more commonly used than nitrates. The use of nitrate by large processors is rare, because the process of converting the nitrate into nitrite within the product is much slower and less reliable than addition of nitrite directly.

Since nitrites and nitrates can be toxic to humans, the use of these ingredients in sausage formulations is carefully controlled. They are sometimes referred to as "restricted ingredients." Supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept securely under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known

and clearly marked accordingly. The maximum level of these additives that is acceptable is spelled out in the FSIS regulations, as indicated below.

Substance	Amount
Sodium or potassium nitrate	2 ¾ oz. to 100 lb. chopped meat
Sodium or potassium nitrite	¼ oz. to 100 lb. chopped meat

The amount of nitrite added to product must be regulated at the formulation step, based on the total amount of meat and meat by-products. Nitrites dissipate quickly in the finished product, and the parts per million in the finished product does not necessarily reflect the amount that was used in formulation. This makes sampling the finished product for nitrite an impractical control measure.

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

Ingredient	Maximum amount
Ascorbic acid	¾ oz. per 100 pounds of meat
Erythorbic acid	¾ oz. per 100 pounds of meat
Sodium erythorbate	7/8 oz. per 100 pounds of meat
Citric acid	May replace up to 50% of above listed ingredients
Sodium citrate	May replace up to 50% of above listed ingredients
Sodium acid pyrophosphate	Alone or in combination with others may not exceed 8 oz. (0.5%)
Glucono delta lactone (GDL)	8 oz. per 100 pounds of meat

Sugars Sugars are used in sausage formulations to reduce the flavor intensity of the salt and flavorings, and to provide a food source to enable microbial fermentation. Sugars used in sausage products include sucrose and dextrose.

Antioxidants Antioxidants are approved for use in fresh sausages to retard oxidative rancidity and protect flavor. Approved antioxidants include butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), propyl gallate, tertiary butylhydroquinone (TBHQ), and tocopherols. These compounds are added to the spice mixtures, based on the actual percentage of fat in the fresh product formulations (typically 0.01% separately, 0.02% in combination), or the total meat block weight for dry sausage formulations (typically 0.003%).

Phosphate Phosphates are used to improve the water-binding capacity of the meat, solubilize proteins, act as antioxidants, and stabilize the flavor and color of the product. Their maximum benefit to the processor is to reduce purge, or water that is cooked out of product. Phosphates also help to increase shelf life of a product. The maximum amount of phosphates approved for sausage products is limited to 0.5 percent of the finished product weight. If used, they must be food-grade.

Mold Inhibitors Mold is a commonly encountered problem in the production of dry sausages. The common technique for inhibiting the growth of mold is to dip the sausage in a mold inhibitor solution, typically 2.5 percent solution of potassium sorbate or a 3.5 percent solution of propylparaben.

Glucono Delta Lactone (GDL) Glucono Delta Lactone (GDL) is a cure accelerator that produces an acid tangy flavor similar to flavor resulting from natural fermentation. It is allowed at 8 oz. to each 100 lb. of meat.

Spices, Seasonings, and Flavorings Spices, seasonings, and flavorings are used to add flavor to the sausage, and also affect the consistency of the ground mixture. The wide range of available spices, seasonings, and flavorings is a primary reason for the variety available in sausages.

Spices are defined as any aromatic vegetable substance that is intended to function as contributing flavoring in food instead of contributing to the nutritional substance of the food. The active aromatic or pungent properties of spices that contribute the most to the flavoring effect are mostly present in the volatile oils, resins, or oleoresins of the spice. These properties are present in the whole spice, or in extracts of the active components. The use of spice extracts has some advantages over using whole spices, including providing more control over the intensity of the flavor, less opportunity for microbial contamination, easier storage, and a less conspicuous visual appearance compared with spice particles.

Spice extracts must be labeled as "*Flavorings*" in the product ingredients list. Flavorings are substances that are extracted from a food (such as fruits, herbs, roots, or meats, seafood, etc.) that are also intended to contribute flavoring instead of nutritional substance.

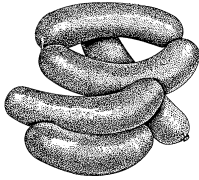
"*Seasonings*" is another general term that refers to any substances that are used to impart flavor to the food product. Some examples of common spices and seasonings include allspice, pepper, cardamom, caraway, coriander, cumin, garlic, sage, mustard, nutmeg, paprika, pepper, rosemary, sage, thyme, and turmeric.

Performing Sausage Formulation Calculations

One of the most important tasks for the inspector in the sausage production facility is to check the formulation of the product. Inspection program personnel should select a batch of sausage product, check the sample batch for accurate identification of the types and weights of the component ingredients, and calculate the maximum and minimum amounts of restricted ingredients.

Establishments which produce sausage product are encouraged to use as a reference a procedure chart that identifies the production process and ingredients for the product.

The chart should include:



- the product type and name;
- the type and amounts of meats and meat by-products in the product;
- the type and amounts of cure agents;
- the method of formulation, such as chopping time and emulsifying time and method;
- the type of casing and method of stuffing;
- the smoking/ cooking time and temperature, along with expected shrinks;
- and the chilling time and expected chill shrinks.

Calculating Added Water, and Antioxidant - Fresh Pork Sausage Formulation (with BHA added to protect flavor)

Ingredients: Pork, water, salt, sugar, spices, BHA (Formulated to yield a finished product fat limit of 40%)

Batch formula

Regular Pork Trimmings (60% fat)	280.00 lb.
Special Pork Trimmings (30% fat)	156.00 lb.
Water	15.00 lb.
Fresh Sausage Seasoning	9.00 lb.
Total	460.00 lb.

**Fresh Pork Sausage
Limitations**

- Limited to 50% Fat or less
- Added Water/ice up to 3%
- Antioxidant amount based on fat – limited to 0.01%

The Fresh Sausage Seasoning formulation is :

Salt	5 lb.
Sugar	2 lb.
Black Pepper	15 oz
Sage	11 oz
Nutmeg	5.64 oz
<u>BHA (Antioxidant)</u>	<u>0.36 oz</u>
Total	9.0 lb.

The inspector reviews the sausage formulation and evaluates a number of issues. For example, the inspector would determine whether the added water content in the above formulation complies with the limit for this type of product, or whether the type and amount of antioxidant is allowed in this type of product. Let's quickly go over the process to answer each of these questions.

Is added water content within limits?

The amount of added water and/or ice in fresh sausage is limited to 3% of the product weight. The inspector will use these steps to determine the amount of water permitted in this formulation.

460 lb. (100%)	First, subtract the water from the total formula
<u>-15 lb. (3%)</u>	weight to determine the total weight minus the
445 lb. (97%)	water.

445/.97 = 458.76

Then divide the formula weight minus the water by the total weight without water (.97) to determine the total formulation weight with the allowed amount of water added.

458.76 lb. X .03 = 13.76 lb.

Then multiply the total formulation weight with the allowed amount of water added by 3% (allowed percentage of water). This results in a total allowed water amount of 13.76 lb. in this formulation. In this case, the added water exceeds the allowable limits for this product.

Is the type and amount of antioxidant within limits?

Antioxidants in fresh sausage are limited to 0.01% of the total amount of fat in the product. In this example, we will assume that the target fat amount of 40% in this formulation has been confirmed.

460
X 0.40
 184 lb.

The first step is to determine the weight of the fat. Multiply the batch weight by the fat content (40%)

184 X 0.0001 = 0.0184 lb.

Then multiply the fat content by the permitted amount of antioxidant (0.01%) to determine the maximum allowable amount of BHA in this formulation.

16oz X 0.0184 = 0.294 oz

Convert pounds to ounces (16 oz/lb.)

In this case, the maximum allowed amount of the antioxidant BHA in this formulation is 0.294 oz. The Fresh Sausage Seasoning formulation specifies 0.36 oz. The BHA in this formulation exceeds the regulatory limit.

Inspectors can use similar calculations to determine a range of issues, such as whether the fat percentage or binder and extender amount targets will be achieved.

Calculating Curing Agents - Frankfurter Formulation

Ingredients: Beef and Pork, water, nonfat dry milk, mustard, spices, erythorbic acid, sodium nitrite

Batch formula

Beef	185 lb.
Pork	225 lb.
Bacon ends and pieces	50 lb.
Water and ice	80 lb.
Rework (like product)	50 lb.
Nonfat dry milk	20 lb.
Salt	9 lb.

Mustard (29% protein)	5 lb.
Spice mix (12% protein)	4 lb.
Erythorbic acid	4 oz.
Cure mix (8% nitrite)	12 oz.

Inspectors analyze sausage formulations to determine if the amount of nitrites is within acceptable limits.

Since it may be difficult to accurately measure small amounts in a commercial production environment, manufacturers often use a commercially premixed cure mix, containing the proper amount of nitrites and nitrates along with a salt carrier. To minimize the risk of using too much of these ingredients, cure mix is often marketed in small packets that are pre-weighed for a certain size batch of product. This eliminates the need to weigh out the cure mix at the facility. It is still important to ensure that the cure mix packet is being added to the proper size batch of product.

$\begin{array}{r} 185 \\ + 225 \\ \hline 410 \end{array}$	<p>For example, to review the amount of nitrites in the above formulation, first determine the total amount of meat and meat by-products. In this case, add the beef and pork. Note that the bacon ends and pieces and rework are not factored in, since they are already assumed to have cure added to their formulation.</p>
---	--

$410/100 = 4.1$	<p>The total allowed amount of nitrites for chopped meat sausage is .25 ounces per 100 pounds of meat and meat-by products, so the next step is to divide the total amount of meat by 100 to determine how many "units" of 100 pounds are in the formulation.</p>
-----------------	---

$4.1 \times .25 = 1.025$ <p>oz nitrite allowed</p>	<p>Then multiply the units of 100 pounds of meat by .25 to determine how many ounces of nitrite are allowed in the formulation.</p>
--	---

$1.025 \div .08 =$ <p>12.81 oz cure mix allowed</p>	<p>Since the amount of nitrite in the cure is 8%, divide the amount of allowed nitrite by .08 to determine the total amount of cure mix that is allowed in this mixture. In this case, the cure mix amount specified for this formulation is within acceptable limits.</p>
---	--

During a 6 month period beginning August 1998, the Center for

Biological Hazards of Concern to Sausage Makers

Disease Control (CDC) reported at least 50 illnesses caused by *Listeria monocytogenes* bacterium. Six adults died, and two pregnant women had spontaneous abortions. The source of the contamination was later traced via routine FSIS monitoring/sampling to hot dogs and deli meats produced by a facility in Michigan.

Estimates of the overall magnitude of the problem are imprecise. During 1998, at least 9787 laboratory-confirmed cases of illness related to foodborne contamination were confirmed, however, only a fraction of the persons who experience foodborne illnesses are believed to seek medical care, and even a smaller number to submit laboratory specimens.

Government health agencies actively monitor foods for the presence of pathogens such as *Campylobacter*, *Escherichia coli* 0157, *Listeria*, *Salmonella*, *Shigella*, *Vibrio*, *Yersinia*, *Cryptosporidium* and *Cyclospora*. Sausage makers must ensure that their products are not contaminated by pathogens such as *Listeria*, *E. coli* 0157, *Salmonella*, *Trichinae*, and *Staphylococcus* enterotoxin.

Public health laboratories around the U.S. now have the capability to conduct molecular subtyping of pathogens present in humans and foods using Pulsed-Field Gel Electrophoresis (PFGE) technology, a type of “fingerprinting” that allows the agencies to link illnesses to specific products, and trace the source of any contaminated products to determine the cause. This is improving the ability of public health agencies to monitor and mitigate the effects of contaminated food products.

In this section we will review some common types of microorganisms and pathogens that can be present in the meats typically used to produce sausages, common methods of reducing or eliminating these pathogens, and product characteristics and conditions that influence the type and rate of growth of these microorganisms and pathogens.

Trichinella spiralis

Trichinosis, the sometimes deadly disease caused by consumption of the trichina parasite, *Trichinella spiralis*, is a major concern of sausage producers. Trichina parasite larva commonly infest pork muscle, so most cases occur in persons who have consumed improperly treated or prepared pork products. Infections from consumption of sausage products typically occur when a fresh sausage product has not been adequately cooked by the consumer, or the sausage product has not been properly treated by the producer.

The microscopic size of the trichina parasite larvae (0.1 mm) makes it difficult to identify in a typical packinghouse operation, so FSIS requires that all pork be treated to destroy the parasite, via heating, refrigeration, or curing.

In the sausage processing industry, heating is the most common

treatment method. A temperature of 144°F is considered fatal to all trichinae organisms. This temperature is typically exceeded during the cooking process, however, products that are partially cooked at lower temperatures, such as smoked pork sausage, require additional treatment. These products typically undergo a formulation and curing process designed to eliminate trichinae. The process includes controlling the size of the chopped meat in the product, ensuring a specific salt content, and specifying the length of time in a drying room at a specific temperature. Another form of treatment to eliminate trichina is freezing. These treatments are described in FSIS regulation § 318.10 and are found in the appendix of this document.

***Escherichia coli* O157:H7** *Escherichia coli* O157:H7 is a bacterial contaminant of sausage and other meat products that can cause serious diarrheal illness, sometimes resulting in complications that can lead to death. The presence of *E. coli* in cooked sausages can be controlled by proper cooking temperatures and times. *E. coli* contamination of dry sausages can be reduced by closely controlling the fermentation heating process, the acid content, and via post-fermentation heating to 145°F or above. And with all sausage products, proper hygiene, handling, and storage procedures are essential to control contamination. One of the five options described by the *Blue Ribbon Task Force* in their *Dry Fermented Sausage and E. coli O157:H7* report can be used to eliminate *E. coli* O157:H7 in the finished product.

Salmonella Nontyphoidal salmonellosis is a leading cause of foodborne illness in the U.S. As with *E. coli*, *salmonella* organisms can be eliminated from cooked sausages by proper cooking processes. In dry sausages, the producer must follow a combination of processes to control the pathogen, including use of a fermentation starter culture, increased product temperatures during fermentation, and careful control of the product pH, cure, and salt content.

In addition, product handling procedures must be designed and monitored to ensure that cross contamination of the finished product with contaminants present in raw materials does not occur.

Listeria monocytogenes *Listeria monocytogenes* is a bacterium found in soil and water that can contaminate meats, and can cause a serious infection in humans, called listeriosis. The organism can be found in many food processing environments, and has been isolated from floor drains and refrigeration drip pans. From these niches the organism gets moved throughout the facility, and can end up on food contact surfaces. Cross contamination between raw and cooked product can also result in the presence of the bacteria on ready to eat product. Detection of post processing product contamination by *Listeria monocytogenes* can include sampling the processing lines and environment.

Processors should consider the following elements in elimination of *Listeria monocytogenes*:

- Examine how raw materials are handled before they are cooked and determine how handling procedures might affect *L. monocytogenes* levels in the product.
- Determine the impact of rework practices on *L. monocytogenes* levels in the raw product.
- Examine product flow, processing patterns and employee practices and determine where opportunities for cross-contamination occur.

Healthy persons rarely develop serious illnesses from exposure to *Listeria*. However, listeriosis is especially dangerous for pregnant women, newborns, and persons with weakened immune systems. Even with prompt treatment using antibiotics, listeriosis can cause death. In the U.S., about 1850 persons become seriously ill with *Listeria* each year, resulting in about 425 deaths.

FSIS has a zero tolerance for *Listeria monocytogenes* in ready-to-eat products, such as hot dogs and luncheon meats, and conducts a monitoring program in facilities to test for the pathogen. Treatment of sausages to eliminate *Listeria monocytogenes* is similar to the steps to eliminate Salmonella, including thorough cooking and proper storage of the product.

FSIS has information available about *Listeria* that is beyond the scope of this project. The FSIS "*Listeria* Guidelines for Industry", May 1999, are included as an appendix. Please consult the FSIS website at <http://www.fsis.usda.gov/> for more information.

Campylobacter jejuni *Campylobacter jejuni* is the most commonly reported bacterial cause of foodborne infection in the U.S., with an estimated 2.1 to 2.4 million cases each year. *Campylobacter jejuni* is found in many foods of animal origin, including poultry and meats. Methods of controlling and reducing *Campylobacter jejuni* in processing facilities include forced air chilling of swine carcasses, and implementation of standard hygienic practices.

Yersinia enterocolitica *Yersinia enterocolitica*, the pathogen that causes the gastroenteritis illness yersiniosis, is another pathogen of concern.

Conditions that Influence Microbial Growth and Product Spoilage A number of product characteristics influence the growth of microorganisms. Each of these characteristics must be controlled to create an environment that is hostile to microbial growth. These characteristics include:

- Water activity (a_w) present in the product
- pH level of the product
- Type/level of fermentable carbohydrate in formulation
- Level of smoke (natural or artificial) used on product
- Phosphate content of product
- Residual nitrite level in product
- Type/amount of spices/condiments applied to product surface

- Time/temperature of product heat processing (cooking)
- Product temperature during packaging
- Amount of vacuum used in packaging
- Rate of oxygen permeability of packaging materials

Microbial growth also results from defects in the product production process and/or during product handling. Microorganisms can survive the heating process due to inadequate heating time and temperatures. Heat resistant bacteria may be present in rework. Contamination can occur after processing, and during handling and packaging. And spoilage can occur during the retail sale phase, if the product is stored for an excessive length of time or at temperatures in excess of 41⁰F.

Producers of each category of sausage must control each of these factors to minimize or eliminate the presence of pathogens.

Pathogen Control in Fresh Sausage

Pathogen control in fresh sausage products presents a great challenge to manufacturers. USDA regulations (9 CFR §318.10) require the treatment of pork muscle to destroy any live trichina in cases where the product may be consumed without being thoroughly cooked, such as fresh sausage products with ingredients that mask the product appearance. These are sausage products with ingredients such as wine, paprika, or annatto which may impart color to the meat formulation that could make it appear cooked and mislead the consumers. The common methods of treatment to destroy trichinae are heating, freezing, and curing.

Treatment is not required for products with a diameter of 1 inch or less, or products stuffed in chubs and labeled with the word pork in the product name. These products are normally sufficiently cooked by the consumer to destroy trichinae.

Pathogen Control in Cooked and Smoked Sausage

Producers of cooked and smoked products also must take steps to control pathogens. The heating process used during the production of cooked sausage products is usually sufficient to destroy pathogenic organisms. For example, manufacturers cook pork at temperatures from 120⁰ – 144⁰ F to destroy trichinae.

In addition, the growth of pathogens such as *L. monocytogenes* is dependent on the temperature of the product, the presence of salts and other inhibitors, and the pH level of the product. The cure mixture used by the manufacturer is designed to reduce the presence of some pathogens. However, research indicates that cure ingredients can have some heat protective effects, potentially resulting in a higher or longer heating requirement.

The USDA has prescribed a 6.5 log reduction of *Salmonella* in meat and a 7 log reduction in poultry during heat treatment or cooking of ready-to-eat meat and poultry products to eliminate or reduce *Salmonella*.

Pathogen Control in Dry and Semi-dry Sausage

Producers of dry and semi-dry sausages must control the fermentation, smoking, and drying processes to reduce any pathogens present in the meat formulations. The pathogens of concern in uncooked fermented sausages such as summer sausage are *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, *Staphylococcus aureus*. FSIS has recommended a 5-log reduction of *E. coli* O157:H7 in fermented sausage by validation of the process. The pH, water activity and moisture-protein ratio of the final product can also control the other pathogens of concern, especially for shelf-stable fermented sausage products.

In addition, FSIS Regulations, section 319.10 contain procedures for curing, drying and smoking pork products in order to destroy the parasite *Trichinella spiralis*. These procedures prescribe different salt content, and time and temperature for each of the stages in the process.

Characteristics of growth for bacterial pathogens associated with meat and poultry sausage products, along with examples of preventative measures

Pathogens	Temperature range for growth	pH	Preventative/control measures
<i>Bacillus cereus</i>	10 – 48 ⁰ C	4.9 – 9.3	Proper holding/cooling temperatures
<i>Campylobacter jejuni</i>	30 – 47 ⁰ C	46.5 - 7.5	Proper pasteurization/ cooking, freezing, avoiding cross-contamination
<i>Clostridium botulinum</i> Group I (Toxin Types A,B,F) Group II (Toxin types B,E, F)	10 – 48 ⁰ C 3.3 – 45 ⁰ C	> 4.6	Addition of nitrites and salt, refrigeration, acidification to below pH 4.6, reduction of moisture below 0.93
<i>Clostridium perfringens</i>	15 – 50 ⁰ C	5.5 – 8.0	Proper holding/cooling temperatures. Proper cooking time/temperatures
<i>Escherichia coli</i> O157:H7	10 – 42 ⁰ C	4.5 – 9.0	Proper holding/cooling temperatures. Proper cooking time/temperatures
<i>Listeria monocytogenes</i>	2.5 – 44 ⁰ C	5.2 – 9.6	Proper heat treatment, strict sanitation program, separation of raw and ready-to-eat production.
<i>Salmonella</i>	5 – 46 ⁰ C	4 – 9	Proper heat treatment, separation of raw and cooked products, fermentation controls, decreased water activity.
<i>Staphylococcus aureus</i>	6.5 – 46 ⁰ C	5.2 – 9	Proper fermentation and pH control, proper heat treatment and post process product handling, reduced water activity.
<i>Yersinia enterocolitica</i>	2 – 45 ⁰ C	4.6 – 9.6	Proper refrigeration, heat treatments, control of salt and acidity, prevention of cross-contamination.

Spoilage Bacteria, yeasts, and molds present on sausage products also contribute to spoilage once the production of the product is complete. Spoilage produces undesirable qualities, such as a sour taste or aroma. The most common types of spoilage occurring on sausage products appear as sliminess, souring, and greening.

Slimy spoilage is caused by yeasts and bacteria, such as *Lactobacillus*, *Enterococcus*, *Weissella*, and *B. thermosphacta*. Colonies of these organisms form a uniform gray layer on the exterior of the sausage casings. Slimy spoilage also appears as polysaccharide ropes between sausages. This type of spoilage generally renders packaged sausages unsaleable.

Souring occurs underneath the casing of the sausage, and is caused when lactobacilli and enterococci consume lactose and sugars, resulting in the production of acids as a metabolic by-product.

Greening typically occurs when anaerobically stored sausages are exposed to air. H_2O_2 forms on the surface, or is created by organisms in the interior of the product.

Spoilage bacteria typically result from contamination during the manufacturing and handling processes that occur after cooking. Spoilage can be reduced and the shelf life of sausages can be increased by using proper hygiene and decontamination procedures at the manufacturing facility to reduce the presence of organisms that produce spoilage.

Shelf life is also increased through vacuum packaging of the product in gas-impermeable packaging materials, and refrigerated storage at appropriate temperatures. These methods all can inhibit the growth of the spoilage bacteria.

Sanitation Issues



As with any food product, proper worker hygiene, raw ingredient handling and storage procedures, and the final product handling and storage procedures are essential to control product contamination by organisms that are harmful to humans. In this section we will look at some of these sanitation issues.

Raw ingredients are typically inspected prior to entering the sausage production facility/area. However, the manufacturer should not assume that these ingredients are free of pathogenic organisms. The manufacturer must ensure that raw ingredients are properly stored in refrigerated areas to minimize the opportunities for growth of pathogens. Workers handling these raw materials must not also handle completed sausage products, since cross contamination can occur. Equipment and facilities should be designed to prevent cross contamination between raw and cooked products. And, of course, sausage production workers should follow the standard hygienic procedures that are required for all food production workers.

Sausage production equipment must be maintained in a clean and sanitary condition, under conditions that minimize the potential for growth of pathogens. Grinding, blending, and stuffing equipment must be completely disassembled and cleaned after each use or at least daily. And when changing to a batch of another species of meat, the entire grinding, blending, and stuffing assembly must be disassembled and cleaned.

Grinders of fresh sausage products should develop and implement rework, carry-over, and lot designation procedures that reflect an acceptable degree of product exposure (i.e., economic risk) in the event that a health risk is identified that results in recalling product that is suspected of presenting a potential hazard to the public. This may include developing a rework tracking system.

More information can be found in the document "*Guidance for Minimizing Impact Associated with a Food Safety Hazard in Raw Ground Meat and Other FSIS Regulated Products*", December, 1998, included in the appendix and also available at the FSIS website, <http://www.fsis.usda.gov/oa/haccp/gbg99.htm>.

And finally, the final products must be handled and stored according to acceptable standards to minimize the opportunities for cross contamination and spoilage.

The same key sanitation principles outlined in the Seafood HACCP requirement can be utilized for retail sausage production:

Safety of water - Water must be potable. Private wells or sources must be certified.

Condition and cleanliness of food contact surfaces - The portions of this area that should be monitored daily are cleaning and sanitizing of equipment, utensils, gloves, and outer garments that come in contact with food, and the condition of gloves and outer garments.

Prevention of cross-contamination - The issues in the area of cross-contamination that should be monitored are employee practices and physical separation of raw and cooked products.

Maintenance of hand-washing, hand-sanitizing, and toilet facilities - The issues that should be monitored are the concentration of hand-sanitizing solutions and that the toilet facilities are in good repair.

Protection from adulterants and toxic compounds - Food must be protected from contaminants such as condensation, floor splash, glass, and toxic chemicals.

Employee health conditions - Employee health conditions must be monitored daily.

Pest control - Pests must be excluded from food handling areas.

For more information please consult the Seafood HACCP materials.

HACCP Plan Implementation

USDA-inspected meat and poultry establishments must have a Hazard Analysis Critical Control Point (HACCP) plan that documents a systematic approach to process control that will be followed at the facility. The FDA model Food Code also requires HACCP plans for retail food establishments that engage in the curing and smoking process. This section is an overview of the steps that the sausage manufacturer follows to develop its HACCP plan. The plan must be designed to identify points in the production process where biological, chemical, or physical hazards are present that may cause a food to be unsafe for consumption. It must also describe the associated preventative measures, if any, that will be implemented to reduce or eliminate the potential problem.

The food establishment develops its own HACCP plan, which will be unique to its processing facility and the products produced by the facility. The first step is to assemble a HACCP team, including one person who is HACCP-trained. Food establishments have flexibility in how they write their HACCP plans, and each HACCP team is required to make its own decisions on how it will apply the HACCP system. Therefore, the inspector will see a wide variety in the HACCP plans encountered at processing facilities.

FSIS provides examples of generic plans for each processing categories, such as raw, ground; fully cooked, not shelf stable; not heat treated, shelf stable; and heat treated, shelf stable; that food establishment HACCP teams can use as the basis for developing their individual, detailed plans. In addition, all food production facilities are expected to have Sanitation Standard Operating Procedures (SSOPs) in place, and may choose to utilize Good Manufacturing Processes (GMP) that the HACCP team can build on to develop their HACCP plan. This program only provides an overview of HACCP implementation, a complete discussion is beyond our scope. Consult the FSIS documents "Guidebook for the Preparation of HACCP Plans" and "Generic HACCP Models" for more information; they are available at the website, <http://www.fsis.usda.gov/OA/haccp/imphaccp.htm>. These documents contain detailed examples of HACCP documents.

In this section we will go over the elements of the HACCP plan, and describe the typical implementation process.

Product Description

The HACCP team must describe each food product for each process category that is manufactured in the establishment. The retail establishment HACCP team should reference the product name, intended consumer, how the product is used, type of package, shelf life, display temperature, where and how displayed,

and labeling. Ingredients used should be identified by listing in order of predominance.

Process Flow Diagram The HACCP team should produce a simple description of the steps involved in the production process.

HACCP team members can confirm that the diagram documents the process flow by physically walking through the facility and correlating each step of the process with each step in the process flow diagram. Appendix A contains examples of process flow diagrams for sausage products.

Hazard Analysis The first part of the hazard analysis is an evaluation of the specific food process and manufacturing establishment, and considers the effect of a wide range of factors on the safety of the food. The potential risk and severity of each hazard is assessed by the HACCP team, and preventative measures are identified.

Examples of Typical Hazards, along with Control and Prevention Measures Hazards addressed by the HACCP team include biological, chemical, or physical properties that may cause a food to be unsafe for consumption.

These hazards can affect both the product ingredients and the production process.

- **Biological hazards** mainly consist of contamination of the product with pathogenic bacteria such as *Salmonella*, and parasites, such as *Trichinella spiralis*. Raw ingredients must be properly treated, stored, and handled. As noted earlier, heating, refrigeration and curing are used to control or prevent these types of biological hazards from contaminating the product.
- **Chemical hazards** consist of contamination of the product by unapproved chemicals or ingredients. Chemical contaminants could include pesticides, fertilizers, cleaners, lubricants, paints, food chemicals such as preservatives and processing aids, and naturally occurring chemicals, such as aflatoxins, lead, arsenic, and PCBs. An excess of approved chemicals in the product also presents a hazard. For example, including an excessive amount of acidifiers or antioxidants in the product formulation creates a chemical hazard. In addition, the packaging materials should be certified by the producer for the intended use to ensure that chemicals present in the packaging are not harmful.
- **Physical hazards** consist of contamination of the product by foreign objects, such as rocks, wood, metal glass, screws, plastics, or jewelry that may inadvertently enter the product mixture.

This chart lists some hazards along with standard control/prevention measures.

Typical hazards along with standard control/prevention measures.

(note: B – Biological contamination, C – Chemical contamination, P – Physical contamination.)

Ingredients	B	C	P	Hazard Description	Control / Prevention measure
Acidifiers, antioxidants, binders/extenders, curing agents, flavorings, mold inhibitors, phosphates, sweeteners		X		Toxicological effects if limits are exceeded	Use ingredients guaranteed to meet product specifications / requirements.
Meat ingredients (beef, pork, poultry and meat by-products)	X			Growth of pathogens due to improper storage, handling, and/or transport. Foreign particle contamination (e.g., bone particles)	Product temperature must be sufficient to limit excess microbial growth. Product must meet specifications. Product must be produced under HACCP plan. Visual examination of product to identify particle contamination.
Packaging materials		X	X	Toxicological effects	Use only packaging materials certified as safe by the manufacturer.
Spices/herbs	X	X	X	Contamination from microorganisms, agricultural chemicals, and/or foreign materials	Use ingredients guaranteed by the manufacturer to meet product specifications / requirements.
Vegetables	X	X	X	Growth of pathogens due to improper storage, handling, contamination with agricultural chemicals, and/or foreign materials	Ingredient spec sheet identifying required ingredient parameters, control storage temperatures to preclude microbial growth.
Processing Steps	B	C	P	Hazard Description	Control / Prevention measure
Cooking	X			Survival of pathogens due to improper procedures	Time/temperature combination adequate to destroy specific pathogens.
Cooling	X			Growth of pathogens due to improper temperatures, germination of spore-forming pathogens due to slow chilling (e.g., <i>C. perfringens</i> .)	Cooked product must be cooled according to established procedures.
Drying (Meat)	X			Bacterial growth due to inadequate control over time, temperature and humidity.	Achieving specific water activity levels to inhibit the growth of pathogenic microorganisms.
Formulation	X	X		Contamination during employee handling, incorrect formulations, contamination through damaged packages.	Maintaining careful employee practices, ensure ingredients are consistent with requirements, ensure packaging is clean and intact.

Freezing (Meats)	X			Survival of parasites due to improper time/temperature application, growth of pathogens due to temperature abuse.	Rapid cooling and freezing.
Grinding	X	X	X	Contamination during handling, contamination from lubricants, contamination from damaged equipment.	Careful employee practices, careful maintenance of equipment, temperature control in grinding room (<50°F).
Packaging	X	X	X	Contamination from packaging, contamination from damaged containers.	Ensure that packaging materials are protected from contamination, ensure that packaging is properly utilized to ensure adequate barrier.
Peeling	X		X	Contamination by pathogens in product accumulations, contamination from employee handling, contamination from foreign materials.	Ensure careful employee handling processes, do not allow product to accumulate in/on equipment, maintain peeling equipment in proper condition.
Receiving	X	X	X	Contamination through damaged containers, inappropriate storage conditions (temp/humidity), contamination on receiving equipment, cross-contamination from non-food chemicals, contamination from extraneous materials.	Product must be received in sound containers, and stored at appropriate temperature.
Reworking	X		X	Contamination during employee handling, contamination from pathogens in improperly stored product, contamination by foreign materials.	Proper/careful employee practices, proper storage temperatures.
Shipping	X		X	Pathogen growth due to inadequate shipping temperatures, contamination from extraneous materials or through damaged packages.	Product must be stored/shipped at proper temperatures, packaging should be intact, transport vehicles must be clean.
Thawing	X			Growth of pathogens due to improper temperatures.	Thawing room temperature should not exceed 50°F.

Hazard Identification The HACCP team creates a list of each of the production steps, and identifies the hazards which might occur at each step in the process and the preventive measures which might be used to prevent, eliminate, or reduce each hazard to an acceptable level. All significant hazards identified in the hazard analysis must be addressed.

HACCP Plan The HACCP team then develops a facility-specific HACCP Plan.

The HACCP team must identify the critical control points (CCPs) in the process. A CCP is a point, step, or procedure in a food process at which control can be applied

and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. The HACCP plan lists the number and location of each CCP.

The HACCP team identifies the critical limits for each identified CCP. The critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a CCP to prevent, eliminate or reduce the hazard to an acceptable level.

The HACCP team establishes the monitoring requirements and frequency for each CCP, including the personnel responsible for monitoring the CCP. Monitoring is an essential element of the food safety management, consisting of a planned sequence of observations and measurements to assess whether the CCP is under control. Monitoring must be designed to produce an unbiased, accurate record for verifying the accomplishment of safety standards and tracking trends. A lack of proper, dated records may be cause for suspending inspections of a facility.

The next step is to establish corrective actions to be taken when monitoring indicates a deviation from the established critical limits for each CCP. The corrective actions include:

- (1) Determining the disposition of the non-compliant product;
- (2) fixing or correcting the cause of the non-compliant product;
- (3) maintaining records of the deviation and the corrective actions; and
- (4) assuring that no hazardous product enters commerce.

Record keeping is very important, and the HACCP plan lists the records that are used to document the HACCP system.

Finally, the HACCP team identifies the procedures to be used for verifying that the HACCP system is working correctly. Verification is one of THE most important steps because it ensures that the HACCP plan is doing its job!

Summary

In this manual you reviewed the sausage production process, concentrating on issues affecting product quality and safety. You reviewed the types of pathogens that may be present in sausages, along with steps to reduce the pathogens present in sausage products. And you received an overview of the Hazard Analysis and Critical Control Point (HACCP) system

that helps manufacturers control the safety of food production processes.

Modern sausage making is based on traditions often hundreds of years in the making. The diversity of sausages currently being manufactured at retail is possible due to use of methods that are sometimes unique to this industry. Detailed proscriptive regulations that dictate exact requirements for retail manufacturing do not exist. Therefore, the 1999 Food Code requires systematic evaluation as part of variance granting process.

We encourage you to use HACCP principles as a systematic approach to evaluating any food facility. While application of HACCP principles at retail is still being discussed, there is general recognition of proven effectiveness of the HACCP methodology.

This course was designed to provide you with basic information to assist you in your evaluations of retail facilities that manufacture sausages. It was beyond the scope of our course to provide highly detailed discussion on any one topic. There is much more information available on these topics, and we encourage you to seek out additional information to build on what we have provided.

We have attempted to identify some of the resources that are currently available. Also, consider contacting processing experts in your local area who can provide invaluable advice regarding specific processes. And feel free to contact us if we can assist you in your problem solving efforts. We look forward to continue to work together to strengthen our working partnership in future years.

For more information contact:

**Association of Food and Drug Officials
(AFDO)**

P.O. Box 3425
York, PA 17402
Phone: (717) 757-2888
Fax: (717) 755-8089
afdo@blazenet.net
<http://www.foodsafety.org/afdo/>

**USDA, Food Safety and Inspection Service
(FSIS)**

<http://www.fsis.usda.gov/index.htm>

**FSIS Food Safety Virtual University
(FSVU)**

<http://www.fsis.usda.gov/of/hrds/fsvu.html>

**FSIS Technical Service Center
(TSC)**

Suite 300 Landmark Center
1299 Farnam Street
Omaha, NE 68102
Phone: (402) 221-7400 or
Toll free: 1-800-233-3935

Sausage Glossary

This Glossary describes FSIS product standards and labeling requirements for sausage products.

Adulteration	The addition or inclusion of unclean, unwholesome, inferior, impure, or foreign material to a food product.
Alessandri	A type of dry Italian sausage. The true product name must be shown on the packaging (i.e., "Alessandri Sausage").
Antioxidants	Ingredients added to cooked or fresh sausages to retard oxidative rancidity and protect flavor. Approved antioxidants include butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), propyl gallate, tertiary butylhydroquinone (TBHQ) and tocopherols.
Arels or D'Arles	A dry sausage similar to Milano Salami and made of coarsely chopped meat and corded "crisscross style".
Ascorbic Acid	Vitamin C. Can be synthetically manufactured from glucose, used to accelerate color fixation in cured meats.
Bacon and Pork Sausage	Sausage product formulated with a high percentage of bacon (usually bacon ends and pieces) with at least 20% pork.
Bangers	A sausage-like product prepared with meat and varying amounts of rusk or other cereals. The label must show percentage of rusk (or other cereals) adjacent to the product name in prominent lettering. May be labeled British, Scottish, or Irish style.
Batch	All the ingredients in the formulation.
Beerwurst, Bierwurst	A cooked smoked sausage.
Berliner	A cooked smoked sausage usually made from coarsely cut cured pork in large casings. When beef is used, it shall not exceed 50% of the meat block. Pork stomachs or beef tripe are not permitted.
Berliner Blood Sausage	A cooked blood sausage containing diced bacon. After cooking, it is dried and smoked. Ham, fat, snouts and lips are not permitted.
Binding	The ability of sausage components to emulsify fats and water.
Bladders	The urinary bladders of slaughtered animals, used as casings for stuffing some sausage products.
Blockwurst	A semi-dry type sausage, with a maximum MPR of 3.7 : 1.
Blood and Tongue Sausage	A cooked sausage formulated with blood and some meat, including cooked pork or beef tongues.

Blood sausage	A cooked sausage formulated with blood and some meat. Usually contains pork skins and/or pork jowls. May also contain sweet pickled ham fat, snouts and lips. Of the product does not contain meat, it must be labeled "Blood pudding".
Boudin	A meat sausage or pudding usually made with chicken and veal, or chicken and pork. It should be labeled "Boudin Sausage" (if it meets the sausage standard), or Boudin Pudding". It may contain by-products and rice, and is usually uncured.
Bratwurst	This sausage may not contain by-products, eggs, liquid milk, vegetables, or cheese. It may contain antioxidants.
Bratwurst, cooked	Chicken has been approved in cooked bratwurst when identified in the product name. Antioxidants are not permitted.
Bratwurst, Cured	Products that meet the requirements for Bratwurst but also contain cures must be labeled "Cured Bratwurst".
Braunschweiger	Liver sausage - May use the following labeling options: <ul style="list-style-type: none"> - Braunschweiger- A Liver sausage (or Liverwurst). - Braunschweiger - (Liver sausage (or Liverwurst).
Breakfast Link Sausage	Regular fresh sausage which does not have to be made with pork.
Breakfast Links or Patties	The names "Breakfast Links" and Breakfast Patties" are product names that must be followed with a descriptive product name. Acceptable without compliance with the fresh pork sausage or breakfast sausage standard. If the names "Breakfast Links" and Breakfast Patties" are without further qualification, the product must meet either the fresh pork standard or the breakfast sausage standard.
Brine	Water saturated or nearly saturated with salt.
Brisket	The anterior lower portion of the chest of a beef carcass.
Bull	An un-castrated mature male bovine.
Bungs	The terminal end of the large intestines of slaughtered hogs, used as casings for stuffing some sausage products. Refers to the cecum or blind gut when derived from cattle.
Butifarra Sausage	An uncured sausage. Labeling that features the term "Butifarra" would require an additional product name: <ul style="list-style-type: none"> - Pork sausage - for products that meet the fresh pork sausage standard. - Fresh Sausage - for products that include by product but do not meet the standard for pork sausage. - Sausage - for products that are incubated or fermented. The term Puerto Rican Style would be applicable if manufactured in Puerto Rico.

Buttermilk (Dried)	Dried buttermilk derived from sweet cream is acceptable as an ingredient in meat food products. Not permitted in sausage.
By-products	The term "by-products" on meat product labels shall be accompanied by the name of the species from which derived and individually named (e.g., Beef By-products - Heart, kidney, liver). They may also be listed by species (e.g., calf liver, beef heart, etc.)
Cacciatore, Cacciatora	A dry Italian sausage. Cacciatora is an Italian term meaning hunter or sportsman.
Calabrese	A salami originating in Southern Italy. Usually made entirely from pork seasoned with hot peppers.
Calicum Caseinate	Is acceptable as a binder in non-specific products.
Carriers	Substances that are used to carry flavoring compounds in the product formulation. Dextrose and/or sugar are commonly used for spice extracts and resins of spice. The carrier must be declared in the ingredients statement. Salt, when used as a carrier will always be declared, regardless of the amount used.
Cartilage	A specialized fibrous, elastic connective tissue found in many locations in the carcass.
Case Hardening	An undesirable crust that sometimes forms on the casing of dry sausage items, it prevents adequate drying of the affected product.
Casing, Artificial	Frankfurters packaged in retail containers with the artificial casing left on must bear a prominent statement (e.g., "remove casing before eating") contiguous to the product name on the label.
Casing (collagen)	Collagen casings are prepared from beef hides specially processed and formed into casings. For classification purposes, they are edible casings but are not considered natural casings.
Cecum	The blind extension of the intestine that opens into the intestinal tract at the junction of the small and large intestine.
Certified Pork	Pork that has been treated for trichinae by one of the approved methods.
Certified Trimmings (Certified Pork)	Pork trimmings or pork that has been frozen to ensure destruction of any live trichinae in the pork muscle and certified by FSIS.
Cervelat	A cured and smoked sausage, often a dry or semi-dry summer sausage. Hog stomachs, beef tripe and extenders are permitted, there is no MPR (moisture protein ratio) requirement.
Charol, Charoil	A natural smoke flavoring.
Cheese Smokies	A cooked smoked sausage that contains cheese.

- Cheesefurter** A meat food product resembling a sausage which consists of a mixture of meat and meat and cheese, The formula shall contain sufficient cheese to characterize the product so it may be labeled "Cheesefurter".
- Cheesewurst, Cheddarwurst** These names are not considered common, usual, or descriptive names, and must be accompanied by a true descriptive name (e.g., Smoked Sausage with Cheese) prominently displayed on the product label.
- Chorizo** The product name "Chorizo" can be used for any type of chorizo sausage that is cooked, dry or semi-dry, cured, or fresh without any further product name qualification. Chorizo is seasoned with Spanish pimento and red pepper. Partially defatted pork fatty tissue is acceptable in chorizo.
- Chorizo, Fresh** These products may contain vinegar. The vinegar used must have a strength of no less than 4 grams of acetic acid per 100 cubic centimeters (20⁰C).
- Chorizo in Lard** Product must contain at least 55% Chorizo.
- Chorizo in Lard, canned** Canned Chorizos that are packed hot, usually in lard, and are not thermally processed must have a moisture protein ratio of 1.8 : 1 and a pH of not more than 5.5. An alternative standard is a water activity (aW) of 0.92.
- Chourico** Is Portuguese for sausage, and is an acceptable product name.
- Chub** An acceptable name to denote a short, usually plump meat food product, unsliced in casing.
- Citric Acid** Citric acid and salts of citric acid, when used alone or in combination with other chemical preservatives have several functions. It is used to help retain fresh meat color, to prolong shelf life without preventing deterioration or spoilage, and to increase the activity of BHA and BHT. When used, it must be declared on the label by it's common name, and it's purpose must be indicated in the product name (e.g., "to help preserve flavor").
- Cocktail Frankfurters** A small frankfurter normally about 2" long and 1/2" in diameter.
- Cold Smoke** Smoke applied to product where the smokehouse temperature is low, generally 90⁰ to 120⁰ F. May be used to apply smoke color and flavor to products not sufficiently darkened or flavored in the original cooking process. Cold smoked meat and poultry products shall be processed at or near ambient temperature so that the internal product temperature does not rise above 41⁰ F. The product and air temperature shall be monitored at all times.
- Cold Spots** The area or areas within a smokehouse that are not exposed to as much heat as the rest of the smokehouse.

Colored Casing	Colored casings on meat and poultry products which do not transfer color to the product, but which change and give a false impression of the true color of the product, must be labeled to indicate the presence of the casings.
Comminution (Comminuting)	The cutting, chopping, or grinding of meat into small particles.
Condimental Substances	Non-meat ingredients such as spices, seasonings, and flavorings that are added to sausage product.
Contaminate	To render impure or unsuitable by contact or mixture with something unclean, impure, polluted or soiled.
Country Style (Farm Style) sausage	When sausage products are labeled “farm style” or “country style” they must be prepared with natural spices with the exclusion of oleoresins, essential oils, or other spice extractives. HVP, MSG and antioxidants are permitted ingredients.
Cow	A mature female bovine, usually refers to an animal that has given birth to one or more calves.
Cross-contamination	Transfer of bacteria or other contaminants to clean product by direct or indirect means, from product, equipment, utensils, clothing, etc.
Cured Smoked Stix	An acceptable name if followed immediately by an ingredients statement. If the product meets the sausage standard it may be identified as “Smoked Sausage”.
Derma	When the term “Derma” is used in the product, only natural casing or skin must be used.
Detached Skin	Detached skin is not permitted in bologna, frankfurters, braunschweiger, or similar sausage.
Dry room	A room in which the atmospheric relative humidity is maintained at a very low level in order to facilitate drying of certain sausage products. The temperature of such rooms is also usually closely controlled.
Emulsion	The semi-fluid mixture of finely chopped meat, water, spices, and curing agents that is stuffed into casings or molds and further processed to produce a variety of sausage products. The combining of solubilized proteins and sometimes water to form a capsule around fat particles.
Emulsion breakdown	The separation of components making up an emulsion, usually during cooking.
Enterotoxin	A toxin that is specific for the cells of the intestinal mucus tissues.
Exotoxin	A toxin formed outside the bacterial cell and found in the medium in which the bacteria is growing.

Extruder	A mechanical device that pushes sausage emulsions or mixtures through a tube into a casing.
Faggots	A combination of beef, veal, and pork cured with salt, nitrates and sugar. Sheep or hog casings are used and sausage is linked in pairs, each about 6 inches long. Classed as cooked smoked sausage.
Farm or Country Style Fresh Sausage	The terms farm or country are not permitted on labeled unless the product is produced on a farm on in the country. Most products are labeled farm-style or country-style, indicating that the product is produced in a similar manner to farm or country sausages.
Farmer Sausage Cervelat	In usually a semi-dry sausage, but may be made in dry form. Usually made of equal parts of pork and beef, delicately seasoned without garlic.
Farmer Summer Sausage	A special type of sausage made of beef, pork salt spices nitrite or nitrate, and heavily smoked. It is classed as "Cervelat" and no extenders are permitted.
Fleischkaese	An acceptable name for a cured, cooked sausage in loaf form.
Fat Cap	The accumulation of unbound fat on the ends of finished sausages, a defect usually caused by emulsion breakdown.
"Fresh", Not Frozen" and Similar Terms When Labeling Poultry Products	The word "Fresh" may not be used in conjunction with the product name of any cured product (e.g., corned beef, smoked cured turkey, and prosciutto); any canned, hermetically sealed, shelf stable, dried or chemically preserved product; or any raw poultry, poultry part, or any edible portion thereof whose internal temperature has been below 26 degrees Fahrenheit.
Galician Sausage	In this type of sausage, cured beef and pork is seasoned and stuffed into beef rounds, then smoked at a high temperature. Cooling is done in a blast of air which produces a wrinkled appearance which is characteristic of Galician sausage.
Gelatin	It is not permitted in products like sausage, luncheon meat, and meat loaves. Gelatin is an acceptable ingredient in soups, jellied beef loaf, head cheese, and canned whole hams. Requires a qualifier if gelatin is added.
Genoa or Genoa Salami	These are dry sausage products with an MPR not in excess of 2.3:1. It is prepared with all pork or with a mixture of pork and a small amount of beef. The meat is given a coarse grind and enclosed in a natural casing. No smoke is used in its preparation.
German Sausages with Milk	Whole milk is a permitted ingredient in these types of sausage products when the ingredients statement is shown immediately under the name of the product or the milk is shown in a qualifying statement contiguous to the product name.

Goteborg	A Swedish dry sausage made of coarsely chopped beef and sometimes pork. Mildly seasoned with thyme. It has a somewhat salty flavor and is heavily smoked, usually in long casings and air dried.
Green Room	A room in which freshly prepared sausages are held, to promote the growth of lactic acid-forming bacteria before they are moved to a drying room.
Ground Beef and Pork	The product must be treated for possible live trichinae. Mixtures of fresh ground pork and beef should not be distributed from official establishments unless the pork is trichinae treated.
Hearts / Heart Meat	Hearts and heart meat may not be labeled as “beef”, “pork”, etc. in the ingredients statement. When used in a product, they must be identified by species (e.g., “Beef Hearts”).
Heat and Eat Sausages	Not the same as Brown and Serve Sausage. When the “heat and eat” term is used, the product must comply with cooked sausage regulations.
Holstein or Holsteiner	Product is the same as Farm Style Sausage, except that it is stuffed into wide casings and heavily smoked, usually in long casings, and then is air-dried. No extenders are permitted.
Hydroflake	A method of thinly slicing or flaking frozen boneless meat prior to grinding.
Inspection Legend	The FSIS official mark or statement authorized by regulations to be placed on a product or container of product to indicate that the product has been inspected and passed for use as human food.
Italian Sausage	Red Pepper is permitted in Italian Sausage under 319.145.
Italian Style	An acceptable term for products containing anise or fennel or Italian type cheese, or at least three of the following (basil, garlic, marjoram, olive oil or oregano).
Jagwurst	The product is the same as yachtwurst, a cooked sausage made from a fine emulsion with cubes of lean meat rather than fat (as in mortadella).
Jowl	The muscles and fatty tissues of the cheek that are cut away from the jaw and left attached to the hog carcass.
Jerky	Jerky products must have an MPR of 0.75:1 or less. The species or kind must be in the name. These products may be cured or uncured, dried, and may be smoked or un-smoked, and air or oven dried.
Jumbo	The term “Jumbo” may be used if the product is of a large size or quantity. When used on frankfurters no more than 8 franks to the pound may be present.

Junior Meat Snacks	This product must conform to the sausage standards going into the jar before processing. Limited to 3 ½% extenders.
Kalberwurst	A product that is similar to Bockwurst with no limit on water or milk.
Kielbasa	A sausage made with coarsely ground pork, sometimes with added beef or mutton, that is cured, cooked, and usually smoked. By-products are not permitted. Also available as a fresh sausage, uncured with no more than 3% water.
Kipperd Beef	A cured dry product similar to beef jerky but not as dry (MPR 2.03:1)
Knackwurst, Knockwurst, or Knoblouch	Oversize frankfurters.
Kolbase, Hungarian Style	Finely ground cured beef and pork seasoned and stuffed into casings and smoked. Classed as a cooked smoked sausage.
Krakow	Acceptable name for a cooked sausage similar to “Berliner”.
Kuemmelwurst	An acceptable name for a product that is similar to Carawaywurst, a cooked sausage of the ring variety, with whole caraway seeds. The usual ingredients are beef, pork salt, caraway, flavorings, and cure.
Labeling of Specific Sausage Products Identified by a Nutrient Content Claim	Modified breakfast sausage, cooked sausage, and fermented sausage products are substitute version of standardized traditional products that have been formulated to reduce fat content to qualify for nutrient content claims, but do not comply with accepted standards for ingredients for each sausage type. These products must follow specific guidelines for product integrity and ingredients.
Labeling of Meat and Poultry Stick Items	Stick items such as beef jerky, pepperoni sticks and beef sticks have specific labeling requirements. Individual items sold in fully labeled bulk containers are not required to be labeled. Individual items sold in un-labeled bulk containers must be individually labeled. Individual items sold in retail boxes or cartons are not required to have individual labels.
Labeling of Modified Substitute Versions of Fresh Sausage	Fresh sausages that contain non-meat or poultry “fat replacing ingredients” must follow nutrition labeling regulations that include specifying contents and conforming to applicable limits on ingredients.
<i>Lactobacillus</i>	A genus of bacteria that form lactic acid as they grow. Cultures of these bacteria are added to certain meat and dairy foods to produce a characteristic flavor and odor.
Landjaeger Cervelat	A semi-dry sausage originating in Switzerland about the size of a large frankfurter but pressed flat, smoked and dried, giving it a black appearance.

- Lola and Lolita** A dry sausage product of Italian origin, consisting of mildly seasoned pork and containing garlic. Lolita comes in 14 oz. Links, while Lola comes in 2 ½ lb. links.
- Longaniza** Longaniza is a fresh sausage product that can include paprika.
- Longaniza and Puerto Rican Longaniza** Longaniza is an acceptable name for Puerto Rican sausage made from pork, which may contain beef but does not contain annatto. Added fat is not permitted.
- Loukanika** An acceptable name for cooked fresh Greek sausage, usually made with lamb and pork, and containing oranges, allspice, whole pepper and salt.
- Lyons Sausage** A dry sausage made exclusively of pork with spices and garlic which is stuffed into large casings, cured and air-dried.
- Meat** Meat is defined by USDA as the part of muscle of any cattle, sheep, swine, goats, or equine animals that is skeletal or that is found in the tongue, diaphragm, heart, or esophagus, with or without an accompanying layer of fat. This also can include accompanying portions of the bone, skin, sinew, nerve, and blood vessels that are not separated from the muscle tissue during the dressing procedure, but does not include the muscle found in the lips, snouts, or ears [refer FSIS Regulations, 9 CFR 301.2(rr)].
- Meat by-products** Meat by-products include any part derived from cattle, sheep, swine, goats, or equine animals, other than the parts defined above as meat, that can be used as human food. These are also referred to as “Variety Meats”. Examples of by-products are snouts, skins, spleens, hearts, livers, and fat.
- Meat Block** The amount of meat and or meat byproducts used to make a specific sausage batch.
- Mettwurst** An uncooked cured smoked sausage in which by-products and extenders are not permitted. Beef heart meat is acceptable. Water is limited to 3%, and fat content shall not exceed 50%.
- Mettwurst, Cooked** Mettwurst which is cooked must be labeled Cooked Mettwurst, and may contain up to 10% water based on the finished product weight.
- Metz Sausage** Cured lean beef and pork and bacon are finely chopped, seasoned, and stuffed into beef middles. It is air dried for 5 days, then given a cool smoke. It is classified as a semi-dry sausage.
- Mexican Style** Acceptable name for products that contain at least four of the following ingredients: jalapeno peppers, chili peppers, green chilies, cumin, cayenne peppers, red or green peppers, chili powder, jalapeno powder, Monterey Jack cheese, or cheddar cheese.
- Middles** Casings derived from the large intestines of slaughtered animals.

Moisture Protein Ratio (MPR)	Used to describe the moisture level in a product. Non-refrigerated or shelf stable sausages, must have a MPR of 3.1:1 or less, and a pH of 5.0 or less, unless commercially sterilized.
Mortadella	Normally a cooked sausage but can be dry or semi-dry. It is similar to salami and cervelat except that it has large chunks of pork fat. Red sweet peppers up to 4% and pistachio nuts up to 1% are acceptable as long as they are shown in the true product name.
Mortadella – Poultry	Poultry Mortadella is a dry, semi-dry, or cooked sausage formulated with poultry. This product may contain large chunks of pork fat and may contain extenders and/or binders.
Mortadella Without Fat Cubes or Chunks	Product must meet the standard for Mortadella and the label qualified to indicate the absence of fat cubes or pork chunks, e.g., “Mortadella without fat cubes”.
Myosin	A major protein in muscle tissue.
Natural Smoked Color	This statement on a label indicates on the product is smoked and not artificially colored. Note that this label allows the use of artificial smoke.
Negative Labeling	Negative labeling is allowed if it is unclear from the product name that the ingredient is not present. For example, the use of the term “No Beef” on the label for Turkey Pastrami would further clarify that the product does not contain beef.
Nonspecific loaf	A loaf produced with no restrictions on water, cereal, Non-Fat-Dry-Milk, starch, corn syrup, etc. There are limitations of nitrite, nitrate, and other chemical additives. The name of such product may not refer to meat. Common names are pickle and pimiento loaf, olive loaf, Dutch loaf, etc.
Non-standardized Cooked Sausage Products Containing Both Livestock and Poultry Ingredients	Cooked sausage products that contain poultry ingredients at more than 15% of the total ingredients (excluding water) must have product names that indicate the species of livestock and the presence of poultry (e.g., “Beef and Turkey Frankfurter”).
Off-condition	Spoiled.
Paprika	Generally, paprika and/or oleoresin or paprika are not permitted in or on fresh red meat products, fresh ground poultry, or fresh poultry sausage, except where such ingredients are expected and accepted (e.g., Italian sausage).
Partially Defatted (Beef or Pork) Fatty Tissue	These are by-products produced from fatty trimmings containing less than 12% lean meat. These ingredients may be used in meat products in which by-products are acceptable.
Pathogenic	Capable of producing disease.

Pepperoni	A dry sausage prepared from Pork or Pork and Beef. Pepperoni must be treated from destruction of possible live trichinae and have a MPR of 1.6:1 or less. Antioxidants are permitted.
Pepperoni, Cooked	Not an acceptable product name.
Pepperoni, with Poultry	Poultry may be added to Pepperoni if properly labeled. If the meat block contains 20% or less poultry, the product is labeled "Pepperoni with Turkey Added". When poultry is over 20% of the meat and poultry block, it is labeled "Pork and Turkey Pepperoni". When poultry is over 50% of the meat and poultry block, it is labeled "Turkey and Pork Pepperoni".
Permeable	Capable of penetration from the inside and outside.
pH	The negative logarithm of the effective hydrogen ion concentration or hydrogen ion activity in gram equivalents per liter; used in expressing both acidity and alkalinity on a scale with values from 0 to 14, with 7 representing neutrality, numbers less than 7 increasing acidity, and numbers greater than 7 increasing alkalinity.
Pickled Products, Dry Packed	Products that are pickled or dry packed should be qualified with the name of the pickle as part of the product name (e.g., "Knockwurst Pickled"). The weight of the package shall be the weight of the product less the weight of the pickle that will weep out of the product.
Pimiento Sausage	Pimientos are permitted when declared in the product name as "Pimiento Sausage".
Pinkelwurst	A cooked product that is stuffed into a casing with a diameter from 1 ½ to 2 inches and a length of about 10 to 12 inches. It is formulated with beef, pork, fat, onions, oat groats, water, and sufficient spice to satisfy seasoning requirements. The product is cooked to an internal temperature of more than 152°F.
Polish Sausage	A sausage that is cured, cooked, and usually smoked. Pork and pork by-products shall comprise at least 50% of the meat and meat by-products ingredients. Products with beef as the predominant ingredient are called "beef and Pork Polish Sausage". Green peppers are permitted up to 4% in total formulation. A uncured (fresh) uncooked variety also with no more than 3% water also exists.
Polynesian Style Sausage	A sausage product that must contain fruit juices, a sweetening agent, and soy sauce.
Pork and Bacon Sausage	Up to 50% bacon is permitted in this type of sausage as long as bacon is brought back to green weight before use, the product is trichinae treated, and the product name is "Pork and Bacon Sausage". The standard for "Pork Sausage and/with Bacon" is 10% to 20% bacon, and for "Pork and Bacon Sausage" is more than 20% but not more than 50% bacon.

Pork Sausage	A product identified as pork sausage does not include the use of pork cheeks. When such an item is offered as “Whole Hog”, tongues, hearts, and cheeks may be used in the natural proportion found in the hog carcass. “Fresh” shall be used in the name when the product is not cured, cooked and/or smoked.
Pork Skins	Pork Skins are not permitted in salami, bologna, frankfurters, vienna sausage, and braunschweiger. When packaged in vinegar pickle, they are not permitted to be artificially colored. When pork skin is used to manufacture meat or poultry products, it must be specifically listed in the ingredients statement (e.g., Pork Skins, Unskinned Pork Jowls, Unskinned Pork Fat, etc.).
Potato Sausage or Ring	A cooked or uncooked meat food product that: is at least 65% meat and no by-products, water limited to 3% at formulation, No extenders or binders permitted, and contains at least 18% potatoes.
Potentially Hazardous Foods (PHF)	<p>Potentially Hazardous Foods (PHF), according to the FDA Food Code, refers to a food that requires temperature control because it is in a form capable of supporting:</p> <ul style="list-style-type: none"> ▪ The rapid and progressive growth of infectious or toxigenic microorganisms; ▪ The growth and toxin production of <i>Clostridium botulinum</i>; or in raw shell eggs, the growth of <i>Salmonella</i> Enteritidis. <p>Potentially hazardous foods include animal foods that are raw or heat-treated, except for:</p> <ul style="list-style-type: none"> ▪ foods with a water activity (a_w) value of 0.85 or less; ▪ foods with a pH level of 4.6 or below; ▪ foods in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution; ▪ a food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms can not occur; or ▪ a food that does not support the growth of microorganisms even though the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.
Ready to Eat	A product that has been cooked and has characteristics of a fully cooked material. Will not receive further cooking by consumer.
Relative Humidity	The amount of water vapor in the air expressed as a percentage of the maximum amount of water the air could hold at a given temperature.
Rework	Fully or partially processed product, rerouted for reasons other than unwholesomeness or adulteration.
Rounds	Casings derived from the small intestines of slaughtered animals.

Shank	The distal end of the fore and hind legs of a dressed carcass.
Shelf Stable	Products that have been sufficiently treated to destroy all viable forms of pathogenic organisms and nonpathogenic organisms capable of reproducing in the product under normal non-refrigerated conditions of storage and distribution.
Silent Cutter	The commercial name for a machine that mixes and grinds sausage ingredients. Ingredients are placed into a revolving tub that carries the ingredients into rapidly rotating knife blades that chop and emulsify the material.
Standard of Identity	The minimum requirements (cut, ingredients, processing, etc.) for a meat food product to be identified or labeled with an established or acceptable name.
Swedish Style	A cooked or uncooked meat food product that: is at least 45% meat and no by-products, water limited to 3% at formulation, extenders or binders up to 3.5% permitted except that 2% of isolated soy protein shall be deemed to be equivalent of 3.5% of any of the other binders or extenders, and contains at least 18% potatoes.
Poultry Sausage	Sausage products made from poultry must be labeled to indicate kind (e.g., "Chicken Sausage", "Turkey Bologna", etc.). Products containing more than one kind of poultry or red meat must declare the added ingredients in the product name (e.g., "Chicken Bologna, Beef Added", "Turkey Franks, Chicken Hearts Added"). The basic sausage standards also apply to poultry, except for added water and ice.
Romanian Brand Sausage	An uncooked smoked sausage made with cured lean pork. Product requires trichinae treatment.
Salami	A dry sausage that requires an MPR of 1.9:1 or less. Extenders and binders are permitted. It may be cooked to shorten drying periods.
Salami, Beef	A cooked, smoked sausage, usually mildly flavored, in a large casing, containing coarsely ground beef. Cereals and extenders are permitted. May contain fat. Product does not have to be labeled "cooked".
Salami, Cooked	The product "Salami" must be labeled to include the word "Cooked" regardless of the type and size of its packaging, unless it is one of the following: <ul style="list-style-type: none"> - A salami with a MPR of no more than 1.9:1. - Genoa Salami with a MPR of no more than 2.3:1 - Sicilian Salami with a MPR for no more than 2.3:1 - Labeled as Kosher Salami, Kosher Beef Salami, Beef Salami, Beer Salami, or Salami for Beer.
Salami, Cotto	A mildly flavored, cooked, cured sausage in a large casing, usually

containing coarsely ground beef and pork. The product contains whole or visible pieces of peppercorns. It is cooked in dry heat.

Salami, German Brand Made in U.S.A. A dry sausage with an MPR of 1.9:1. It is made with beef and pork and seasoned with garlic. Less highly flavored but usually more heavily smoked than Italian Salami. It is tied with loops of twine that gives it a scalloped appearance.

Salami, Italian This dry salami is usually prepared in the San Francisco area and is easily distinguished by its covering of a white mold. It consists of about 80% finely chopped pork, to which a small amount of pork fat may be added. Nonfat dry milk can comprise 3½ % of the finished product. The remainder consists of chopped beef, seasoning, salt, and curing agent. The product should have an MPR of not in excess of 1.9:1 to ensure the fat content and dryness properties associated with a “Dry salami”.

Salami, Sicilian Brand Made in U.S.A An acceptable name for an uncooked dry sausage. This is a type of “Genoa Salami” except it is uncooked and contains no garlic. Antioxidants are permitted. Trichinae treatment is required.

Salchichon A Spanish term meaning “Large Sausage”. This term may only be used for large casing sausage products that are 3 inches in diameter or more. Label must show true product name.

Salcina (Portuguese Brand – Made in U.S.A.) Sausage usually contains pork, green onions, parsley, vinegar, salt, sugar, spices, and garlic.

Salpicao A smoked sausage. The label must show a true product name (e.g., Smoked Sausage”). No more than 3% water can be added at formulation.

Salsiccia A fresh pork sausage, highly spiced, in which paprika is permitted. It is a rope style sausage made of finely cut pork trimmings.

Sarno A dry smoked sausage that is air-dried. The label must show a true product name (e.g., “Smoked Sausage”). Coarsely chopped beef, pork, and garlic are not permitted.

Sausage Sausage refers to a product prepared with ground or finely comminuted meat and meat by-products, usually seasoned with spices, seasoning and flavorings, and containing water and fat in varying amounts. Foreign names for sausage are wurst (German), kielbasa (Polish), kobacica (Croatian), salchia (Spanish), korv (Swedish), loukaniko (Greek), naknik (Jewish), salsiccia (Italian), ispin (Irish), saucisse (French), or sucik (Turkish).

Sausage Classifications – Fresh Sausage Made of fresh uncured meat, generally cuts of fresh pork and sometimes beef. (See this manual for more on this classification of sausage)

Sausage Classifications – Has the same characteristics of Fresh Sausage, except that it is smoked, producing a different flavor and color.

Uncooked Smoked Sausage

Sausage Classifications – Cooked Sausage and/or Smoked Sausage

These products are chopped or ground, seasoned, cooked and/or smoked. (See this manual for more on this classification of sausage).

Sausage Classifications – Dry or Semi-Dry Sausage

Dry sausages may or may not be characterized by a bacterial fermentation, and undergoes a carefully controlled air drying process to preserve the product. (See this manual for more on this classification of sausage).

Sausage Containing Cheese

Sausages may contain cheese under the following conditions: if there is a standard for that particular sausage, it must be met as though it contained no cheese; The cheese must characterize the product and appear as part of the product name (for example, "Italian Sausage with Cheese").

Sausage Containing Poultry

Red meat sausages may contain raw and/or cooked poultry or poultry meat. Poultry by-products are permitted when a sausage standard permits by-products. Mechanically deboned poultry must have kidneys and sex glands removed. Labeling standards must be followed.

Sausage – Shelf Stable

Dry sausages must have an MPR of 1.9:1 or less, unless an MPR is cited under **Moisture Protein Ratio**. 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, unless commercially sterilized, or unless an MPR is stated under **Moisture Protein Ratio**.

Alternately, non-refrigerated, semi-dry, shelf stable sausages are those that:

- are fermented to a pH of 4.5 or lower (or pH may be as high as 4.6 if combined with product water activity no higher than 0.91),
- are in an intact form, or, if sliced, are vacuum packed,
- have internal brine concentration no less than 5%,
- are cured with nitrite or nitrate, and
- are smoked with wood.

Sausage, Raw Skeletal Muscle Meat Used in Emulsified Product (Bologna, Franks, etc.)

The term "raw skeletal muscle meat" includes beef cheek meat, diaphragm meat, uncooked ham trimmings, and bacon or bacon ends and pieces. The bacon ingredient is limited to not more than 10% of the meat, meat and meat by-products, or meat, meat by-products and poultry products in a sausage formula. See FSIS Regulation §318.180.

Sausage, Rework

This term refers to a fully or partially processed product (excluding uncooked trimmings) re-routed for reasons other than unwholesomeness or adulteration and intended for inclusion in cooked sausage, loaves, or similar products.

Sausage, Smoked	Smoked product will be identified as such unless the specific product name conveys a smoked product or it is obvious from the packaging.
Sausage Type Products with Fruit and Vegetables	Sausage type products that contain unexpected ingredients that significantly alter the character of the product may be descriptively labeled with the characterizing ingredient (e.g., Cherry Pecan Sausage, Wild Rice Sausage, etc.). The sausage portion must meet the applicable standards based on the product weight prior to adding the unexpected ingredient.
Sausage (Species)	(Species) sausages must comply with the applicable standards before being processed if the product name is to include the species. For example cooked, cured sausages may be labeled “cooked cured sausage” or “cooked cured sausage made with (species)”.
Saveloy	A cooked smoked sausage. It is an English sausage similar to bologna made of beef and pork. The label must show a true product name.
Schickenwurst	This product is made of two parts, one is an emulsion prepared from pork and beef cuts, the other consists of chunks of ham measuring from 2 to 3 inches in size. The parts are mixed, stuffed into large casings and smoked while being cooked. The final product appears as a luncheon sausage with large pieces of red ham meat held together by a light pink binder. The ham portion must comprise at least 50% of the product, and the product has a distinctive smoked flavor.
Serkelki, Serdelowa	A cooked smoked sausage of Polish origin, made from pork. The label must show a true product name (e.g., Smoked Sausage).
Smoke	Although not required or customary, smoke can also appear in the ingredients statements of domestically produced products which are physically smoked. If included in the ingredients statement, smoke should appear last.
Smoke Flavoring	The use of smoke flavoring (natural or artificial) in a component of a meat or poultry food product does not require that the product name be qualified to indicate the presence of the smoke flavoring. However, the smoke flavoring must be declared on the ingredients statement.
Smoked Products	The guidelines for approving labels for products prepared with natural smoke and/or smoke flavoring are as follows: <ul style="list-style-type: none"> - Products that have been exposed to smoke generated from burning hardwoods may be labeled as “Smoked”, or with the term “Naturally Smoked” to indicate that the traditional smoking process was used. - Products that have been exposed to natural liquid smoke flavor that has been transformed into a true gaseous state by application of heat, or transformed into vapor by mechanical

- means, may be labeled “Smoked”.
- Products that have been exposed to natural liquid smoke flavor via spraying, dipping, liquid flooding, or similar processes prior to or during heat processing, may be labeled “Smoked”.
- Products that have been exposed to natural or artificial smoke flavor via direct application to the product surface or via injection must be labeled to identify the smoke flavor as part of the product name (e.g., “Pork Sausage, Natural Smoke Flavor Added”.)

Smoked Sausage, Country Style	An uncured or cooked smoked sausage with natural spices and sugar. It is made with beef and pork and requires trichinae treatment.
Smoked Thuringer Links	A cooked smoked sausage made with pork only.
Smoky Snax	A smoked sausage. The label must show a true product name (“Smoked Sausage” or “Dry Sausage”).
Southern Hots	A cooked smoked sausage made in the South. Southern Hots is a coined name that must be accompanied by a true product name.
Soy Protein Products	Whenever soy products are used in a meat or poultry product, they must be called by their common or usual name (e.g., soy flour, soy protein isolate, etc.). If these products are textured, then “textured” should also be included in the name.
Spices	The term spices refers to genuine natural spices, whole or ground. Spices may be listed as “Flavorings”.
Summer Sausage	A semi dry or cooked sausage that can contain meat by-products and extenders.
Teawurst or Teewurst	A cooked or uncooked product processed without curing and cold smoked 2 to 5 days. It is ground or coarsely chopped as is characterized by a soft spreadable texture. Typical meat ingredients include pork, beef, pork bellies and bacon.
Texas Hots	A coined name for a sausage made in Texas. The label must show a true product name.
Thuringer	A sausage usually classified as semi-dry, with an MPR of 3.7:1. It is smoked and usually complies with the following factors: <ul style="list-style-type: none"> - Heat meat (beef or pork) may comprise up to 50% of the meat ingredients. - Tongue meat (beef or pork) may comprise up to 10% of the meat ingredients. - Cheek meat (beef or pork) may comprise up to 50% of the meat ingredients. - No binders or extenders are allowed. - Cooked Thuringer can contain up to 10% added water. - Acceptable names for uncooked thuringer include “Beef

Summer Sausage”, “Thuringer Cervelat”, and “Summer Sausage - Thuringer Cervelat

- Touristen wurst** A semi-dry type sausage with an MPR of 3.7:1.
- Trichinae Treatment** All sausage and meet food products containing pork that are neither cooked or understood by the public as needing to be cooked prior to serving must be treated by one of the prescribed methods. See FSIS Regulations §318.10.
- Tripe** First and second stomach compartments of ruminant animals, usually cattle, cleaned and with the mucosal lining removed.
- Turkey Braunschweiger** The product name must be shown on the label as “Turkey Liver Sausage”. No by-products other than liver are permitted in the product.
- Ukrainian Sausage** A dry sausage made from lean pork and/or veal chunks, containing large amounts of garlic that dominates the flavor. It is cooked and smoked at high temperatures (around 180 – 185⁰F) for 4-5 hours then air-dried. The water activity or the finished product shall not exceed 0.92 or an MPR of 2.0:1 or less.
- Uncured (Labeling Requirements Labeled As)** Products in which nitrites or nitrates are required or expected, may be prepared without such cures when the product name is immediately preceded by the term “Uncured” as part of the product name in the same size and style of lettering. The “uncured” product must comply with the standard performance characteristics for the cured product. See FSIS Regulation §319.2.
- Vacuum Mixer** A mechanical device used to mix sausage emulsions under vacuum in order to reduce the occurrence of air pockets in the finished product.
- Variety Meats in Franks** Cooked sausages with variety meats must contain not less than 15% red skeletal meat based in the total meat block.
- Weisswurst** An acceptable name for fresh sausage. It is usually made of pork or veal and must be thoroughly cooked before eating.
- Whole Hog Sausage** Must contain all primal parts of a hog, such as hams and loins. Hearts and tongues, in natural proportions, are permitted ingredients when declared in the ingredients statement. Other meat by-products are not permitted. See FSIS Regulations §319.144.
- Wholesomeness** Not adulterated. All meat and meat by-products used in sausage formulations must be clean, wholesome and properly labeled. The manufacturing facility must inspect all incoming meat to ensure that is not contaminated. Even previously inspected meat must be re-inspected to ensure that it has not become contaminated during transit.

Appendices

This manual contains the following appendices:

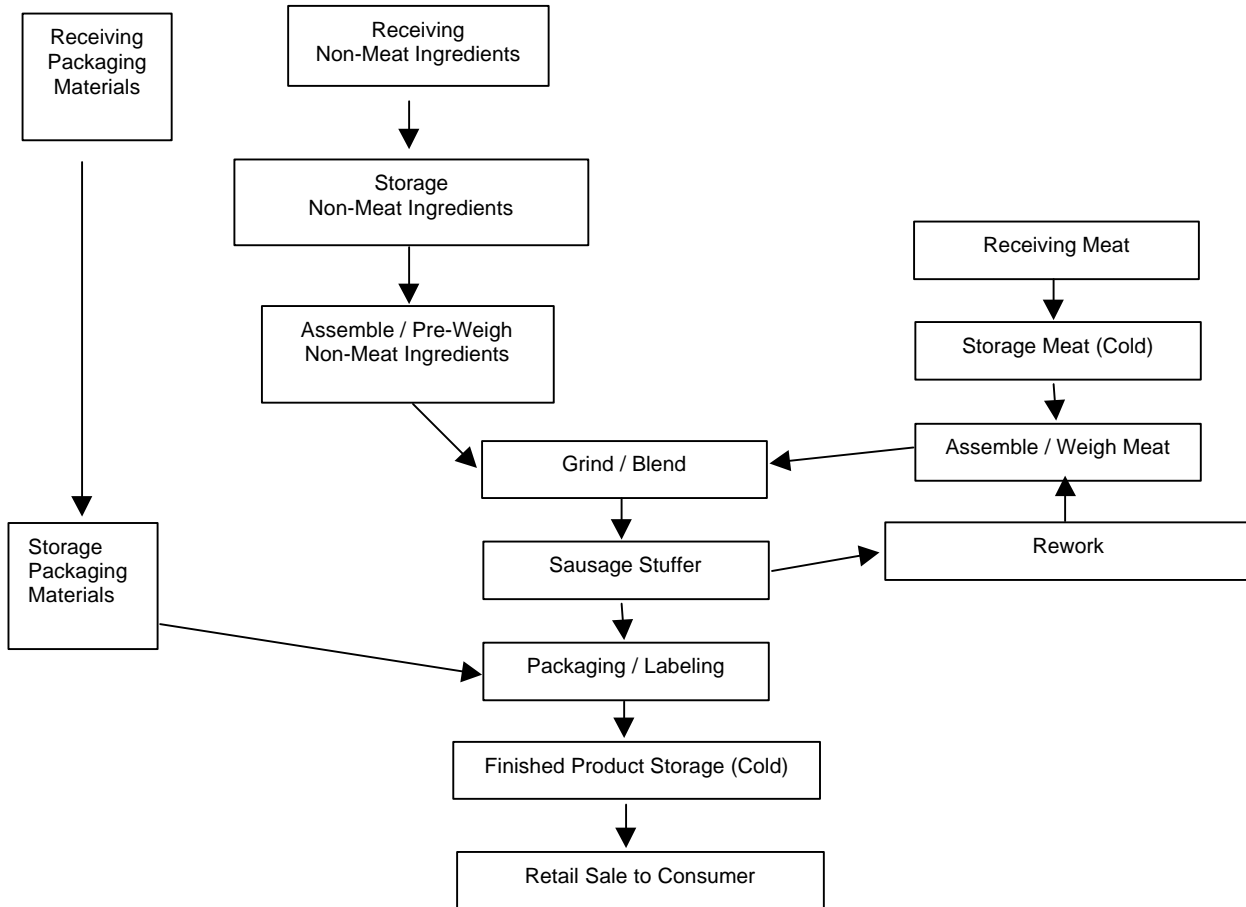
- Appendix A: Process Flow Diagrams
- Appendix B: Applicable FSIS Regulations
- Appendix C: FSIS Listeria Guidelines for Industry, May, 1999
- Appendix D: Guidance for Minimizing Impact Associated with a Food Safety Hazard in Raw Ground Meat and Other FSIS Regulated Products”, December, 1998

Appendix: A

Process Flow Diagram

Process Category: Raw Product, Ground

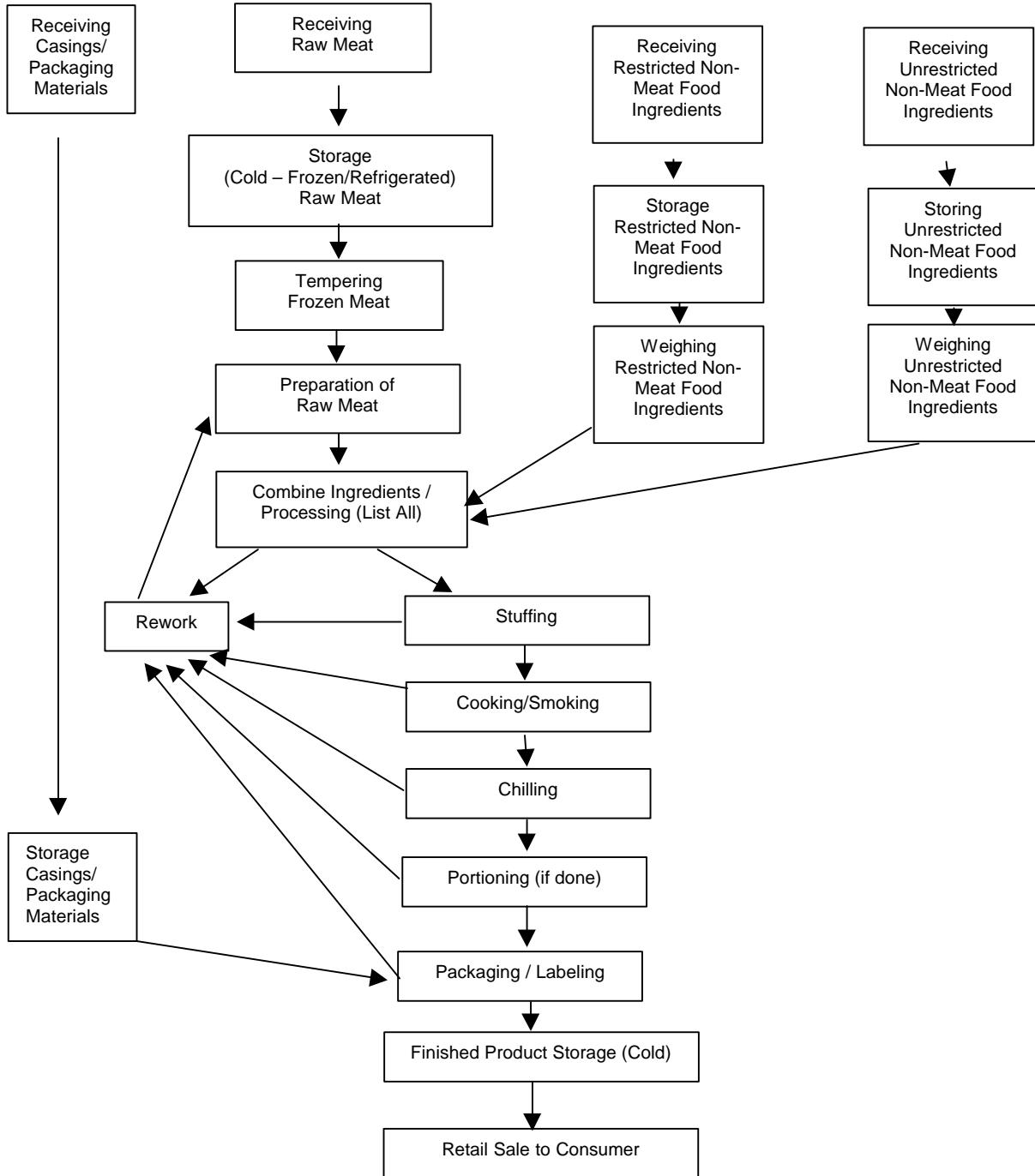
Product: Fresh Pork Sausage



Process Flow Diagram

Process Category: Fully Cooked, Not Shelf Stable

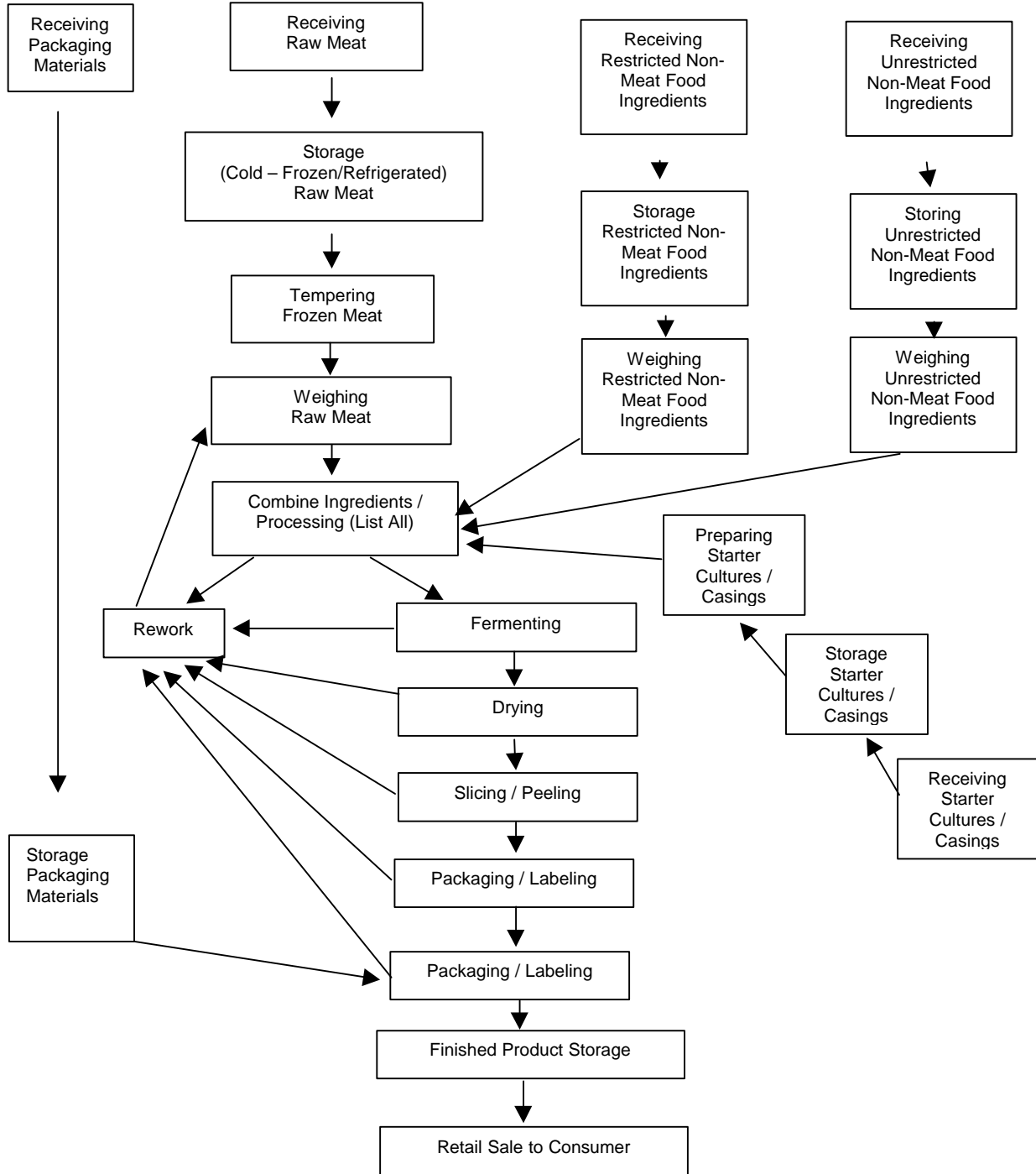
Product: Frankfurters and Bologna



Process Flow Diagram

Process Category: Not Heat Treated, Shelf Stable

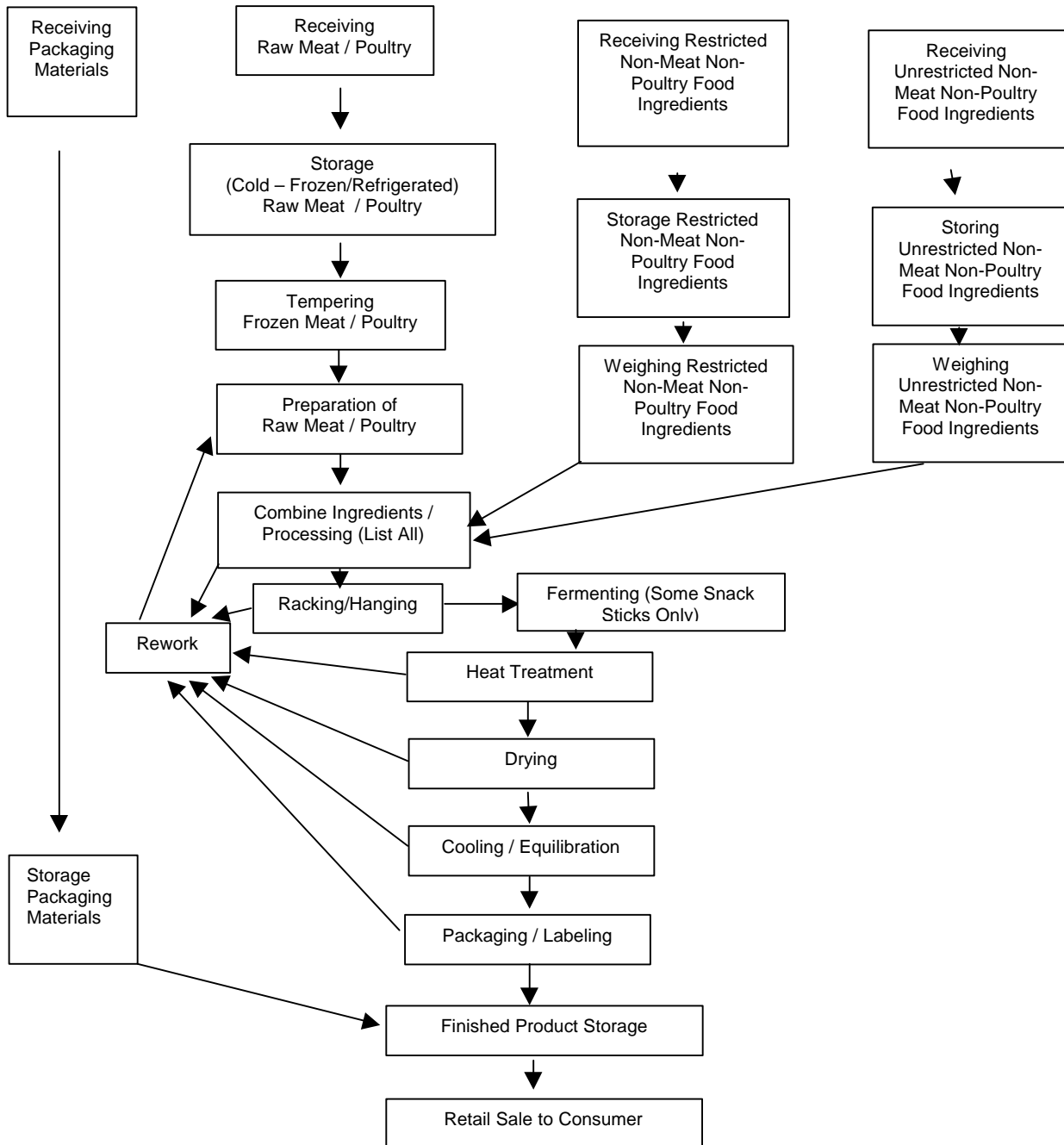
Product: Pepperoni and Salami



Process Flow Diagram

Process Category: Heat Treated, Shelf Stable

Product: Snack Sticks, Jerky



Appendix: B Applicable FSIS Regulations

Selected text of the FSIS Regulations that pertain to this training program;
*** marks missing material; please see
<http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html#page1> for complete text.

Code of Federal Regulations

TITLE 9--ANIMALS AND ANIMAL PRODUCTS

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

PART 318--ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS-

Sec. 318.6 Requirements concerning ingredients and other articles used in preparation of products.

(a) All ingredients and other articles used in the preparation of any product shall be clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated. Official establishments shall furnish inspectors accurate information on all procedures involved in product preparation including product composition and any changes in such procedures essential for inspectional control of the product.

(b)(1) The only animal casings that may be used as containers of product are those from cattle, sheep, swine, or goats.

(2) Casings for products shall be carefully inspected by Program employees. Only those casings which have been carefully washed and thoroughly flushed with clean water immediately before stuffing and are suitable for containers, are clean, and are passed on such inspection shall be used, except that preflushed animal casings packed in salt or salt and glycerine solution or other approved medium may be used without additional flushing provided they are found to be clean and otherwise acceptable and are thoroughly rinsed before use.

(3) Hog and sheep casings intended for use as containers of product may be treated by soaking in or applying thereto sound, fresh pineapple juice or papain or bromelin or pancreatic extract to permit the enzymes contained in these substances to act on the casings to make them less resistant. The casings shall be handled in a clean and sanitary manner throughout and the treatment shall be followed by washing and flushing the casings with water sufficiently to effectively remove the substance used and terminate the enzymatic action.

Sec. 318.10 Prescribed treatment of pork and products containing pork to destroy trichinae.

(a)(1) All forms of fresh pork, including fresh unsmoked sausage containing pork muscle tissue, and pork such as bacon and jowls, other than those covered by paragraph (b) of this section, are classed as products that are customarily well cooked in the home or elsewhere before being served to the consumer. Therefore, the treatment of such products for the destruction of trichinae is not required.

(2) Pork from carcasses or carcass parts that have been found free of trichinae as described under paragraph (e) or (f) of this section is not required to be treated for the destruction of trichinae.

(b) Products named in this paragraph, and products of the character thereof, containing pork muscle tissue (not including pork hearts, pork stomachs, and pork livers), or the pork muscle tissue which forms an ingredient of such products, shall be effectively heated, refrigerated, or

cured to destroy any possible live trichinae, as prescribed in this section at the official establishment where such products are prepared: Bologna, frankfurter, vienna, and other cooked sausage; smoked sausage; knoblauch sausage; mortadella; all forms of summer or dried sausage, including mettwurst; flavored pork sausages such as those containing wine or similar flavoring materials; cured pork sausage; sausage containing cured and/or smoked pork; cooked loaves; roasted, baked, boiled, or cooked hams, pork shoulders, or pork shoulder picnics; Italian-style hams; Westphalia-style hams; smoked boneless pork shoulder butts; cured meat rolls; capocollo (capicola, capicola); coppa; fresh or cured boneless pork shoulder butts, hams, loins, shoulders, shoulder picnics, and similar pork cuts, in casings or other containers in which ready-to-eat delicatessen articles are customarily enclosed (excepting Scotch-style hams); breaded pork products; cured boneless pork loins; boneless back bacon; bacon used for wrapping around patties, steaks and similar products; and smoked pork cuts such as hams, shoulders, loins, and pork shoulder picnics (excepting smoked hams, and smoked pork shoulder picnics which are specially prepared for distribution in tropical climates or smoked hams delivered to the Armed Services); ground meat mixtures containing pork and beef, veal, lamb, mutton, or goat meat and other product consisting of mixtures of pork and other ingredients, which the Administrator determines at the time the labeling for the product is submitted for approval in accordance with part 317 of the regulations in this subchapter or upon subsequent reevaluation of the product, would be prepared in such a manner that the product might be eaten rare or without thorough cooking because of the appearance of the finished product or otherwise. Cured boneless pork loins shall be subjected to prescribed treatment for destruction of trichinae prior to being shipped from the establishment where cured.

(c) The treatment shall consist of heating, refrigerating, or curing, as follows:

(1) *Heating.* (i) All parts of the pork muscle tissue shall be heated according to one of the time and temperature combinations in the following table:

Minimum internal temperature		
Degrees fahrenheit	Degrees centigrade	Minimum time
120.....	49.0	21 hours.
122.....	50.0	9.5 hours.
124.....	51.1	4.5 hours.
126.....	52.2	2 hours.
128.....	53.4	1 hour.
130.....	54.5	30 minutes.
132.....	55.6	15 minutes.
134.....	56.7	6 minutes.
136.....	57.8	3 minutes.
138.....	58.9	2 minutes.
140.....	60.0	1 minute.
142.....	61.1	1 minute.
144.....	62.2	Instant.

(ii) Time and temperature shall be monitored by a calibrated recording instrument that meets the requirements of paragraph (d) of this section, except for paragraph (c)(1)(iv).

(iii) The time to raise product temperature from 60 deg. F. to 120 deg. F shall not exceed 2 hours unless the product is cured or fermented.

(iv) Time, in combination with temperatures of 138 deg. F to 143 deg. F, need not be monitored if the product's minimum thickness exceeds 2 inches

(5.1 cm) and refrigeration of the product does not begin within 5 minutes of attaining 138 deg. F (58.9 deg. C).

(v) The establishment shall use procedures which insure the proper heating of all parts of the product. It is important that each piece of sausage, each ham, and other product treated by heating in water be kept entirely submerged throughout the heating period; and that the largest pieces in a lot, the innermost links of bunched sausage or other massed articles, and pieces placed in the coolest part of a heating cabinet or compartment or vat be included in the temperature tests.

(2) *Refrigerating.* At any stage of preparation and after preparatory chilling to a temperature of not above 40 deg.F. or preparatory freezing, all parts of the muscle tissue of pork or product containing such tissue shall be subjected continuously to a temperature not higher than one of those specified in table 1, the duration of such refrigeration at the specified temperature being dependent on the thickness of the meat or inside dimensions of the container.

Table 1--Required Period of Freezing at Temperature Indicated

Temperature deg.F.	Group 1 (Days)	Group 2 (Days)
5	20	30
-10	10	20
-20	6	12

(i) Group 1 comprises product in separate pieces not exceeding 6 inches in thickness, or arranged on separate racks with the layers not exceeding 6 inches in depth, or stored in crates or boxes not exceeding 6 inches in depth, or stored as solidly frozen blocks not exceeding 6 inches in thickness.

(ii) Group 2 comprises product in pieces, layers, or within containers, the thickness of which exceeds 6 inches but not 27 inches, and product in containers including tierces, barrels, kegs, and cartons having a thickness not exceeding 27 inches.

(iii) The product undergoing such refrigeration or the containers thereof shall be so spaced while in the freezer as will insure a free circulation of air between the pieces of meat, layers, blocks, boxes, barrels, and tierces in order that the temperature of the meat throughout will be promptly reduced to not higher than 5 deg.F., -10 deg.F., or -20 deg.F., as the case may be.

(iv) In lieu of the methods prescribed in Table 1, the treatment may consist of commercial freeze drying or controlled freezing, at the center of the meat pieces, in accordance with the times and temperatures specified in Table 2.

Table 2--Alternate Periods of Freezing at Temperatures Indicated

Maximum internal temperature		
Degrees Fahrenheit	Degrees centigrade	Minimum Time
0.....	-17.8	106 hours.
-5.....	-20.6	82 hours.
-10.....	-23.3	63 hours.
-15.....	-26.1	48 hours.
-20.....	-28.9	35 hours.
-25.....	-31.7	22 hours.
-30.....	-34.5	8 hours.
-35.....	-37.2	1/2 hour.

(v) During the period of refrigeration the product shall be kept separate from other products and in the custody of the Program in rooms or

compartments equipped and made secure with an official Program lock or seal. The rooms or compartments containing product undergoing freezing shall be equipped with accurate thermometers placed at or above the highest level at which the product undergoing treatment is stored and away from refrigerating coils. After completion of the prescribed freezing of pork to be used in the preparation of product covered by paragraph (b) of this section the pork shall be kept under close supervision of an inspector until it is prepared in finished form as one of the products enumerated in paragraph (b) of this section or until it is transferred under Program control to another official establishment for preparation in such finished form.

(vi) Pork which has been refrigerated as specified in this subparagraph may be transferred in sealed railroad cars, sealed motortrucks, sealed trailers, or sealed closed containers to another official establishment at the same or another location, for use in the preparation of product covered by paragraph (b) of this section. Such vehicles and containers shall be sealed and transported between official establishments in accordance with Sec. 325.7 of this subchapter.

(3) *Curing--(i) Sausage.* The sausage may be stuffed in animal casings, hydrocellulose casings, or cloth bags. During any stage of treating the sausage for the destruction of live trichinae, except as provided in Method 5, these coverings shall not be coated with paraffin or like substance, nor shall any sausage be washed during any prescribed period of drying. In the preparation of sausage, one of the following methods may be used:

Method No. 1. The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage shall be thoroughly mixed with the ground or chopped meat. After being stuffed, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, shall be held in a drying room not less than 20 days at a temperature not lower than 45 deg.F., except that in sausage of the variety known as pepperoni, if in casings not exceeding 1 3/8 inches in diameter measured at the time of stuffing, the period of drying may be reduced to 15 days. In no case, however, shall the sausage be released from the drying room in less than 25 days from the time the curing materials are added, except that sausage of the variety known as pepperoni, if in casings not exceeding the size specified, may be released at the expiration of 20 days from the time the curing materials are added. Sausage in casings exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing, shall be held in a drying room not less than 35 days at a temperature not lower than 45 deg.F., and in no case shall the sausage be released from the drying room in less than 40 days from the time the curing materials are added to the meat.

Method No. 2. The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage shall be thoroughly mixed with the ground or chopped meat. After being stuffed, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, shall be smoked not less than 40 hours at a temperature not lower than 80 deg.F., and finally held in a drying room not less than 10 days at a temperature not lower than 45 deg.F. In no case, however, shall the sausage be released from the drying room in less than 18 days from the time the curing materials are added to the meat. Sausage exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing, shall be held in a drying room, following smoking as above indicated, not less than 25 days at a temperature not lower than 45 deg.F., but in no case shall the sausage be released from the drying room in less than 33 days from the time the curing materials are added to the meat.

Method No. 3. The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage shall be thoroughly mixed with the ground or chopped meat. After admixture with the salt and other curing materials and before stuffing, the ground or chopped meat shall be held at a temperature not lower than 34 deg.F. for not less than 36 hours. After being stuffed, the sausage shall be held at a temperature not lower than 34 deg.F. for an additional period of time sufficient to make a total of not less than 144 hours from the time the curing materials are added to the meat, or the sausage shall be held for the time specified in a pickle-curing medium of not less than 50 deg. strength (salometer reading) at a temperature not lower than 44 deg.F. Finally, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, shall be smoked for not less than 12 hours. The temperature of the smokehouse during this period at no time shall be lower than 90 deg.F.; and for 4 consecutive hours of this period the smokehouse shall be maintained at a temperature not lower than 128 deg.F. Sausage exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of

stuffing shall be smoked, following the prescribed curing, for not less than 15 hours. The temperature of the smokehouse during the 15-hour period shall at no time be lower than 90 deg.F., and for 7 consecutive hours of this period the smokehouse shall be maintained at a temperature not lower than 128 deg.F. In regulating the temperature of the smokehouse for the treatment of sausage under this method, the temperature of 128 deg.F. shall be attained gradually during a period of not less than 4 hours.

Method No. 4. The meat shall be ground or chopped into pieces not exceeding one-fourth of an inch in diameter. A dry-curing mixture containing not less than 2 ½ pounds of salt to each hundredweight of the unstuffed sausage shall be thoroughly mixed with the ground or chopped meat. After admixture with the salt and other curing materials and before stuffing, the ground or chopped sausage shall be held as a compact mass, not more than 6 inches in depth, at a temperature not lower than 36 deg.F. for not less than 10 days. At the termination of the holding period, the sausage shall be stuffed in casings or cloth bags not exceeding 3 1/3 inches in diameter, measured at the time of stuffing. After being stuffed, the sausage shall be held in a drying room at a temperature not lower than 45 deg.F. for the remainder of a 35-day period, measured from the time the curing materials are added to the meat. At any time after stuffing, if the establishment operator deems it desirable, the product may be heated in a water bath for a period not to exceed 3 hours at a temperature not lower than 85 deg.F., or subjected to smoking at a temperature not lower than 80 deg.F., or the product may be both heated and smoked as specified. The time consumed in heating and smoking, however, shall be in addition to the 35-day holding period specified.

Method No. 5. The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage shall be thoroughly mixed with the ground or chopped meat. After being stuffed, the sausage shall be held for not less than 65 days at a temperature not lower than 45 deg.F. The coverings for sausage prepared according to this method may be coated at any stage of the preparation before or during the holding period with paraffin or other substance approved by the Administrator.

Method No. 6. (A) Basic requirements. The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3.33 pounds of salt to each hundredweight of the unstuffed sausage, excluding the weight of dry ingredients, shall be thoroughly mixed with the ground or chopped meat. After the curing mixture has been added, the sausage shall be held for two time periods, a holding period and a drying period. The holding period will be for a minimum of 48 hours at a room temperature not lower than 35 deg.F. This holding period requirement may be fulfilled totally or in part before the drying period and then the remainder, if any, after the drying period or as an extension of the drying period. During the drying period, the sausage shall be held in a drying room at a temperature not lower than 50 (10.0 deg.F. 10.0 deg.C) for a period of time determined by Tables 3A, 3B, and 4. The length of the drying period, established in (c)(3)(i)(A), may be modified as provided in paragraphs (c)(3)(i)(B) and (c)(3)(i)(C) of this section.

Table 3A--Sausage Drying Room Times by Method No. 6

Diameter of casing at time of stuffing\1\	Days in drying room\2\

Up to:	
1 inches.....	14
1 ½ inches.....	15
2 inches.....	16
2 ½ inches.....	18
3 inches.....	20
3 ½ inches.....	23
4 inches.....	25
4 ½ inches.....	30
5 inches.....	35
5 ½ inches.....	43
6 inches.....	50

\1\ The drying room times for flattened or oval sausages shall use a diameter derived by measuring the circumference and dividing by 3.14 (pi).

\2\ Drying room time may be modified as set forth in Tables 3B and 4.

(B) *Reduction in Drying Room Time.* During the holding period, the sausage may be smoked or fermented. If the temperature is increased to 70 deg.F. (21.1 deg.C) or higher, while the sausage is being held after adding curing materials but before the drying period, the subsequent drying room times prescribed for this method may be reduced according to the schedule in Table 3B. No interpolation of values is permissible.

Table 3B--Percentage Reduction in Drying Room Time (Table 3A) Permitted by

Holding Times and Temperatures Prior to Drying \1\

Minimum temperature \2\										

Minimum Time	70F	75F	80F	85F	90F	95F	100F	105F	110F	120F

	21.1C	23.9C	26.7C	29.5C	32.2C	35.0C	37.9C	40.6C	43.3C	48.9C

24 hour	4	5	8	10	15	23	37	57	90	\3\100
48 hours	9	12	18	25	35	49	88	\3\100	\3\100	100
72 hours	14	19	28	39	55	74	\3\100	100	100	100
96 hours	19	26	38	53	75	98	100	100	100	100
120 hours	24	33	48	67	95	\3\100	100	100	100	100

\1\ In computing the days to be deducted, the number with any fraction shall be rounded to the next lower whole number and shall be deducted from the required total drying time. Example: Sausage stuffed in 3" diameter casing requires 20 days in the drying room (from Drying Room Times, Table 3A). If allowed to ferment, after addition of curing materials, at 80 F. for 48 hours, the 20 day drying time may be reduced 18% (from Table 3B). Eighteen percent of 20 day equals 3.6 days. Twenty days minus 3 days equals 17 days. The total drying time required in the drying room, therefore, will be 17 days.

\2\ Either room temperature or internal product temperature shall be used for sausages that will be subsequently dried to a moisture-protein ratio of 2.3:1 or less. Internal product temperature shall be used for all other sausages.

\3\ Trichinae will be destroyed during fermentation or smoking at the temperature and length of time indicated. Therefore, no drying room period is required for products so treated.

(C) *Reduced Salt Content--Drying Room Times.* Salt content of less than 3.33 pounds for each hundredweight of sausage formulation, excluding dry ingredients, (such as salts, sugars, and spices), may be permitted provided the drying time is increased according to the schedule contained in Table 4.

Trichina Treatment of Sausage by Method No. 6; Table 4--Reduced Salt Content--Drying Room Times[Required percentage increase in drying room time (table 3A) for added salt of less than 3.33 pounds per hundredweight of sausage]

Minimum pounds of salt added to sausage \1\	Increase in drying room time \2\

3.3.....	1
3.2.....	4
3.1.....	7
3.0.....	10
2.9.....	13
2.8.....	16
2.7.....	19
2.6.....	22
2.5.....	25
2.4.....	28
2.3.....	31
2.2.....	34
2.1.....	37
2.0.....	40

\1\ Calculate the salt content for column 1 as follows: Multiply the pounds of salt in the sausage formulation by 100. Then divide this number by the total weight of sausage formulation minus the weight of dry ingredients and round down to the next lowest 0.1%. Percents may be substituted for pounds.

Example: 120 lbs. pork, 3.56 lbs. salt, 2 lbs. spices, 0.5 lbs. wine, 1 lb. water and starter culture, 0.8 lbs. sugar, .012 lbs. sodium nitrite total weight is 127.872 lbs.

$$(3.56 \times 100) / (127.872 - 3.56 - 2 - .8 - .012) = 356 / 121.5 = 2.93$$

Therefore, the sausage drying time must be increased by 13 percent.

\2\ In computing the days to be added to the required total drying time, fractions shall be rounded to the next higher whole number and added to the required total drying time. Example: Sausage stuffed in 3 1/2 inch diameter casing requires 23 days in the drying room (from Drying Room Times). If the quantity of salt added per hundredweight of sausage is 2 pounds instead of 3.33 pounds, the drying room time must be increased by 40 percent (from Reduced Salt Content-

Drying Room Times), or 9.2 days. The 9.2 is rounded up to 10 days and is added to the 23 days to equal 33 days. The total drying time required in the drying room, therefore, will be 33 days.

Method No. 7, Dry Sausages.

(A) *General Requirements.* The establishment shall use meat particles reduced in size to no more than 1/4 inch in diameter. The establishment shall add a curing mixture containing no less than 2.7 pounds of salt per hundred pounds of meat and mix it uniformly throughout the product. The establishment shall hold, heat, and dry the product according to paragraph (B) or (C) below.

(B) *Holding, Heating, and Drying Treatment, Large Sausages.* Except as permitted in (C) below, the establishment shall subject sausages in casings not exceeding 105 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods.

Treatment Schedule for Sausages 105 Millimeters (4 1/8 Inches) or Less in Diameter

Minimum chamber temperature		Minimum time (hours)
(deg.F)	(deg.C)	
50.....	10	12
90.....	32.2	1
100.....	37.8	1
110.....	43.3	1
120.....	48.9	1
125.....	51.7	7

Following the preceding treatment, the establishment shall dry the sausages at a temperature not lower than 50 deg.F (10 deg.C) for not less than 7 days.

(C) *Heating and Drying Treatment, Small Sausages.* Alternatively, the establishment may subject sausages in casings not exceeding 55 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods.

Treatment Schedule for Sausages 55 Millimeters (2 1/8 Inches) or Less in Diameter

Minimum chamber temperature		Minimum time (hours)
(deg.F)	(deg.C)	
50.....	10	12
100.....	37.8	1
125.....	51.7	6

Following the preceding heat treatment, the establishment shall dry the sausages at a temperature not lower than 50 deg.F (10 deg.C) for not less than 4 days.

(d) General instructions: When necessary to comply with the requirements of this section, the smokehouses, drying rooms, and other compartments used in the treatment of pork to destroy possible live trichinae shall be suitably equipped, by the operator of the official establishment, with accurate automatic recording thermometers. Circuit supervisors are authorized to approve for use in sausage smokehouses, drying rooms, and other compartments, such automatic recording thermometers as are found to give satisfactory service and to disapprove and require discontinuance of use, for purposes of the regulations in this subchapter, any thermometers (including any automatic recording thermometers) of the establishment that are found to be inaccurate or unreliable.

PART 319--DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

Sec. 319.2 Products and nitrates and nitrites.

Any product, such as frankfurters and corned beef, for which there is a standard in this part and to which nitrate or nitrite is permitted or

required to be added, may be prepared without nitrate or nitrite and labeled with such standard name when immediately preceded with the term ``Uncured'' in the same size and style of lettering as the rest of such standard name: Provided, That the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate and nitrite: And provided further, That labeling for such product complies with the provisions of Sec. 317.17(c) of this subchapter.

E--Sausage Generally: Fresh Sausage

Sec. 319.140 Sausage.

Except as otherwise provided in this section, or under the Poultry Products Inspection Act with respect to products consisting partly of poultry, sausage is the coarse or finely comminuted meat food product prepared from one or more kinds of meat or meat and meat byproducts, containing various amounts of water as provided for elsewhere in this part, and usually seasoned with condimented proportions of condimental substances, and frequently cured. Certain sausage as provided for elsewhere in this part may contain binders and extenders as provided in Sec. 318.7(c)(4) of this subchapter. Sausage may not contain phosphates except that phosphates listed in Sec. 318.7(c)(4) of this subchapter may be used in cooked sausage. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of sausage which is not cooked in an amount not to exceed 3 percent of the total ingredients in the formula. Cooked sausages such as Polish sausage, cotto salami, braunschweiger, liver sausage, and similar cooked sausage products may contain no more than 10 percent of added water in the finished product. Sausage may contain Mechanically Separated (Species) used in accordance with Sec. 319.6.

Sec. 319.141 Fresh pork sausage.

``Fresh Pork Sausage'' is sausage prepared with fresh pork or frozen pork or both, but not including pork byproducts, and may contain Mechanically Separated (Species) in accordance with Sec. 319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

Sec. 319.142 Fresh beef sausage.

``Fresh Beef Sausage'' is sausage prepared with fresh beef or frozen beef, or both, but not including beef byproducts, and may contain Mechanically Separated (Species) used in accordance with Sec. 319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 30 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

Sec. 319.143 Breakfast sausage.

``Breakfast sausage'' is sausage prepared with fresh and/or frozen meat; or fresh and/or frozen meat and meat byproducts, and may contain Mechanically Separated (Species) in accordance with Sec. 319.6, and may be seasoned with condimental substances as permitted in part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate

chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used. Binders or extenders may be added as provided in Sec. 318.7(c)(4) of this subchapter.

Sec. 319.144 Whole hog sausage.

``Whole Hog Sausage'' is sausage prepared with fresh and/or frozen meat from swine in such proportions as are normal to a single animal, and may include any Mechanically Separated (Species) produced from the animal and used in accordance with Sec. 319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

Sec. 319.145 Italian sausage products.

(a) Italian sausage products are cured or uncured sausages containing at least 85 percent meat, or combination of meat and fat, with the total fat content constituting not more than 35 percent of the finished product. Such products shall be prepared in accordance with the provisions of paragraph (a) (1), (2) or (3) of this section, and shall contain salt, pepper, and either fennel or anise, or a combination of fennel and anise. Such products may contain any or all of the optional ingredients listed in paragraph (b) of this section.

(1) ``Italian Sausage'' shall be prepared with fresh or frozen pork, or pork and pork fat, and may contain Mechanically Separated (Species) in accordance with Sec. 319.6.

(2) ``Italian Sausage with Beef,'' ``Italian Sausage with Veal,'' or ``Italian Sausage with Beef and Veal,'' shall be prepared so that fresh or frozen pork constitutes the major portion of the meat content requirement of this paragraph. Mechanically Separated (Species) may be used in accordance with Sec. 319.6. When pork muscle tissue is combined with beef or veal, or both, in the preparation of bulk-packed products, or patties, it shall be treated for the destruction of possible live trichinae in accordance with Sec. 318.10 of this subchapter.

(3) ``Italian Beef Sausage'' or ``Kosher Italian Beef Sausage'' shall be prepared with fresh or frozen beef or beef and beef fat. ``Italian Veal Sausage'' or ``Kosher Italian Veal Sausage'' shall be prepared with fresh or frozen veal or veal and veal fat. Mechanically Separated (Species) may be used in accordance with Sec. 319.6.

(4) Italian sausage products made in conformance with the provisions of paragraphs (a) (1), (2), and (3) of this section, and with paragraphs (b) and (c) of this section, may contain sodium nitrite or potassium nitrite in amounts not to exceed those allowed in the chart following Sec. 318.7(c)(4), provided that such products are labeled with the word ``cured'' in the product name, such as ``Cured Italian Sausage.'' The word ``cured'' shall be displayed on the product label in the same size and style of lettering as other words in the product name.

(b) Optional ingredients permitted in Italian sausage products include:

- (1) Spices (including paprika) and flavorings.
- (2) Water or ice to facilitate chopping or mixing, but not to exceed 3 percent of the total weight of all ingredients including the water.
- (3) Red or green peppers, or both.
- (4) Dehydrated or fresh onions, garlic, and parsley.
- (5) Sugar, dextrose, corn syrup, corn syrup solids, and glucose syrup.
- (6) Monosodium glutamate and antioxidants in accordance with the chart of substances in Sec. 318.7(c)(4) of this subchapter.

(c) If Italian sausage products are cooked or smoked, determination of compliance with the provisions of paragraphs (a) and (b) of this section shall be based on the uncooked or unsmoked product. The product before cooking or smoking shall contain no more than 3 percent water as specified in paragraph (b)(2) of this section. Product which is cooked shall be labeled with the word ``cooked'' in the product name, such as ``Cooked Italian Sausage'' or ``Cooked Cured Italian Sausage.'' Product which is smoked shall be labeled with the word ``smoked'' in the product name, such as ``Smoked Italian Sausage'' or ``Smoked Cured Italian Sausage.'' The words ``cooked'' and ``smoked'' shall be displayed on the product label in the same size and style of lettering as other words in the product name.

F--Uncooked, Smoked Sausage

Sec. 319.160 Smoked pork sausage.

``Smoked Pork Sausage'' is pork sausage that is smoked with hardwood or other approved nonresinous materials. It may be seasoned with condimental substances as permitted in part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water, or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

G--Cooked Sausage

Sec. 319.180 Frankfurter, frank, furter, hotdog, weiner, vienna, bologna, garlic bologna, knockwurst, and similar products.

(a) Frankfurter, frank, furter, hot-dog, wiener, vienna, bologna, garlic bologna, knockwurst and similar cooked sausages are comminuted, semisolid sausages prepared from one or more kinds of raw skeletal muscle meat or raw skeletal muscle meat and raw or cooked poultry meat, and seasoned and cured, using one or more of the curing agents in accordance with Sec. 318.7(c) of this chapter. They may or may not be smoked. The finished products shall not contain more than 30 percent fat. Water or ice, or both, may be used to facilitate chopping or mixing or to dissolve the curing ingredients but the sausage shall contain no more than 40 percent of a combination of fat and added water. These sausage products may contain only phosphates approved under part 318 of this chapter. Such products may contain raw or cooked poultry meat and/or Mechanically Separated (Kind of Poultry) without skin and without kidneys and sex glands used in accordance with Sec. 381.174, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and Mechanically Separated (Species) used in accordance with Sec. 319.6. Such poultry meat ingredients shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of Sec. 381.118 of this chapter.

(b) Frankfurter, frank, furter, hot-dog, wiener, vienna, bologna, garlic bologna, knockwurst and similar cooked sausages that are labeled with the phrase ``with byproducts'' or ``with variety meats'' in the product name are comminuted, semisolid sausages consisting of not less than 15 percent of one or more kinds of raw skeletal muscle meat with raw meat byproducts, or not less than 15 percent of one or more kinds of raw skeletal muscle meat with raw meat byproducts and raw or cooked poultry products; and seasoned and cured, using one or more of the curing ingredients in accordance with Sec. 318.7(c) of this chapter. They may or may not be smoked. Partially defatted pork fatty tissue or

partially defatted beef fatty tissue, or a combination of both, may be used in an amount not exceeding 15 percent of the meat and meat byproducts or meat, meat byproducts, and poultry products ingredients. The finished products shall not contain more than 30 percent fat. Water or ice, or both, may be used to facilitate chopping or mixing to dissolve the curing and seasoning ingredients, the sausage shall contain no more than 40 percent of a combination of fat and added water. These sausage products may contain only phosphates approved under part 318 of this chapter. These sausage products may contain poultry products and/or Mechanically Separated (Kind of Poultry) used in accordance with Sec. 381.174, individually or in combination, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and may contain Mechanically Separated (Species) used in accordance with Sec. 319.6. Such poultry products shall not contain kidneys or sex glands. The amount of poultry skin present in the sausage must not exceed the natural proportion of skin present on the whole carcass of the kind of poultry used in the sausage, as specified in Sec. 381.117(d) of this chapter. The poultry products used in the sausage shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of Sec. 381.118 of this chapter. Meat byproducts used in the sausage shall be designated individually in the ingredient statement on the label for such sausage in accordance with Sec. 317.2 of this chapter.

(c) A cooked sausage as defined in paragraph (a) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst. When such sausage products are prepared with meat from a single species of cattle, sheep, swine, or goats they shall be labeled with the term designating the particular species in conjunction with the generic name, e.g., ``Beef Frankfurter,'' and when such sausage products are prepared in part with Mechanically Separated (Species) in accordance with Sec. 319.6, they shall be labeled in accordance with Sec. 317.2(j)(13) of this subchapter.

(d) A cooked sausage as defined in paragraph (b) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst, in conjunction with the phrase ``with byproducts'' or ``with variety meats'' with such supplemental phrase shown in a prominent manner directly contiguous to the generic name and in the same color on an identical background.

(e) One or more of the binders and extenders as provided in Sec. 18.7(c)(4) of this subchapter may be used in cooked sausage otherwise complying with paragraph (a) or (b) of this section. When any such substance is added to these products, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance.

(f) Cooked sausages shall not be labeled with terms such as ``All Meat'' or ``All (Species),'' or otherwise to indicate they do not contain nonmeat ingredients or are prepared only from meat.

(g) For the purposes of this section: Poultry meat means deboned chicken meat or turkey meat, or both, without skin or added fat; poultry products mean chicken or turkey, or chicken meat or turkey meat as defined in Sec. 381.118 of this chapter, or poultry byproducts as defined in Sec. 381.1 of this chapter; and meat byproducts (or variety meats), mean pork stomachs or snouts; beef, veal, lamb, or goat tripe; beef, veal, lamb, goat, or pork hearts, tongues, fat, lips, weasands, and spleens; and partially defatted pork fatty tissue, or partially defatted beef fatty tissue.

Sec. 319.181 Cheesefurters and similar products.

``Cheesefurters'' and similar products are products in casings which resemble frankfurters except that they contain sufficient cheese to give definite characteristics to the finished article. They may contain binders and extenders as provided in Sec. 318.7(c)(4) of this subchapter. Limits on

use as provided in Sec. 318.7 are intended to be exclusive of the cheese constituent. When any such substance is added to these products, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance. These products shall contain no more than 40 percent of a combination of fat and added water, and no more than 30 percent fat and shall comply with the other provisions for cooked sausages that are in this subchapter.

Sec. 319.182 Braunschweiger and liver sausage or liverwurst.

(a) ``Braunschweiger'' is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, and/or veal livers computed on the weight of the fresh livers. It may also contain pork and/or beef fat. Mechanically Separated (Species) may be used in accordance with Sec. 319.6. Binders and extenders may be used as permitted in Sec. 319.140. The product may have a smoked taste characteristic, which may be imparted by use of smoked meats, smoke flavoring or smoking. If prepared from components of a single species, the product name may reflect the species, e.g., ``Beef Braunschweiger.'' Braunschweiger may also be labeled as any of the following: ``Braunschweiger--A Liver Sausage,'' ``Braunschweiger--A Liverwurst,'' or ``Braunschweiger (Liver Sausage)'' or ``Braunschweiger (Liverwurst).''

(b) ``Liver Sausage'' or ``Liverwurst'' is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, veal, sheep, and/or goat livers computed on the weight of the fresh livers. It may also contain pork and/or beef byproducts. Mechanically Separated (Species) may be used in accordance with Sec. 319.6. Binders and extenders maybe used as permitted in Sec. 319.140. If prepared from components of a single species, the product name may reflect that species, e.g., ``Pork Liver Sausage.''

K--Luncheon Meat, Loaves and Jellied Products

Sec. 319.260 Luncheon meat.

``Luncheon Meat'' is a cured, cooked meat food product made from comminuted meat. Mechanically Separated (Species) may be used in accordance with Sec. 319.6. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of luncheon meat in an amount not to exceed 3 percent of the total ingredients.

Sec. 319.261 Meat loaf.

``Meat Loaf'' is a cooked meat food product in loaf form made from comminuted meat. Mechanically Separated (Species) may be used in accordance with Sec. 319.6. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

Appendix: C FSIS Listeria Guidelines for Industry, May, 1999

The Food Safety and Inspection Service (FSIS) has published a Federal Register notice to ensure that the owners and operators of federally inspected establishments are aware of the Agency's views about the application of its hazard analysis and critical control point (HACCP) system regulations to contamination with *Listeria monocytogenes*, and to provide the public with an opportunity to comment on the Agency's views.

FSIS believes that the findings from testing a range of ready-to-eat products and information from investigations of outbreaks of listeriosis constitute changes that could affect an establishment's hazard analysis and could alter the HACCP plan for affected products. Therefore, under 9CFR417.4, establishments must reassess their HACCP plans for ready-to-eat meat and poultry products. If reassessment results in a determination that *L. monocytogenes* contamination is a food safety hazard reasonably likely to occur in the production process, then it is a type of microbiological contamination that must be addressed in a HACCP plan.

The Agency is in the process of revising FSIS Directive 10,240.2, Microbial Sampling of Ready-to-Eat Products Produced By Establishments Operating Under A HACCP System. The revision will address when inspection personnel should not collect product samples for testing by FSIS if establishments are testing. The Agency is considering a policy similar to that contained in FSIS Directive 10,010.1, Microbiological Testing Program For *Escherichia coli* O157: H7 in Raw Ground Beef. Until FSIS Directive 10,240.2 is revised and issued, inspection personnel will continue to collect product samples regardless of any testing being done by the establishment.

PURPOSE OF THIS DOCUMENT

The purpose of this document is: (1) to assist establishments that have implemented HACCP and produce RTE product other than thermally processed, commercially sterile, in reassessing their HACCP plans with respect to the hazard that may be presented by *L. monocytogenes*, and (2) to provide for those establishments that conclude, after such reassessment, that their HACCP plans must address the hazard presented by *L. monocytogenes*, examples of practices that have been used successfully by other meat and poultry producing establishments to prevent the occurrence of this pathogen in their RTE products.

This document has been assembled using currently available scientific and technical information from within the Agency and other parts of the government, from meat and poultry processing establishments that have shared their successful approaches, and from trade associations that have also shared their collective best thinking on how to handle this difficult problem.

(the page before this should be 76, there is no page 1)

BACKGROUND

The Organism *Listeria* is ubiquitous in nature. It is commonly found in the intestines of animals and humans without causing illness. It can survive for long periods of time in soil, leaf litter, sewage, silage dust, vegetation, and water. The organism has been found in many domestic and wild animals, fish, birds, insects, and snails. It has been isolated from a variety of products, including raw milk, cheese made from unpasteurized milk, soft cheese, meat and poultry and their products, cole slaw, and cabbage.

L. monocytogenes bacteria are found frequently in the food-processing environment and can form biofilms on solid surfaces commonly found in the food processing plants, including stainless steel and rubber under experimental conditions. *Listeria* can also survive adverse conditions on apparently smooth surfaces.

Recent Experiences with Meat and Poultry Products

In recent months there have been several recalls of RTE meat and poultry products because of adulteration with *L. monocytogenes*. Foodborne illnesses and deaths have been linked to some recalled products. It has generally been concluded that the adulteration occurred through cross-contamination from environmental sources following cooking. Industry for the most part, has identified this as an SSOP failure.

REASSESSMENT OF HACCP PLANS

Below are points to consider when an establishment is developing or reassessing its HACCP plan(s).

- What are the levels of *L. monocytogenes* on source materials for your products? Do levels fluctuate significantly depending on suppliers? Do levels fluctuate significantly because of your practices regarding the use of rework product in various products?

Raw meat and poultry have been shown to be a source of *L. monocytogenes*. Knowing the worst possible incoming levels of *L. monocytogenes* can help you to determine whether your kill step is adequate. Raw materials should be used on a first in, first out basis to minimize time in storage and potential increase in *L. monocytogenes* levels. Product used as rework because it has been found to be positive for *L. monocytogenes* in end product testing would add to the microbial load.

Listeria monocytogenes in FSIS Nationwide Sampling Programs

Product	<i>Listeria monocytogenes</i>		
	Prevalence	High Value	Geometric Mean ^a
Steer / Heifer carcasses	4.1%	>11 MPN / cm ²	0.2 MPN / cm ²

Cow / Bull carcasses	11.3%	43 MPN / cm ²	0.3 MPN / cm ²
Market Hog carcasses	7.4%	46 MPN / cm ²	0.3 MPN / cm ²
Broiler Chicken carcasses	15.0%	51 MPN / cm ²	0.025 MPN / cm ²
Turkey carcasses	5.9%	0.30 MPN / cm ²	0.02 MPN / cm ²
Raw ground beef	11.7%	>110 MPN / g	2.9 MPN / gram
Raw ground chicken	41.1%	430 MPN / g	1.03 MPN / gram
Raw ground turkey	30.5%	93 MPN / g	0.75 MPN / gram

^a Calculated from positive samples only.

- What do your validation results tell you about the efficacy of kill steps used in your processes? What in-plant experience do you have which confirms the efficacy of the kill step you use on products produced from all types of source materials?

Challenge studies, scientific literature, computer modeling programs, and expert advice from processing authorities can be used to validate a HACCP plan. However, the effectiveness of the kill step under actual in-plant conditions would be evaluated through the HACCP plan verification.

- If your products are exposed to an environment not known to be free of *L. monocytogenes*, what post-kill step controls prevent their contamination by that environment? What do your records reveal about sources of *L. monocytogenes* in your facility? What do your records tell you about the success of efforts to remove particular sources?

An environmental testing program can be a means of confirming that the establishment's controls are effective in maintaining a plant environment that will minimize the hazard of pathogens including *Listeria monocytogenes*. In addition to measuring the effectiveness of a sanitation program, a correctly designed environmental testing program may:

- Provide information about sources of environmental contaminants
 - Identify the extent of pathogen contamination of the environment
 - Provide information about faulty equipment design or operation
 - Identify probable post processing cross-contamination sites
- Do you produce meat and poultry products that will support the growth of *L. monocytogenes*? What is the basis of your view? What are the implications for storage temperatures and shelf-life?

Currently available information indicates that establishments should view a RTE meat or poultry product as a food that supports the growth of *Listeria monocytogenes* unless the 1999 Food Code (DHHS, U. S. Public Health Service, FDA) excludes the product from its definition of a "Potentially hazardous food" (excerpts) because (1) the product has an aw value of 0.85 or less; (2) the product's pH is 4.6 or below when measured at 24°C (75°F); (3) a food, in an

unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution; (4) laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *C. botulinum* can not occur, and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or (5) the product does not support the growth of microorganisms..."

- What does finished product testing reveal about the status of your products with respect to microbial contamination?

FSIS believes that findings of *L. monocytogenes* in finished product are significant evidence that *L. monocytogenes* contamination may be a food safety hazard reasonably likely to occur in the production process for that product.

Since 1989, FSIS has conducted finished product testing for *L. monocytogenes* in several RTE meat and poultry product categories. The results found are as follows:

Listeria monocytogenes in FSIS RTE Sampling Programs, 1989 to present

Product	<i>Listeria monocytogenes</i>		
	Tested	Positive	Percent Positive
Jerky	575	4	0.7
Large Diameter Sausages	3099	51	1.6
Cooked Uncured Poultry	6055	148	2.4
Roast/Corned/Cooked Beef	4900	150	3.1
Salads and Spreads	3619	124	3.4
Small Diameter Sausages	4980	219	4.4
Sliced Ham/Luncheon Meats	1360	78	5.7

CURRENT THINKING ON BEST PRACTICES

A number of trade associations have produced "Best Practice" or GMP documents that cover production practices such as sanitation, raw materials handling, and employee hygiene. These documents are listed in the bibliography; copies may be obtained from these organizations.

SAMPLING PROGRAMS

The Agency envisions two types of sampling programs that establishments may use: environmental and end product. Environmental sampling includes non-product contact

surfaces, such as floors and drains, and product contact surfaces, such as conveyors, belts, slicers, and peelers. End product testing covers RTE product. Examples of testing programs in use in industry are provided in Attachment 1.

Establishments with limited resources should establish end product sampling as their top priority, followed by product contact surface/non-product contact surface testing. A comprehensive flowchart outlining environmental and end product testing is provided in Attachment 2.

ENVIRONMENTAL TESTING: A Commonly Used Tool

Sample Sites and Frequency

Selection of sample sites and sampling frequency for non-product and product contact surfaces depends on establishment features such as plant layout, overhead structures, number of production lines/products, location of processing equipment, and product flow. A sampling protocol should include the sample sites, sample area size, sampling frequency and sample collection techniques. In general, sample sites should be selected randomly. However, some sites may be designated for sampling on a regular basis based on the hazard analysis. Sample size can be determined based on the nature of equipment or surfaces e.g. flat surfaces, inside of equipment, etc. The plan should also detail appropriate, progressive actions the establishment will take as positive samples are found.

Methods

Environmental samples, including swabs and sponges, should be placed in a neutralizing medium immediately after collection, in order to neutralize any residual disinfectants that may be picked up from equipment or other environmental sampling sites. Samples should be stored and shipped to laboratories using standardized procedures. A reputable laboratory should analyze samples. The establishment is responsible for determining the competency of the laboratory used. The laboratory conducting the sample analyses should have properly trained personnel, suitable facilities and equipment, a written quality assurance program that is available to all personnel, and reporting and record keeping capabilities. Presently there is no AOAC-approved method for analyzing environmental samples for *Listeria*. Laboratories can use published methods after validation. Laboratories can also use FSIS' L. monocytogenes method published in the Microbiology Laboratory Guidebook, 3rd edition (Chapter 8, Revision #1, 1/12/99).

An establishment may choose to perform its own indicator organism testing using a screening test. Such tests are available but should be validated as part of the HACCP plan.

Record Keeping

The results of environmental sampling are not available until after products are produced. Therefore, adequate and accurate records are essential because the

environmental sampling program is of retrospective value only. For example, identification of the site sampled (drain #1 in peeling room) and the visible condition of the site (clean, smooth surface) is necessary to effectively utilize the sampling results.

Results and Follow-up: Non-product contact surfaces

If positive samples are found from non-product contact surfaces, follow-up actions should be taken, and may include thorough cleaning of suspect areas and equipment with subsequent intensified/expanded testing.

Results and Follow-up: Product contact surfaces

If positive samples are found on product contact surfaces, different follow up actions should be taken, including follow up sampling of product produced on that line, as follows:

1. Once the product contact surface is found to be positive for the number of samples indicated in the HACCP plan for *Listeria* spp., the next lot of product produced from the line should be sampled and tested for *L. monocytogenes*.
2. Minimum production time prior to sampling should be determined by the plant and followed. The time may depend on individual line configuration, clean up, and sanitizing procedures. The testing plan should include variations in the time of sampling to detect the increase in *Listeria* that could occur during the production shift.
3. After product sampling, the line may need to be cleaned and/or operational procedures reviewed, before production of the next lot.
4. The product lot sampled may be held, pending laboratory results.
5. If a sampled lot is found to be positive for *L. monocytogenes*, and is already in commerce, it will be subject to recall.
6. Product sampling may be intensified, such as testing several consecutive lots. All product produced on positive lines may be held pending laboratory results.
7. After the predetermined number of lots has tested negative for *L. monocytogenes*, the plant may resume its regular regime of environmental and product sampling.
8. The establishment should document the reason for contamination and steps taken to prevent future incidents.

END PRODUCT TESTING: A Potential Verification Tool

An end product sampling program for RTE meat and poultry products may serve as verification of the HACCP plan. An end product testing program should include several elements, such as sampling frequency, sampling procedures, laboratory methods, follow-up actions, and record keeping. Suggested scientific references that may be helpful are listed in the bibliography.

Sample Frequency and Procedures

The frequency of end product sampling should take into consideration the number and types of different products produced, complexity of processing procedures, the amount of product produced, whether an environmental sampling program is in place, and

establishment history. Establishments can base their sampling frequencies on any validated statistical sampling program that achieves their objectives.

Products that have direct exposure to the establishment's processing environment after a kill step is applied may be at greater risk from environmental contaminants than a product cooked and distributed in the same packaging. An establishment may want to increase the frequency of sampling of the former type of products. If no environmental sampling is taking place, more frequent product sampling may be advisable because the early warning of a potential *L. monocytogenes* problem that environmental sampling may provide will not be available. An establishment that has a prior history of *L. monocytogenes* findings by either FSIS or its own sampling program may also need to test more frequently.

Sampling should be done as randomly as possible, with all lines and shifts eligible for selection. From the selected lot, multiple sample packages should be collected from the beginning, various middle time points, and towards the end of the production to test a sample representative of the entire lot. Whenever practical, intact packages should be sent to the laboratory for analysis, as they will provide better control of aseptic sampling. Otherwise, an establishment should aseptically collect a portion of each package and place the sample into a sterile bag or other sterile container for shipment to the laboratory.

Methods

Samples should be stored and shipped to laboratories using standardized procedures. A reputable laboratory should analyze samples. The establishment is responsible for determining the competency of the laboratory used. The laboratory conducting the sample analyses should have properly trained personnel, suitable facilities and equipment, a written quality assurance program that is available to all personnel, and reporting and record keeping capabilities. Laboratory methods employed should be AOAC approved or the FSIS *L. monocytogenes* method published in the Microbiology Laboratory Guidebook, 3rd edition (Chapter 8, Revision #1, 1/12/99).

Results and Follow-up

If a sampled lot is found to be positive for *L. monocytogenes*, the establishment should take the appropriate actions.

BIBLIOGRAPHY

- "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients," Subcommittee on Microbiological Criteria, Committee on Food Protection, Food and Nutrition Board, National Research Council, National Academy Press, Washington, DC, 1985.
- "Choice of Sampling Plan and Criteria for *L. monocytogenes*," International Commission on Microbiological Specifications for Foods, International Journal of Food Microbiology 22(1994): 89-96.
- "Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs), and Environmental Sampling/Testing

Recommendations (ESTRs) – Ready to Eat Products," coordinated by National Meats Association, April 1999. (*)

- [<http://www.nmaonline.org/guifinal.pdf>]
- "Guidelines to Prevent Post-Processing Contamination from *Listeria monocytogenes*," National Food Processors Association, submitted to Dairy, Food, and Environmental Sanitarian, April, 1999. (**)
- "Interim Guidelines: Microbial Control During Production of Ready-to-Eat Meat and Poultry Products," Joint Industry Task Force on Control of Microbial Pathogens in Ready-to-Eat Meat and Poultry Products, Washington, DC, February 1999. (***) [http://meatami.org/Guidelines_Microbial_Pathogens_299.pdf]
- "Microorganisms in Foods, Volume 2, Sampling for Microbiological Analysis: Principles and Specific Applications," 2nd edition, International Commission on Microbiological Specifications for Foods, University of Toronto Press, Toronto, Canada, 1986.

Sources:

- (***) American Meat Institute, 1700 N. Moore Street, Suite 1600, Arlington, VA 22209
- (**) National Food Processors Association, 1350 I Street, NW, 3rd Floor, Washington, DC 20005
- (*) National Meats Association, 1970 Broadway, Suite 825, Oakland, CA 94612

Attachment 1: Examples of Environmental Monitoring Programs

Example A

Company A makes ready-to-eat salads, including potato salad, chicken salad, ham salad, etc. for delicatessens in grocery stores. The company manufactures product in two 8-hour shifts, 6 days a week. The third shift is reserved for sanitation. The company targets the salad assembly area in the environmental monitoring component of its *L. monocytogenes* control program. They have identified three tiers in their sampling program: environmental sampling points, product contact surface points and finished product testing.

They have identified 30 environmental sampling sites, including the walls next to the preparation tables, the exterior of the mixing kettles, the mixer shaft, the drains under the preparation tables, etc. Each week they randomly pick 15 of the 30 sites for testing for *Listeria* spp.: these 15 sites are tested twice a week ("routine monitoring") before production. Results are tracked as total number of positives over time and also by site. When a positive is detected at any site, it is given extra attention during the next sanitation. If the number of positives exceeds 15% (e.g., if there are 5 positives out of 30) during the week (two test periods, rolling window), or if the same environmental site comes up positive more than 50% of the time in a month, these sites are given extra attention during the next sanitation, and the areas are re-swabbed daily until there are three consecutive days of negatives.

Once this has occurred, the plant reverts to routine monitoring. If the problem is not corrected within 5 days, the plant enters the "trouble shooting" mode, which includes more stringent decontamination procedures, such as disassembly and sanitizing, fogging with sanitizers, changing sanitizers, double sanitizing, and heat treatments. Company A also conducts routine random product contact surface testing, they have identified 20 key product contact surfaces. Each week 10 of these are randomly selected and tested for *Listeria* spp. twice a week at the end of production before cleaning. If a positive is detected, the site is given extra attention during the next sanitation and the site is re-swabbed. The site is tested daily for 5 days. If the site is positive twice during this 5-day period, the line is shut down and, if appropriate, torn apart, taking trouble-shooting swabs during the disassembly. The product contact surface and surrounding areas receive extra sanitation and the line is re-assembled. Product contact surface swabs are then taken every two hours during production and all product is placed on hold. If any swab tests positive, product from the 2-hour time period and from each period on either side is tested for *L. monocytogenes*. Product that is negative is released. Product that tests positive is destroyed, since re-processing is not an option for this product

The company conducts random product testing of one salad product each month by taking one package every two hours and compositing product from x packages. This results in two tests for each shift of product. Product is tested for *L. monocytogenes*. Product found to be positive for *L. monocytogenes* is destroyed and routine product contact monitoring testing for *Listeria* spp. is conducted daily for a week, with appropriate action taken as described for routine monitoring of product contact surfaces. If product is found to be positive for *Listeria* spp., including *L. monocytogenes*, the company undertakes investigations to determine the cause of the problem. The *L. monocytogenes* control program is also reviewed and revised as appropriate.

Company B

Company B produces fully cooked, breaded chicken products, The company manufactures product on three separate lines in two 8-hour shifts, 6 days a week. The third shift is reserved for sanitation. The company's environmental monitoring component of its *L. monocytogenes* control program targets the area where product exits the fryer, is chilled and then packaged. There are two parts to this company's program: product contact surface testing and non-product contact surface testing. The company monitors 20 environmental (non-product contact) surfaces on a weekly basis for *Listeria* spp. (routine monitoring). Whenever a positive is detected, the company investigates to determine if the positive is an isolated incident by re-sampling the site and by taking additional swabs in the immediate area of the positive. If there are no additional positives, the plant considers the initial positive to be an isolated incident and returns to routine monitoring. If additional positives are detected, the plant institutes corrective actions, which may include a. review of the current *L. monocytogenes* control program, revising GMPs, changing sanitizes, enhanced sanitation in clean areas, employee retraining, etc. The company then monitors twice a week (enhanced monitoring) until there are 4 consecutive negative periods, at which point the company returns to routine monitoring.

The company also monitors 15 product contact surfaces on each line at the end of each shift of production every other week. For each line, 5 swabs are composited, resulting in 3 tests per line for a shift. If a positive is detected, company investigates by re-swabbing and testing the swabs individually, as well as by taking additional swabs in the area. If the swabs are all negative, they return to routine monitoring. If there is a positive, the plant institutes corrective actions, which may include intensified cleaning, changing sanitizer, etc. The plant then takes swabs to confirm that the actions taken have been effective. If there are no positives, the plant returns to routine monitoring. If there are any positives, the plant escalates its corrective actions, which may include tearing apart pieces of equipment and sanitizing, heating pieces of equipment, etc. They would also evaluate the need to conduct finished product testing based on all the existing evidence. This plant does not conduct any random finished product testing because they have determined that their control program is effective and that such sampling would serve no purpose.

Company C

Company C produces three types of semi-dry, fermented sausages. They have established a control program for *L. monocytogenes* that targets processing and packaging operations, sanitation practices and personnel hygiene. They do not have a routine environmental testing program; there is limited random testing done in the environment and on some product contact surfaces. The plant has elected to verify the effectiveness of its *L. monocytogenes* control program through finished product testing. They take one sample from each lot of product and test for *Listeria* spp. by compositing portions of 5 samples, retaining the remainder. Product is held pending results of the test. If there is a positive, the company tests the retained portions for *L. monocytogenes*, releasing the negative lots and destroying those that are positive.

Appendix D: Guidance for Minimizing Impact Associated with a Food Safety Hazard in Raw Ground Meat and Other FSIS Regulated Products

**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Pathogen Reduction/HACCP & HACCP Implementation
December 1998

Guidance for Beef Grinders to Better Protect Public Health

Guidance for Minimizing Impact Associated with a Food Safety Hazard in Raw Ground Meat and Other FSIS Regulated Products

Based upon sporadic cases, outbreaks, and product recalls involving *Escherichia coli* (*E. coli*) O157:H7, FSIS has concluded that guidance can help grinders to develop and implement procedures that better protect public health. This guide is intended to illustrate how grinders can avail themselves of opportunities to minimize food safety hazards associated with their products. It does not prescribe regulatory requirements under the Federal Meat Inspection Act (FMIA).

The guidance provided in this document is premised on three main points.

- First, grinders should structure their operations in a manner that takes into account the safety of their raw materials and their potential product safety responsibilities through to the end user.
- Second, grinders should realize that they are in an excellent position to implement process and distribution controls that reduce public health concerns associated with ground beef contaminated with *E. coli* O157:H7.
- Third, there must be an emphasis throughout the production and distribution chain on maintaining the records that are necessary to identify, trace, and retrieve from commerce any ground beef products that may pose a threat to public health.

Grinding operations (which traditionally buy raw materials from one or more sources and sell the processed products to others) have a primary responsibility and unique opportunity to specify purchase requirements related to incoming raw materials, to process raw materials under processing and recordkeeping controls designed to ensure the safety and traceability of their products, and to distribute products to destinations in a manner such that products can be effectively recalled if food safety hazards are identified. Putting aside any legal considerations, it is essential that grinding operators assume that they are responsible for their products until the products' end use. This is especially true for grinding operators who produce products in retail-ready packages. This guidance material, through several guiding principles and associated detailed explanations and recommendations, is intended to identify how grinding operations can reduce public health risk.

Processing operations are presently required to have SSOP's (Sanitation Standard Operating Procedures) and a few are already required to have functional HACCP (Hazard Analysis Critical Control Points) systems. This guidance material is specifically designed to augment these activities, especially the development and operation of a HACCP plan^{1,2}. Grinding operations not already required to have HACCP plans are encouraged to develop and implement their HACCP plans earlier than required as soon as possible³. Although this guidance material highlights issues associated with ground beef, the guidance can be applied to most raw products. This guide is not intended to be prescriptive, in a regulatory sense, but rather offers examples of opportunities to improve food safety through purchase requirements, increased process control, and recordkeeping.

Records that facilitate trace back and trace forward are essential whenever there is an outbreak of foodborne illness. Although grinding operators may not have access to records of the farm sources of their raw material, or records maintained by the plants that slaughter, dress, and bone their raw materials, they are advised to purchase raw materials from suppliers that maintain such records. In addition, they are advised to keep records regarding the disposition of their products to enable tracing their products forward to consumers and back to suppliers. In instances where grinders do not control their products through distribution and retail sale, the chain of records necessary to trace products that raise a public health concern should not be broken. Intermediate handlers, such as distributors and wholesalers, should assume responsibility for keeping adequate records regarding the disposition of ground beef products that pass through their hands. The Federal Meat Inspection Act (FMIA) requires that every person, firm, or corporation engaged in buying or selling of meat food products must maintain records that fully and correctly disclose all transactions in its business subject to the FMIA (21 USC 642). The recordkeeping requirements are set out in Title 9, Code of Federal Regulations, Section 320 (9 CFR 320). Grinders are advised to impress upon all intermediate handlers of their products the importance of records that will facilitate the efficient retrieval from consumers of ground beef products that are a public health concern.

The pathogen *E. coli* O157:H7 is of particular concern to grinding operations because it is considered an adulterant in ground beef (Taylor, 1994; Texas Food Industry Association v. Espy)⁴, and because it produces severe and sometimes fatal consequences at a very low infectious dose. Buchanan and Doyle (1997)⁵ emphasized that "HACCP plans that do not include a lethal step that kills pathogens are more complex, since the focus is on risk reduction instead of risk elimination." At present, applying a lethal step such as heat processing or integrated lethality using fermentation or pH is the only approved method of making food harboring *E. coli* O157:H7 safe for consumption. Results from microbiological testing can provide only a limited measure of assurance that this pathogen is not present. Total reliance upon sampling is inadequate because *E. coli* O157:H7, if present, is present sporadically and at extremely low levels. Therefore, microbiological testing should be used in combination with strict process controls in order to reduce, as much as possible, the likelihood that the pathogen is present in the finished product. The Agency issued on February 1, 1998, FSIS Directive 10,010.1 Microbiological Testing Program For *Escherichia coli* O157:H7 in Raw Ground Beef, which provides current instructions to FSIS personnel for selecting, collecting, and submitting ground beef samples.

The guide consists of two sections: Section I., Guiding Principles; and Section II., Suggested Procedures For Grinding Operations. This material will be continually updated and made available through the FSIS internet web page located at <http://www.fsis.usda.gov>. Copies of this Guidance for Beef Grinders to Better Protect Public Health may also be requested by fax or mail from FSIS Public Outreach, 202-720-9063; Room 1180 South Building, Washington D.C. 20250. Comments regarding this guide should be directed to William J. Hudnall, at 202-205-0495, and fax at 202-401-1760.

This guide is an updated version of the guidance material that FSIS made available to the public in March 1998. It has been modified in response to the suggestions and comments by several organizations and to incorporate some details on rework and product recall plan derived from the guidance provided by the National Meat Association and the American Meat Institute. This type of incorporation was discussed during the April 22 public meeting at which each of these organizations presented guidelines along with FSIS' guidance material. This is the first update of the Agency's Guidance.

Section I. Guiding Principles:

These guiding principles are supplemented with suggested procedures in Section II.

- A. Grinders should determine the specifications for microbial safety that are necessary to ensure that their products will be safe and should only accept starting materials and ingredients that meet their specifications. In developing such specifications, grinders should consider the intended use for the starting materials and ingredients and what, if any, pathogen reduction actions by their suppliers would be beneficial.
- B. Grinders should keep abreast of new technologies and interventions that could be introduced into their processes to help prevent adulterated products or to identify product that is adulterated before it enters commerce.
- C. Grinders should develop and implement processes and packaging procedures to maintain or improve the microbial integrity of their starting materials in order to ensure that they produce safe consumer products.
- D. Grinders should implement controls to identify and segregate for special handling, product that pose a greater risk of being adulterated. Alternate outlets, such as diversion to FSIS inspected or state-inspected processors that employ a bacterial kill-step (such as cooking), should be acquired for such products.
- E. Grinders should develop and implement rework, carry-over, and lot designation procedures that reflect an acceptable degree of product exposure (i.e., economic risk) in the event that a health risk is identified that results in recalling product that is suspected of presenting a potential hazard to the public.
- F. In cooperation with their customers, grinders should develop and implement handling and distribution procedures that will not compromise the safety of their ground products once those products leave their establishments.
- G. Grinders should develop a system of records, which fits into a farm-to-table continuum, that will facilitate trace back to the suppliers and trace forward to the distributors in the event that a public health risk is identified.
- H. Grinders should consider both the intended use of their product (hotel, restaurant, institution, or home setting) and the most vulnerable potential user; and should provide information and education aimed at minimizing the potential for foodborne illnesses at the level of the ultimate consumer. Moreover, such information and education can help to assure consumers that product found to have *E. coli* O157:H7 can be made safe by thorough cooking. Steps are available to ensure that product presumed or known to have *E. coli* O157:H7 is made safe as opposed to destroying it.

Section II. Suggested Procedures for the Guiding Principles

Receiving Meat (Guiding Principles A and B)

- Develop purchase specifications to ensure receipt of safe and wholesome incoming raw materials. Purchase specifications should take the end use of the product into consideration. For example, purchase specifications for raw materials for processing products with potentially high risk end use, such as raw patties, should include either:

1. microbial specifications, and testing by supplier or grinder, or
2. supplier operation under HACCP plans with critical control points (CCP's) that address pathogen intervention or anti-microbial programs, such as hot water rinses, acid spray, steam pasteurization, or irradiation*.

*The Food and Drug Administration amended its regulations to include use of a source of radiation to treat refrigerated or frozen meat in December 1997. FSIS is currently preparing rulemaking on procedural and labeling requirements.

- Require suppliers to maintain records of farm source or slaughter plant to facilitate traceback.
- Examine condition of transport for sanitation-related and other product handling concerns, including:
 1. sanitation of the carrier or truck
 2. presence of cracks, debris, foreign material, or off-odor
 3. condition of insulation and door seals
 4. temperature inside transport vehicles and of meat
 5. length of time of transport.
- Examine and record condition of raw material:
 1. Note and document species identity, origin, age and temperature of both refrigerated and frozen materials, supply source, boning date/slaughter date.
 2. Conduct organoleptic examination (appearance, smell, any defects or abnormalities).
 3. Check integrity of immediate container, protective covering, or other packaging materials used.
 4. Document type of raw materials [e.g., trimmings, cheek meat, finely textured product, and product resulting from advanced meat recovery systems, and other comminuted products which have undergone additional handling and processing].
 5. Verify that all units are appropriately marked or coded for trace back purposes.
- Identify and separate incoming material according to the potential risk of the product's end use. Small mass products such as raw beef patties are "higher risk" because they are thin, are cooked for a short time, are preferred not fully cooked by some consumers, and the internal temperature is not easily obtained. Large mass products such as meat loaf or chili are "lower risk" because they are denser and are cooked evenly for a longer time. Ready-to-eat (RTE) products such as cooked beef patties are "lower risk" because these are subjected to a processing step lethal to pathogens.
- Affix grinding operation's code after acceptance of raw materials for tracking purposes.

Storage of Raw Material (Guiding Principle C)

- Develop storage schedule for incoming materials to facilitate product identification and inventory control and to maintain package/pallet integrity. Raw materials can be rotated using a First In-First Out (FIFO) system or a plant specified product rotation/inventory control schedule.
- Determine which units will be refrigerated or frozen, and for how long.
- Record specific locations, times, dates, and temperature of storage.
- Provide ample spaces between boxes or pallets to allow for air circulation.
- Monitor and record temperature of meat during storage.
- If material is to be thawed, monitor, and record time and temperature of thawing.

Grinding Process including weighing, coarse grinding, blending, mixing, final grinding, and forming (Guiding Principles C, D, E)

- Observe and record pre-operational and operational SSOP conformance, including those for equipment, floor, ceilings, walls, and employees. Adopt testing (e.g., microbial, ATP bioluminescence) to measure effectiveness of SSOP.
- Develop a lotting or sub-lotting system for coding and tracking purposes. Assign lot numbers that will enable tracking lot to the raw material source up to the finished products. Lotting can be based on a full day's production or production from clean-up to clean-up. All lots produced between clean-ups would be implicated in any public health-based action (e.g., recall) unless based on the specific circumstances, the problem can be restricted to a subset of the plant's production between cleanups.
- Separate processing of meat into lower risk and higher risk categories. Separation can be by processing lines, lots, shifts, or production day. Large processing plants may be able to use different processing lines for different categories. In small plants, the categories can be separated by shifts or lots, in which case, processing of "lower risk" raw materials should always precede "higher risk" raw materials.

Separation of raw materials into these two categories (i.e. lower risk and higher risk) will prevent possible cross contamination among products with different handling history.

- Divert "higher risk" meat to:
 1. RTE product such as fully cooked beef patties. RTE processing incorporates a kill-step such as heat processing, or cooking to eliminate pathogens including *E. coli* O157:H7.
 2. Large mass products such as meat for meat loaf or chili. This diversion will help ensure adequate heat processing of the product before consumption, because these large mass products are more fully and evenly cooked than thin meat patties.

Diverting "higher risk" meat to RTE or large mass product processing is an in-house method to reduce the risk of foodborne illness because these products are in general, adequately cooked before consumption. In diversifying, grinders that have no facilities for processing RTE products need outlets for their "higher risk" products. Grinders should obtain a list of federally- and state-inspected establishments that can process ground beef RTE products.

- Monitor and record temperature of the meat and the processing room during the whole operation.
- Develop a rework tracking system
 1. Estimate the amount of meat for the production shift or day, so that the amount of carry-over or rework (excess raw materials at the end of the production period that are not in final product form) is minimal, or there is no rework at all.
 2. If rework is unavoidable, use only rework meat from the immediately preceding lot or shift, and not more than the past 24 hours. Controls should be instituted to prevent this practice from incriminating a whole week's or month's production if a food safety hazard is identified.
 3. Include all rework with "higher risk" meat and process at the last shift or the end of the production day; or divert to RTE product processing.
 4. Develop a recording system for rework that includes the time, quantity, area and processing step it was collected from, the original lot or batch number/code, and the code of the lot or batch it was added to or included in.
- Develop contingency plans or strategies to address unprocessed raw materials remaining due to line failure or not meeting specifications. Maintain adequate records of the origin, handling and disposition of these raw materials.
- Maintain a record of source, handling, and amount of outside trimmings added (i.e., trimmings not from the same batch or lot as the rest of the raw materials)
- Monitor the time and temperature of finished products, e.g., freezing of beef patties.
- Test for *E. coli* O157:H7 at any point during the grinding operation. To reduce the risk of a recall, hold the product until the test results confirm that none has been detected. FSIS Directive 10,101.1 on Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef sets out instructions for sampling ground beef that take into account industry action to reduce the presence of *E. coli* O157:H7. FSIS has instructed inspection program personnel that (unless otherwise directed) they are not to collect samples at an inspected establishment which makes only raw ground products that are tested daily for *E. coli* O157:H7, that are made from boneless beef lot which is certified to have tested negative for *E. coli* O157:H7, or that are made from carcasses which are subjected to a valid pathogen reduction intervention, the effectiveness of which is routinely verified and confirmed by testing, so long as no sample has tested positive for *E. coli* O157:H7, in the past six months.
- Testing may help to determine whether to divert to other products. Because of the low incidence of *E. coli* O157:H7 in meat, testing is not a guarantee of the absence of the pathogen, and the amount and frequency of sampling from different volumes of meat being processed will vary. The point of sampling, whether raw material or the finished product, will also vary, depending on the condition of the raw material, whether there was previous testing, the system of controls in the plant, and the type of finished product.

Packaging, Cooling, and Storage (Guiding Principle C)

- Monitor temperature or frozen condition of finished product during the packing operation.
- Use only clean food grade immediate container liners.

- Monitor finished product package integrity (seal, durability).
- Monitor and record the temperature of the refrigerator/freezer and the product during storage.
- Include production code and sell-by-date on package label, in addition to the required handling statement and safe handling instructions.
- Install a time-temperature indicator on the package to indicate adequate temperature of storage, distribution, and display (in grocery and other retail establishments).

Shipping, Handling, and Distribution (Guiding Principle F)

- Develop and maintain an inventory control schedule for products in storage. The FIFO inventory control schedule could also be used at this point.
- Transport coded products in clean, sanitized, temperature-controlled and well-maintained carriers to distributors.
- Maintain records of primary and secondary distributors.
- Develop recommendations for distributors concerning the safe handling, distribution, and coding of the finished products.
- Maintain and record product temperature and package integrity during loading, unloading and holding of finished products.
- Separate and divert to "higher risk" any product that was returned after having left the plant and been out of the control of the plant.
- Develop an in-house recall plan to test the efficiency of the plant's recording or coding system. Conducting product recovery drills (mock recalls) regularly can determine and assess the ongoing effectiveness of the recall plan. A practical and effective recall plan that is understood by all employees should contain the following elements:
 1. step-by-step procedures to follow in the event of product recall
 2. list of people who will take part in any recall activities, including their assignments, business and home phone numbers
 3. measures to retrieve documentation identifying the product coding system and product designation
 4. measures to retrieve product distribution records
 5. means of coordinating recall with regulatory authority or authorities
 6. means of notifying distributors, wholesalers, retailers and customers
 7. measures for assuring the speedy return of recalled product
 8. methods for disposition of recalled product

The following information should be given to regulatory authorities and press: product name, product brand name, product codes, reason for the recall, areas of distribution, contact person within the company.

Recordkeeping System (Guiding Principle G)

- Develop a recording or coding system so that each shipping container or a retail-ready package of ground beef has trace back and trace forward codes.

A coding system could be as simple as indicating the shift, date and production line. For example, a code of 1/020898/2 would mean produced on 'first shift of February 8, 1998, line 2'. Corresponding records of all incoming products used on February 8, by shift and line, would enable full trace back to sources. These codes should facilitate tracking or trace back to the farm source, slaughter plant, and boning plant; a determination whether the meat was reconditioned, had intervention treatment, or had rework meat added to it; and a determination of the dates of slaughter and fabrication, lot number, storage, and transport records.

- Encourage primary and secondary distributors to maintain a record of the companies to which they supply finished products. This will ensure effective trace forward of all products, if the need arises.

Thorough recordkeeping, including tracing back and forward, will facilitate recall efforts. This will make possible rapid identification of sources of microbial contamination leading to containment of any product that could result in foodborne illness and public health implications. This will minimize the economic impact of recalls on affected plants, by narrowing down implicated products to a certain lot or production code.

Education (Guiding principle H)

- Grinding plants that have developed programs to educate their employees, distributors, food handlers, and consumers of the risks of foodborne illness associated with the production of ground beef products should continually monitor and update their programs. If needed, training in the language understood by food handlers and other employees should be provided.
- Grinding plants without such programs should develop training and educational programs for employees, distributors, food handlers, and consumers on the microbiological risks that may be associated with ground beef products, and on measures to prevent foodborne illness. Training in the language understood by the people concerned should be provided, if necessary.
- Safe handling instructions are currently required on the labels of not-ready-to-eat products when distributed to consumers, hotels, restaurants, or similar institutions [9 CFR 317.2(1)]. Grinding plants should include handling information on products distributed between establishments.
- Grinding plants should include cooking instructions that are targeted to the specific purchaser (e.g., product distributed to institutions with elderly, young, or immunocompromised populations should include more rigorous cooking and handling instructions than those provided for the general population).

A list of already developed free materials that may aid grinding plants in training and education may be ordered by mail or fax from the FSIS Public Outreach and communications Office at (202) 720-9352 or FAX (202) 720-9063. Many free educational materials are also accessible on the FSIS web site <http://www.fsis.usda.gov>. Other educational and training materials are also accessible via USDA/FDA Foodborne Illness Education Center at: <http://www.nal.usda.gov/fnic/foodborne/foodborn.htm> .

For Further Information Contact:

FSIS Food Safety Education and Communications Staff
Room 2932-South Building; 1400 Independence Ave. S.W.
Washington, D.C. 20250
Phone: (202) 720-9352
Fax: (202) 720-9063

Comments on the guide should be directed to:

William J. Hudnall
Phone: (202) 205-0495
Fax: (202) 401-1760

Footnotes:

1. USDA, FSIS (1997) Generic HACCP Model for Raw, Ground Meat and Poultry Products, HACCP-3
2. USDA, FSIS (1997) Generic HACCP Model for Beef Slaughter, HACCP-13.
3. Federal Register: January 30, 1998 (Volume 63, Number 20) p. 4622
4. Taylor, M. (1994) Change and Opportunity: Harnessing Innovation To Improve The Safety of the Food Supply. Speech given at the American Meat Institute Annual Convention, San Francisco, California, September 29, 1994. Texas Food Industry Association v. Espy, 870F.supp.143,149,(W. D. Tex.1994)
5. Buchanan, R. L., and Doyle, M. P. (1997) Foodborne disease significance of Escherichia coli O157:H7 and other enterohemorrhagic E. coli. Food Technol. 51(10): 69-76.