

Good Manufacturing Practices
for
Fermented Dry & Semi-Dry Sausage Products

by
The American Meat Institute Foundation

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ANALYSIS OF MICROBIOLOGICAL HAZARDS ASSOCIATED WITH DRY AND SEMI-DRY SAUSAGE PRODUCTS

Staphylococcus aureus

The Microorganism

Staphylococcus aureus is often called "staph." It is present in the mucous membranes--nose and throat--and on skin and hair of many healthy individuals. Infected wounds, lesions and boils are also sources. People with respiratory infections also spread the organism by coughing and sneezing. Since *S. aureus* occurs on the skin and hides of animals, it can contaminate meat and by-products by cross-contamination during slaughter.

Raw foods are rarely the source of staphylococcal food poisoning. Staphylococci do not compete very well with other bacteria in raw foods. When other competitive bacteria are removed by cooking or inhibited by salt, *S. aureus* can grow. USDA's Nationwide Data Collection Program for Steers and Heifers (1995) and Nationwide Pork Microbiological Baseline Data Collection Program: Market Hogs (1996) reported that *S. aureus* was recovered from 4.2 percent of 2,089 carcasses and 16 percent of 2,112 carcasses, respectively.

Foods high in protein provide a good growth environment for *S. aureus*, especially cooked meat/meat products, poultry, fish/fish products, milk/dairy products, cream sauces, salads with ham, chicken, potato, etc.

Although salt or sugar inhibit the growth of some microorganisms, *S. aureus* can grow in foods with low water activity, i.e., 0.86 under aerobic conditions or 0.90 under anaerobic conditions, and in foods containing high concentrations of salt or sugar. *S. aureus* is not strongly inhibited by nitrite and can multiply in curing solutions or cured meats if conditions are favorable for growth. The low pH of commercial mayonnaise inhibits the growth of *S. aureus*, but growth can occur if the pH of the mayonnaise is raised or buffered by other ingredients in a salad.

The Foodborne Illness

Food poisoning associated with *S. aureus* is caused by an intoxication and is one of the most common foodborne illnesses in the United States. Illness results from ingestion of the toxin produced by *S. aureus* and is not transmittable to others.

Onset of illness can occur within 30 minutes to eight hours after consumption of food containing the *S. aureus* toxin, although most illnesses occur within four hours. Symptoms include nausea, vomiting, retching, abdominal cramping, sweating, chills, prostration, weak pulse, shock, shallow respiration, and subnormal body temperature. The illness is rarely fatal, and recovery usually occurs within 24-48 hours.

Control Principles

S. aureus is pervasive in both animal and human environments and many foods can support the growth; therefore, control of the microorganism is difficult. Contamination is most often caused by human contact with hands after the product is cooked. This contamination can be controlled by hand sanitation and the use of disposable gloves.

For staphylococcal food poisoning to occur, the food must be held under conditions that promote growth of *S. aureus* to a million ($\geq 10^6$) or more cells per gram of food. Temperature control is the best way to minimize the growth of *S. aureus* and development of its toxin. In addition, good sanitation practices dictate the removal of any food handler who has an infected wound or lesion.

Control of *S. aureus* growth in fermented foods, such as Lebanon bologna, summer sausages, and pepperoni requires controlling a number of factors, the most important of which is pH. A rapid drop to pH 5.3 slows *S. aureus* enough so that little or no multiplication of the bacteria or development of enterotoxin can occur until the sausage reaches a lower pH. The addition of solutes or drying foods to A_w below 0.85 also prevents growth of, and enterotoxin production by *S. aureus*. USDA has implemented a *Staphylococcus* enterotoxin monitoring program for ready-to-eat fermented dry and semi-dry sausages (see Appendix A).

***E. coli* O157:H7**

The Microorganism

Escherichia coli O157:H7 can colonize the intestinal tracts of animals, providing an opportunity for contamination of muscle meat at slaughter. Cattle have been identified as an important reservoir of *E. coli* O157:H7. The organism resides in the intestinal tract, and can be shed in feces.

During the slaughter process, the organism can contaminate the carcass. USDA's Nationwide Beef Microbiological Baseline Collection Program for Steers and Heifers reported an incidence of 0.2 percent for *E. coli* O157:H7 on raw beef carcasses (no *E. coli* O157:H7 was detected on pork carcasses in the market hog study). *E. coli* O157:H7 contamination in foods is most often associated with animal products, especially ground beef, although cross contamination from animal food to other foods has been reported.

E. coli O157:H7 is a pathogen that can survive both refrigerator and freezer storage. If present, the bacterium can multiply very slowly at 44°F and may be present in a fermented product because it is able to survive in an environment of pH 3.6 to 7.0 for substantial periods, unless it is destroyed by heat or other procedures in the process. The specific procedures to be used for destruction of *E. coli* O157:H7 often include a combination of controls for pH, A_w control, temperature and microflora in raw materials. Several studies have identified specific combinations of ingredients and processes designed to destroy *E. coli* O157:H7 should it be present in raw ingredients.

The Foodborne Illness

E. coli O157:H7 is uniquely different from a number of pathogenic *E. coli* strains. Most pathogenic strains can cause diarrheal syndromes that are self-limiting, whereas *E. coli* O157:H7 infection often requires medical intervention and can be life-threatening. Illness caused by *E. coli* O157:H7 is manifested in three different ways: hemorrhagic colitis, hemolytic uremic syndrome (HUS), and thrombotic thrombocytopenic purpura (TTP).

The symptoms of hemorrhagic colitis are severe abdominal pain accompanied by watery and bloody diarrhea. The recovery period is usually between two and nine days after the onset of illness. In some cases, hemorrhagic colitis can be a precursor to other more serious disease states. HUS is another manifestation of *E. coli* O157:H7 and is the leading cause of renal failure in children. Death occurs in about 5 percent of HUS cases. TTP is similar to HUS except that the central nervous system is primarily affected. Patients with TTP often develop blood clots in the brain, usually resulting in death. Illness from *E. coli* O157:H7 can be caused by ingestion of contaminated food or water and by intimate contact with persons suffering from the food infection.

Control Principles

Fail-safe procedures for the production of *E. coli*-free raw meat products have not been developed; therefore, controlling *E. coli* O157:H7 in raw product and eliminating the microbe if it is present in raw materials destined for cooked or processed product depends upon a company's total commitment to a long term undertaking by all levels of management and production employees.

A Hazard Analysis and Critical Control Point (HACCP) program is effective for generally assessing the microbiological condition of ingredients, controlling the process on a continuing basis, and developing trends for the conditions under which product is handled and stored.

A HACCP program for the supplier of raw meat products will also help monitor microbial condition of products entering the processing plant. In addition, separation of raw and ready-to-eat (RTE) processing areas, and sanitation and cleanup procedures are essential to reduction in the potential for *E. coli* O157:H7 contamination and cross contamination. FSIS published an inspection alert regarding special sanitation and employee hygiene requirements for dry, semi-dry or fermented sausages (Appendix B) to verify process/sanitation actions taken by manufacturers.

Further, based on the information available, producers of dry and semi-dry fermented sausages must include a kill step in the process (or validate the process ability to reduce *E. coli* O157:H7 in the product by ≥ 5 logs in inoculated samples) and must prevent recontamination through a combination of GMP's and good sanitation practices in order to eliminate *E. coli* O157:H7. There is no evidence at this time that pH, brine concentration, competitive exclusion, and/or drying would be sufficient to control *E. coli* O157:H7. Currently, heating after fermentation is the only documented procedure accepted without further validation for destroying *E. coli* O157:H7 (see USDA's Safe Handling Procedures for more information on proper cooking to destroy *E. coli* O157:H7).

USDA's Food Safety and Inspection Service requires (FSIS, 1995) that manufacturers of dry and semi-dry sausage products either 1) demonstrate, through a process validation study, the ability to reduce a 7 log inoculum of *E. coli* O157:H7 by ≥ 5 logs, or 2) institute a statistically based sampling program for finished product which affirms the absence of *E. coli* O157:H7 (Appendix B).

In 1996 FSIS (Appendix B) expanded the options to permit one of the following five options for demonstrated prevention of *E. coli* O157:H7 contamination in dry and semi-dry fermented sausage (FSIS, 1996, Appendix B):

1. Utilize a heat process as listed in 9 CFR 318.17 (145°F for 4 min).
-Processor must provide documentation of the heat process.
2. Include a validated 5D inactivation treatment (Appendix B “Challenge Study”, validation procedure).
-Processor using a 5D inactivation treatment will have met requirements for validation.
3. Conduct a “hold and test” program for finished product.
-Testing finished product as the only means of assuring safety is contrary to the philosophy of HACCP; this option involves finished product testing, requires no knowledge of raw ingredients or process, and is expensive.
4. Propose other approaches to assure at least a 5D inactivation.
-Processor could propose any combination that will demonstrate a collective 5D control but must provide precise documentation.
5. Initiate a Hazard Analysis Critical Control Point (HACCP) system that includes raw batter testing and a 2D inactivation. The Food Research Institute has completed the first phase of a process validation study that minimally established parameters necessary to achieve a 5 log (5D) reduction of *E. coli* O157:H7. Based on the results of the study, FSIS has concluded that some combination of raw material testing, processing through fermentation, thermal processing and drying, and finished product testing can be used to demonstrate the adequacy of a given process to assure the safety of dry and semi-dry fermented sausage products.
-Processor could include a HACCP plan combined with GMPs for fermented sausage; the option combines raw batter testing and documentation of at least a 2D lethality of *E. coli* O157:H7 between stuffing and shipping. This is a very practical solution to assuring the safety of certain dry fermented sausage products.

Within Option #5 are several key points that must be considered:

- Analytical method must be equivalent to USDA/FSIS in raw batter testing.
- Sample size and compositing procedure must ensure a detection level of one cfu/g. It is recommended that fifteen 25g samples be taken across each lot; these 15 samples could then be composited into five, 75g analytical samples.
- Definition of “lot” must be scientifically statistically sound.

- GMPs must be applied.
- Processors must have data to document the 2D destruction between stuffing and shipping.
 - As in the case of Options #1 through #4, Option #5 must address *Salmonella*, *Trichinella* and *Staphylococcus*. FSIS expanded the *Staphylococcus aureus* monitoring program to include *E. coli* O157:H7 (Appendix B).
 - Lots of batter which test positive must be subjected to conditions that provide a total 5D process; procedures for dealing with positive lots must be defined in the HACCP plan.

Since some fermented products are fully cooked, it should be reiterated that thorough cooking destroys *E. coli* O157:H7; post process contamination must be avoided.

Listeria monocytogenes

The Microorganism

Listeria monocytogenes has only recently been added to the list of foodborne pathogens. Historically, listeriosis was classified as merely a veterinary concern; it had been primarily associated with abortions and encephalitis in sheep and cattle. However, in the 1980's several listeriosis outbreaks in humans were traced to coleslaw, raw vegetables, and soft cheeses, and *L. monocytogenes* was more closely examined as a foodborne pathogen affecting humans.

L. monocytogenes is present in soil, vegetation, and water and can be carried by humans and animals. It has also been isolated in fodder and straw and in every level of the meat processing chain, including slaughter and plant environments. *L. monocytogenes* has been detected in drains, condensed or stagnant water, floors, residues and process equipment.

A wide variety of meats and meat products can be contaminated with *L. monocytogenes* including beef, pork, minced meat, ham, smoked and fermented sausages, salami, paté, and others. *L. monocytogenes* is primarily a surface contamination. USDA's Nationwide Beef Microbiological Baseline Data Collection Program for Steers and Heifers reported an incidence of 4 percent for *L. monocytogenes* on raw beef carcasses; some 7.4 percent of pork carcasses were reported to be positive for *L. monocytogenes* in USDA's Nationwide Pork Microbiological Baseline Data Collection Program: Market Hogs. Recent data by the CDC have shown, and CDC has concluded that unheated hot dogs are no longer a risk factor for listeriosis.

L. monocytogenes is a distinctive organism because of its ability to grow under adverse conditions. It can grow under aerobic and anaerobic conditions, and can survive in dry conditions. It is also a very salt-tolerant organism. *L. monocytogenes* has a wide temperature growth range of 36.5-112°F (2.5-44°C). It has been noted that at 39.2°F (4°C), *L. monocytogenes* doubled its numbers every 1.5 days.

The Foodborne Illness

People with the highest risk for listeriosis are pregnant women and their fetuses, infants, the elderly, and immunocompromised individuals. After the microbe, *L. monocytogenes*, is ingested the bacteria invade macrophages (large, white blood cells in the body that take up and usually destroy foreign invaders, such as bacteria).

After the invasion, virulent strains of *L. monocytogenes* can multiply causing septicemia. When that occurs, *L. monocytogenes* has access to all parts of the body including the central nervous system, the heart, and the fetuses of pregnant women. Abortion can occur. Meningitis is the most common manifestation of listeriosis with a sudden onset and a fatality rate as high as 70 percent. Listeriosis infection is communicable to others.

The incubation period for *L. monocytogenes* ingestion can be as short as one day or can be from one to several days. Scientists still do not know the infectious dose of *Listeria monocytogenes*. For most healthy individuals, *Listeria* presents no health risk. Death is rare in healthy adults, however, for the immunocompromised, newborn or very young, the mortality rate is approximately 30 percent.

Control Principles

Because of its ubiquity, control of *L. monocytogenes* requires a strict, comprehensive sanitation program. Control begins at the raw product source, and the sanitation program must ensure that containers shipping raw product to the plant--including cartons, boxes, tankers, trucks, or rail cars--are clean.

During slaughter and processing, product flow must guard against potential cross-contamination between raw and finished product. Any aspect of cross-connection -- including human, equipment, water, air, or piping arrangement--should be carefully analyzed to eliminate potential cross-contamination.

In fermented dry and semi-dry sausage products, *L. monocytogenes* is controlled through a combination of low pH, high brine concentration, competitive exclusion from starter cultures (and in some cases bacteriocin production), varying degrees of heat processing, and the drying process. Additional steps for controlling *L. monocytogenes* include:

- 1) A rigid environmental sanitation program encompassing personal hygiene, separation of raw and ready-to-eat processing areas and sanitation and clean-up procedures that have been monitored for proven effectiveness.
- 2) A Hazard Analysis and Critical Control Point (HACCP) program to monitor microbiological quality of ingredients and products, control of the process on a continuing basis; written SSOPs should also define the sanitary conditions under which product is handled and stored, and trained personnel to supervise the sanitation operations.
- 3) Trained, knowledgeable supervision for sanitation operations.

Not all problems should be attributed to poor sanitation programs. To control *L. monocytogenes* effectively, a high level of performance is required at all segments of the manufacturing process. USDA (1997) added *Listeria monocytogenes* to its *S. aureus* enterotoxin monitoring program (Appendix C); monitoring will be greatest among those producers of dry and semi-dry fermented sausages who have failed to validate their processes for destruction of *E. coli* O157:H7.

Salmonella

The Microorganism

Although *Salmonella* is often discussed as though it is a single organism; in actuality, there are more than 2,000 serovars or strains of *Salmonella*. Some strains of *Salmonella* are highly virulent (fewer than 100 organisms can cause illness), other strains require thousands of organisms to cause illness and some may not even be pathogenic to humans.

Salmonella can be carried in the intestinal tracts of sheep, cattle, swine and poultry. Salmonellae infections in animals often are not detected and are carried into feedlots, holding pens, and slaughter plants, increasing the possibility of cross-infection and cross-contamination. Stress from transportation and holding may increase the number of animals (symptomatic or asymptomatic animals) shedding salmonellae in their feces and spreading contamination.

USDA's nationwide beef and pork microbiological collection programs reported an incidence of 1.0 percent for *Salmonella* on raw beef carcasses and 8.7 percent on pork carcasses.

The Foodborne Illness

Foods of animal origin are the primary vehicles for salmonellosis outbreaks. Salmonellosis can be divided into four syndromes: the carrier state (convalescent or asymptomatic), enteric fever (typhoid or paratyphoid fever), gastroenteritis (food infection), and septicemia (characterized by brief febrile illness or a prolonged illness). The most common syndrome is acute gastroenteritis. For this type of salmonellosis, a person must ingest live *Salmonella* bacteria which survive digestion and reproduce in the small intestine in sufficient quantities to cause illness.

Salmonellosis occurs frequently among young children, the elderly, and individuals who are immunosuppressed--although most individuals, regardless of age, are susceptible to infection. Typical symptoms include: diarrhea, followed by abdominal cramps, fever, nausea, vomiting, chills, and headache. The incubation period is six to 48 hours after eating food containing *Salmonella*, and the symptoms last for only two to three days.

The transmission of the disease is usually from animals to humans by ingestion of food of animal origin. Cross contamination of non-animal foods is possible, as is direct transmission from human to human, from human to animal, and from animal to human.

Control Principles

Salmonella are heat-sensitive and mild heat treatments, like those used for cooking meat (150-165°F, 65-74°C), rapidly kill large numbers of the organism. The pathogen-destroying effect of cooking is decreased by drying, as in dry sausage and semi-dry fermented sausage or pre-cooked roast beef. The humidity applied in these processes is important because increased humidity enhances the growth opportunities for *Salmonella*.

Refrigeration retards salmonellae growth, but is not an effective means of killing the organism. The growth of *Salmonella* is very slow below 50°F (10°C), although it can withstand freezing conditions. Salmonellae grow with or without oxygen and in a range of temperatures from 40-117°F (5-47°C). A pH of less than 4.6 prevents growth; pH values of 6.5-7.5 are ideal for growth. . USDA (1997) added *Salmonella* to its *S. aureus* enterotoxin monitoring program (Appendix C); monitoring will be greatest among those producers of dry and semi-dry fermented sausages who have failed to validate their processes for destruction of *E. coli* O157:H7.

Salmonellosis can be prevented by proper cooking of food, avoiding recontamination of cooked food, maintaining low storage temperatures, proper hygienic practices by food handlers, and avoiding contamination of food, water, etc. from feces (i.e., diaper changing, etc.). All of these precautions must be observed in order to prevent salmonellosis. If food is improperly cooked, held at temperatures conducive to the growth of *Salmonella* and cross-contaminated either by exposure to raw foods or by poor employee hygiene, the risk of salmonellosis is dramatically increased (Oblinger, 1988).

In sausage manufacturing, fermentation must simultaneously decrease pH, decrease water activity and build up microbial flora (using starter cultures) to compete with or inhibit growth of *Salmonella*. If the fermentation process proceeds rapidly, *Salmonella* growth is more likely to be inhibited.

Trichinella spiralis

Trichinosis is a disease caused by the nematode *Trichinella spiralis* and occurs when uncooked or undercooked commercial pork products are consumed. Dry and semi-dry fermented sausage products containing pork must be treated to control *Trichinella*. *Trichinella* may be controlled through appropriate thermal processing, freezing pork raw materials and holding for various periods. Other heating, refrigerating or curing methods to destroy/control *Trichinella* are defined in federal meat and poultry regulations (Appendix D).

Damage caused by *Trichinella* infection varies with the intensity of the infection and the tissues invaded. The vast majority of individuals infected are asymptomatic, probably because low numbers of larvae are ingested. Classical trichinosis is usually described as a febrile disease with gastrointestinal symptoms, periorbital edema, petechial hemorrhage and eosinophilia. During the intestinal stage of infection, gastrointestinal symptoms such as nausea, vomiting, “toxic” diarrhea or dysentery, fever (over 100°F), and sweating may be observed. Onset of symptoms occurs usually within 72 hours after infection and may last for two weeks or longer.

GOOD MANUFACTURING PRACTICES

GMPs are programs that comprise the basic, universal steps and procedures that control operating conditions within establishments and ensure favorable conditions for the production of safe food. HACCP systems relate to hazards within a specific process. GMPs are the control factors that relate to the entire operation and are not process-specific. GMPs include such programs as pest control, recall procedures, construction/maintenance and sanitation.

In order to ensure that GMPs are carried out, there are step-by-step descriptions that instruct individuals as to how, when and what tasks are to be performed for a required GMP. The FSIS Pathogen Reduction/HACCP rule published in July, 1996 combines the concepts of Hazard Analysis and Critical Control Point systems with the FSIS requirement for written Sanitation Standard Operating Procedures (SSOPs). In order to avoid confusion, it is important to have a clear understanding of how the HACCP concepts relate to SSOPs as well as the relationship between the SSOPs, Good Manufacturing Practices (GMPs), and HACCP plans that many companies already have in place.

PRODUCT GOOD MANUFACTURING PRACTICES

This document is intended to provide the Good Manufacturing Practices (GMPs) for dry and semi-dry sausages. Special attention is directed toward the microbiological condition of the products given the emphasis currently placed on the microbiological quality and safety of processed meats. In 1997, FSIS initiated intensified and expanded microbiological testing of dry and semi-dry fermented sausages for *E. coli* O157:H7, *Listeria* sp., *Salmonella* sp. and *Staphylococcus aureus*; testing requirements are part of the GMPs that follow.

Dry sausages are chopped or ground meat products that, as a result of bacterial action or direct addition of organic acids, reach a pH of 5.3 or less and are then dried to remove 25 to 50% of the moisture, resulting in a moisture/protein ratio complying with Federal Meat and Poultry Inspection requirements.

Semi-dry sausages are chopped or ground meat products that, as a result of bacterial action or direct addition of organic acids, reach a pH of 5.3 or less and are then dried to remove 15% of the moisture, resulting in a moisture/protein ratio complying with Federal Meat and Poultry Inspection requirements. Some semi-dry sausages receive a pasteurization treatment following the fermentation period and some are shelf stable. Since the pH is lowered during the fermentation period, the degree-hour concept applies only to the time required to reach pH 5.3. FSIS Policy Memo 056 (see Appendix A) requires that these shelf stable products be nitrite cured, fermented, smoked, reach a final pH of 5.0 or less, and have a moisture/protein ratio of 3.1/1.0 or less.

PROCESS CONTROL POINTS

I. pH Control

Fermented and acidulated sausages shall attain a pH of 5.3 or lower through the action of lactic acid forming bacteria or by direct acidulation within the time frame defined in Part II of this GMP. It is important to reach a pH below 5.3 to control the growth of pathogenic microorganisms including staphylococci and pathogenic *E. coli*. To assure that the pH decreases normally, pH readings must be taken from each lot. It is important to record all pH measurements before the product surface temperature reaches 110°F or before the degree/hour limitation has been reached and before any final heat treatment, if used, is initiated.

A. Fermentation

There are two general means recommended for use by which lactic acid forming bacteria used for fermentation may be incorporated into the chopped or ground meat to produce fermented products safely.

1. The preferred and most reliable method is to use a commercially prepared culture which is handled and used as prescribed by the manufacturer.
2. A less acceptable procedure is the use of a portion of a previously fermented and controlled "mother" batch. Since this is less precise than using a commercial culture, it is important that the inoculum derived from the mother batch be composed of a vigorous culture capable of producing a rapid pH decline.

A third method, used historically, relied on lactic acid bacteria which naturally occur in fresh meat to initiate the fermentation. While this practice had been used in the past and was the original art of making fermented sausage; the method is highly unreliable and **should not be used**.

B. Acidulation

An alternative to commercial starter cultures for reducing pH in sausage batters is direct acidulation by USDA-approved acidulants such as citric acid, lactic acid or glucono delta lactone (GDL). These ingredients should be incorporated into sausage batter following procedures recommended by the manufacturer.

II. Time-Temperature Control for Fermentation and Direct Acidulation

A. Degree-Hour Control (see Definitions)

A process is acceptable when it controls the growth of *E. coli* O157:H7 and staphylococci in the product and consistently reaches a pH of 5.3 or less using the following criteria:

1. Fewer than 1200 degree-hours when the highest chamber temperature is less than 90°F.
2. Fewer than 1000 degree-hours when the chamber temperature is between 90 and 100°F.

3. Fewer than 900 degree-hours when the chamber temperature is greater than 100°F.

B. Constant Temperature Processes

The time-temperature relationships for constant temperature processes are as follows:

Degree-Hours Above 60°F	Chamber Temperature (°F)	Maximum Hours to pH 5.3
1200	75	80
1200	80	60
1200	85	48
1000	90	33
1000	95	28
1000	100	25
900	105	20
900	110	18

EXAMPLES OF CONSTANT TEMPERATURE PROCESSES

Process A: Constant 80°F for 55 hours with a pH decline to 5.3

Degrees: 80 - 60 = 20
 Hours: 55
 Degree-Hours: (20) x (55) = 1100 degree-hours

Process A **passes** the guideline (Limit: 1200 degree-hours)

Process B: Constant 90°F for 40 hours with a pH decline to 5.3

Degrees: 90 - 60 = 30
 Hours: 40
 Degree-Hours: (30) x (40) = 1200 degree-hours

Process B **fails** the guideline (Limit: 1000 degree-hours)

C. Variable Temperature Processes

In testing each process, each step-up in the progression is analyzed for the number of degree-hours it contributes, with the highest temperature used in the fermentation process determining the degree-hour limitation as follows:

Process C:

Hours	Chamber (°F)	Critical Temp. Adjustment	Degrees	Degree-Hours
10	75	75 - 60	15	150
10	85	85 - 60	25	250
16	95	95 - 60	35	560
				Total= 960

pH= 5.3: Process C **passes** the guideline, since a pH of 5.3 is attained in less than 1000 degree-hours.

Process D:

Hours	Chamber (°F)	Critical Temp. Adjustment	Degrees	Degree-Hours
10	75	75 - 60	15	150
10	95	85 - 60	25	250
18	98	98 - 60	38	684
				Total= 1084

pH= 5.3: Process D **fails** the guideline because the guideline limit is set at 1000 degree-hours for times and temperatures and it has taken 1084 degree-hours to attain pH 5.3.

III. Processing Schedule Adjustment

If a sausage manufacturer's regular or new processing schedule fails to meet the above guidelines, suggestions on potential process improvements may be obtained from consultants in industry, academia, or trade associations¹. These experts can provide advise regarding validation of processes for control of *E. coli* O157:H7; experts also can provide technical assistance in evaluating the accuracy of temperature sensing devices and pH measuring equipment that are critical to evaluating a production process.

IV. Lots Falling Outside Guideline

If the pH has not reached 5.3 by the time the guideline limitations are met, samples should be taken from the oven for analysis before the temperature is advanced. It is recommended that three samples be obtained from each mixer/batch of product for routine microbial testing. [Sample collection schemes are provided under Option #5 for raw product testing *E. coli* O157:H7 process validation.]

Such samples must be selected at random from all locations within the oven. Only the outer 1/8 inch of the sausage should be sampled. The samples should be analyzed according to FDA's Bacteriological Analytical Manual for the presence of **coagulase positive** staphylococci. When samples are positive for significant levels of **coagulase positive** staphylococci, the laboratory should perform recognized tests for the presence of thermonuclease. Positive thermonuclease readings would strongly indicate that a product should be destroyed.

DEFINITIONS

1. Fermentation

Fermentation is that part of the process in which lactic acid producing bacteria (from the starter culture or "mother" culture) convert fermentable carbohydrate (i.e., dextrose or sucrose) in the meat mixture to lactic acid, and thus lower the pH. Once the pH reaches 5.3 or less, the environment for *S. aureus* and other pathogenic microbes growth is effectively controlled if the process continues lowering the pH to a more stable value or the process begins drying the product at a low temperature. However, reducing pH to 5.3 is insufficient to destroy *E. coli* O157:H7 without a cook step in the sausage-making process. Fermentation to a pH of ≤ 4.6 @90°F or @ 110°F requires further holding and potentially a heat process in order to destroy *E. coli* O157:H7 if it were present.

During fermentation of sausages to a pH of 5.3, it is necessary to limit the time during which the sausage meat is exposed to temperatures exceeding 60°F.

¹The American Meat Institute can help provide contact information, please call our Scientific & Technical Affairs Department at (703) 841-2400.

2. Acidulation

Acidulation is the process of reducing the pH by the direct addition of organic acids. The majority of acidulants in common use require the protection of an encapsulation process. Since many different encapsulating agents are in use, adherence to the supplier's specific recommendations is required.

3. Degree-Hours

Degrees are measured as the excess over 60°F (the critical temperature at which staphylococcal growth effectively begins). Degree-Hours is the product of time in hours at a particular temperature and the "degrees." Degree-Hours is calculated for each temperature used during fermentation. The limitation of the number of degree-hours depends upon the highest temperature in the fermentation process prior to the time that a pH of 5.3 or less is attained. Processes attaining less than 90°F prior to reaching pH 5.3 are limited to 1200 degree-hours, processes exceeding 89°F prior to reaching pH 5.3 are limited to 1000 degree-hours, and processes exceeding 100°F prior to reaching pH 5.3 are limited to 900 degree-hours.

SANITATION REQUIREMENTS

USDA/FSIS is requiring (Appendix E) meat and poultry establishments to develop and implement a written Standard Operating Procedure for sanitation (Sanitation SOPs) which addresses sanitation in facilities, in/on equipment and utensils in federally inspected establishments. An establishment's adherence to its written Sanitation SOP will demonstrate knowledge of and commitment to sanitation.

Sanitation encompasses many areas and functions of an establishment. There are certain sanitary procedures that must be addressed and maintained on a daily basis to prevent direct product contamination or adulteration.

FACILITIES

- The processing environment can be a source of contaminating microorganisms. Properly maintained facilities and equipment, well trained employees, and well designed process flow are fundamental to an effective cleaning and sanitation program.
- Effort must be made to control the following sites to prevent contamination of product and food contact surfaces.

Areas or Item (Examples)

Requirement:

Ceiling, walls, and floors

smooth, sealed, moisture-free

Drains	operative, clean, no standing water
Pipes and insulation	dry and in good repair
Doors and windows	tight fitting
Overheads and conveyors	accessible, cleanable, free of condensate
Air supply	dry, filtered
Production equipment	free of recesses, open seams, gaps, protruding ledges, inside threads, inside shoulders, exposed bolts and rivets, and dead ends
Cleaning and sanitizing	dependable equipment, equipment designed for job
Pallets	good repair, clean and dry
Blowers and ducts	cleaned routinely
Wet/dry vacuum canisters	cleaned and sanitized after use
Refrigeration units	cleaned and sanitized routinely

CLEANING AND SANITIZING

Mid-shift Cleanup

- The traditional wet mid-shift cleanups are detrimental to good microbial control. Plants are encouraged to adopt FSIS-approved control programs to avoid wet mid-shift cleanups.

Food Contact Surfaces:

- Clean and sanitize food contact surfaces; conveyors, peelers, collators, belts, gloves, slicers, and tables can be sources of direct product contamination.
- Clean and sanitize daily or more often when required. Where possible, have equipment running during cleaning and sanitizing for complete exposure to chemicals.
- Avoid contaminating cleaned surfaces with aerosols.
- Review procedures for proper selection and application of detergents, sanitizers, temperatures, pressures, and flow rates. Consult a reliable supplier of sanitation equipment and chemicals for a review of your program.
- Use potable water rinse; without a potable water rinse, USDA regulations permit:
200 parts per million quaternary ammonia
25 parts per million iodine
200 parts per million available chlorine
- Verify the effectiveness of sanitation procedures by microbiological monitoring. Do not limit sampling to flat surfaces.

Non-Food Contact Surfaces

- Establish a regular schedule for cleaning and sanitizing based on results of microbiological monitoring.
- Clean and sanitize floors routinely. The frequency (e.g., daily, weekly) of cleaning depends upon the type of operation and whether the floor can be kept clean and dry.
- Use extensive cleanup and sanitation to follow drain backup prior to resumption of packaging operation. Never use a high pressure hose to free a blocked drain.
- Remove free water from floors after cleanup. Wet/dry vacuums and squeegees are effective if routinely cleaned and sanitized. Avoid splashing or formation of aerosols during the final stages of cleanup when equipment is clean and ready for sanitizing.

- Assure outer protective clothing of cleaning crew is properly washed, sanitized, and dried after use.

Cleaning aids

- Wash and sanitize mops, squeegees, wet/dry vacuums, and condensate removal equipment after use. When possible, they should be stored in a sanitizing solution.
- Eliminate brooms made with absorbent materials. Use only brooms with plastic handles and bristles. Clean and sanitize on a regular basis.
- Replace rags with disposable wipes and discard scouring pads daily.
- Remove hoses from production area after cleanup. Clean, sanitize, and store on hooks off the floor.

Personnel

- Plant management and supervision personnel must set example.
- All employees must feel a sense of personal responsibility for quality and safety of food products.
- All employees must be educated on correct food handling practices.
- Only properly trained line personnel should be used in operations that are most susceptible to post-processing contamination.
- Outer clothing should be changed daily or more often when needed, and must be removed when leaving RTE areas.
- Hands must be washed and sanitized before starting work, upon returning to work stations, and after contacting floors or unclean surfaces.
- Waterproof footwear that can be cleaned and sanitized must be used.
- Operator hand tools should not be stored in personal lockers. This equipment must remain in the RTE area at all times and must be cleaned and sanitized before storage and again before use.
- Disposable plastic gloves, aprons, and sleeves should be used in RTE areas. Change frequently when soiled. Do not use cotton gloves.

PRODUCTION AND PROCESS CONTROLS

Refrigeration

- Equipment must have adequate capacity and sufficient air circulation to maintain desired temperature and control humidity under all climatic conditions.

Cross Contamination

- Establish traffic patterns to prevent movement of personnel, meat containers, meat, ingredients, pallets, and refuse containers between raw and finished product areas.
- Avoid personnel employment in both raw and RTE areas whenever possible. If employees must work in both areas (smokehouses, cook rooms), they must change outer clothing, wash hands, change gloves, clean and sanitize footwear, equipment and utensils before entering RTE product areas.
- Identify employees in raw and RTE areas by color of hat or frock.
- Change outer clothing and wash and sanitize tools and hands prior to entering RTE areas required by all personnel, including maintenance personnel.
- Employees must change outer clothing before moving to RTE product areas.
- Hallways common to raw and RTE areas must be kept clean and dry. Frequent use of vacuum scrubbers is recommended.
- Restrooms, locker rooms, and lunch rooms should be kept clean and orderly.

Condensation Control

- Outside air infiltration must be controlled, intake air must be conditioned, adequate insulation must be provided, and refrigeration systems must be used for maintaining dry environment.

Airborne Contamination

- Protect product from aerosols, splashes, and condensate.
- Filter intake air supply by a properly maintained filtration system. Inspect air source frequently for cleanliness.
- Clean and sanitize refrigeration units on a regular schedule. Use of finless, stainless steel coils is an alternative which is being tested and should be investigated when replacements are planned.

Repackaged, Rework, Returned, and Accidentally Contaminated Product

- The first priority is to design systems and operating practices which minimize losses from rework, retained product, and floor contamination.
- Repackaging of product from defective packages should be performed under controlled conditions which minimize contamination.
- Rework product must always be fully cooked during reprocessing.
- Returned product that has been under producer control may be used after careful evaluation. Product outside producer control should not be used upon return. Under no circumstances should such product be allowed to commingle with current production.

CRITICAL OPERATIONS

Equipment Wash Areas

- These areas represent an ideal environment for the spread of *Listeria*, other pathogenic and spoilage microorganisms.
- Separate wash areas for raw and RTE product must be maintained.
- Wash areas should be located where clean RTE equipment does not cross raw meat areas of the plant.
- Entire room must be cleaned and sanitized daily.

Slicing and Packaging Equipment

- Complete mechanical disassembly is required to prevent contaminants from accumulating and to allow thorough sanitation.
- All food contact surfaces must be cleaned and sanitized daily.
- Moisture must be controlled during production and breaks. Use disposable wipes soaked with sanitizers to clean work areas.
- Install conveyors which are easy to clean and at a height which avoids contamination from floors and drains.
- Protective covers over control panels, motors and equipment, and other food contact surfaces may be a source of microbial contamination. When removed, all covered areas must be dried with disposable towels. Store covers in a clean, dry place when not in use.
- Heat shrinking equipment, including exhaust ducts, must be cleaned and sanitized daily to avoid spreading contamination from water and steam to packing lines.

SUMMARY

Control of *Listeria monocytogenes*, *Salmonella*, *Staphylococcus aureus* and *Escherichia coli* O157:H7 contamination and growth in fermented dry and semi-dry sausage products requires more intensive control measures than provided by previously recognized good manufacturing practices. Research has shown that *E. coli* O157:H7 and *Listeria* may survive in a fermented sausage product; therefore, in order to control *E. coli* O157:H7, it is best to follow the GMP's developed in this guideline. It is mandatory that processes for production of dry or semi-dry fermented sausages be validated (or are acceptable under one of the five options detailed in this guideline) for ability to destroy *E. coli* O157:H7 should it be present in the product. Two essential elements for control include (1) an effective HACCP plan by both the processor and the supplier and (2) a well-designed sanitation program that eliminates the possibility of cross contamination

APPENDIX A

USDA Policy Memo 056

USDA Monitoring Program for Staphylococcal enterotoxin in Dry and Semi-Dry Fermented Sausages

USDA Questions & Answers Regarding the Monitoring Program

APPENDIX B

FSIS Notice (19-95): Inspection Alert - Special Sanitation and Employee Hygiene Requirements for Dry, Semi-Dry, or Fermented Sausages

FSIS Communication (8/21/95) to Plant Managers: Approaches to Ensure Safety of Products in Lieu of Individual Process Validations

FSIS Letter with Approval for Option #5 for Dry Fermented Sausages

Hazard Assessment-- *E. coli* O157:H7 in Fermented Sausage

FSIS Challenge Study (1/23/95) Guidelines-- *Escherichia coli* O157:H7 in Fermented Sausage

FSIS Responses to Industry Questions Regarding Process Validation

APPENDIX C

FSIS Directive on Monitoring *Listeria* and *Salmonella* in Dry/Semi Dry Fermented Sausages

APPENDIX D

USDA Prescribed Treatment of Pork and Products Containing Pork to Destroy Trichinella

APPENDIX E

USDA/FSIS Guidelines for Developing an SSOP in Federally Inspected Meat and Poultry Establishments