Meat and Poultry Hazards and Controls Guide

Food Safety and Inspection Service

United States Department of Agriculture

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Table of Contents

Introduction

FSIS developed this Guide to help FSIS personnel to evaluate all aspects of an establishment's system for producing processed meat and poultry products. The Guide identifies all process steps that may be employed in each process category, lists common food safety hazards for each process step, and cites some of the controls frequently used by processors to address these hazards. This Guide provides the FSIS personnel with the information that he/she needs to determine whether the establishment considered for each process step all the possible hazards therein as part of its hazard analysis and to verify that the analysis and the resultant plan are adequate and appropriately take into account the relevant food safety information. With this Guide, FSIS personnel should be able to verify more effectively whether an establishment's food safety system has appropriately accounted for the hazards that are reasonably likely to occur in its operations.

This Guide should be used by FSIS personnel in performing the verification activities set out in FSIS Directive 5000.1 with the following guiding principles in mind:

a. This Guide is **not** intended to suggest where Critical Control Points should be placed.
b. The statement "no common hazard" is based on the available information and may change as a result of research or outbreak and recall investigations. Unforeseen hazards and the results of the reassessments may also identify a possible hazard in a processing step where none was previously identified.
c. The common hazards listed may not be the only possible hazards for a particular step.
d. Entries in the "Frequently used controls" column should not be taken as the only valid controls that establishments may have in place for a particular hazard. The establishment must have supporting documentation for any controls they have in place for identified hazards, whether they are the ones listed in this document or not. Other validated controls for a particular hazard may be used in an establishment's food safety system.
e. A set of suggested general and process-specific verification questions is included in this Guide. These questions will provide the FSIS personnel with an analytical thought process that may lead the FSIS personnel to ask additional questions in evaluating the process steps. FSIS personnel should use the general and process-specific questions in evaluating each process step. It is important for FSIS personnel to realize that these questions are not meant to be all inclusive but as a Guide to the types of questions that should be answered when verifying regulatory compliance.

This Guide should also be valuable to establishment personnel, particularly those in small and very small plants, in developing the hazard analyses and supporting documentation. The common hazards and frequently used controls in this Guide are neither a guaranteed path to safe food, nor are they the only hazards and applicable hazard controls available to an establishment operator.

Each plant must design its own food safety system to meet its needs.

The Guide consists of the following major sections:

- alphabetical listing of process steps that may be used in the production of processed meat and poultry products and the page numbers where they can be found;
- quick reference table of process steps by process category, which provides a quick reference to the most common process steps in the production of products under the processing categories listed in 9 CFR 417.2;
- an individual listing of 27 processing steps with some currently identified common hazards and frequently used controls for each process step; and
- definitions of terms used in the guide and a list of references for easy access to current information on regulations and other guidance material.

Click on the links below to be directed to each process step.

Quick Reference Table of Process Steps by Category

Process Steps	Page No.	Process Categories							
		Raw Not Ground	Raw Ground	Fully Cooked, Not Shelf Stable	Heat Treated Not Fully Cooked	Heat Treated Shelf Stable	Not Heat Treated Shelf Stable	Secondary Inhibitors	Thermally Processed, Commercially Stable
Receiving meat raw materials; Storage prior to use	p. 6	•	•	•	•	•	•	•	•
Receiving and storage of packaging materials and non-meat ingredients	p. 7	•	•	•	•	•	•	•	•
Thawing frozen meat	p. 8	•	•	•	•	•	•	•	•
Formulation	p. 9	•	•	•	•	•	•	•	•
Mixing/grinding/boning/ fabrication	p. 10		•	•	•	•	•	•	•
Preblending	p. 10		•	•	•	•	•	•	•
Patty formation	p. 10		•	•	•	•	•		•
Stuffing	p. 10	•	•	•	•	•	•	•	•
Injection/tumbling	p. 10	•		•	•	•	•	•	•
Rework	p. 11	•	•	•	•	•	•	•	•
Fermentation	p. 12			•	•	•	•	•	
Cooking/smoking	p. 13			•		•			
Heating/smoking/ charring	p. 14				•	•			
Breaded and pre-browned	p. 14				•	•			
Drying	p. 15	•				•	•		
Filling	p. 16								•
Sealing/closing/capping	p. 17								•
Retorting	p. 18								•
Can cooling	p. 19								•
Brine chilling	p. 20			•	•	•			
RTE product handling after cooking Peeling Slicing Dicing Chopping Mincing Surface rub Repackaging	p. 21			•	•	•		•	
Storage after chilling	p. 23	•	•	•	•	•			•
Packaging	p. 24	•	•	•	•	•	•	•	•
RTE post-lethality treatment	p. 25			•	•	•			
Irradiation of raw products	p. 26	•	•						
Storage prior to shipping; Product handling at shipping time	p. 28	•	•	•	•	•	•	•	•
Returned product	p. 29	•	•	•	•	•	•	•	•
Controlling outgrowth of *L. monocytogenes*	p. 30			•		•	•	•	

Suggested General Verification Questions for Most Process Steps

This set of general questions should be asked when evaluating the production process in light of the relevant process steps. It is intended to assist inspection personnel in verifying the adequacy of the establishment's approach to each processing step. Individual processing steps in this Guide include additional questions that are specific to each processing step.

- Has the establishment included this process step in the flow chart and hazard analysis?
- Does the establishment have a prerequisite program that addresses this step?
- Has the establishment identified any hazards associated with this step?
- Is this process step a CCP?
- Is the establishment following all procedures identified in the hazard analysis?
- Does the establishment maintain records associated with this step?
- Do records contain information that indicates a reassessment of the hazard analysis or HACCP plan is necessary?
- Are records made available to FSIS?
- Is the equipment used clean, sanitary, and well maintained?

Process Steps, Common Hazards, and Frequently Used Controls

Process Step	Common Hazards	Frequently Used Controls
• Receiving meat raw materials • Storage prior to use	Biological—Potential presence and outgrowth of the following common hazards: • Raw beef and veal products—*Salmonella* and *E. coli* O157:H7 • Raw chicken, turkey and other poultry—*Salmonella* and *Campylobacter jejuni/coli* • Raw pork and other products (e.g., sheep, equine— *Salmonella*)	• Ensure product has been prepared and handled by the source establishment in a manner that minimizes the possibility of pathogen contamination (e.g., letters or certificates of guarantee, product temperature tracking, microbial testing).
	Chemical—No common hazard	• Ensure product has been properly handled prior to acceptance, maintain package integrity.
	Physical—No common hazard	

Suggested verification questions:

1. Are products received held under refrigeration to preclude the growth of pathogens?

2. Are products protected from environmental contamination such as dust, moisture, or other physical contaminants?

Process Step	Common Hazards	Frequently Used Controls
• Receiving and storage of packaging materials and non-meat ingredients Physical—No common hazard with written guarantee from suppliers and enclosed during transportation	Biological—Contamination with biological material	•• Procure letters of guarantee that materials are free of hazards when received and store in proper conditions to prevent a breach in safety. Dry goods storage should be protected from pests and environmental contamination.

Suggested verification questions:

1. Are materials guaranteed by the manufacturer?
2. Are materials protected from environmental contamination (e.g., are containers kept closed and properly stored in acceptable storage areas)?

Process Step	Common Hazards	Frequently Used Controls
•Thawing frozen raw meat	Biological—Cross-contamination and outgrowth of the following common hazards: •Raw beef and veal products— *Salmonella* and *E. coli* O157:H7 •Raw chicken, turkey and other poultry—*Salmonella* and *Campylobacter jejuni/coli* •Raw pork and other products— *Salmonella*	•Maintain product at an acceptable temperature. •When thawing meat, surface temperature is a concern and should be monitored. In many cases surface temperature may rise above common holding temperatures for a short time period. The duration that the surface temperature is within the growth range should be kept to a minimum.
	Chemical—No common hazard	•Maintain package integrity.
	Physical—No common hazard	

Suggested verification questions:

1. Is the process performed at temperatures that preclude pathogen growth?
2. Is the process performed under clean, sanitary conditions?
3. Is package integrity and/or product identity maintained throughout the process?

Process Step	Common Hazards	Frequently Used Controls
•Formulation Note: Formulation to include an antimicrobial agent against *L. monocytogenes* to meet the *Listeria* Rule requirements for Alternatives 1 and 2 is discussed in a separate process step.	Biological—Outgrowth of certain pathogens in the final ready-to-eat (RTE) product. •Examples include nitrate/nitrite for *Clostridium botulinum*	•Checks to ensure the proper ingredient additions should be in place. Time and temperature combinations should not be abused with reliance on nitrates or nitrites. •Proper formulation ensures effectiveness of antimicrobial additives in preventing outgrowth of certain pathogens in the final RTE product.
	Chemical—Addition of improper levels of nitrite or nitrate or other restricted ingredients. •Other restricted ingredients include, but are not limited to, ○ antioxidants ○ antimicrobial agents ○ cure accelerators ○ flavoring agents (protectors and developers) ○ tenderizing agents	•When using nitrate or nitrite, a check system should be in place to ensure the correct amounts are used. •The USDA limit for nitrite is 156 ppm in comminuted product; 200 ppm in pumped, tumbled, or immersed product (other than bacon); and 120 ppm in pumped bacon. •A 6.25% mixture of sodium nitrite in salt is preferred for consumer safety.
	Physical—No common hazard	•Maintain protection from environment.

Suggested verification questions:

1. Are ingredients being used in the actual formulation in amounts that agree with the establishment's documented formulation for the particular product?
2. Are amounts of restricted ingredients used in compliance with regulations for restricted ingredients?
3. Is rework included in product formulations? If yes, see rework process step.
4. Are all ingredients being used in actual formulation included in product formula and listed in descending order of predominance that agrees with the ingredient statement on the approved label for the product?

Process Step	Common Hazards	Frequently Used Controls
•Mixing/grinding/boning /fabrication •Preblending •Patty formation •Stuffing •Injection/tumbling	Biological—Potential outgrowth of raw product pathogens, including •Raw beef and veal products—*Salmonella* and *E. coli* O157:H7; •Raw chicken, turkey, and other poultry—*Salmonella* and *Campylobacter jejuni*/*coli*; and •Raw pork and other products—*Salmonella*	•Maintain product at an acceptable temperature.
	Biological—Contamination from unclean equipment Note: No common hazard with adequate Sanitation Standard Operating Procedure (SSOP)	•Proper cleaning procedures, visual inspection, and effective SSOPs. •Pathogen contamination in meat is not destroyed by cold storage and must be prevented or eliminated.
	Chemical—No common hazard	•See formulation hazard.
	Physical—Metal and other physical contamination from grinder, mixer, or chub clips	•Implement an appropriate screening procedure for monitoring equipment and/or product. •FSIS Directive 7310.5 states that a processor should use the most sensitive detection technique available.

Suggested verification questions:

1. Is ingoing product wholesome and free of physical contaminants?
2. Is rework included in the process? If yes, see rework process step.
3. Are ingredients included in product formulas in amounts that agree with the establishment's documented formula for the particular product?
4. Are amounts of restricted ingredients used in compliance with regulations for restricted ingredients?

Process Step	Common Hazards	Frequently Used Controls
•Rework	Biological—For raw product that is reworked, outgrowth of pathogens in raw product: •Raw beef and veal products—*Salmonella* and *E. coli* O157:H7 •Raw chicken, turkey, and other poultry— *Salmonella* and *Campylobacter jejuni/coli* •Raw pork and other products—*Salmonella* Biological—For RTE product that is reworked, cross-contamination from raw products and outgrowth of *Listeria monocytogenes*	•Maintain product at an acceptable temperature.
	Chemical—No common hazard	
	Physical—Metal and other physical contamination from grinder, mixer, chub clips, etc.	•Appropriate screening procedure for monitoring equipment and/or product.

Suggested verification questions:

1. Have products to be used for rework been properly stored to preclude pathogen growth and contamination?
2. Are there any hazards associated with rework that are different from hazards associated with the product it is being added to?
3. Does the establishment have any additional controls for rework product (e.g., length of time in storage, results of examination when received)?
4. Does the establishment conduct microbiological testing of rework product?
5. Are all ingredients of the rework declared on the label of the finished product, and are they listed in the correct order of predominance?

Process Step	Common Hazards	Frequently Used Controls
•Fermentation	Biological—Raw product pathogens including •Raw beef and veal products—*Salmonella* and *E. coli* O157:H7; •Raw chicken, turkey, and other poultry—*Salmonella* and *Campylobacter jejuni/coli*; and •Raw pork and other products— *Salmonella*. Biological—Semi-dry/fermented product pathogens including •Outgrowth of *Staphylococcus aureus* and *Clostridium* spp. that might occur from inadequate fermentation. Note: Some semi-dry/ fermented products undergo marginal processing treatments. Therefore, the microbiological quality of ingredients is crucial to the final product's safety.	•Reduce pH of product to an acceptable level in an acceptable time period to prevent possible outgrowth and toxin production from *S. aureus*. •Meat pH should decline to 5.3 within an acceptable time temperature combination (temperature in degrees F (°F), time in hours). To calculate degree hours, the following equation can be used. •[Fermentation Temperature (°F) – 60] x time (hours) = degree hours and the process is acceptable if ○ Fewer than 1,200 degree hours when the lowest fermentation temperature is less than 90°F (32°C). ○ Fewer than 1,000 degree hours when the highest fermentation temperature is between 90°F (32°C) and 100°F (38°C). ○ Fewer than 900 degree hours when the highest fermentation temperature is greater than 100°F (38°C).
	Chemical—No common hazard	•Maintain protection from environment.
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment conduct microbiological testing of ingredients?
2. Does the establishment conduct microbiological testing of finished products?
3. Are starter cultures used at the manufacturer's recommended levels and not in excess of the amount permitted by regulation?
4. Are times, temperatures, pH, water activity, and drying conditions monitored throughout the process?
5. Does the process result in a shelf-stable finished product?
6. If the finished product is not shelf stable, is the product accurately labeled?

Process Step	Common Hazards	Frequently Used Controls
•Cooking/smoking (fully cooked)	Biological—Raw product pathogens and parasites including •Raw beef and veal products— *Salmonella* and *E. coli* O157:H7; •Raw chicken, turkey, and other poultry—*Salmonella* and *Campylobacter jejuni/coli*; and •Raw pork and other products— *Salmonella* and *Trichinella spiralis.*	•The final internal temperature and dwell time of the product are recommended to reach a *Salmonella* lethality level of 6.5 log units for beef and 7.0 log units for poultry.
	Chemical—No common hazard	•Maintain protection from environment.
	Physical—No common hazard	

Suggested verification questions:

1. Does the process achieve the required lethality treatment?
2. Does the establishment conduct microbiological testing of products?
3. Are time/temperature combinations monitored throughout the process?
4. Does the establishment have validated procedures for reprocessing in the event of a process deviation?

Process Step	Common Hazards	Frequently Used Controls
•Heating/smoking/charring •Breaded and pre-browned (i.e., not fully cooked [not RTE]), (e.g., bacon)	Biological—Outgrowth of raw product and other pathogens that might occur because of improper time and temperature: •Raw beef and veal products— *Salmonella* and *E. coli* O157:H7 •Raw chicken, turkey, and other poultry—*Salmonella* and *Campylobacter jejuni/coli* •Raw pork and other products—*Salmonella* •All raw products—outgrowth of *Clostridium botulinum* and *Clostridium perfringens*	•When a product is not a fully cooked product, the final internal temperature is not required to reach a specific temperature; however, the time that the product is in the danger zone of microbial growth should be minimized.
	Chemical—No common hazard	•Maintain protection from environment.
	Physical—No common hazard	

Suggested verification questions:

1. Is the heating/smoking one part of a multistep "treatment?" If so, the link to the rest of the treatment element is also critical.
2. Does the heating/smoking result in an RTE product? If the finished product is NRTE, the product must be accurately labeled to inform the consumer of that fact.
3. Does the establishment conduct microbiological testing of products?
4. Are time/temperature combinations monitored throughout the process?
5. Does the finished product exhibit a "cooked" appearance without being fully cooked?

Process Step	Common Hazards	Frequently Used Controls
•Drying	Biological—Raw product pathogens including •Raw beef and veal products— *Salmonella* and *E. coli* O157:H7; •Raw chicken, turkey, and other poultry—*Salmonella* and *Campylobacter jejuni/coli*; and •Raw pork and other products— *Salmonella*. •All raw products—Outgrowth of *Staphylococcus aureus*, *Clostridium botulinum,* and *Clostridium perfringens*	•As the water activity of a product decreases, most bacteria cannot grow. Ensure that the water activity, pH, and temperature of a product prevent pathogen outgrowth.
	Chemical—No common hazard	•Maintain protection from environment.
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment conduct microbiological testing of products?
2. Are temperature, relative humidity, and air flow controlled throughout the process so that drying proceeds properly?
3. Are times, temperatures, pH, water activity, and drying conditions monitored throughout the process?
4. How is the establishment ensuring that process deviations do not result in adulterated product?

Process Step	Common Hazards	Frequently Used Controls
•Filling (can or retortable pouch)	Biological—*Clostridium botulinum* spores	•Overfilling can compromise the commercial sterility process that ensures destruction of *C. botulinum* spores. Consult a thermal process authority to ensure proper filling and retorting procedures.
	Chemical—No common hazard	•Maintain protection from environment.
	Physical—No common hazard	

Suggested verification questions:

1. Are empty containers, closures, and flexible pouch stock evaluated by the establishment to ensure that they are clean and free of structural defects and damage?
2. Are rigid containers used?
3. Are rigid containers cleaned just before filling per 9 CFR 318.301 (a) (3) and 381.301 (a) (3)?

Process Step	Common Hazards	Frequently Used Controls
Sealing/closing/capping (can or retortable pouch)	Biological—No common hazard Chemical—No common hazard Physical—No common hazard	Maintain protection from environment. Ensure proper sealing by appropriate testing.

Suggested verification questions:

1. Did a closure technician examine the double seams formed by each closing machine head?
2. Was the entire container examined for product leakage or obvious defects?
3. Was a visual inspection performed on at least one container from each closing machine head, and were the observations along with any corrective actions recorded?
4. Were visual examinations conducted with sufficient frequency to ensure proper closure?
5. Were visual examinations conducted at least every 30 minutes of continuous closing machine operation?
6. Are closure examinations and physical tests carried out in accordance with 9 CFR 318.301 and 381.301?

Process Step	Common Hazards	Frequently Used Controls
•Retorting	Biological—*Clostridium botulinum* spores	•Consult a thermal process authority for proper retorting and commercial sterility procedures.
	Chemical—No common hazard	•Maintain can/package integrity.
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment have a process schedule?
2. Has there been a change in product formula and, if so, has the schedule been updated?
3. Are appropriate letters/written communications from the processing authority on file?
4. Are the critical factors specified in the process schedule measured, controlled, and recorded by the establishment?
5. Is each retort equipped with at least one temperature device measuring the actual temperature within the retort?
6. Is each thermal processing system equipped with at least one temperature/time recording device to provide a permanent record of temperature within the system?
7. Is each retort equipped with an automatic steam controller?
8. Do air and water valves comply with 9 CFR 318.305 and 381.305?
9. Are the requirements of 9 CFR 318.305 (5) (b) (c) (d) (e) and (f) and 381.305 (5) (b) (c) (d) (e) and (f) met?

Process Step	Common Hazards	Frequently Used Controls
•Can cooling	Biological—Microbial contamination of product	•Bacterial contamination of cooling water should be minimized to reduce the risk of contamination into cans while the seams are stressed.
	Chemical—No common hazard	•Maintain can/package integrity.
	Physical—No common hazard	

Suggested verification questions:

1. Is potable water used for cooling, except as provided for in 9CFR 318.305 (h) and 381.305(h)?
2. Is cooling canal water chlorinated or treated with a chemical appropriate for this use?
3. Are cooling waters that are recycled or reused handled in systems so designed for such use?
4. Is system equipment such as pipelines, cooling towers, and holding tanks constructed and installed so they may be easily cleaned and inspected?

Process Step	Common Hazards	Frequently Used Controls
•Chilling, including brine chilling	Biological—*Clostridium perfringens* and *Clostridium botulinum* outgrowth due to time and/or temperature abuse.	•Cool product within proper window of time to prevent growth of *Clostridium perfringens* and *Clostridium botulinum* spores that germinated after cooking.
	Biological—Contamination from chilling solution	•Sanitation of chilling solution. •NaCl concentration and temperature of the brine solution should be kept at levels that destroy or prevent growth of pathogens.
	Chemical—No common hazard	•Maintain protection from environment.
	Physical—No common hazard	

Suggested verification questions:

1. Is the solution maintained at the proper concentration and temperature?
2. If the solution is reused, is it properly filtered and maintained free of contaminants?
3. Are FSIS personnel notified when a deviation occurs?

Process Step	Common Hazards	Frequently Used Controls
•RTE product handling after cooking, including ○ Peeling ○ Slicing ○ Dicing ○ Chopping ○ Mincing ○ Surface rub ○ Repackaging	Biological—Contamination and outgrowth of *Listeria monocytogenes* from food contact surfaces and other environmental sources Biological—Contamination by pathogens from raw product areas, including *Salmonella, Campylobacter,* and *E. coli* O157:H7 Biological—Outgrowth of *Staphylococcus aureus, Clostridium perfringens,* and *Clostridium botulinum*	•All post-cook handling should be minimized and the utmost care given to everything that may come into contact with the cooked product. •Prevent cross-contamination from uncooked product. Sequester raw and cooked product areas and regulate the flow of personnel, carts, and equipment between those areas. •Post-process sanitation is critically important. Sampling and testing food contact surfaces and other environmental surfaces for *Listeria* spp. or *Listeria*-like organisms provide information on potential sources for *Listeria monocytogenes* contamination. On-site construction can free harbored *L. monocytogenes* within the plant environment, requiring extra diligence put toward testing and sanitation. See FSIS *Listeria* Rule, Directive and Compliance Guidelines for additional information on *L. monocytogenes* control in RTE establishments. ·Pathogen contamination in meat is not destroyed by cold storage and must be prevented or eliminated. •Ensure the cleanliness and microbiological quality of spices added to cooked product as a surface rub. •Unless other methods such as pH or water activity level are used to prevent growth, proper temperature and time limits should be maintained.
	Chemical—No common hazard	•Maintain protection from environment
	Physical—No common hazard	

Suggested verification questions:

1. Has the establishment selected one of the three alternatives per 9 CFR 430.4 (b)?
2. Is the post-lethality treatment included in the establishment's HACCP plan?
3. Is the antimicrobial agent or process included in the establishment's HACCP plan, SSOP, or prerequisite program?
4. Has the establishment validated the effectiveness of the treatment?
5. Is product separation maintained to prevent contamination from uncooked product?
6. Does the establishment perform microbiological testing of ingredients such as spices and coatings that are added to the product after cooking?

Process Step	Common Hazards	Frequently Used Controls
•Storage after chilling	Biological—For raw products in storage, outgrowth of raw product pathogens including •Raw beef and veal products— *Salmonella* and *E. coli* O157:H7; •Raw chicken, turkey, and other poultry—*Salmonella* and *Campylobacter jejuni/coli*; and •Raw pork and other products— *Salmonella*. Biological—For RTE products in storage, outgrowth of *Staphylococcus aureus, Clostridium botulinum,* and *Clostridium perfringens* and potential for outgrowth of *Listeria monocytogenes*.	•Unless product is shelf stable, other methods must be used to prevent growth (e.g., low pH, freezing, low water activity, refrigeration temperature and time limits).
	Chemical—No common hazard	•Maintain protection from environment.
	Physical—No common hazard	

Suggested verification questions:

1. Are products properly refrigerated after chilling?
2. Does the establishment use methods other than refrigeration to prevent pathogen growth? If so, are the methods validated as effective and monitored?

Process Step	Common Hazards	Frequently Used Controls
•Packaging	Biological—No common hazard	•Packaging material should be adequate to prevent bacterial, chemical, or physical contamination. •All post-cook handling should be minimized and the utmost care given to everything that may come into contact with the cooked product.
	Chemical—No common hazard	•Maintain package integrity.
	Physical—No common hazard	

Suggested verification questions:

1. Are packaging materials covered by letters of guaranty or statements of assurance from the suppliers?
2. Are packaging materials properly stored and protected from environmental contamination?

Process Step	Common Hazards	Frequently Used Controls
•RTE post-lethality treatment including post-packaging heat treatment or high pressure treatment Note: This step must be designated a CCP to meet the requirements of Alternative 1 or 2 described in The *Listeria* Rule.	Biological—*Listeria monocytogenes* that may have contaminated product after cooking and/or other processing	•Treatment must be validated to reduce *Listeria monocytogenes* by a minimum of 1 log (i.e., one factor of ten). The validation reference cited for critical limits must be directly relevant to the product and process used by the establishment. •Examples of critical limit parameters: o Post-process heat treatment—dwell time and temperature o High pressure—dwell time and pressure o Validation study must be relevant to the product and critical limits in question for data to be valid.
	Chemical—No common hazard	•Maintain package integrity.
	Physical—No common hazard	

Suggested verification questions:

1. Is package integrity maintained throughout the process?
2. Does the process achieve the required lethality levels?
3. Does the establishment conduct microbiological testing of products?

Process Step	Common Hazards	Frequently Used Controls
•Irradiation of raw products	Biological—For raw products, raw product pathogens including •Raw beef and veal products—*Salmonella* and *E. coli* O157:H7; •Raw chicken, turkey, and other poultry—*Salmonella* and *Campylobacter jejuni/coli*; and •Raw pork and other products—*Salmonella*.	•Ensure that irradiation treatment is adequate to destroy pathogens. The current regulations state that 4.5 kGy is maximum allowed for refrigerated raw meat and 7.0 kGy is the maximum for frozen meat. •Laboratory procedures for determining absorbed dose value •Calibration criteria verifying the accuracy and consistency of any means of measurement •Procedures for mapping regions of minimum and maximum product unit absorbed dose •Accounting procedures for total absorbed dose •Procedures for verifying routine dosimetry (i.e., assuring each production lot receives the total absorbed dose) •Procedures for verifying the relationship of absorbed dose to time exposure of the product unit to the radiation source •Procedures for verifying the integrity of the radiation source and processing procedure
	Chemical—No common hazard	Maintain package integrity.
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment have all procedures in place to comply with the requirements of 9 CFR 424.22 (c) and 21 CFR 179.26?
2. Does the establishment have validated laboratory procedures for determining absorbed dose value?
3. Does the establishment have validated calibration criteria verifying the accuracy and consistency of any means of measurement?
4. Does the establishment have validated procedures for mapping regions of minimum and maximum product unit absorbed dose?
5. Does the establishment have validated accounting procedures for total absorbed dose?
6. Does the establishment have validated procedures for verifying routine dosimetry (i.e., assuring each production lot receives the total absorbed dose)?
7. Does the establishment have validated procedures for verifying the relationship of absorbed dose to time exposure of the product unit to the radiation source?
8. Does the establishment have validated procedures for verifying the integrity of the

radiation source and processing procedure?

9. Are packaging materials used suitable for exposure to radiation?

Process Step	Common Hazards	Frequently Used Controls
•Storage prior to shipping •Product handling during shipping	Biological—For raw products, outgrowth of raw product pathogens, including •Raw beef and veal products— *Salmonella* and *E. coli* O157:H7; •Raw chicken, turkey and other poultry—*Salmonella* and *Campylobacter jejuni/coli*; and •Raw pork and other products—*Salmonella*.	•Maintain product at an acceptable temperature.
	Biological—For RTE products, outgrowth of *Staphylococcus aureus*, *Clostridium botulinum*, and *Clostridium perfringens* and outgrowth potential for *Listeria monocytogenes*	
	Chemical—No common hazard	•Maintain package integrity.
	Physical—No common hazard	

Suggested verification questions:

1. Are products properly refrigerated and not held in areas without refrigeration for extended periods of time?
2. Are products protected from environmental contamination such as dust, moisture, or other physical contaminants?

Process Step	Common Hazards	Frequently Used Controls
Returned product	Biological—For raw products, outgrowth of raw product pathogens, including •Raw beef and veal products— *Salmonella* and *E. coli* O157:H7; •Raw chicken, turkey, and other poultry—*Salmonella* and *Campylobacter jejuni/coli*; and •Raw pork and other products—*Salmonella*.	The condition of product that has been out of the processor's control usually cannot be verified. Other product that has been in the processor's control may be reworked depending on time and/or temperature abuse. When receiving returned cans and other shelf-stable products, package integrity can be an important consideration in evaluating product wholesomeness.
	Biological—For RTE products, outgrowth of *Staphylococcus aureus*, *Clostridium botulinum*, and *Clostridium perfringens* and outgrowth of *Listeria monocytogenes*.	
	Chemical—No common hazard if packaging is intact and product has not been exposed.	
	Physical—No common hazard if packaging is intact and product has not been exposed.	

Suggested verification questions:

1. Are returned products stored in a designated area separate from other product?
2. Are packages in good condition?
3. Do containers exhibit evidence of mishandling? If so, does the establishment have procedures and controls in place to effectively ensure the product's wholesomeness?
4. Are all containers correctly labeled?
5. Is returned product used as rework? If yes, see rework process step.

Process Step	Common Hazards	Frequently Used Controls
•Antimicrobial agent or process for controlling outgrowth of *Listeria monocytogenes*, as defined in The *Listeria* Rule. Note: An antimicrobial agent or process can qualify as Alternative 1 without an additional post-lethality treatment if it provides at least 1 log of lethality by the time the product is shipped.	Biological—For RTE products covered under The *Listeria* Rule, outgrowth of *L. monocytogenes* during the course of the product shelf life Chemical—No common hazard if approved levels are not exceeded Physical—No common hazard	•Formulate product or interior packaging with levels of antimicrobial agent that have been approved by FSIS for use in RTE products and have been shown through validation to be effective in inhibiting or limiting *L. monocytogenes* outgrowth as defined in the *Listeria* Rule Compliance Guidelines. o Example: Lactate/diacetate in deli meats or franks •Alternatively, a process that has been shown through validation to inhibit or limit outgrowth might be employed. •Validation study must be relevant to the product and critical limits in question for data to be valid.

Suggested verification questions:

1. Has the antimicrobial agent used been approved by FSIS for use in RTE products?
2. Has the antimicrobial agent been validated as effective to control outgrowth of Listeria monocytogenes?

D or D value:

A measure in minutes at a given temperature to kill 1 $\log_{10}$ of a bacterial population. For instance, Appendix A prescribes 77 minutes at 132°F for a 7 $\log_{10}$ or 7D *Salmonella* lethal heat treatment. Thus, that is a $D_{132^\circ F}$ of 11 minutes for *Salmonella* in roast beef.

Degree hours:

A specific term used in determining the inhibitory activity of a sausage fermentation culture against *Staphylococcus aureus.*

Calculate degree hours by subtracting 60°F from the fermentation temperature in °F, then multiplying that remainder by the number of hours required to reach pH5.3. The higher the fermentation temperature, the fewer degree hours permitted to reach pH5.3 for effective staphylococcal inhibition.

See the AMI or AFDO guidelines for those degree hour limits and how to calculate multi-temperature processes.

"log" or **$\log_{10}$:**

The number of the exponent when 10 is the base number. Thus, 2 $\log_{10}$ is 10^2 or 100; 4 $\log_{10}$ is 10^4 or 10,000. A 3 $\log_{10}$ increase is an increase of 1,000 times; Conversely, a 3 $\log_{10}$ decrease eliminates 99.9% of the original population.

Because bacteria can grow to extremely high levels (i.e., approaching a billion per gram), microbiologists generally refer to outgrowth or death in terms of factors of ten. "1 log" lethality is a reduction in numbers of bacteria by a factor of ten (i.e., one-tenth of the original number remains, for instance, 10 down to 1, 100 to 10 or 1,000 to 100). Likewise, "1 log" of outgrowth is an increase in numbers of bacteria by a factor of 10 (i.e., 1 increasing to 10, 10 to 100, 100 to 1,000, etc.).

pH:

Derived from the German term "potenz Hydrogen" or "power of Hydrogen"; thus the H is always capitalized.

This is the acidity or alkalinity of the product; pH= 7 is regarded as neutral with acidity increasing as the pH value decreases.

Scientifically pH is the negative $\log_{10}$ of the hydrogen ion activity in moles. Thus, 10^{-5} (pH 5) is ten times more acidic than 10^{-6} (pH 6). Because neutral water (H-OH) dissociates equal amounts of hydrogen (H+) and hydroxide (OH-) at 10^{-7} moles each, the neutral pH (and neutral OH) is pH
7.
If pH is verified within the establishment, the pH electrode should be calibrated before each use or according to the manufacturer's instructions.

Most food is slightly acidic. Meat after rigor is usually between pH 5.4 and pH 5.6 because of the conversion of muscle glycogen to lactic acid.

Shelf stable:

A product that does not require refrigeration to remain wholesome. See 9 CFR 317.2(k). Other terms are "non-perishable," "Does Not Require Refrigeration for Safety," and "Not a Potentially Hazardous Food" or "Not PHF" ("PHF" is commonly used in FDA-inspected and retail operations).

The critical limits for a shelf-stable product will vary according to its final composition. General critical limits include the following:

. •aw <0.85: Inhibits enterotoxigenic staphylococcal growth aerobically, but the manufacturer will have to take additional measure to prevent mold growth.
. • pH <4.6: Inhibits *Clostridium botulinum* growth and toxigenisis under ordinary conditions. For retorted (canned foods) pH 4.6 is the border between "high acid" and "low acid" products. In non-retorted products, other pathogens can grow below pH 4.6, but additional factors such as nitrite, lack of moisture, or solutes such as salt are usually contributing inhibitory factors. If an establishment cites pH 4.6, its validation must include those other factors.
. • Moisture Protein Ratio (MPR) of 3.1:1 or less and a pH of 5.0: This is a policy listed in the "Labeling Policy Book: <http://www.fsis.usda.gov/OPPDE/larc/policies/PolicyBook.pdf>. Moisture Protein Ratio is a "product standard" not a critical limit for shelf stability unless the MPR is scientifically linked to formulation and other validated factors such as pH, brine, or aw.

Water activity (a_w : little "a", subscript capital "W"):

21 CFR 110.3(r): Water activity (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature."

Thus, water has an aw 1.0. Raw meats and most cooked uncured products are generally aw 0.98 or greater. More practically, water activity is an approximation of water available to bacteria or the humidity within the food. Adding solutes (e.g., salt or sugar) or drying decreases a product's water activity.
If water activity is verified within the establishment, the instrument should be calibrated periodically according to the manufacturer's instructions.

Terms from the *Listeria* Rule

Refer to "References for *Listeria monocytogenes*" for additional information.

Post lethality treatment (PLT): An intervention applied to product that reduces the relative number of *Listeria monocytogenes* that might have contaminated product after cooking and before packaging. A PLT must provide at least 1 log of lethality prior to product release to qualify for consideration.

Antimicrobial agent or process (AMA or AMP): An intervention, usually an additive, that inhibits outgrowth of *Listeria monocytogenes* to no more than 2 logs during the course of the claimed shelf life.

Alternative 1: For RTE products covered under The *Listeria* Rule, these are regarded as the least risky and should be sampled less often than Alternative 2 or 3 products. To qualify for Alternative 1, both a PLT and AMA/AMP are necessary to reduce possible *L. monocytogenes* contaminants and prevent outgrowth of any that might possibly remain. An additive that not only reduces the number of *L. monocytogenes* but prevents their significant outgrowth during the shelf life may qualify to be considered both a PLT and AMA and thus meet the requirements of Alternative 1.

Alternative 2: For RTE products covered under The *Listeria* Rule, these are regarded as more risky than Alternative 1 but less risky than Alternative 3 and should be sampled less often than Alternative 3 products. To qualify for Alternative 2, either a PLT or AMA/AMP is necessary.

Alternative 3: For RTE products covered under The *Listeria* Rule, these are regarded as the most risky and should be sampled more often than Alternative 1 or 2 products.

Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products
http://www.fsis.usda.gov/oa/fr/95033F-a.htm

Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)
http://www.fsis.usda.gov/oa/fr/95033F-b.htm

Heat-processing and stabilization requirements for uncured meat patties
http://a257.g.akamaitech.net/7/257/2422/11feb20051500/edocket.access.gpo.gov/cfr_2005/janqtr/pdf/9cfr318.23.pdf

Operations and procedures, generally
http://a257.g.akamaitech.net/7/257/2422/11feb20051500/edocket.access.gpo.gov/cfr_2005/janqtr/pdf/9cfr381.65.pdf

Pathogen Modeling Program
http://www.arserrc.gov/mfs/pathogen.htm

Requirements for the production of cooked beef, roast beef, and cooked corned beef products
http://a257.g.akamaitech.net/7/257/2422/11feb20051500/edocket.access.gpo.gov/cfr_2005/janqtr/pdf/9cfr318.17.pdf

Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips
http://a257.g.akamaitech.net/7/257/2422/11feb20051500/edocket.access.gpo.gov/cfr_2005/janqtr/pdf/9cfr381.150.pdf

Requirements for specific classes of product
http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240-4.pdf
http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240.4/10240_4Int.pdf
http://www.fsis.usda.gov/Regulations_&_Policies/RD_10240_4/index.asp

Temperatures and chilling and freezing procedures
http://a257.g.akamaitech.net/7/257/2422/11feb20051500/edocket.access.gpo.gov/cfr_2005/janqtr/pdf/9cfr381.66.pdf

Use of food ingredients and sources of radiation
http://a257.g.akamaitech.net/7/257/2422/11feb20051500/edocket.access.gpo.gov/cfr_2005/janqtr/pdf/9cfr424.21.pdf

FSIS References for *Listeria monocytogenes*
Compliance Guidelines (for The Listeria Rule)
http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F/Lm_Rule_Compliance_Guidelines_2004.pdf

Directive 10,240.4
http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240-4.pdf

FSIS Web Site *Listeria* Page
http://www.fsis.usda.gov/fact_sheets/listeria_monocytogenes/index.asp

The Interim Final Rule for Listeria
http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F.htm

FSIS References for *Escherichia coli* O157:H7
Directive 10,010.1
http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10.010.1.pdf

The FSIS E. coli O157:H7 Web Page
http://www.fsis.usda.gov/fact_sheets/E_coli/index.asp

For General Information on Foodborne Pathogens:
The Bad Bug Book (FDA)
http://vm.cfsan.fda.gov/~mow/intro.html

FSIS References on Egg Safety

The FSIS Egg Safety Web Page
http://www.fsis.usda.gov/OA/topics/eggsafe.htm

FSIS Information on Campylobacter
http://www.fsis.usda.gov/OA/background/campy_qa.htm

CDC Information on Botulism

http://www.cdc.gov/ncidod/dbmd/diseaseinfo/botulism_g.htm

Labeling and Consumer Protection Policies
http://www.fsis.usda.gov/regulations_&_policies/labeling_policies/index.asp

PR/HACCP Issues
http://www.fsis.usda.gov/Science/hazard_analysis_&_pathogen_reduction/index.asp

Guidebook for Preparation of HACCP Plans
http://www.fsis.usda.gov/Science/Generic_HACCP_Models/index.asp

Food Security and Emergency Preparedness
http://www.fsis.usda.gov/Food_Security_&_Emergency_Preparedness/index.asp

FSIS Microbiology Laboratory Methods
http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook/index.asp

Packaging materials
http://www.fsis.usda.gov/OA/pubs/meatpack.htm