

Meat and Poultry Hazards and Controls Guide

Food Safety and Inspection Service

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Introduction

FSIS developed this guide to help FSIS inspection program personnel (IPP) to evaluate different aspects of a meat or poultry establishment's hazard analyses and support for the hazard analyses decisions when they perform the Hazard Analysis Verification (HAV) task in accordance with FSIS Directive 5000.6, Performance of the Hazard Analysis Verification (HAV) Task. This guidance may be also beneficial to small and very small establishments as they develop their hazard analyses, support their hazard analyses decisions, and amend existing HACCP systems after reassessment.

This guide describes the usual process steps employed by establishments for various processing categories. The guide lists potential biological, physical, and chemical hazards and frequently used controls and preventative measures for each step. FSIS has updated the guide to include slaughter sections for beef, swine, and poultry. FSIS has also updated this guide to provide additional examples of potential hazards and frequently used controls.

It is important to note that this guide represents FSIS's current thinking and is not intended to suggest where a Critical Control Point (CCP) should be placed. Differences between the guide and an establishment's hazard analysis are not, in themselves, sufficient to support findings of noncompliance with 9 CFR 417.2(a)(1). Entries in the "Frequently Used Controls" column should be taken as examples of the controls or preventative measures that establishments may have in place for a particular hazard or that can be used to support that a particular hazard is not reasonably likely to occur. Other validated controls for a particular hazard may be used in an establishment's HACCP system. The statement "no common hazard" is based on the available information and may change as a result of research or outbreak and recall investigations.

The guide also provides a list of general verification questions and additional suggested verification questions for each step in different processing categories. This is intended to provide an analytical thought process to guide IPP decision making. These questions are not meant to be all-inclusive, but to provide examples of the types of questions that may arise when verifying regulatory compliance.

Quick Reference Table of Process Steps in Slaughter

Processing category: Slaughter			
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	Beef*	Swine	Poultry
Receiving and holding	p.5	p.13	
Receiving live birds and live bird hanging			p.23
Stunning and bleeding		p.14	p.25
Stunning/shooting, bleeding, hide removal	p.7		
Head removal/rodding the weasand (esophagus)	p.8		
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* There may be similar processes, hazards, and controls for other livestock species (e.g., sheep, goats, or other small ruminants.)

Quick Reference Table of Process Steps in Processing

Process Steps	Page No.	Processing Categories							
		Raw Intact	Raw Non-Intact	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/poultry raw materials	p.32	•	•	•	•	•	•	•	•
Storage of raw meat/poultry ingredients prior to use	p.34	•	•	•	•	•	•	•	•
Receiving and storage of packaging materials and non-meat ingredients	p.35	•	•	•	•	•	•	•	•
Thawing/tempering frozen raw meat/poultry	p.36	•	•	•	•	•	•	•	•
Weighing/formulation	p.37	•	•	•	•	•	•	•	•
Curing	p.38			•	•	•	•	•	•
Mixing, grinding, boning, fabrication, preblending, injection, tumbling, needle tenderizing	p.39		•	•	•	•	•	•	•
Patty formation	p.39		•	•	•	•	•		•
Stuffing	p.39	•	•	•	•	•	•	•	•
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Cooking/smoking (fully cooked)	p.42			•		•			
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Drying	p.44	•				•	•		
Cooling/chilling /stabilization/brine chilling (cooked products)	p.45			•	•	•			
RTE product handling after cooking: peeling, slicing, dicing, chopping, mincing, surface rub, repackaging	p.46			•		•		•	
RTE post-lethality treatment	p.47			•		•			
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Packaging/labeling	p.52	•	•	•	•	•	•	•	•
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Finished product storage	p.55	•	•	•	•	•	•	•	•
Shipping	p.56	•	•	•	•	•	•	•	•

Suggested General Verification Questions

This set of general questions should be considered 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?
- Can the establishment support that the hazard is not reasonably likely to occur (NRLTO)?
- Did the establishment validate the control methods, including preventive measures and prerequisite programs, for this hazard?
- Is the establishment following all procedures (i.e., prerequisite or other programs) 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, Potential Hazards, and Frequently Used Controls: Beef Slaughter

Process Step	Potential Hazards	Frequently Used Controls
Receiving and holding	Biological—Pathogens (<i>Salmonella</i> and STEC) on carcasses; Note: Bacterial load depends on herd or farm management practices, transport and holding practices, and feedlot conditions and controls. Additionally, the season of the year, the age and the type of cattle are other factors that will influence the microbial load. Parasitic: <i>Taenia saginata</i> (Cysticercosis) or tapeworm cysts; SRMs	• Pre-harvest: Farm/feedlot management practices to reduce fecal shedding during transport and handling. • Purchase specification programs: cattle are obtained from producers that employ one or more production systems or controls to reduce the carriage of STEC and <i>Salmonella</i>. • Mud/fecal material scoring systems. • Holding pens, ramps, unloading chutes, curbs, and runways are of such construction, materials, and finish that they can be readily and thoroughly cleaned and provide adequate spacing. • Cattle washes that reduce pathogen loads from hides and hooves of incoming cattle. • Retention in cold storage or heat treatment per 9 CFR 311.23 to control parasites. • Procedures to identify animals 30 months of age and older.
	Chemical—Residues-antibiotics	• Residue certification presented for live animals. • Residue control program designed to control residue violations.
	Physical—Sharp objects or foreign materials (e.g., needles, hardware in intestinal tract)	• Visual examination of carcass, parts, and viscera.

Note: See FSIS Directives, Notices, and Compliance Guidelines for additional information on controls used in beef slaughter. There may be similar processes, hazards, and controls for other livestock species (e.g., sheep, goats, or other small ruminants.)

Suggested verification questions:

1. Does the establishment implement pre-harvest strategies or purchase specification programs to address incoming pathogen loads?

2. How is the establishment maintaining sanitation in the holding pens, ramps, chutes, runways, etc.?
3. Does the establishment implement a scoring system or other controls (e.g., cattle wash) to address excessive amounts of mud or feces present on the hides of incoming cattle?
4. Does the establishment have procedures in place to identify animals 30 months of age and older?
5. How does the establishment handle non-ambulatory animals?
6. How does the establishment ensure residues are not present in edible tissues above legal tolerances?
7. Does the establishment monitor the repeat violator list? How does the establishment address animals received which are supplied by repeat violators?
8. Does the establishment have procedures to restrict employee movement from dirty (e.g., holding pens) to clean areas of the establishment?

Process Step	Potential Hazards	Frequently Used Controls
Stunning/shooting, bleeding, hide removal	Biological—Pathogens (<i>Salmonella</i> and STEC) from the following sources: - contaminated outside hide surface - contamination of carcass from floor - cross-contamination by equipment or utensils - contamination by employee handling - contamination from esophageal contents - contamination from udder	- Minimize cross-contamination through sanitary dressing procedures; Sanitation SOPs. - Bleeding and skinning procedures to prevent hair or visible fecal material contamination of the carcass. - Careful employee practices included in sanitary dressing procedures or operational sanitation procedures. - Udder and pizzle removal procedures to prevent contamination of edible product.
	Chemical—No common hazard	
	Physical—Bullet fragments if firearm is used	Dispose of head, brain and cheek meat if firearm is used (9 CFR 310.18(b)).

Suggested verification questions:

1. Does the establishment have procedures or controls to minimize incidental and cross contamination throughout the slaughter and hide removal process?
2. Are establishment personnel properly sanitizing knives, gloves, and other equipment between carcasses?
3. Does the establishment remove visible contamination at the cut line?
4. If the establishment uses a firearm, does it take the necessary measures to address physical hazards?
5. If the establishment uses an antimicrobial, how does the establishment monitor and support its use?
6. Does the establishment have measures in place to avoid contamination of digestive tract contents or specified risk materials?

Process Step	Potential Hazards	Frequently Used Controls
Head removal/rodding the weasand (esophagus)	Biological—Pathogens (<i>Salmonella</i> and STEC), SRMs	- Minimize contamination and cross-contamination through sanitary dressing procedures; Sanitation SOPs. - Esophagus is tied to prevent escape of stomach contents. - Procedures for the removal, segregation and disposition of SRMs.
	Chemical—Inappropriate use of antimicrobial	Procedures to address the preparation, application and monitoring of antimicrobial use to ensure appropriate use.
	Physical—Bullet fragments, if firearm is used	Dispose of head, brain and cheek meat if firearm is used; only tongue meat is saved (9 CFR 310.18(b)).

Suggested verification questions:

1. If the establishment uses an antimicrobial, how does the establishment monitor and support its use?
2. Does the establishment have sanitation procedures to prevent cross-contamination during head removal?
3. Does the establishment have measures in place to avoid contamination with digestive tract contents or specified risk materials?

Process Step	Potential Hazards	Frequently Used Controls
Evisceration Note: Evisceration includes multiple processes and ends at the final wash.	Biological—Pathogens (<i>Salmonella</i> and STEC), from cross-contamination from broken viscera SRMs	- Minimize cross-contamination through sanitary dressing procedures; Sanitation SOPs. - Bung is dropped with sanitized knife and bagged and tied to prevent escape of feces. - Viscera are removed intact. - Procedures for the removal, segregation, and disposition of SRMs.
	Chemical—No common hazard	
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment have procedures or controls that address incidental and cross-contamination throughout the evisceration process?
2. Do establishment personnel sanitize knives, gloves, and other equipment as frequently as necessary to prevent cross-contamination?
3. Do the carcasses move along the rail in a manner to prevent cross-contamination of carcasses?

Process Step	Potential Hazards	Frequently Used Controls
Variety meats or edible offal processing	Biological—Pathogens (<i>Salmonella</i> and STEC) from cross-contamination or outgrowth; outgrowth of <i>Clostridium</i> spp. during cooling of offal that receives a heat treatment (e.g., scalding of tripe) SRMs	- Minimize cross-contamination through sanitary dressing procedures; Sanitation SOPs. - Cooling times should be sufficient to prevent outgrowth of pathogens. - Procedures for the removal, segregation and disposition of SRMs
	Chemical—Inappropriate use of antimicrobial if used	Procedures to address the preparation, application and monitoring of antimicrobial use to ensure appropriate use.
	Physical—Metal (e.g., hardware in intestinal tract)	Visual examination of parts.

Suggested verification questions:

1. Does the establishment have procedures or controls that address incidental and cross-contamination during the harvesting of edible offal?
2. How does the establishment address foreign material contamination in its HACCP system?
3. Does the establishment monitor time/temperature during cooling and storage of offal products to prevent outgrowth of pathogenic bacteria?
4. If the establishment does not follow Appendix B or have other validation data for cooling of scalded offal products, is there data to indicate products remain in the danger zone for growth (120 to 80°F) for greater than 1 hour?
5. Does the establishment conduct microbiological testing of offal products?
6. Does the establishment have procedures to address the removal, segregation and disposition of SRMs in offal products?
7. If the establishment uses an antimicrobial, how does the establishment monitor and support its use?

Process Step	Potential Hazards	Frequently Used Controls
Final wash (and antimicrobial intervention)	Biological—Outgrowth of pathogens (<i>Salmonella</i> and STEC) through insufficient wash or spreading of pathogens	• Appropriate use of antimicrobial by adherence to validated parameters (e.g., temperature, pressure, etc.) • Monitor antimicrobial concentrations, temperatures, nozzles condition and pressure level regularly to verify effectiveness and to prevent driving contamination into the tissues. • Minimize overspray of water or solution from the cabinet. • Remove contamination and visible dressing defects prior to wash.
	Chemical—Inappropriate use of antimicrobial	• Documentation supporting the application of the antimicrobial • Procedures to address the preparation and monitoring of antimicrobial use to ensure appropriate use.
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment incorporate its final wash and antimicrobial intervention in the HACCP system (HACCP plan, Sanitation SOP or prerequisite or other program)?
2. Does the establishment have supporting documentation that identifies critical operating parameters such as coverage of the application, contact time, pH, temperature, and concentration of the intervention?
3. Is the antimicrobial that the establishment uses listed in Directive 7120.1 or 9 CFR 424.21(c)?
4. Does the establishment monitor critical operating parameters during production?
5. Does the establishment have procedures to monitor and remove visible contamination prior to carcasses entering the wash?

Process Step	Potential Hazards	Frequently Used Controls
Chilling	Biological—Outgrowth of pathogens (<i>Salmonella</i> and STEC)	• Monitoring of carcass or ambient temperature and time. • Adequate carcass spacing. • SSOPs, sanitary procedures to prevent contamination when moving carcasses in cooler.
	Chemical—No common hazard	
	Physical—No common hazard	

Suggested verification questions:

1. How does the establishment incorporate its chilling procedures in the HACCP system (HACCP plan, Sanitation SOP or prerequisite or other program)?
2. Does the establishment have validation support for the time and temperature parameters?
3. Does the establishment monitor time and temperature during chilling?
4. Are the carcass halves adequately spaced in the cooler to allow for proper chilling?

Process Steps, Potential Hazards, and Frequently Used Controls: Swine Slaughter

Process Step	Potential Hazards	Frequently Used Controls
Receiving and holding	Biological— <i>Salmonella</i> and other pathogens	Pre-harvest: Farm management measures to reduce <i>Salmonella</i>; transportation controls to reduce stress and fecal shedding, as well as cross-contamination.
	Parasitic*: <i>Trichinella spiralis</i> and <i>Toxoplasma gondii</i> (especially in feral or non-confinement raised swine)	- Trichinae Certification Program or another APHIS approved validated <i>Trichinella</i> pre-harvest safety program that complies with the World Organization for Animal Health's (OIE's) guidance for <i>Trichinella</i>. - Maintain adequate sanitation in pens; this could be covered as part of a plant's Good Manufacturing Practices (GMPs). - Adequate treatment of carcass and parts (e.g., freezing, cooking, etc.) to destroy parasites.
	Chemical—Residues-antibiotics	Certification for live animals; residue control program.
	Physical—Foreign material-needles, buckshot, etc.	Visual examination of carcass for foreign material during slaughter.

* See FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork and Products Containing Pork for additional information on parasitic controls in swine slaughter.

Note: See FSIS Directives, Notices, and Compliance Guidelines for additional information on controls in swine slaughter.

Suggested verification questions:

1. Does the establishment implement pre-harvest strategies or purchase specification programs to address incoming pathogen loads?
2. How is the establishment maintaining sanitation in the holding pens, ramps, chutes, runways?
3. How does the establishment address parasites in its hazard analysis?
4. How does the establishment ensure residues are not present in edible tissues above established tolerances?
5. Does the establishment monitor the repeat violator list? How does the establishment address animals that are supplied by repeat violators?
6. Does the establishment have procedures to restrict employee movement from dirty (e.g., holding pens) to clean areas of the establishment?

Process Step	Potential Hazards	Frequently Used Controls
Stunning and bleeding	Biological— <i>Salmonella</i> and other pathogens from cross-contamination	Sanitation SOPs; sanitary dressing procedures to minimize cross-contamination.
	Chemical—No common hazard	
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment have procedures or controls to minimize incidental and cross-contamination during bleeding?
2. Are establishment personnel properly sanitizing knives, gloves, and other equipment between carcasses?

Process Step	Potential Hazards	Frequently Used Controls
Scalding	Biological— <i>Salmonella</i> and other pathogens due to contamination from scalding medium	- Plant time/temperature limits for scalding. - Equipment design and proper adjustment (e.g., counter current application to increase heating efficiency and water cleanliness). - Vertical steam scald allows for a constant supply of clean steam and prevents the organic load that would accumulate if a water system was used. - Prompt or immediate trimming of stick wound after scalding.
	Chemical—Contamination with chemicals via stick wound	Chemical concentration not to exceed manufacturer's recommendations.
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment use a counter current application (fresh or recirculated scald water that flows into the scalding in an opposite direction from that of the carcasses) to increase heating efficiency and water cleanliness?
2. Does the establishment clean or treat the scald water at a frequency that prevents accumulations of hair and protein?
3. Is the scalding water maintained at an adequate temperature to reduce growth of *Salmonella*?
4. Does the scalding medium include an antimicrobial? If so, does the establishment maintain adequate scientific or technological support for its use?

Process Step	Potential Hazards	Frequently Used Controls
De-hairing, de-hiding, gambrelling, singeing, polishing, knife trimming	Biological— <i>Salmonella</i> and other pathogen contaminations from equipment, medium, or outside surface of hide	• Cleaning/disinfection of equipment. • Remove visible hair to an acceptable level without breaking skin; chemically treated water. • Pasteurization after de-hairing. • Full (multiple heat sources) singe process to reach adequate surface carcass temperatures. • Steam or hot water vacuuming; knife trimming to remove fecal contamination and other dressing defects. • Equipment design and proper adjustment. • Monitor parameters such as time and temperature, pressure, and nozzle. • Minimize cross-contamination through sanitary dressing procedures; Sanitation SOPs.
	Chemical—No common hazard	
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment have procedures for cleaning and disinfecting de-hairing/de-hiding equipment?
2. Does the establishment have procedures to prevent cross-contamination during de-hiding?
3. Does the establishment pasteurize hog carcasses using hot water (185 °F or higher) after de-hairing? For hand shaving, does the establishment use a sharp knife to prevent cutting through the skin and introducing bacteria into the interior of the carcass?
4. Does the establishment assure that carcasses are not contaminated on the gambrel table by hogs that evacuate bowels post de-hairing?
5. Does the establishment apply steam vacuuming to carcasses after de-hairing, singeing, polishing, or de-hiding? If so, do they monitor equipment temperature, pressure, and nozzle?
6. Does the establishment use an antimicrobial treatment during vacuuming? If so, have they validated this process?
7. Is the carcass surface temperature during singeing reaching an appropriate temperature to

reduce microbial contamination? Does the establishment monitor carcass surface temperature?

8. Does the polishing step use high pressure water jets, flair or whip wet polisher? Is the polishing equipment thoroughly and frequently cleaned?
9. Does the establishment use knife trimming before treating carcasses with a pre-evisceration rinse or spray to address visibly contaminated carcasses?

Process Step	Potential Hazards	Frequently Used Controls
Pre-evisceration wash (and antimicrobial intervention)	Biological—Outgrowth of <i>Salmonella</i> and other pathogens through insufficient wash or spreading of pathogens	• Hot water, organic rinse, steam, or other approved antimicrobial intervention. • Monitor concentrations, temperatures, nozzles and psi regularly to verify effectiveness and to prevent driving contamination into the tissues. • Minimize overspray of water or solution from the cabinet.
	Chemical—Inappropriate antimicrobial use	• Proper control and use of approved antimicrobial.
	Physical—No common hazard	

Suggested verification questions:

1. How does the establishment incorporate its pre-evisceration wash into the HACCP system (HACCP plan, Sanitation SOP or prerequisite or other program)?
2. Does the establishment have supporting documentation that identifies critical operating parameters such as contact time, pH, temperature, and concentration of the intervention?
3. Does the establishment monitor critical operating parameters during production?
4. Does the establishment monitor visible contamination on carcasses entering the wash to prevent cross-contamination and spreading of pathogens?

Process Step	Potential Hazards	Frequently Used Controls
Evisceration Note: Evisceration includes multiple processes e.g., head dropping and bung isolation, etc. through evisceration and up until the final wash.	Biological— <i>Salmonella</i> and other pathogen contaminations from: • Equipment/utensils • Stomach, intestines or bladder contents • Employee handling	• Hot water, organic rinse, steam, or other approved antimicrobial intervention (see “Final Wash” step). • Sanitary dressing procedures; Sanitation SOPs and other GMPs. • Sanitary dressing guidelines for beef may be applied to swine.
	Chemical—No common hazard	
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment have procedures or controls that address incidental and cross-contamination throughout the evisceration process?
2. Do establishment personnel sanitize knives, gloves, and other equipment as frequently as necessary to prevent cross-contamination?

Process Step	Potential Hazards	Frequently Used Controls
Variety meats or edible offal processing	Biological— <i>Salmonella</i> and other pathogens from cross-contamination or outgrowth; outgrowth of <i>Clostridium</i> spp. during cooling of offal that receives a heat treatment (e.g., pork stomachs)	- Minimize cross-contamination through sanitary dressing procedures; Sanitation SOPs. - Cooling times should be sufficient to prevent outgrowth of pathogens.
	Chemical—No common hazard	
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment have procedures or controls that address incidental and cross-contamination during the harvesting of edible offal?
2. Does the establishment monitor time/temperature to ensure adequate cooling of offal products to prevent outgrowth of pathogenic bacteria?
3. If the establishment does not follow Appendix B or other validation data for cooling of scalded offal products, is there data to indicate products remain in the danger zone for growth (120 to 80°F) for greater than 1 hour?
4. Does the establishment conduct microbiological testing of offal products?

Process Step	Potential Hazards	Frequently Used Controls
Final wash (and antimicrobial intervention)	Biological—Outgrowth of <i>Salmonella</i> and other pathogens through insufficient wash or spreading of pathogens	• Hot water, organic rinse, steam, or other approved antimicrobial intervention. • Monitor concentrations, temperatures, nozzles and psi regularly to verify effectiveness and to prevent driving contamination into the tissues. • Minimize overspray of water or solution from the cabinet. • Remove contamination and visible dressing defects prior to wash.
	Chemical—Inappropriate antimicrobial use	• Proper control and use of approved antimicrobials.
	Physical—No common hazard	

Suggested verification questions:

1. How does the establishment incorporate its final wash and antimicrobial intervention in the HACCP system (HACCP plan, Sanitation SOP or prerequisite or other program)?
2. Does the establishment have validation support that identifies critical operating parameters such as adequate coverage, contact time, pH, temperature, and concentration of the intervention?
3. Does the establishment monitor critical operating parameters during production?
4. Does the establishment have procedures to monitor and remove visible contamination prior to carcasses entering the wash?

Process Step	Potential Hazards	Frequently Used Controls
Chilling	Biological—Outgrowth of <i>Salmonella</i> and other pathogens	• Monitoring of carcass or ambient temperature and time. • Sanitation procedures during cooler holding/movement
	Chemical—No common hazard	
	Physical—No common hazard	

Suggested verification questions:

1. How does the establishment incorporate its chilling procedures in the HACCP system (HACCP plan, Sanitation SOP or prerequisite or other program)?
2. Does the establishment have validation support for the time and temperature parameters?
3. Does the establishment monitor time and temperature during chilling?

Process Steps, Potential Hazards, and Frequently Used Controls: Poultry Slaughter

Process Step	Potential Hazards	Frequently Used Controls
Receiving live birds and live bird hanging	Biological—<i>Salmonella</i> and <i>Campylobacter</i> on birds Note: <i>Salmonella</i> and <i>Campylobacter</i> spp. are usually present on incoming live birds. Therefore, establishments should use multiple steps in the process to reduce these hazards to acceptable levels. For example, the pre-harvest and transport practices reduce pathogen loads, so that later controls (e.g., sanitary dressing procedures and antimicrobial) function as intended to effectively control the hazards.	• Birds raised and transported in a manner that reduces the risk of pathogen contamination. • Obtain birds produced from a system of breeder flocks, hatcheries, and grow out houses that use best pre-harvest practices to reduce exposure and colonization of <i>Salmonella</i> and <i>Campylobacter</i>. • Determine pathogen status, prior to collecting birds for harvest (e.g., boot swab, drag swab, cloacal swab, and litter sampling). • Transport and slaughter birds from negative <i>Salmonella</i> and <i>Campylobacter</i> farms or houses separately from birds from positive farms or houses. • Routinely clean and disinfect transport cages between loads. • Routinely clean and disinfect the live bird areas (e.g., dump cage, conveyor belt, live hang area). • Control employee traffic patterns and air flow to prevent cross contamination and reduce <i>Salmonella</i> and <i>Campylobacter</i> levels. Maintain positive air flow from the inside to the outside of the establishment. • Employee hygiene standard operating procedures and training to restrict employee movement from the live hang area to cleaner areas, and separate facilities for employees in live hang and dirty areas.
	Chemical—Antibiotic residue contamination	• Obtain birds produced from a system of grow out houses that use best pre-harvest practices to prevent antimicrobial residue contamination.
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment keep records of the sample result for each grower to determine which growers produce birds with higher incoming bacterial loads? If so, does the establishment stage slaughter based on bacterial loads (e.g., flocks with higher bacterial loads slaughtered at the end of the day or shift) or adjust line speed or interventions when slaughtering flocks with high bacterial loads?
2. Does the establishment have procedures and training (e.g., Standard Operating Procedures or Employee Hygiene Procedures) that include separate facilities for employees that work in dirty (e.g., live hang, stunning, bleeding) vs. clean areas and restrict employee movement from dirty to clean areas of the establishment?

Process Step	Potential Hazards	Frequently Used Controls
Stunning and bleeding	Biological— <i>Salmonella</i> and <i>Campylobacter</i> cross-contamination from: • Wing flapping and movement during stunning • Birds voiding feces during stunning	• Proper application of stunning methods and maintenance of stunning equipment. • Well-timed feed withdrawal practices to reduce feces release during stunning. • Employee hygiene standard operating procedures. • Airflow.
	Physical—No common hazard	
	Chemical—No common hazard	

Suggested verification questions:

1. Does the establishment verify that the growers maintain effective feed withdrawal practices to reduce fecal contamination?
2. Is the stunner operated in a manner to minimize wing flapping and movement during stunning?

Process Step	Potential Hazards	Frequently Used Controls
Scalding	Biological— <i>Salmonella</i> and <i>Campylobacter</i> contamination from pathogens in scalding medium	• Pre-scald brush system to clean bird prior to the scalding. • High water flow rates with adequate agitation to dilute dry matter and bacteria. • Water moves counter current to carcasses (e.g., opposite direction) to result in lower bacteria levels where the birds exit the scalding compared to the where the birds enter the scalding. • Multi-staged tanks for immersion scalding. • Water pH maintained either above or below optimum pH for <i>Salmonella</i> and <i>Campylobacter</i> growth. • Antimicrobials in scald water (e.g., inorganic or organic acids). • Post-scald rinse.
	Chemical—Inappropriate antimicrobial use	• Proper control and use of antimicrobials, defoamers, feather looseners, acidifiers.
	Physical—No common hazard	

Suggested verification questions:

1. Is the immersion scalding water flow moving counter current (opposite direction) to carcasses?
2. Are the water flow rates and water agitation adequate to dilute dry matter and bacteria?
3. Does the scalding medium include an antimicrobial? If so, does the establishment maintain adequate scientific or technological support for its use?
4. Is the scalding water maintained at a pH that reduces the *Salmonella* growth rate (e.g., either above or below pH 6.5 – 7.5)?
5. Does the establishment reuse water from the evisceration process or the chiller in the scalding (9 CFR 416.2(g)(3))? If so, do they take measures to reduce physical, chemical, and microbiological contamination, and maintain adequate scientific or technological support for such reuse? Does the establishment perform any water sampling (APC, coliforms etc.)?

Process Step	Potential Hazards	Frequently Used Controls
Picking	Biological— <i>Salmonella</i> and <i>Campylobacter</i> cross-contamination from equipment and adjacent birds	• Regular equipment maintenance. • Pre-operational and operational sanitation to prevent accumulation of feathers or other debris on equipment. • Post-picking antimicrobial intervention.
	Chemical—No common hazard	
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment maintain adequate sanitation in the picking room during operations?
2. Does the establishment reuse water from the evisceration process or chiller in the picking room (9 CFR 416.2(g)(3)? If so, do they take measures to reduce physical, chemical, and microbiological contamination, and maintain adequate scientific or technological support for such reuse?

Process Step	Potential Hazards	Frequently Used Controls
Evisceration Note: Evisceration includes multiple processes and begins at rehang and ends when the carcass enters the chiller. This also includes giblet harvest.	Biological—<i>Salmonella</i> and <i>Campylobacter</i> contamination from the gastrointestinal systems.	• Multiple <i>Salmonella</i> and <i>Campylobacter</i> controls throughout the evisceration process to include: - Sanitary dressing procedures. - Ongoing machinery adjustments to accommodate bird size. - Employee training and hygiene practices. - Antimicrobial rinses or sprays for machinery. - Antimicrobial interventions for carcasses and parts. • Procedures to prevent carcasses and parts contamination by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation (9 CFR 381.65(g)). • Microbiological sampling programs (9 CFR 381.65(g)).
	Chemical—Inappropriate antimicrobial use	• Proper control and use of approved antimicrobials.
	Physical—Sharp objects or foreign material in gizzards; broken machinery or shackle parts	• Monitor giblets for foreign materials. • Metal detection at a later step.

Suggested verification questions:

1. How does the establishment incorporate its procedures to prevent carcasses and parts contamination by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation (9 CFR 381.65(g)) into its HACCP system (HACCP plan or Sanitation SOP or other prerequisite program)?
2. Does the establishment implement a program to monitor and adjust evisceration equipment to accommodate different bird sizes to prevent intestinal rupture and prevent viscera from being caught in machinery?
3. Does the establishment have adequate rinses or sprays for evisceration machinery and hand-held equipment, employees, and utensils with adequate pressure to remove contamination?
4. How does the establishment use antimicrobial compounds (e.g., carcass washes, interventions, machinery sprays or rinses, reprocessing and salvage programs)?
5. Does the establishment use the antimicrobials in accordance with the scientific and technical documents that it uses to validate the HACCP plan?
6. Does the establishment have a supportable microbiological sampling plan to assess process

control, which includes sampling frequency, microbes for analysis, acceptable microbiological levels, and action levels?

7. Does the establishment periodically include *Salmonella* and *Campylobacter* testing in its sampling plan?

Process Step	Potential Hazards	Frequently Used Controls
Reprocessing and salvage	Biological— <i>Salmonella</i> and <i>Campylobacter</i> cross contamination and outgrowth	• Online and offline reprocessing procedures to remove accidental digestive tract contamination (e.g., ingesta and feces) in a sanitary manner and apply approved antimicrobials. • Approved online and offline reprocessing systems and antimicrobial applications. • Written salvage procedures to remove localized pathologic lesions (e.g., airsacculitis, inflammatory processes) in a sanitary and timely manner. • Chilling procedures for carcasses held for rework.
	Chemical—Inappropriate antimicrobial use	• Proper control and use of approved antimicrobials.
	Physical—No common hazard	

Suggested verification questions:

1. How does the establishment incorporate its online and offline reprocessing system into its HACCP system (HACCP plan or Sanitation SOP or other prerequisite program (9 CFR 381.91(b)))?
2. Does the establishment use only approved online and offline reprocessing systems and monitor all the parameters (e.g., antimicrobial application method, concentration, pH, contact time, temperature, pressure, volume) described in FSIS Directive 7120.1?
3. Is the establishment implementing and monitoring the online and offline reprocessing systems?
4. Do the monitoring procedures include examination of carcasses after exiting the systems to ensure that all visible contamination was removed?

Process Step	Potential Hazards	Frequently Used Controls
Chilling	Biological— <i>Salmonella</i> and <i>Campylobacter</i> outgrowth and cross contamination	- To prevent pathogen outgrowth, establishments meet the chilling parameters (e.g., product temperature achieved with a specific time) in the HACCP plan. - Antimicrobials in immersion chiller water. - Maintain effective water flow rates (e.g., input and overflow) in immersion chillers. - Written procedures to prevent carcasses with visible fecal contamination from entering the chiller (9 CFR 381.65(f)). - In establishments under the New Poultry Inspection System (NPIS), written procedures to prevent carcasses affected with septicemic and toxemic conditions from entering the chiller (9 CFR 381.76(b)(6)(ii)(C)).
	Chemical—Inappropriate antimicrobial use	Proper control and use of approved antimicrobials and CO₂.
	Physical—Foreign material contamination	- Post chill Poultry Finished Product Standards (FPS) monitoring. - Monitoring giblets for quality standards and foreign material.

Suggested verification questions:

1. How did the establishment incorporate its chilling procedures into its HACCP system (HACCP plan, Sanitation SOP or prerequisite or other program)?
2. How does the establishment incorporate its procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller into its HACCP system (HACCP plan or Sanitation SOP or other prerequisite program)?
3. How does the establishment incorporate its procedures to ensure that poultry carcasses with septicemic and toxemic conditions do not enter the chiller (HACCP plan or Sanitation SOP or other prerequisite program)?
4. How does the establishment support the time and temperature chilling parameters?
5. Does the establishment monitor carcasses and giblets for foreign material contamination after they exit the chilling systems?

Process Steps, Potential Hazards, and Frequently Used Controls: Processing

Process Step	Potential Hazards	Frequently Used Controls
Receiving raw meat/poultry materials	Biological—Presence and outgrowth of pathogens: - Raw beef and veal products—<i>Salmonella</i> and STEC* - Raw chicken, turkey and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> - Raw pork, sheep, goat and other products—<i>Salmonella</i> Survival of parasites: - Raw pork—<i>Trichinella spiralis</i> and <i>Toxoplasma gondii</i> (especially in feral or non-confinement raised swine)	- Monitor temperature when a shipment is received. - Inspect products for package integrity. - Ensure product has been prepared and handled by the supplying establishment (including self-supplier) in a manner that minimizes or eliminates the possibility of pathogen contamination: - Letters of guarantee - Certificates of Analysis Note: Both letters of guarantee and Certificates of Analysis are necessary at receiving to support that STEC is NRLTO in non-intact beef product or beef products intended for non-intact use in the absence of additional interventions. - Antimicrobial intervention to reduce pathogen contamination. - Pork from swine producer participating in the Trichinae Certification Program or another APHIS approved validated <i>Trichinella</i> pre-harvest safety program that complies with the World Organization for Animal Health's (OIE's) guidance for <i>Trichinella</i>.
	Biological—SRMs from cattle**	- Documented procedures to segregate, remove, and dispose of SRMs. - Control with purchasing program.
	Chemical—Allergens	- Ensure product received does not contain any undeclared allergens that is not included on finished product label by: - Letters of guarantee - Certificates of Analysis - Approved supplier program

	Physical—Metal, rubber, plastic, wood, etc.	• Control with purchasing program or letters of guarantee. • Inspect products for package integrity. • Visual inspection for foreign material.
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* See FSIS Rule and Directive for additional information on STEC in certain raw beef products.

** See FSIS Rule and Directive for additional information on SRMs from cattle.

Suggested verification questions:

1. Are products received held under refrigeration to preclude the growth of pathogens?
2. Does the establishment have a program to check incoming product?
3. Are products protected from environmental contamination such as dust, moisture, or other physical contaminants?
4. Are the products received from an approved supplier?
5. If the product contains allergens, does the final product label declare all ingredients?
6. Does the list of ingredients include all sub-ingredients on incoming packaged product?
7. Does the establishment maintain communication with its suppliers concerning formulation changes or its supplier's allergen control programs?
8. Does the establishment follow the specified intended use from the supplier for beef and veal products?
9. If the product contains SRMs, does the establishment have procedures for the removal, segregation, and disposition of SRMs in their HACCP plans, Sanitation SOPs or other prerequisite programs per 9 CFR 310.22?

Process Step	Potential Hazards	Frequently Used Controls
Storage of raw meat/poultry ingredients prior to use	Biological—Outgrowth of pathogens: • Raw beef and veal products—<i>Salmonella</i> and STEC • Raw chicken, turkey and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> • Raw pork, sheep, goat and other products—<i>Salmonella</i>	• Monitor environmental and product temperatures and holding time. • Routinely calibrate thermometers. • Maintain protection from environment.
	Chemical—Allergens	• Ensure allergen-containing products are segregated to prevent contamination of allergen-free products.
	Physical—No common hazard	• Proper storage of product to protect from foreign materials.

Suggested verification questions:

1. Are products protected from environmental contaminations such as moisture, or other physical contaminants?
2. Does the establishment segregate allergen-containing products from allergen-free products?

Process Step	Potential Hazards	Frequently Used Controls
Receiving and storage of packaging materials and non-meat ingredients	Biological—Contamination with pathogens. Examples: - Frozen fruit and vegetables—<i>Listeria monocytogenes</i> - Spices and herbs—<i>Salmonella</i> - Leafy greens—STEC	- Letters of guarantee. - Certificates of Analysis. - Antimicrobial treatments. - Examination of products for package integrity. - Proper storage of non-meat ingredients under temperature control if needed. - Procedure to protect non-meat ingredients from pests and environmental contamination.
	Chemical—Allergens, pesticides.	- Letters of guarantee. - Certificates of Analysis. - Approved supplier program. - Proper storage to prevent contamination of allergen-free products.
	Physical—Metal, rubber, plastic, wood, etc.	- Visual inspection for foreign material. - Metal detector. - Protect packaging materials from environment.

Suggested verification questions:

1. Are materials guaranteed by the manufacturer?
2. Does the establishment maintain communication with its suppliers concerning formulation changes or its suppliers' allergen control programs?
3. Are materials protected from environmental contamination (e.g., are containers kept closed and properly stored in acceptable storage areas)?
4. For non-meat ingredients added post-lethality, can the establishment support the safety of each lot through Certificate of Analysis, intervention, or validated control measure?
5. If the product contains allergens, does the final product label declare all ingredients?
6. Does the list of ingredients include all sub-ingredients on incoming packaged product?

Process Step	Potential Hazards	Frequently Used Controls
Thawing/tempering frozen raw meat/poultry	Biological—Cross-contamination and outgrowth of pathogens: • Raw beef and veal products—<i>Salmonella</i> and STEC • Raw chicken, turkey and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> • Raw pork and other products—<i>Salmonella</i>	• Monitor surface temperature and time to ensure no pathogen growth occurs. • Maintain package integrity.
	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 or product identity maintained throughout the process?

Process Step	Potential Hazards	Frequently Used Controls
Weighing/formulation	Biological—No common hazard	• Proper formulation to ensure effectiveness of antimicrobial additives in preventing outgrowth of certain pathogens in the final product (e.g., nitrate/nitrite for <i>Clostridium botulinum</i>, lactate and diacetates for <i>Listeria monocytogenes</i> *).
	Chemical—Cross-contamination of allergens and excessive addition of restricted ingredients/additives, such as: • antioxidants • antimicrobial agents • curing agents/accelerators • flavoring agents (protectors and developers) • tenderizing agents	• Allergen control program to include designated equipment that is clearly labeled for allergen-containing ingredients use. • Ensure all allergens are included on finished product label. • Proper formulations to ensure levels of restricted ingredients/additives are safe and suitable.
	Physical— No common hazard	

* See FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products for more information regarding the use of antimicrobial agents for controlling outgrowth of *Listeria monocytogenes*.

Suggested verification questions:

1. Are all 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. Are the ingredients that the establishment uses listed in Directive 7120.1 or 9 CFR 424.21(c)?
4. For RTE product, has the antimicrobial agent or process been validated as effective to control outgrowth of *Listeria monocytogenes* throughout the shelf life of the product?
5. Is rework included in product formulations? If yes, see rework process step.
6. 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?
7. Is this a new product formulation? If so, is the final product label declaring all ingredients?
8. Has the product formulation been changed? If so, has the final product label been updated accordingly?

Process Step	Potential Hazards	Frequently Used Controls
Curing	Biological—Outgrowth of pathogens: - Meat and poultry products—<i>Clostridium botulinum</i> and <i>Clostridium perfringens</i> Survival of parasites: - Raw Pork—<i>Trichinella spiralis</i> and <i>Toxoplasma gondii</i> (especially in feral or non-confinement raised swine)	- Validated curing process to provide adequate microbial inhibition in product. - Proper control of holding temperature and time.
	Chemical— Excessive curing agents	Proper weighing and formulation.
	Physical— No common hazard	

* See FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork and Products Containing Pork for additional information on parasitic controls in swine.

Suggested verification questions:

1. Are all meat or poultry ingredients thoroughly thawed before curing?
2. Does the establishment properly control the curing temperature and time and follow the established curing procedure?
3. For dry and immersion curing, are ingredient pieces prepared to uniform sizes to ensure uniform cure penetration?
4. If tumbling or massaging is used as an aid to hasten curing, does the establishment take proper sanitation to prevent contamination during this operation?
5. If the pork products are from feral or non-confinement raised swine, does the establishment have a validated curing process, or other validated processes, to eliminate parasites such as *Trichinella spiralis* and *Toxoplasma gondii*?

Process Step	Potential Hazards	Frequently Used Controls
Mixing Grinding Boning Fabrication Preblending Patty formation	Biological—Presence and outgrowth of pathogens in raw products: - Raw beef and veal products—<i>Salmonella</i> and STEC - Raw chicken, turkey, and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> - Raw pork and other products—<i>Salmonella</i>	- Maintain product at an acceptable temperature. - Proper employee handling through Sanitation SOPs and GMPs. - Ensure that STEC is below detectable levels in raw non-intact beef products*: - antimicrobial intervention - purchasing program
Stuffing Injection Tumbling	Biological—SRMs from cattle	Documented procedures to segregate, remove, and dispose of SRMs**.
Mechanical tenderization	Biological—Contamination from unclean equipment and employees	Proper cleaning procedures, visual inspection, GMPs, and effective Sanitation SOPs.
	Chemical—Cross-contamination of allergens	Ensure that equipment used for processing allergen-containing ingredients are properly labeled or cleaned prior to use in allergen-free ingredients/products.
	Physical—Metal, bone, rubber, plastic, wood, etc.	Appropriate screening procedure for monitoring equipment or product such as metal detector, screens or X-ray detector.

* See FSIS Rule and Directive for additional information on STEC in certain raw beef products.

** See FSIS Directive 6100.4 for additional information on SRMs from cattle.

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. When marinade is used in injection and tumbling, is the establishment using any provisions to prevent cross-contamination from marinade, such as avoiding reuse of marinade or validated treatment to decontaminate marinade before reuse?
5. Is the product properly labeled if it is a mechanically tenderized beef product per 9 CFR 317.2(e)(3)?

Process Step	Potential Hazards	Frequently Used Controls
Rework	Biological—Outgrowth of pathogens: • Raw beef and veal products—<i>Salmonella</i> and STEC • Raw chicken, turkey, and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> • Raw pork and other products—<i>Salmonella</i> • RTE products —Cross-contamination from raw products and outgrowth of <i>Listeria monocytogenes</i>	• Maintain product at an acceptable temperature and time. • Proper employee handling through Sanitation SOPs and GMPs. • Lotting program
	Chemical— Allergens and excessive addition of restricted and non-restricted ingredients/additives	• Ensure proper formulation is used. • Ensure amounts of restricted and non-restricted ingredients/additives are safe and suitable. • Lotting program • Ensure all allergens are included on finished product label.
	Physical—Metal and other physical contamination from grinder, mixer, chub clips, etc.	• Appropriate screening procedure for monitoring equipment or product such as an inline metal detector or X-ray detection system.

Suggested verification questions:

1. Have products to be used for rework been properly stored to preclude pathogen growth and contamination?
2. Does the reworked product include returned product, and if so, does the establishment have a procedure for ensuring the safety of the product?
3. Are there any hazards associated with rework that are different from hazards associated with the product it is being added to?
4. Does the establishment have any additional controls for rework product (e.g., length of time in storage, re-inspection results)?
5. Does the establishment conduct microbiological testing of rework product?
6. 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	Potential Hazards	Frequently Used Controls
Fermentation/ acidulation	Biological—Survival of pathogens from raw products, including: • All meat and poultry products—<i>Staphylococcus aureus</i> and <i>Listeria monocytogenes</i> • Raw beef and veal products—<i>Salmonella</i> and STEC • Raw chicken, turkey, and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> • Raw pork and other products—<i>Salmonella</i>	• Reduce product pH to 5.3 within a defined number of hours at defined temperatures (degree-hour concept*) to control outgrowth and toxin production of <i>Staphylococcus aureus</i>. • Use properly validated fermentation/acidulation process to ensure expected levels of pathogen reductions. • Monitor and control critical operational parameters, as described in scientific support (e.g., journal article or challenge study), such as fermentation temperature, relative humidity, product characteristics, come up time/hold time, equipment, pH and time to reach target pH, etc.**
	Chemical—No common hazard	• Maintain protection from environment. • Possible chemical hazard controlled by following manufacturer's instructions.
	Physical—No common hazard	

* See Degree-hour concept: Good Manufacturing Practices for Fermented Dry and Semi-dry Sausage Products, American Meat Institute

** See FSIS compliance Guideline: Lebanon bologna

Suggested verification questions:

1. How does the establishment control the microbiological quality of ingredients?
2. Does the establishment conduct microbiological testing of ingredients?
3. Does the establishment conduct microbiological testing of finished products?
4. Are starter cultures and encapsulated acids used at the manufacturer's recommended levels and not in excess of the amount permitted by regulation?
5. Are times, temperatures, pH, water activity monitored throughout the process?
6. Does the process result in a shelf-stable finished product?
7. If the finished product is not shelf-stable, are other methods, such as low pH, drying, freezing and refrigeration, used to prevent pathogen growth?

Process Step	Potential Hazards	Frequently Used Controls
Cooking/smoking (fully cooked)	Biological—Raw product pathogens and parasites including - Raw beef and veal products—<i>Salmonella</i> and STEC - Raw chicken, turkey, and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> - Raw pork—<i>Salmonella</i>, <i>Trichinella spiralis</i> and <i>Toxoplasma gondii</i> (especially in feral or non-confinement raised swine*)	- Use a temperature-time-humidity combination adequate to achieve a recommended 6.5-log reduction of <i>Salmonella</i> in beef and other red meat products and 7.0-log reduction in poultry**. - Achieve a 5.0-log reduction of <i>Salmonella</i> for dried, cured and fermented meat and poultry products such as jerky***. - Use temperature-time combinations in 9 CFR 318.23(b) for cooked meat patties.
	Chemical—No common hazard	Maintain protection from environment.
	Physical—No common hazard	

* See FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork and Products Containing Pork for additional information on parasitic controls in swine.

**See FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A.

*** See FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments.

Suggested verification questions:

1. Does the establishment use a validated process for destruction of relevant pathogens, such as *Salmonella*, STEC, *Listeria monocytogenes* and *Trichinella spiralis*?
2. Are time-temperature combinations monitored throughout the process?
3. Does the validated lethality method require monitoring of the humidity throughout the process?

Process Step	Potential Hazards	Frequently Used Controls
Heating/smoking/charring/ breaded and pre-browned (not fully cooked)	Biological—Outgrowth of pathogens because of improper time and temperature: • Raw beef and veal products—<i>Salmonella</i> and STEC • Raw chicken, turkey, and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> • Raw pork and other products—<i>Salmonella</i> • All raw meat and poultry products—Outgrowth of <i>Staphylococcus aureus</i>, <i>Clostridium botulinum</i> and <i>Clostridium perfringens</i> • Hydrated batter mixes — <i>Staphylococcus aureus</i> toxin formation	• Minimized the time for product to be at the temperatures allowing pathogen growth. • Validated cooking instruction and other labeling features for NRTE product that appears RTE. • Control holding time and temperature of batter mix.
	Chemical—No common hazard	• Maintain protection from environment.
	Physical—No common hazard	

Suggested verification questions:

1. Is the heating/smoking one component of a multi-hurdle lethality process? If so, the association with the entire lethality process is also critical.
2. Does the finished product exhibit a “cooked” appearance without being fully cooked?
3. Is the product labeled with validated cooking instructions and safe food handling statement if the finished product is NRTE?
4. Does the establishment conduct microbiological testing of products?
5. Are time, temperature and humidity, if applicable, monitored and controlled throughout the process?

Process Step	Potential Hazards	Frequently Used Controls
Drying	Biological— Outgrowth of pathogens: • Raw beef and veal products—<i>Salmonella</i> and STEC • Raw chicken, turkey, and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> • Raw pork and other products—<i>Salmonella</i> • All products—<i>Staphylococcus aureus</i>, <i>Listeria monocytogenes</i>, <i>Clostridium botulinum</i>, <i>Clostridium perfringens</i> and molds	• Ensure the water activity, pH and temperature of a product is sufficient to preclude pathogen growth. • Adequate control over time, temperature, relative humidity, air flow during drying. • Use short inventory pull dates, antimycotics, coatings, packaging, or any combination of these measures to control molds.
	Chemical—No common hazard	• Maintain protection from environment.
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment measure water activity to verify the adequacy of the process or shelf stability?
2. Are temperature, relative humidity, and airflow controlled throughout the process so that drying proceeds properly?
3. Are times, temperatures, pH, water activity, and drying conditions monitored throughout the process?
4. Can the establishment support that these times and temperatures are effective to achieve a safe product?

Process Step	Potential Hazards	Frequently Used Controls
Cooling/chilling/ stabilization/brine chilling for cooked products	Biological—Outgrowth of <i>Clostridium perfringens</i> and <i>Clostridium botulinum</i> due to time or temperature abuse	Cool product within supportable time and temperature parameters*.
	Biological—Cross-contamination of <i>Listeria monocytogenes</i> from chilling solution	- Sanitation of chilling solution. - Keep NaCl concentration and temperature of the brine solution at levels that destroy or prevent growth of pathogens. - Adequate sampling plan for <i>Listeria monocytogenes</i>.
	Chemical—No common hazard	Maintain protection from environment.
	Physical—No common hazard	

*See FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B.

Suggested verification questions:

1. Is the establishment using a cooling process validated to meet FSIS's stabilization performance standards for preventing the growth of spore-forming bacteria? How does the establishment monitor the cooling process?
2. Is the chilling solution maintained at the proper concentration and temperature?
3. If the chilling solution is reused, is it properly filtered and maintained free of contaminants?
4. Does the establishment sample the brine for *Listeria monocytogenes* or indicator organism if it is used to cool post-lethality exposed RTE products?
5. Does the stabilization validated method consider the product composition, such as curing agent or salt content?

Process Step	Potential Hazards	Frequently Used Controls
RTE product handling after cooking, including: Peeling Slicing Dicing Chopping Mincing Surface rub Repackaging	Biological—Contamination and outgrowth of pathogens: <i>Listeria monocytogenes</i> from food contact surfaces and other environmental sources - Contamination by ingredients, sauce and raw product—<i>Salmonella</i>	- Prevent cross-contamination from uncooked product, environment and food handlers*. - Maintain proper product temperature and time limits. - Ensure the microbiological quality of ingredients and sauces added to cooked product as a surface rub by microbiological testing, Certificates of Analysis, or treatments (i.e., irradiation of spices). - Prevent outgrowth of pathogens by controlling pH or water activity level or antimicrobial agents. - Reduce pathogens with post lethality treatment.
	Chemical—No common hazard	- Maintain protection from environment. - Ensure no foreign material from spices: - Letters of guarantee - Certificates of Analysis
	Physical—Metal and other physical contamination from grinder, mixer, chub clips, etc.	- In-line metal detector - X-ray detection system

*See FSIS *Listeria* Rule, Directive and Compliance Guidelines for additional information on *L. monocytogenes* control in RTE establishments.

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. Has the establishment validated the effectiveness of the treatment?
4. Is the antimicrobial agent or process included in the establishment's HACCP plan, Sanitation SOP, or prerequisite program?
5. Is RTE product separation maintained to prevent contamination from uncooked product?
6. Does the establishment sequester raw and cooked product areas and regulate the flow of personnel, carts, and equipment between those areas?
7. Does the establishment perform microbiological testing of ingredients such as spices, sauces and coatings that are added to the product post-lethality?
8. Does the establishment sample and test food contact surfaces and other environmental surfaces for *Listeria* spp. to provide information on potential sources for *Listeria monocytogenes* contamination?

Process Step	Potential Hazards	Frequently Used Controls
RTE post-lethality treatment	Biological— <i>Listeria monocytogenes</i> that may have contaminated product after cooking or other processing	• Treatment to reduce <i>Listeria monocytogenes</i> by a minimum of 1 log (i.e., 90%) is recommended. • Examples of critical limit parameters: - Post-process heat treatment—dwell time and temperature. - High pressure—temperature, dwell time and pressure. - Ultraviolet (UV) treatment—fluence (dose).
	Chemical—No common hazard	• Maintain package integrity.
	Physical—No common hazard	

Suggested verification questions:

1. Is this step designated as a CCP to meet the requirements of Alternative 1 or Alternative 2, Choice 1 described in 9 CFR 430?
2. Is package integrity maintained throughout the process?
3. If there is separation between the treatment and packaging, can the establishment show that the potential contamination between the treatment and the packaging is eliminated?
4. Does the process achieve the required lethality reduction levels?
5. Does the establishment conduct microbiological testing of products?
6. If a PLT is used to reprocess *L. monocytogenes* positive product, is the process validated to achieve at least a 5-log reduction of *L. monocytogenes* or an indicator organism?
7. Does the validation study parallel the product composition and critical limits?

Process Step	Potential Hazards	Frequently Used Controls
Filling (can or retortable pouch)	Biological— <i>Clostridium botulinum</i> spores	- Follow the process schedule established by a qualified processing authority. - Control proper filling level.
	Chemical—No common hazard	- Letters of guarantee from vendor. - Maintain protection from environment.
	Physical—No common hazard	Exam and clean containers procedures prior to use.

Suggested verification questions:

1. Does the establishment have a statistical sampling plan for evaluating incoming containers and the rejection actions, if needed?
2. 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 per 9 CFR 318.301(a)(1) and 318.301(a)(1)?
3. Are rigid containers used?
4. Are rigid containers cleaned just before filling per 9 CFR 318.301(a)(3) and 381.301(a)(3)?

Process Step	Potential Hazards	Frequently Used Controls
Sealing/closing/capping (can or retortable pouch)	Biological—No common hazard	• Closure examinations at a sufficient frequency to ensure proper sealing and vacuum level. • Maintain protection from environment.
	Chemical—No common hazard	• Letters of guarantee from vendor.
	Physical—No common hazard	

Suggested verification questions:

1. Does a closure technician examine the double seams formed by each closing machine head?
2. Is the entire container examined for product leakage or obvious defects?
3. Is 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. Are visual examinations conducted with sufficient frequency to ensure proper closure?
5. Are 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	Potential Hazards	Frequently Used Controls
Retorting	Biological— <i>Clostridium botulinum</i> spores	- Follow the process schedule specific to each product, container type and size, and retorting system as established by a processing authority. - Monitor and control the product initial temperature and other critical factors. - Maintain can/package integrity with overpressure during process if needed.
	Chemical—No common hazard	
	Physical—No common hazard	

Suggested verification questions:

1. Does the establishment have a process schedule from their processing authority on file for each product?
2. Has there been a change in product formula and, if so, has the schedule been updated by a processing authority?
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 to ensure that these factors remain within the limits used to establish the process schedule?
5. Are the types of ingredients prepared or utilized in the product formulation as specified in the process schedule?
6. If there is any change to the retort and pipe configuration, are those changes reviewed by a processing authority?
7. Is each retort equipped with at least one temperature device measuring the actual temperature within the retort?
8. Is each thermal processing system equipped with at least one temperature/time recording device to provide a permanent record of temperature within the system?
9. Is each retort equipped with an automatic steam controller?
10. Do air and water valves comply with 9 CFR 318.305 and 381.305?
11. 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	Potential Hazards	Frequently Used Controls
Can cooling	Biological—Microbial contamination of product	- Minimize bacterial contamination of cooling water as described in 9 CFR 318.305(h). - Maintain can/package integrity with overpressure during process if needed.
	Chemical—No common hazard	
	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 the residual level of free chlorine or other sanitizer used to sanitize the cooling water measured and monitored by the establishment?
3. Is cooling canal cleaned and replenished with portable water to prevent the buildup of organic matter and other materials?
4. Is cooling water that is recycled or reused (e.g., hydrostatic retort) handled in systems so designed for such use?
5. Is system equipment such as pipelines, cooling towers, and holding tanks constructed and installed so they may be easily cleaned and inspected?

Process Step	Potential Hazards	Frequently Used Controls
Packaging/labeling	Biological—Pathogens in product. Examples: - RTE product—<i>Listeria monocytogenes</i> - Mechanically tenderized beef products—STEC	- Minimize post-cook handling. - Ensure sanitary condition of food contact surfaces. - Proper material and sealing to ensure adequate barrier formation. - Labels including proper safe handling/validated cooking instructions.
	Chemical—Allergens	- Declare all allergens on the label. - Ensure correct label application to product.
	Physical—Packaging material, metal contamination	- Maintain package integrity. - Metal detector.

Suggested verification questions:

1. Are packaging materials covered by letters of guarantee or statements of assurance from the suppliers?
2. If packaging material for RTE products contains antimicrobial agents, how does the establishment ensure the levels of restricted ingredients/additives are safe and suitable?
3. Are packaging materials properly stored and protected from environmental contamination?
4. Does the establishment verify that the metal detector is functioning as intended?
5. Is the packaging clearly labeled “Keep Refrigerated” or “Keep Frozen” if this is required for safety?
6. Does the package include validated cooking instruction (i.e., cooking instruction for mechanically tenderized beef and uncooked, breaded, boneless poultry products) by the end users?
7. If the product contains allergens, does the final product label declare all ingredients?
8. Does each package contain the correct label?

Process Step	Potential Hazards	Frequently Used Controls
High pressure processing (HPP)	Biological—Pathogens in product: • RTE products—<i>Listeria monocytogenes</i> • Raw beef and veal products—<i>Salmonella</i> and STEC • Raw chicken, turkey, and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> • Raw pork— <i>Salmonella</i>, <i>Trichinella spiralis</i> and <i>Toxoplasma gondii</i> (especially in feral or non-confinement raised swine)	• Provide supporting documentation that is consistent with the actual process and product characteristics. • Monitor and control critical operational parameters such as pressure, dwell time, temperature, and water activity, etc. • Ensure package integrity to prevent post-treatment contamination.
	Chemical—No common hazard	
	Physical—No common hazard	

Suggested verification questions:

1. Has the establishment validated the effectiveness of the treatment for the specified product for the destruction of relevant pathogens, such as *Salmonella*, STEC, *Listeria monocytogenes* and *Trichinella spiralis*?
2. Does the process achieve the required critical operational parameters such as pressure level, dwell time, temperature, etc.?
3. Does the establishment refrigerate the products after treatment, if the product bears a “Keep Refrigerated” statement?

Process Step	Potential Hazards	Frequently Used Controls
Irradiation of raw products	Biological—Bacterial and parasitic pathogens: - Raw beef and veal products—<i>Salmonella</i> and STEC - Raw chicken, turkey, and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> - Raw pork—<i>Salmonella</i>, <i>Trichinella spiralis</i> and <i>Toxoplasma gondii</i> (especially in feral or non-confinement raised swine)	- Reduce pathogens at irradiation doses that do not exceed the regulatory limits. Note: The current maximum allowed limits are 4.5 kGy for refrigerated raw meat/poultry and 7.0 kGy for frozen meat/poultry per 21 CFR 179.26(b). - Laboratory procedures for dosimetry in accordance with 9 CFR 424.22(c)(2).
	Chemical—No common hazard	Ensure 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?
10. Are segregation procedures implemented for irradiated and non-irradiated product?

Process Step	Potential Hazards	Frequently Used Controls
Finished product storage	Biological—Outgrowth of pathogens: • Raw beef and veal products—<i>Salmonella</i> and STEC • Raw chicken, turkey, and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> • Raw pork and other products—<i>Salmonella</i> • RTE products—<i>Staphylococcus aureus</i>, <i>Listeria monocytogenes</i>, <i>Clostridium botulinum</i>, and <i>Clostridium perfringens</i>	• Monitor and maintain temperature at storage room. • Ensure product temperature above or below a level sufficient to preclude pathogen growth*. • Sanitation SOPs and GMP.
	Chemical—No common hazard	• Maintain package integrity.
	Physical—No common hazard	

*See FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B.

Suggested verification questions:

1. Are products properly maintained at refrigerated temperatures after chilling?
2. Does the establishment use methods other than refrigeration, such as low pH, low water activity, and freezing, to prevent pathogen growth? If so, are the methods validated as effective and monitored?

Process Step	Potential Hazards	Frequently Used Controls
Shipping	Biological—Outgrowth of pathogens, including: • Raw beef and veal products—<i>Salmonella</i> and STEC • Raw chicken, turkey, and other poultry—<i>Salmonella</i> and <i>Campylobacter</i> • Raw pork and other products—<i>Salmonella</i> • RTE products—<i>Listeria monocytogenes</i> • RTE Product hold hot—<i>Clostridium botulinum</i> and <i>Clostridium perfringens</i>	• Ensure transportation refrigeration unit functioning properly if product requires refrigerated storage. • Keep product above 140°F if product requires to be shipped hot*. • Monitor temperature during transportation.
	Chemical—No common hazard	• Maintain package integrity.
	Physical—No common hazard	

*See FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B.

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?

Glossary:

Shiga Toxin-producing *Escherichia coli* (STEC):

Shiga Toxin-producing *Escherichia coli* or STEC are a group of *E. coli* that cause disease by making a toxin called Shiga toxin. The most commonly identified STEC in North America is *E. coli* O157:H7. In addition, many other serogroups of STEC, including *E. coli* O26, O45, O103, O111, O121 and O145, have been identified. Those top six serogroups of STEC are often called non-O157 STEC. Symptoms of infection of STEC vary from person to person but often involve severe gastroenteritis, bloody diarrhea, vomiting, and mild fever if present. STEC can also cause hemorrhagic colitis and hemolytic uremic syndrome in humans, especially in children, the elderly, and those in weakened immune states. Hemorrhagic colitis and hemolytic uremic syndrome are more commonly associated with infections resulting from *E. coli* O157:H7. FSIS has declared STECs as adulterants in raw non-intact beef and beef intended for non-intact use under the Federal Meat Inspection Act (21 U.S.C. 601(m)(1)).

Specified Risk Materials (SRMs):

SRMs are defined as inedible tissues in 9 CFR 310.22(a), including (1) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from cattle 30 months of age and older, and (2) The distal ileum of the small intestine and the tonsils from all cattle. SRM tissues in cattle affected with Bovine Spongiform Encephalopathy (BSE) are likely to contain the infective prion agent known to cause BSE.

Edible offal (variety meats):

The properly cleaned and prepared edible organs, parts, or other meat by-products including but not limited to the brain (cattle less than 30 months of age), tongue, thymus gland, testicles, liver, pancreas, spleen, kidneys, intestines, stomach and other edible parts of livestock species.

D value:

The amount of time needed to kill 1 log₁₀ of a bacterial population at a given temperature. For instance, Appendix A prescribes 77 minutes at 132°F for a 7 log₁₀ or 7D *Salmonella* lethal heat treatment. Thus, that is a D_{132°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 pH 5.3. The higher the fermentation temperature, the fewer degree hours permitted to reach pH 5.3 for effective staphylococcal inhibition.

See the American Meat Institute Foundation guidelines for those degree hour limits and how to calculate multi-temperature processes.

“Log” or Log₁₀:

The number of the exponent when 10 is the base number. Thus, 2 log₁₀ is 10² or 100; 4 log₁₀ is 10⁴ or 10,000. A 3 log₁₀ increase is an increase of 1,000 times; conversely, a 3 log₁₀ 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.).

Log reduction:

A 90% reduction of a pathogen. For example, a 2-log₁₀ reduction is a 99% reduction of a pathogen.

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 log₁₀ 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:

Foods that can be safely stored at room temperature, or “on the shelf,” are called “shelf-stable.” 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:

- $a_w < 0.85$: 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 toxigenesis 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.

Water activity (a_w):

21 CFR 110.3(r): Water activity (a_w) 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, a_w of water is 1.0. Raw meats and most cooked uncured products are generally a_w 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.

Post lethality treatment (PLT):

A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure (9 CFR 430.1). A PLT must provide at least 1 log of lethality prior to product release to qualify for consideration.

Antimicrobial agent (AMA):

A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *Listeria monocytogenes* (*Lm*), or that has the effect of suppressing or limiting growth of a pathogen, such as *Lm*, in the product throughout the shelf life of the product. Examples include potassium lactate and sodium diacetate, both of which limit the growth of *Lm* (9 CFR 430.1).

Antimicrobial Process (AMP):

An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *Lm*, in the product throughout the shelf life of the product (9 CFR 430.1).

AMAP:

Antimicrobial agents and processes are referred to together as AMAP. It is FSIS’s expectation that AMAPs are designed to allow no more than 2 logs of growth of *Lm* over the shelf life of the product.

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 *Lm* contaminants and prevent outgrowth of any that might possibly remain. An additive that not only reduces the number of *Lm* 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. Under Alternative 3, the establishment does not apply a PLT to reduce or eliminate *Lm* or an AMAP to control the growth of *Lm* in the post-lethality exposed product. Instead, it relies on sanitation alone to control *Lm* in the product.

References:

CDC Information on Botulism

<http://www.cdc.gov/botulism/index.html>

Compliance Guideline for Controlling *Salmonella* in Market Hogs

<https://www.regulations.gov/document?D=FSIS-2014-0002-0001>

Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products

<http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling-Lm-RTE-Guideline.pdf?MOD=AJPERES>

Control of *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Products

<https://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec430-4.pdf>

Directive 6100.4 Verification Instructions Related to Specified Risk Materials

<http://www.fsis.usda.gov/wps/wcm/connect/3aaf25d8-8e2e-4dbd-bedf-b1af39a793be/6100.4.pdf?MOD=AJPERES>

Directive 10,010.1 Sampling Verification Activities for Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef Products

<http://www.fsis.usda.gov/wps/wcm/connect/c100dd64-e2e7-408a-8b27-ebb378959071/10010.1.pdf?MOD=AJPERES>

Directive 10,010.2 Verification Activities for Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef Products

<http://www.fsis.usda.gov/wps/wcm/connect/01356525-06b7-4f20-af3a-037bf24dc16e/10010.2.pdf?MOD=AJPERES>

Directive 10,240.4 Verification Activities for the *Listeria monocytogenes* (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program

<http://www.fsis.usda.gov/wps/wcm/connect/b8cd03ed-222c-4cef-ad92-3647e3be6c53/10240.4.pdf?MOD=AJPERES>

Dry Fermented Sausage and *E. coli* O157:H7

http://www.beefresearch.org/cmdocs/beefresearch/safety_meeting_exec_summaries/1996_dry_fermented_sausage.pdf

Federal Register (76 FR 58157) Shiga Toxin-Producing *Escherichia coli* (STEC) in Certain Raw Beef Products

<https://www.gpo.gov/fdsys/pkg/FR-2011-09-20/pdf/2011-24043.pdf>

Food Security and Emergency Preparedness

<http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/emergency-preparedness>

FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A.

<https://www.fsis.usda.gov/wps/wcm/connect/bf3f01a1-a0b7-4902-a2df-a87c73d1b633/Salmonella-Compliance-Guideline-SVSP-RTE-Appendix-A.pdf?MOD=AJPERES>

FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B.

<https://www.fsis.usda.gov/wps/wcm/connect/9ac49aba-46bc-443c-856b-59a3f51b924f/Compliance-Guideline-Stabilization-Appendix-B.pdf?MOD=AJPERES>

FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork and Products Containing Pork for additional information on parasitic controls in swine.

<https://www.fsis.usda.gov/wps/wcm/connect/2ca75475-3efd-4fa7-8f34-7393c245a1df/Trichinella-Compliance-Guide-03162016.pdf?MOD=AJPERES>

FSIS Compliance Guideline: Lebanon bologna

http://www.fsis.usda.gov/wps/wcm/connect/d5be2be1-3c57-45f6-af53-e71393eaaeb6/Compliance_Guideline_Lebanon_Bologna.pdf?MOD=AJPERES

FSIS Compliance guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments

<http://www.fsis.usda.gov/wps/wcm/connect/5fd4a01d-a381-4134-8b91-99617e56a90a/Compliance-Guideline-Jerky-2014.pdf?MOD=AJPERES>

FSIS Web Site *Listeria* Page

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/listeria>

FSIS Information on *Campylobacter*

http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/foodborne-illness-and-disease/campylobacter-questions-and-answers/ct_index

FSIS Microbiology Laboratory Methods

<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook/microbiology-laboratory-guidebook>

Good Manufacturing Practices for Fermented Dry and Semi-dry Sausage Products

http://meathaccp.wisc.edu/assets/Heat_Treated_Shelf_Stable/AMIF_degreehours.pdf

Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing *Escherichia Coli* (STEC) and *Salmonella* in Beef (including Veal) Slaughter Operations

<https://www.fsis.usda.gov/wps/wcm/connect/1c7b15f7-2815-41d4-9897->

[2b0502d98429/Compliance-Guideline-STECSalmonella-Beef-Slaughter.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/3ec95930-e7fe-4e61-90ad-675e6b483591/HACCP-1.pdf?MOD=AJPERES)

Guidebook for Preparation of HACCP Plans

<http://www.fsis.usda.gov/wps/wcm/connect/3ec95930-e7fe-4e61-90ad-675e6b483591/HACCP-1.pdf?MOD=AJPERES>

Heat-processing and Stabilization Requirements for Uncured Meat Patties

<https://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec318-23.pdf>

Labeling and Consumer Protection Policies

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling>

Meat and Poultry Packaging Materials

<http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/packaging-materials/meat-poultry-packaging-materials>

Pathogen Modeling Program

<http://pmp.errc.ars.usda.gov/default.aspx>

Pathogen Reduction & HACCP Guidance Documents

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/pr-and-haccp-guidance-documents/pathogen-reduction-haccp-guidance>

Pre-Harvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing *Escherichia coli* Shedding in Cattle: An Overview of Current Research

<http://www.fsis.usda.gov/wps/wcm/connect/d5314cc7-1ef7-4586-bca2-f2ed86d9532f/Reducing-Ecoli-Shedding-in-Cattle.pdf?MOD=AJPERES>

Requirements for the production of thermally processed, commercially sterile product

<https://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-part318-subpartG.pdf>

Requirements for the production of cooked beef, roast beef, and cooked corned beef products

<https://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec318-17.pdf>

Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips

<https://www.gpo.gov/fdsys/pkg/CFR-2011-title9-vol2/pdf/CFR-2011-title9-vol2-sec381-150.pdf>

Requirements for specific classes of product

<https://www.gpo.gov/fdsys/pkg/CFR-2011-title9-vol2/pdf/CFR-2011-title9-vol2-part430.pdf>

Temperatures and chilling and freezing procedures

<https://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec381-66.pdf>

The FSIS *E. coli* O157:H7 and other Shiga Toxin-producing *E. coli* (STEC) Web Page

http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/foodborne-illness-and-disease/escherichia-coli-o157h7/ct_index

The Bad Bug Book (FDA)

<http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm2006773.htm>

Use of food ingredients and sources of radiation

<https://www.gpo.gov/fdsys/pkg/CFR-2015-title9-vol2/pdf/CFR-2015-title9-vol2-sec424-21.pdf>

76 FR 58157

<https://www.gpo.gov/fdsys/pkg/FR-2011-09-20/pdf/2011-24043.pdf>