A Generic HACCP Model for New Swine Inspection System (NSIS)

The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model's focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics.

With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan.

Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used "as is". FSIS recommends that establishments tailor the model(s) to fit the establishment's operation.

Establishments that slaughter market hogs may choose to operate under NSIS. Market hog slaughter establishments that do not choose to operate under the NSIS may operate under the traditional inspection system. FSIS has published a generic HACCP model for Traditional Swine Slaughter.

The NSIS model's critical control points (CCPs) do not necessarily apply to all NSIS operations. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources to meet regulatory validation requirements. This model includes references for guidance on the selection of critical limits.

The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP records (CFR 417.5(a)). Ensure you maintain the documents produced while developing a HACCP plan.

For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.

EXAMPLE PRODUCT DESCRIPTION[1]

Process / Product Name: New Swine Inspection System (NSIS)

Market Hog Slaughter and Variety Meats

Process / Product name	NSIS Market Hog Slaughter and Variety Meats (carcasses, variety meats (offal) and head meat)
Important product characteristics (A_w, pH, Preservatives, etc.)	Not Applicable
Intended use[2]	For further processing at this facility or another establishment or Intended for cooking by end consumer
Packaging (durability and storage conditions)	Vacuum-packaged, bagged, boxed or in combos (catch weights)
Shelf life and at what temperature	Carcasses: 7 days when stored at less than 40°F Variety Meats: 15 days at less than 40°F, Frozen – 180 Days at less than 10°F
Where it will be sold (specify intended consumers, especially at-risk populations[3])	Carcasses and variety meats are either further processed in-house or sold direct to another establishment or to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI).
Labeling instructions	Product name, inspection legend and establishment number, handling statement, net weight statement, address line, nutrition facts, and safe handling instructions.
What special distribution controls are required?	Keep refrigerated < 40°F or frozen < 10°F

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[1] Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the NSIS generic HACCP model are intended for establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.

[2] The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product's intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2).

[3] At-risk populations include young children, the elderly and immunocompromised persons.

EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL[4]

Process / Product Name: NSIS Market Hog Slaughter and Variety Meats

Meat and meat by-products	Live hogs
Non-meat food ingredients	None
Antimicrobials[5] or processing aids[6]	Scald agents, organic acid
Packaging material	Foam bone protectors, cardboard boxes and combos, self-adhesive labels, plastic vacuum bags, plastic combo bin and box liners.
Restricted ingredients or allergens	None
Other	None

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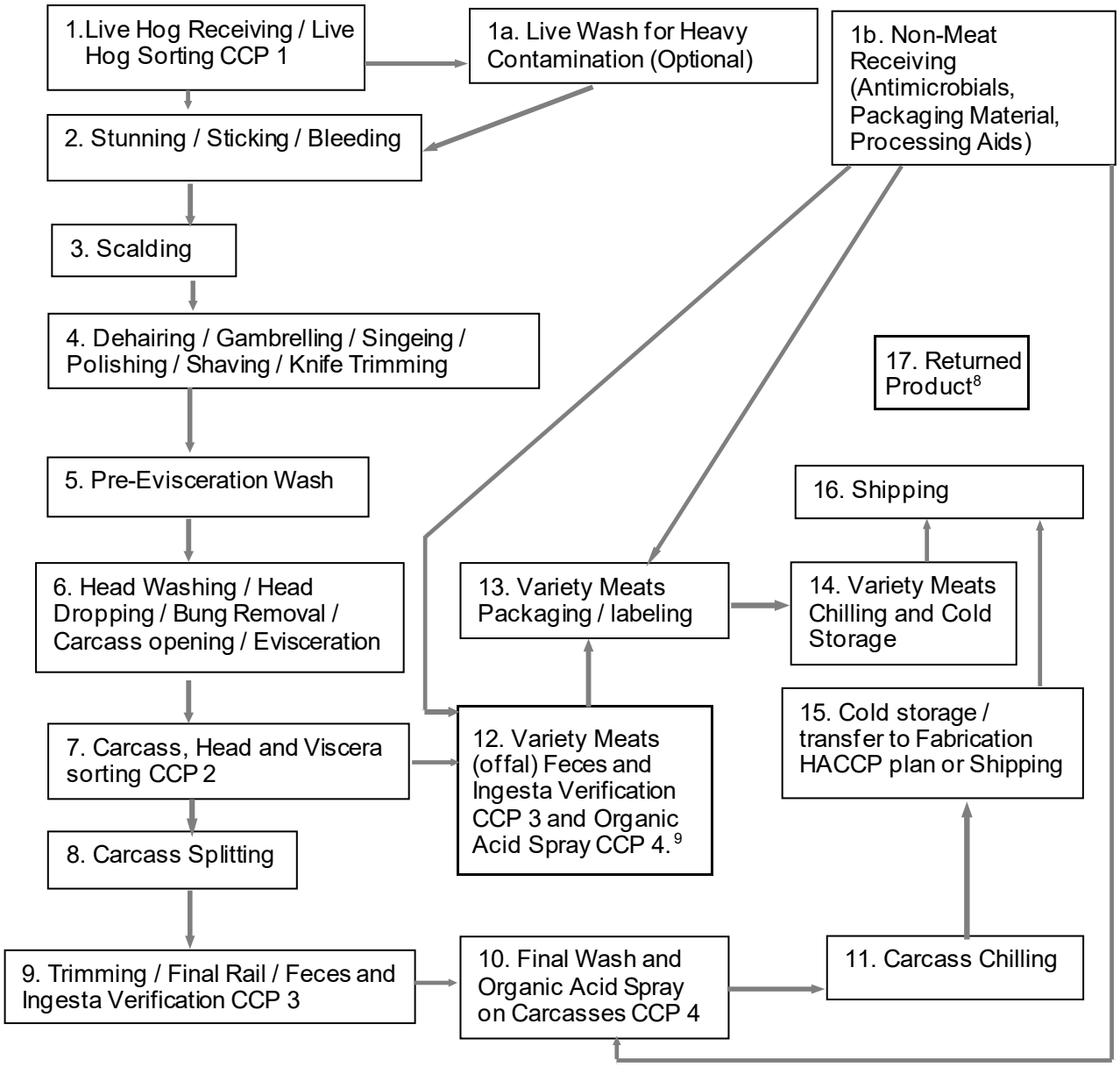
[4] List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan.
[5] FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients.
[6] There are many different organic acids (for example, lactic acid, acetic acid). Establishments will need to research the various organic acids and select the antimicrobial intervention best suited for their unique circumstances and validate its effectiveness. Antimicrobial agents are listed in FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products.

EXAMPLE PROCESS FLOW DIAGRAM[7]

Process / Product Name: NSIS Market Hog Slaughter and Variety Meats



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[7] This is an example flow diagram. Establishments' flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis.

[8] The Returned Product step (16) is shown as not connected to another process step. Returned product may re-enter the production system at different process steps depending on condition or food safety concerns. Returned product may be relabeled, re-processed, discarded, etc.

[9] This model demonstrates the use of a CCP to ensure carcasses, heads and variety meats (offal) intended for human consumption are free of visible feces and ingesta. 9 CFR 310.18(a) states: "Carcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter".

EXAMPLE NSIS MARKET HOG SLAUGHTER AND VARIETY MEATS HAZARD ANALYSIS[10]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Ingredient / Process Step	**Potential Hazards (Introduced or Controlled) at This Step[11]**	**Is the Potential Food Safety Hazard Reasonably Likely to Occur[12] (RLTO) (Yes or No)**	**Justification / Basis for Decision[13]**	**If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels?[14]**	**Is this Step a Critical Control Point CCP)?[15]**

[10] See FSIS Compliance Guideline for Controlling Salmonella in Market Hogs, FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork, and FSIS Compliance Guide: Modernization of Swine Inspection – Developing Microbiological Sampling programs in Swine Slaughter Establishments for suggested slaughter best practices and a list of scientific and technical references.

[11] Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used, or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification.

[12] Place the justification for your decision in column 4. Include control measures in column 4 for hazards not reasonably likely to occur and place them in column 5 for hazards reasonably likely to occur. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls.

[13] Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then HACCP system design must be supported by documentary evidence – that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan.

[14] Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5).

[15] To determine a CCP, see Guidebook for the Preparation of HACCP Plans for a CCP decision tree. Use the tool to evaluate the areas of control (column 5) to determine the best CCP to control, reduce, or eliminate a hazard.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
1. Live Hog Receiving / Live Hog Sorting	B: Live animals showing physical signs of central nervous system (CNS) disease, pyrexia, or moribund conditions.	Yes	Market hogs may exhibit physical signs of CNS disease, pyrexia, or moribund conditions.	CCP 1 Live Hog Sorting Sorters follow written Live Hog Sorting Standard Operating Procedure (SOP). Sorting procedures to remove hogs exhibiting conditions described in 9 CFR 309.19 prior to FSIS ante-mortem inspection	CCP 1
	Pathogens (*Salmonella)*	Yes	Well documented that *Salmonella* are known to be present in digestive tracts swine.	Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray Maintain adequate sanitation in holding pens, part of Good Manufacturing Practices (GMPs).	No
	Trichinella[16]	No	Acquire market hogs from herds with a Trichinae Certification Program. Therefore, *Trichinella* is a hazard not reasonably likely to occur and treatment of such products for the destruction of Trichinae is not necessary.		
	C: Drug residues	No	Low risk per FSIS Residue Monitoring Program, Compliance Guide for Residue Prevention. Residue certifications for live animals. Written Drug Residue Control SOP.		

[16] See FSIS Compliance Guideline for Controlling Salmonella in Market Hogs, FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork for options used to prevent the control of Trichinella in pork and pork products.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	P: Foreign material / metal (needles, buckshot, bullets, hardware in intestinal tract)	No	Recorded historic data from written Foreign Material Standard Operating Procedure[17] indicates low likelihood at this establishment and from suppliers.[18]		
1a. Live Wash for Heavy Contamination[19] (Optional)	B: Pathogens (*Salmonella)*	Yes	Skin and hair from swine are a significant source of contaminants in slaughter operations.	Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic acid spray. Written Optional Wash SOP with conditions for use of optional wash (processing conditions, suppliers, customer specifications, etc.); wash parameters to decrease pathogens and prevent cross- contamination and ensure humane handling of swine.	No
	C: None				
	P: None				
1b. Non-Meat Receiving (Antimicrobials,	B: None				
	C: Incorrect chemical /	No	Letters of Guarantee (LOG) from suppliers.		

[17] This Foreign Material SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historic data.

[18] Note: this "historical data" must be supported with evidence from the establishment through the establishment's history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide which states "visual examination of carcass for foreign material during slaughter" is a frequently used control for foreign material hazards in swine slaughter.

[19] The criteria used to determine when the live wash will be used should be clearly established in a prerequisite program.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
Packaging Material, Processing Aids)	concentration received.[20]		Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]) Safety Data Sheets (SDS) sheets.		
	P: None				
2. Stunning / Sticking / Bleeding	B: Pathogen (*Salmonella)*	Yes	It is well documented that *Salmonella* is known to be present in digestive tracts of warm-blooded animals including swine. Contaminants on swine hair or skin maybe transferred to product during dressing procedures.	Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic acid spray. Written Slaughter SOP describing removal (trimming) of visible contaminants from the stick wound and sanitation of the stick knife (heat or chemical) prior to each use.	No
	C: None				
	P: None				
3. Scalding	B: Pathogens (*Salmonella)*	Yes	Potential for cross-contamination through stick wound as well as scalding process.	Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Written Scalding SOP for procedures to minimize contamination during scalding and use of processing aids, scald agent, anti-foam, and time and	No

[20] Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
				temperature parameters used in scalding process to decrease pathogen load. Written Sanitation SOP for maintaining sanitary conditions of scalder (carcass transit time, water temperature, easy to clean and in good repair, counter current application to increase heating efficiency and water cleanliness). Trimming of stick wound after scalding.	
	C: Inappropriate chemical or concentration of scald agent used.	No	LOG from suppliers. SDS on file. Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number])		
	P: None				
4. Dehairing, Gambrelling, Singeing / Polishing / Shaving / Knife Trimming	B: Pathogen (*Salmonella)*	Yes	Pathogens may be present on hog's skin. Potential for cross-contamination during dehairing operation. Singeing may reduce pathogens somewhat but is not a means to eliminate pathogens on skin.	Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Written Sanitation SOP to maintain equipment in sanitary conditions and to minimize cross-contamination. Written Sanitary Dressing SOP to minimize cross-contamination through adequate sanitary dressing procedures, remove visible hair to an acceptable level without breaking skin, describe procedures for steam or hot	No

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
				water vacuuming de-hairing, trim fecal contaminants, and other dressing defects. Sanitary Dressing SOP includes pre-evisceration sampling at this step per 9 CFR 310.18(c).	
	C: None				
	P: None				
5. Pre-Evisceration Wash[21]	B: Pathogen (*Salmonella)*	Yes	Pathogens may be present on hog's skin. Washing may reduce pathogens, but washing is not a means to eliminate pathogens from the skin.	Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Written Pre-evisceration Wash SOP to minimize overspray from cabinet. Written Pre-evisceration Carcass Wash SOP for control parameters (hot water, organic acid rinse, steam or other approved antimicrobial intervention, monitoring of chemical concentrations, water temperatures, nozzles, and solution application pressure regularly to verify effectiveness and to prevent driving contaminants into the tissues and overspray) at this step to prevent cross-contamination and reduce pathogen loads. Process Control SOP for sampling of microbial organisms to monitor the	No

[21] Pre-evisceration wash can be a control step where application parameters are monitored and documented in a prerequisite program. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products for the list of suitable compounds for pre-evisceration wash. Concentrations and control parameters in prerequisite programs should be evaluated (see FSIS Compliance Guide HACCP Systems Validation).

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
				establishment's ability to maintain process control (9 CFR 310.18).	
	C: Inappropriate antimicrobial use or concentration	No	LOG from suppliers. SDS on file. Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number])		
	P: None				
6. Head Washing / Head Dropping / Bung Removal / Carcass Opening / Evisceration	B: Pathogens (*Salmonella)*	Yes	Well documented that *Salmonella* are known to be present in digestive tracts of warm-blooded animals including swine. Contaminants may be transferred to product during dressing procedures. Cross-contamination from unsanitary dressing procedures and employee handling.	Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Documentation of properly trained employees.[22] Written Sanitation SOP for procedures and compliance of equipment sanitized between each carcass to minimize cross-contamination. Written SOP for tying the esophagus to prevent contamination with stomach contents. Written Head Wash SOP to minimize overspray from cabinet.	No
	C: None				
	P: None				

[22] FSIS recommends that slaughter operations focus on their sanitary dressing procedures in order to prevent carcass contamination and the creation of insanitary conditions. Document the training of employees and training material used. Poor sanitary dressing procedures result in carcass contamination (visible or invisible, for example, microbial contaminants) and limit the effectiveness of antimicrobial interventions.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
7. Carcass, Head and Viscera Sorting	B: Septicemia, Toxemia, Pyemia, or cysticercosis	Yes	Carcasses, heads and viscera may exhibit signs of septicemia, toxemia, pyemia, and cysticercosis.	CCP 2 Carcass, Head and Viscera Sorting. Sorters follow written Carcass, Head and Viscera Sorting SOP. Establishment post-mortem sorting procedures to remove carcasses, heads and viscera with septicemia, toxemia, pyemia, or cysticercosis prior to FSIS inspection in accordance with 9 CFR 310.26.	CCP 2
	C: None				
	P: None				
8. Carcass Splitting	B: Pathogen (*Salmonella*)	Yes	Meat may become contaminated with pathogens during dressing procedures and processing. The splitting saw may transfer contaminants from carcass to carcass. Recorded historic data from written Sanitation SOP Split Saw Check (sanitation of the saw between carcasses to prevent cross-contamination) indicates low likelihood of occurrence.[23, 24]	Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Written Sanitary Dressing SOP for minimizing carcass transit time, and for monitoring time and temperature of product to move quickly through process to reduce pathogen growth.	No
	C: None				
	P: None				

[23] Note: this "historical data" must be supported with evidence from the establishment through the establishment's history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide, which identifies "minimize cross-contamination through sanitary dressing procedures; Sanitation SOPs" as a frequently used control of biological hazards in swine slaughter.

[24] Documentation to support this statement using in-plant data collected from prerequisite program (Sanitation SOP) validation and on-going verification check.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
9. Trimming / Final Rail / Feces and Ingesta Verification	B: Pathogen (*Salmonella)*	Yes	Well documented that carcasses, parts and organs are to be handled in a sanitary manner to prevent contamination with fecal material or ingesta.	CCP 3 Feces and Ingesta Verification	Yes CCP 3[25]
	C: None				
	P: None				
10. Final wash and Organic Acid Spray on Carcasses	B: Pathogen (*Salmonella)*	Yes	*Salmonella* are known to be present on skin and in digestive tracts of warm-blooded animals including swine. Contaminants may be transferred to product during dressing procedures.	CCP 4 Organic Acid Spray. Organic Acid sprays documented to reduce contaminants on carcasses, variety meats (offal), and meat.[26]	Yes CCP 4
	C: Inappropriate concentration of organic acid	No	Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]). Written Final Wash and Acid Spray SOP to minimize overspray from cabinet and ensure complete coverage.		
	P: None				

[25] The CCP to reduce, control, or eliminate the previous hazards associated with fecal material and ingesta as designated by "yes" in column 6.

[26] If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameters (FSIS Compliance Guideline HACCP Systems Validation, page 27).

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
11. Carcass Chilling	B: Pathogen outgrowth (*Salmonella)*	No	Written Chilling SOP to monitor carcass time and temperature chilling parameters. Sanitation procedures in coolers and sanitary handling while moving carcasses in the coolers. Process Control SOP for sampling of microbial organisms to monitor the establishment's ability to maintain process control (9 CFR 310.18).		
	C: None				
	P: None				
12. Variety Meats (Offal) Feces and Ingesta Verification CCP 3 and Organic Acid Spray CCP 4	B: Pathogen outgrowth	Yes	It is well documented that *Salmonella* are known to be present in digestive tracts of warm-blooded animals including swine. Contaminates may be transferred to product during carcass dressing procedures.	CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Organic acid sprays documented to reduce contaminants on carcasses, variety meats (offal), and meat. Properly trained[27] employees to examine variety meats (offal) for feces and ingesta. Written Sanitation SOPs to prevent cross-contamination and for time temperature conditions to minimize outgrowth of pathogens.[28]	Yes CCP 3 CCP 4
	C: Inappropriate concentration of organic acid		Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]).		

[27] Document training of personnel and training material used.
[28] Reference can be used to justify temperature and time during processing (e.g., Tompkin, R.B. 1996. The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F. Presented during the Joint FSIS/FDA Conference on Time/Temperature, November 18-20, 1996 Washington, DC).

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
			Written Final Wash and Acid Spray SOP to minimize overspray from cabinet and ensure complete coverage.		
	P: None				
13. Variety Meats Packaging / Labeling	B: Pathogen outgrowth (*Salmonella*	No	Written Fabrication SOP to address temperature control for the processing room to reduce pathogen outgrowth (Tompkin, R.B. 1996). Written Sanitation SOP includes procedures for sanitary handling of product.		
	C: None				
	P: None				
14. Variety Meats Chilling and Cold Storage	B: Pathogen outgrowth (*Salmonella)*	No	Chilling SOP to monitor variety meats time and temperature chilling parameters. Sanitation procedures in coolers and sanitary handling while moving product. Written Cooler Storage SOP for proper cooler storage temperature when product is present in the coolers. (Tompkin, R.B. 1996)		
	C: None				
	P: None				
15. Cold Storage / Transfer to Fabrication	B: Pathogen outgrowth (*Salmonella)*	No	Written Cooler Storage SOP for proper cooler storage temperature when carcasses are present. (Tompkin, R.B. 1996) Written Sanitation SOP to address cooler sanitation.		

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
HACCP plan or Shipping			Sanitary Dressing SOP includes post-chill sampling at this step.[29] Sanitation procedures in coolers and sanitary handling while moving product.		
	C: None				
	P: None				
16. Shipping	B: None				
	C: None				
	P: None				
17. Returned Product	B: None		Reinspection SOP implemented before accepting returned product. Entity returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted.		
	C: None				
	P: None				

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[29] Official swine slaughter establishments, except for very low-volume establishments, must collect and analyze carcass samples for microbial organisms at the pre-evisceration and post-chill points in the process (9 CFR 310.18(c)(1)).

Example NSIS Market Hog Slaughter HACCP Plan[30]									
Critical Control Point (CCP)	**Significant Hazard(s)**	**Critical Limits for Each Control Measure**	**Monitoring Procedures**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
CCP 1 Live Hog Sorting	Pyrexia, central nervous system (CNS) disorders, and moribundity. 9 CFR 309.19	All hogs exhibiting signs of pyrexia, central nervous system disorders, and moribundity are sorted before the point of FSIS ante-mortem inspection.	Monitor for hogs exhibiting signs of pyrexia, central nervous system disorders, and moribundity.	Observe 300 hogs in motion and 300 hogs at rest for animals exhibiting signs of pyrexia, central nervous system disorders, and moribundity.	Twice per shift.	Auditor or designee	When the auditor observes a hog exhibiting signs of pyrexia, central nervous system disorders, or moribundity, which was not identified during the sorting activity, the auditor will observe the remaining hogs in the group. Additionally, the auditor will again monitor the group while it is held for slaughter and just prior to the group going to slaughter. Hogs observed exhibiting signs of pyrexia, central nervous system disorders, or moribundity are to be segregated and prevented from entering the slaughter department. A member of management will ensure that corrective actions are completed. The production supervisor will per 9 CFR 417.3(a): 1. Hold all product produced until appropriate disposition taken (no product injurious to health will be sold); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; and 4. Take measures to prevent recurrence.	Supervisor will conduct daily direct observations of monitoring activities and corrective actions. Supervisor will review records daily. Daily-calibrate thermometer used to measure pyrexia.	Ante-mortem audit log HACCP deviation log Pre-shipment Records review form

[30] This information is best suited for establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.

Example NSIS Market Hog Slaughter HACCP Plan									
Critical Control Point (CCP)	**Significant Hazard(s)**	**Critical Limits for Each Control Measure**	**Monitoring Procedures**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
CCP 2 Carcass, Head and Viscera Sorting	Carcasses, heads and viscera exhibiting septicemia, toxemia, pyemia, or cysticercosis (condemnable conditions listed in 9 CFR 310.26).	All carcasses, heads and viscera exhibiting septicemia, toxemia, pyemia, or cysticercosis are sorted before the point of FSIS post-mortem inspection of carcasses.	Monitor for carcasses, heads and viscera exhibiting septicemia, toxemia, pyemia, or cysticercosis.	Observe 12 carcasses, 12 heads and 12 viscera sets for lesions consistent with septicemia, toxemia, pyemia, and cysticercosis.	Once per three hours of production time.	Auditor or designee.	If one or more carcasses, heads or viscera sets are observed with septicemia, toxemia, pyemia, or cysticercosis, the auditor will document food safety disease or condition found and inform a supervisor so the supervisor can initiate the appropriate corrective action and preventive measures. All affected product will be disposed of. Conduct a recheck of an additional set of 12 carcasses, heads, or viscera within 15-30 minutes. If recheck finds the condemnable conditions, reduce the line speed by 5% and increase the frequency of checks to once every ½ hour. Isolate the carcasses, heads, and viscera in the cooler produced after the last acceptable check for re-auditing. A member of management will ensure that corrective actions are completed. The supervisor will per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; and 4. Take measures to prevent recurrence.	Supervisor will conduct daily direct observation verification. Supervisor will review records daily.	Carcass, Head and Viscera Sorting Audit form HACCP deviation log Pre-shipment Records review form

Example NSIS Market Hog Slaughter HACCP Plan									
Critical Control Point (CCP)	**Significant Hazard(s)**	**Critical Limits for Each Control Measure**	**Monitoring Procedures**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
CCP 3 Feces and Ingesta Verification (Carcass and Variety Meats) 9 CFR 310.18	B: Pathogens: *Salmonella*	No visibly detected fecal material, milk, or ingesta contaminants on carcasses, head meat, cheek meat, weasand meat and offal.	Select and examine 12 carcasses and 20 pounds of head meat, cheek meat, weasand meat and offal.	Observe all surfaces of each split carcass before the FSIS inspection station. Observe all sides of each piece of head meat, cheek meat, weasand meat and offal at packaging.	Once every three hours of production.	QA Tech designee	Contaminants are knife trimmed. Contaminated carcasses may be railed out for trimming.[31] The production supervisor will per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; and 4. Take measures to prevent recurrence. A member of management will ensure that corrective actions are completed.	Once per day a QA Manager will directly observe the monitoring of carcasses, head meat, cheek meat, weasand meat and offal. QA Manager will conduct a daily record review.	Feces and Ingesta Verification Form[32] HACCP Deviation Log Verification Records Pre-shipment Records review form

[31] For example, an SOP describing the corrective actions might include this statement "each carcass with a deviation will be railed out by the employee and reported and shown to the supervisor. The supervisor will determine the cause of the deviation, take whatever measures are necessary to restore the CCP to control, and document the corrective actions in the Corrective Actions log. If more than one deviation is found in a shift, the line will be slowed x% until xx minutes' production successfully passes the CCP."

[32] One form for all three CCP monitoring locations and verification activities.

Example NSIS Market Hog Slaughter HACCP Plan									
Critical Control Point (CCP)	**Significant Hazard(s)**	**Critical Limits for Each Control Measure**[33]	**Monitoring Procedures**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
CCP 4 Organic Acid Spray (Carcass, head meat, cheek meat, weasand meat, and offal)	B: Pathogens: *Salmonella*	The application of an organic acid[34] (for example, organic acid at 2-5%). Mix solution per manufacturer's instructions to achieve 2-5% solution of organic acid not to exceed 55°C (131°F) sprayed directly onto carcasses, head meat, cheek meat, weasand meat and offal at 20-30 psi[35] until all surfaces are dripping wet and some of the solution drips off.	Observe the preparation and mixing of the solution and its application to verify the operational parameters are achieved.	Observe the mixing of the solution and test the concentration of the organic acid (test kit). Observe the pressure gauges to determine the pressure at which the solution is being applied. Check thermometer for the temperature of the solution at the point of application. Observe for complete coverage of the product at the point the solution is applied.	Once during each hour of slaughter operations.	QA Tech or designee	If a deviation from the critical limit occurs, the QA manager or designee will take corrective actions per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; and 4. Take measures to prevent recurrence.	Randomly, once per week, QA Manager observes QA Tech performing monitoring functions. Each week, a QA Tech calibrates the pressure of the sprayers per manufacturer's instructions. Weekly calibrate cabinet thermometers by checking temperature with a calibrated hand-held thermometer. Daily Records Review QA will review Organic Acid Wash CCP	CCP 4 Organic Acid Spray Form. Corrective Action Log Pre-shipment Records review form Verification Records

[33] FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products identifies the ingredients that are safe to use; however, each establishment must validate their own process. See FSIS Compliance Guideline HACCP Systems Validation for validation guidance.

[34] FSIS does not endorse any specific antimicrobial intervention. "Organic acid" is used as an example. If an antimicrobial is used, each establishment will need to find an antimicrobial intervention that works with their unique situation and they will need to validate the product's use. The critical limits should closely match the specific parameters for use as found in the technical or scientific supporting documentation.

[35] NOTE: Critical operating parameters need to be addressed in this section as they are related to the scientific justification for use. Critical parameters include but are not limited to the following: type of sprayer (hand, cabinet), volume, coverage, chemical contact time, solution temperature, etc. The defined operational parameters are specific to each establishment.