HACCP Model for Raw Non-Intact Beef

The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996 mandating all USDA inspected meat and poultry establishments implement a HACCP system. Hazard Analysis Critical Control Point (HACCP) is a systematic and scientific method of process control for the production of safe food products. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to improve the safety of their products. The HACCP models' focus 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 revised 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". Establishments are to tailor the model(s) to fit the establishment's operation.

The model's critical control points (CCPs) do not necessarily apply to all operations or products. 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. Each model includes references for guidance on the selection of critical limits.

This model illustrates how establishments might include, in the production of ground beef, products from beef intended for intact use and from beef intended for non-intact use. The "sources" here include beef from: 1) in-house slaughter product that underwent antimicrobial interventions and verification testing for STEC (shiga toxin-producing *E. coli* strains O157, O26, O45, O103, O111, O121 and O145); 2) purchased product intended for non-intact use with a certificate of analysis (COA) for STEC testing; and 3) product purchased without a COA and intended for intact use.

The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP records (CFR 417.5(a)). The selection of processing categories and HACCP models are preliminary steps to completing a hazard analysis. The documents produced during the selection process are HACCP records. 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: Raw, Non-Intact Beef

Process / Product Name	Raw Non-Intact Beef: Ground Beef, Beef Patties, Jalapeno Cheddar Burgers, Tenderized Steaks, and Cubed (tenderized) Steaks.
Important product characteristics (Aw, pH, preservatives, etc.)	None
How it is to be used[2]	Intended for cooking.
Packaging (durability and storage conditions)	Plastic chubs, tray packages, vacuum sealed packages or in butcher paper.
Shelf Life and at what temperature	Not shelf stable – Keep refrigerated (7 days at ≤40°F) or frozen (180 days at ≤10°F).
Where it will be sold (specify intended consumers, especially at-risk populations[3])	Sold 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, ingredients statement, address line, nutrition facts, and safe handling instructions. Validated cooking instructions for needle and blade tenderized products.
What special distribution controls are required?	None

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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 generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do 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: Raw, Non-Intact Beef

Meat and Meat by-products	1. Beef and beef heart meat intended for non-intact use from In-house slaughter department. 2. Purchased beef intended for non-intact use and with a COA (certificate of analysis). 3. Purchased beef intended for intact use and without a COA.
Non-meat food ingredients	Wheat, Non-Fat Dry Milk, Soy, Cheese, Vegetables (Jalapenos), binders, spices, seasonings, and solutions for injection.
Antimicrobial[5] Interventions and processing aids	Organic Acid[6]
Packaging Material	Plastic, foam, or paper.
Restricted Ingredients and Allergens	Allergens - Wheat, Non-Fat Dry Milk, Cheese and Soy.
Other	None

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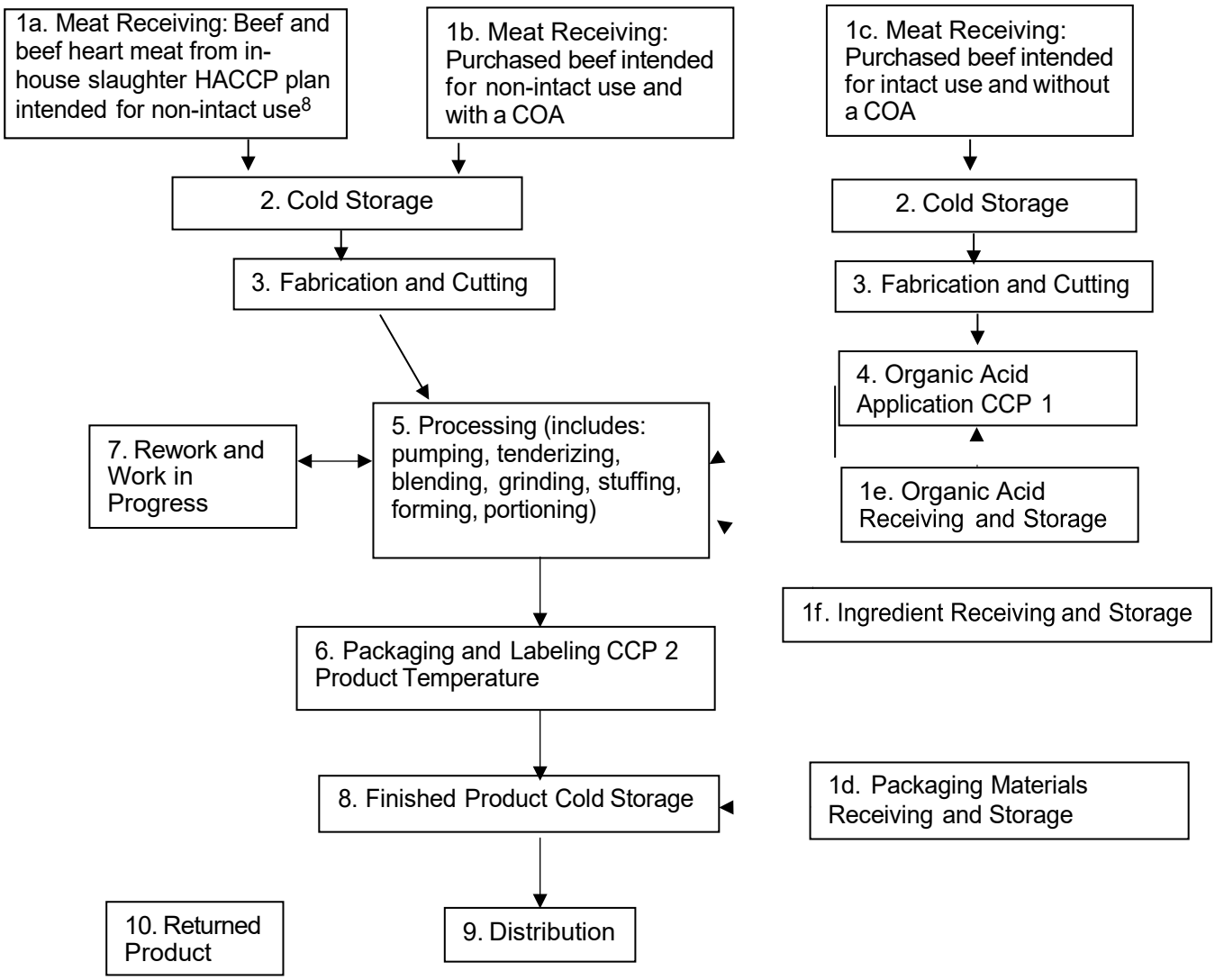
[4] List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. To review restrictions on the use of nitrite and sodium ascorbate or sodium erythorbate, see 9 CFR 424.22(b).

[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 a product best suited for their unique circumstances and validate its effectiveness.

EXAMPLE PROCESS FLOW DIAGRAM[7]

Process / Product Name: Raw, Non-Intact Beef



[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 flow diagram and hazard analysis demonstrate the use of three differently sourced beef products. They are from in-house slaughter production (step 1a) that underwent interventions as part of the slaughter HACCP plan, purchased product intended for non-intact use (with COA) (step 1b) and purchased product intended for intact use (without a COA) (step 1c). Note that CCP 1 Organic Acid Application (step 4) is a control measure only for purchased beef intended for intact use and without a COA. Also note the organic acid application occurs before the beef (in step 1c) is ground or subject to other further processing (step 5). Three source types are used to illustrate how establishments might address STEC in incoming materials that have received different interventions and microbial analysis.

EXAMPLE HAZARD ANALYSIS[9]

Process / Product Name: Raw, Non-Intact Beef

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Ingredient / Process Step	**Potential Hazards (introduced or controlled) at this Step[10]**	**Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No)[11]**	**Justification / Basis for Decision[12]**	**If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels[13]**	**Is this Step a Critical Control Point (CCP)?**

[9] See Meat and Poultry Hazards and Controls Guide for lists of potential biological, physical, and chemical hazards and frequently used controls and preventive measures.

[10] 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.

[11] 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.

[12] 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 source, 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.

[13] 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).

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
1a. Meat Receiving: Beef and beef heart meat from in-house slaughter HACCP Plan intended for non-intact use	B: Presence of pathogens:				
	- Shiga-toxin producing *Escherichia coli* (STEC) (*E. coli* O157:H7, O26, O45, O103, O111, O121 and O145)	No	STEC known to be present and may cause illness if not controlled. In-house product from slaughter operations was subjected to slaughter sanitary dressing procedures, a Zero Tolerance CCP, and an Organic Acid CCP. In-house product from slaughter operations is subject to the Written Raw Beef Testing SOP for verification of STEC controls. Product that tests positive for STEC is removed from human food supply (inedible), or fully cooked under federal inspection.		
	- *Salmonella*	No	In-house product from slaughter operations was subjected to slaughter sanitary dressing procedures, a Zero Tolerance CCP, an Organic Acid CCP.		
	B: Outgrowth of pathogens STEC and *Salmonella.*	No	Written Cold Storage Program to maintain product ≤45°F to prevent outgrowth (Tompkin, R.B. 1996).[14]		
	B: Bovine Spongiform Encephalopathy (BSE) Prions associated with Specified Risk Materials (SRM) (9 CFR 310.22).	No	Written SRM Program to remove, segregate and dispose of SRMs (9 CFR 310.22).		
	C: None				
	P: None				
1b. Meat Receiving: Purchased beef intended	B: Presence of pathogens: STEC and *Salmonella*.	No	STEC and *Salmonella* are known to be present and may cause illness if not controlled.		

[14] The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F (Tompkin, R.B. 1996)

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
for non-intact use and with COA.	B: Outgrowth of pathogens STEC and *Salmonella.*	No	An annual Letter of Guarantee[15] (LOG) from each supplier indicating the STEC and *Salmonella* controls were applied, and the products are intended for non-intact use. A COA for each purchased lot supporting STEC are not present. Written Raw Beef Testing SOP for verification of STEC controls. Written Receiving Program to receive product ≤45°F to prevent outgrowth (Tompkin, R.B. 1996).		
	B: BSE / SRMs	No	SRMs are required to be removed by supplier prior to receipt. Only boneless beef received and supplier LOG on file.		
	C: None				
	P: None				
1c. Meat Receiving: Purchased beef intended for intact use and without COA	B: Presence of pathogens: STEC and *Salmonella*	Yes	STEC and *Salmonella* are known to be present and may cause illness if not controlled. Supplier intends for product to remain intact. The product was not subject to interventions and microbial analysis.	Controlled later at CCP 1. Written Raw Beef Testing SOP for verification of STEC and *Salmonella* controls.	
	B: Outgrowth of pathogens STEC and *Salmonella*	No	Written Receiving Program to receive product ≤45°F to prevent outgrowth (Tompkin, R.B. 1996).		
	B: BSE / SRMs	No	Only boneless beef received. SRMs are required to be removed by supplier prior to release into commerce.		
	C: None				
	P: None				

[14] An annual update for Letters of Guarantee (LOG) is not a regulatory requirement. Each establishment must determine the frequency at which the LOG are updated. The frequency should be sufficient to adequately describe the supplier's process to support the decision(s) made.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
1d. Packaging Materials Receiving and Storage	B: Contamination with Pathogens	No	Procedure to protect packaging materials from pests and environmental contamination.		
	C: Non-food grade materials	No	LOG for packaging materials (9 CFR 317.24) and safely stored.		
	P: Foreign materials	No	Visual inspection for foreign material. Protect packaging materials from environment.		
1e. Organic Acid Receiving and Storage	B: None				
	C: Non-Food Grade Chemical	No	LOG maintained for organic acid. Low risk of receipt of inappropriate chemicals and inappropriate chemical compounds. Identify and list all approved chemicals used in the operations. Check each chemical at receiving to assure that it is on the list at the correct concentration and is appropriately labeled. Safety Data Sheets (SDS).		
	P: None				
1f. Ingredient Receiving and Storage	B: Contamination with Pathogens	No	Procedure to protect ingredients from pests and environmental contamination. Spices and flavorings may introduce pathogens. Written Incoming Material SOP include procedures used to examine materials including temperature and sanitary conditions. LOG from suppliers describing quality controls and prevention procedures.		
	C: Allergens	No	Written Allergen Program to monitor allergens, labels and prevent cross-contamination.		
	P: None				
2. Cold Storage	B: Outgrowth of pathogens STEC and *Salmonella*	No	Written Cold Storage Program to maintain product ≤45°F to prevent outgrowth (Tompkin, R.B. 1996).		

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	C: None				
	P: None				
3. Fabrication and Cutting	B: Outgrowth of pathogens STEC and *Salmonella.*	Yes	Processing could result in product temperatures above 45°F, permitting pathogen growth.	Controlled at CCP 2 Product Temperature. Temperature Control SOP for production room temperature.	No
	C: None				
	P: None				
4. Organic Acid Application (including solution preparation)	B. Presence of pathogens: STEC and *Salmonella.*	Yes	Eliminate or reduce pathogens. Organic acid applied to purchased product that was intended for intact use and without a COA.	CCP 1 Organic Acid Application. Organic Acid applied and effectiveness verified through in-house STEC testing.[16] Written Raw Beef Testing SOP.	CCP 1
	B: Outgrowth of pathogens STEC and *Salmonella.*	Yes	Processing could result in product temperatures above 45°F, permitting pathogen growth.	Product temperature controlled later at CCP 2. Temperature Control SOP for production room temperature.	
	C: Incorrect acid concentration	No	Written Acid Preparation and Monitoring Program.[17] Chemical used in accordance with supporting		

[16] 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. (FSIS Compliance Guideline HACCP Systems Validation, page 27).

[17] 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
			documentation and FSIS Directive 7120.1.		
	P: None				
5. Processing (includes tenderizing, cubing, blending, grinding, stuffing, forming)	B: Presence of pathogens: STEC and *Salmonella.*	No	Previous controls applied to eliminate STEC (COA for outside sources, in-house slaughter interventions or CCP 1 for outside product without COA) regularly verified through in-house STEC verification testing.		
	B: Outgrowth of pathogens STEC and *Salmonella.*	Yes	Processing could result in product temperatures above 45°F, permitting pathogen growth.	Controlled later at CCP 2. Temperature Control SOP for production room temperature.	No
	C: Allergens	No	Written Allergen Program to monitor allergens, labels and prevent cross-contamination.		
	P: Foreign Material, Metal.	No	No history of findings from daily equipment pre-operational inspections (covered in Sanitation SOPs).[18] No history of consumer complaints.		
6. Packaging and Labeling	B: Outgrowth of pathogens STEC and *Salmonella.*	Yes	Processing could result in product temperatures above 45°F, permitting pathogen growth. Product temperature taken at packaging.	CCP 2 Product Temperature Temperature Control SOP for production room temperature.	CCP 2
	C: Allergens	No	Written Allergen Program to monitor allergens, labels and prevent cross-contamination.		
	P: None				
7. Rework and Work in Progress	B: Presence of pathogens, STEC and *Salmonella.*	No	Previous controls applied to eliminate STEC (COA for outside sources, in-house slaughter interventions or CCP 1 for outside product without COA) verified through in-house STEC verification testing.		No

[18] Note: this "historical data" must be supported with evidence from the establishment through the establishment's history or validation data. 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 "appropriate screening procedure for monitoring equipment" is a frequently used control for foreign material hazards in processing.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	B: Outgrowth of pathogens STEC and *Salmonella.*	Yes	Processing could result in product temperatures above 45°F, permitting pathogen growth.	Controlled later at CCP 2. Temperature Control SOP for production room temperature.	
	C: Allergens	No	Written Allergen Program to monitor allergens, labels and prevent cross-contamination.		
	P: None				
8. Finished Product Cold Storage	B: Outgrowth of pathogens STEC and *Salmonella.*	No	Written Cold Storage Program to maintain product ≤45°F to prevent outgrowth (Tompkin, R.B. 1996).		
	C: None				
	P: None				
9. Distribution	B: None				
	C: None				
	P: None				
10. 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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EXAMPLE HACCP PLAN for Raw, Non-Intact Beef									
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 Organic Acid Application	Presence of pathogens: STEC (*E. coli* O157:H7, O26, O45, O103, O111, O121 and O145)	Mix the solution using the volume of water and other components as indicated in the manuf acturer's guidance to achieve 2-5% solution of organic acid. [19] The solution will be applied to each piece until all surf aces are dripping wet and some of the solution drips off.	The components are correctly measured and mixed. The solution is correctly applied to beef pieces. Observations documented.	Observe the employee measure the components and mix the solution. Observe the application of the solution to beef pieces. Document on the Organic Acid Application Form.	Monitor the mixing once at the beginning of the slaughter day. Monitor the application of the solution twice per shif t.	Designee	If a deviation from the critical limit occurs, the manager will: 1. Hold all product produced af ter 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; 4. Take measures to prevent recurrence 9 CFR 417.3	Once per week, a manager will directly observe the designee performing monitoring f unctions and record their observations. Once per week, a manager will conduct the records review. Once bef ore the shif t begins and once during the remainder of the shif t a manager verif ies the concentration of the organic acid with a test kit recommended by the manuf acturer.	Organic Acid Application Form Verif ication Form Corrective Action Form Pre-shipment Review Form Organic Acid Spray SOP

[19] These limits, proced ures and freq uencies are examples. Limits, proced ures and freq uencies can vary by establishment. Title 9 CFR 417.2(c) req uires each CCP to include a critical limit, and 9 CFR 417.5(a)(2) requires support for the selection and development of the CCP and critical limits. Title 9 CFR 417.2(c) requires the HACCP plan to include monitoring and verification proced ures and freq uencies, and 9 CFR 417.5(a)(2) requires support for the select proced ures and freq uencies. Title 9 CFR 417.4 requires each HACCP plan to be validated. If an establishment implements a process consistent with the process specifications described in the scientific sup port, and the scientific support contains microbiological data specifying the level of pathogen red uction 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. (FSIS Compliance Guideline HACCP Systems Validation, page 27).

EXAMPLE HACCP PLAN for Raw, Non-Intact Beef									
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 Product Temperature	Pathogen outgrowth: STEC (*E. coli* O157:H7, O26, O45, O103, O111, O121 and O145)	Internal product temperature is ≤45°F at packaging.	Product temperature is measured at packaging. Observations documented.	Observe the employee measure product temperature with a handheld digital thermometer. Record results on the Product Temperature Form.	Twice each day	Designee	If a deviation from the critical limit occurs, the manager will: 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; 4. Take measures to prevent recurrence 9 CFR 417.3	Once per week, a manager will directly observe the monitoring activity, conduct the records review and calibrate the thermometer (per manufacturer's instructions).	Product Temperature Form Verification Form Corrective Action Form Pre-shipment Review Form Thermometer Calibration Form

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