HACCP Model for Fully Cooked—Not Shelf Stable Roast Beef

The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule in July 1996 mandating all USDA inspected meat and poultry establishments implement a HACCP system. 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.

This Fully Cooked—Not Shelf Stable HACCP model applies to products that receive a full lethality heat process step to achieve food safety. The full lethality heat process step makes these products safe to eat with no further preparation required by the consumer. However, these products are not shelf stable. Therefore, these products must be frozen or refrigerated throughout their shelf-life to maintain product safety. These products also meet the definition of ready-to-eat (RTE) product, as defined in 9 CFR 430.1.

The Fully Cooked—Not Shelf Stable 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.

The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP decisionmaking records (CFR 417.5(a)). The selection of a HACCP model is a preliminary step 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.[1]

[1] This information is best suited 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 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.

EXAMPLE PRODUCT DESCRIPTION

Process Type and Product Name: Fully Cooked—Not Shelf Stable Roast Beef

Process Type and Product Name[2]	Fully Cooked–Not Shelf Stable, Roast Beef
Important product characteristics (A_w, pH, Preservatives, etc.)	None
How it is to be used[3]	Ready-to-eat
Packaging (durability and storage conditions)	Vacuum package, Catch weights < 8 lbs.
Shelf Life and at what temperature[4]	21 days at 40°F
Where it will be sold (specify intended consumers, especially at-risk populations)[5]	Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI).
Labeling instruction and requirements	Product name, inspection legend and establishment number, handling statement, net weight statement, ingredients statement, address line, and nutrition facts.[6]
Special distribution control	Keep refrigerated

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[2] 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 Guidebook is intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417.
[3] 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).
[4] Each establishment may have their own defined shelf life.
[5] At-risk populations include young children, pregnant women, the elderly, and immunocompromised persons.
[6] See the FSIS Labeling Overview and Generic Label Approval guideline for information on required labeling features.

EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL

Process Type and Product Name: Fully Cooked—Not Shelf Stable Roast Beef

Meat and meat byproducts[7]	Fresh beef (beef eye rounds)
Non-meat food ingredients	Spice mixture (Sea Salt, Black Pepper, Natural Beef Stock & Flavor (Contains Smoke))
Antimicrobial interventions and processing aids[8]	None
Packaging material	Plastic vacuum bags
Restricted ingredients and allergens	None[9]
Other	None

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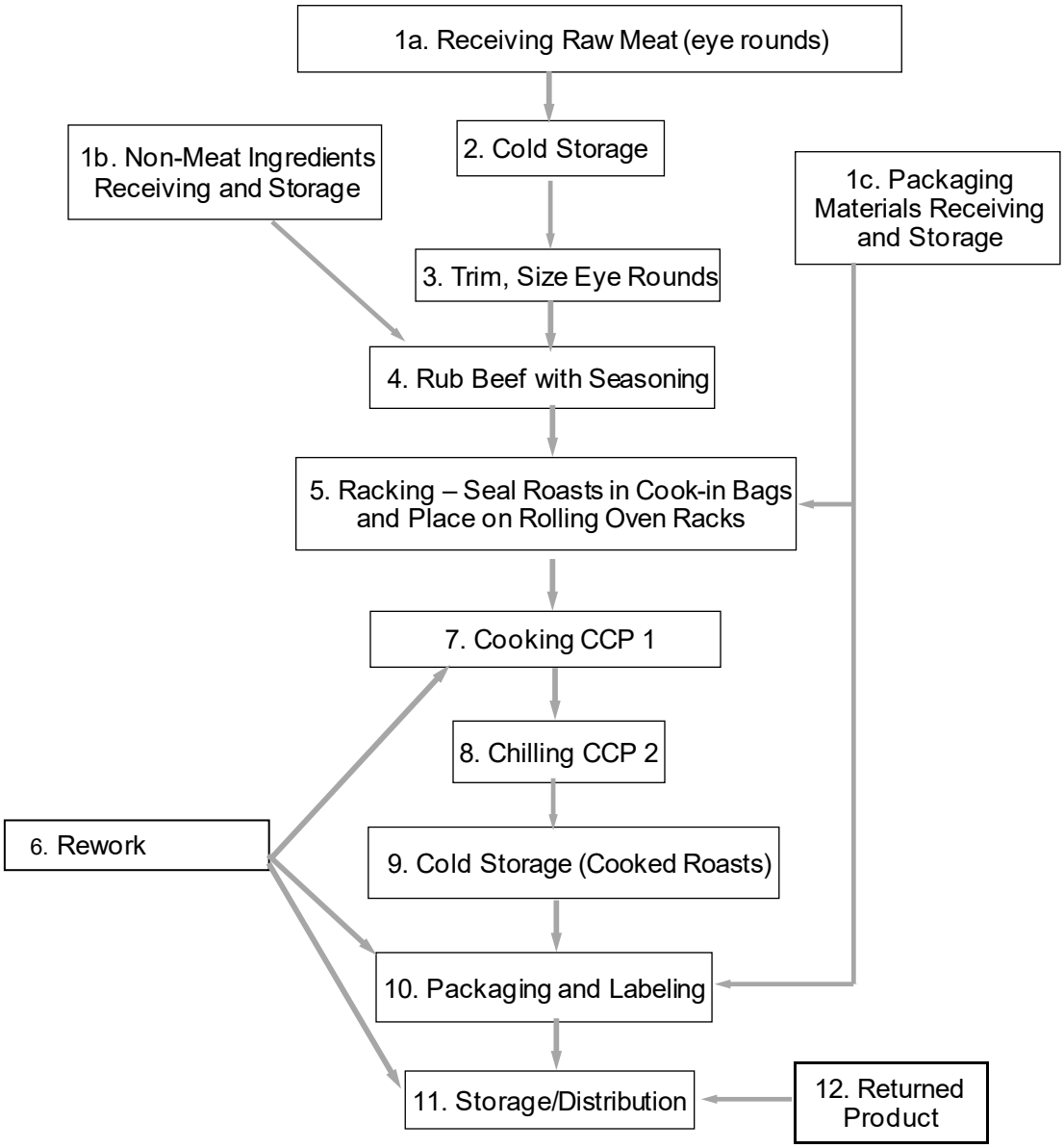
[7] List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens 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).

[8] 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.

[9] With this model, the establishment does not incorporate allergenic compounds or restricted ingredients into any products and so these ingredients are not present in the facility. For that reason, this model's hazard analysis does not demonstrate controls for allergenic compounds or restricted ingredients. Review the HACCP Model for Ready-to-Eat, Heat-Treated, Shelf-Stable (Beef Jerky) to see how allergen controls might be included in a hazard analysis.

EXAMPLE PROCESS FLOW DIAGRAM[10]

Process Type and Product Name: Fully Cooked—Not Shelf Stable Roast Beef[11]



[10]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.

[11] See FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) and FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) for guidance on the production of products in the Fully Cooked—Not Shelf Stable processing category.

EXAMPLE HAZARD ANALYSIS[12]

Process Type and Product Name: Fully Cooked—Not Shelf Stable Roast Beef (Eye Rounds)

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Ingredient / Process Step	**Potential Hazards (introduced or controlled) at this Step[13]**	**Is the Potential Food Safety Hazard Reasonably Likely to Occur? (Yes or No)[14]**	**Justification for Decision[15]**	**What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce to Acceptable Levels[16]**	**Is this Step a Critical Control Point (CCP)?**
1a. Receiving Raw Meat (eye rounds)	B: Presence of pathogens: *Salmonella*, Shiga-toxin producing *Escherichia coli* (STEC) (*E. coli* O157:H7, O26, O45	Yes	STEC and *Salmonella* are known to be present and may cause illness if not controlled. An annual Letter of Guarantee[17] (LOG) from each supplier indicating the STEC and *Salmonella* controls were applied.	Hazards controlled at step 7 CCP 1 Cooking	No

[12] See Meat and Poultry Hazards and Controls Guide for lists of potential biological, physical, and chemical hazards and frequently used controls and preventive measures.
[13] 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.
[14] Place the justification for your decision in column 4. Control measures either go in column 4 for hazards not reasonably likely to occur or go 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.
[15] 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.
[16] 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).
[17] An annual update for a 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
	O103, O111, O121 and O145).		Written Sanitation standard operating procedure (Sanitation SOPs) for procedures used to protect ingredients from environmental contamination.		
	B: Outgrowth of pathogens: STEC and *Salmonella.*	No	Written Receiving SOP to ensure product is received at ≤45°F to prevent outgrowth (Tompkin, R.B. 1996).[18]		
	B: Bovine Spongiform Encephalopathy (BSE) Prions associated with Specified Risk Materials (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: Foreign Materials	No	Written Incoming Material SOP for procedures to visually evaluate incoming packaged product for foreign material contamination.[19] Records demonstrate no incidents of foreign materials detected in products received.[20]		
1b. Non-Meat Ingredients Receiving and Storage	B: Pathogens: *Salmonella*	Yes	Spices and flavorings may introduce pathogens. LOG from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to examine incoming non-meat ingredients for package integrity and sanitary conditions. Written Sanitation SOP for procedures used to protect ingredients from environmental contamination.	Hazards controlled at step 7 CCP 1 Cooking	No

[18] 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, Washington, DC).

[19] 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.

[20] Note: The establishment must maintain copies of all the documents referenced in the hazard analysis that are designated as support for the decisions (9 CFR 417.5(a)(1) including establishment historical records. Such historical records are often gathered as part of in-plant validation (9 CFR 417.4(a)(1). When historical records are 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. See the guide for frequently used hazard controls.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	C: Undeclared allergens	No	LOG from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to verify that each lot of incoming materials does not contain allergenic ingredients. Approved supplier program and ongoing communication with suppliers to verify LOG.		
	P: None				
1c. Packaging Materials Receiving and Storage	B: Contamination with pathogens		Procedure to protect packaging materials from environment.		
	C: Non-food grade materials.	No	Packaging materials may introduce chemical hazards. LOG for all packaging materials describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to examine incoming materials including sanitary conditions. Written Sanitation SOP for procedures used to protect packaging materials from environmental contamination.		
	P: None				
2. Cold Storage	B: Pathogen outgrowth: *Salmonella,* STEC,	No	Written Temperature Control SOP for maintaining product at temperatures that preclude *Salmonella* and STEC growth (<45°F, (Tompkin, R.B. 1996).		
	C: None				
	P: None				
3. Trim, Size Eye Rounds	B: Pathogen outgrowth: *Salmonella,* STEC,	No	Written Temperature Control SOP for maintaining product work area at temperatures that prevent outgrowth of microorganisms. Duration of this step (Trimming) is short enough that outgrowth is not reasonably likely to occur. According to Tompkin, R.B. 1996 Table 2, *Salmonella* and STEC growth is limited to < 1-log if product temperatures are no more than 70°F for up to 9 hours.[21] Nine hours is		

[21] The University of Wisconsin Center for Meat Process Validation hosts a pathogen modeling tool (THERM 2.0) designed for evaluating the safety of meat or poultry held at temperatures between 50°F and 115°F. See THERM 2.0 for alternative time and temperature combinations that support the production of safe products.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
			longer than a shift, so outgrowth is not reasonably likely to occur. Written Good Manufacturing Practices to prevent or minimize cross-contamination.		
	C: None				
	P: None				
4. Rub Beef with Seasoning	B: Pathogen outgrowth: *Salmonella,* STEC	No	Written Temperature Control SOP for maintaining product work area at temperatures that prevent outgrowth of microorganisms. Duration of this step (Rub Beef with Seasoning) is short enough that outgrowth is not reasonably likely to occur. According to Tompkin, R.B. 1996 Table 2, *Salmonella* and STEC growth is limited to < 1-log if product temperatures are no more than 70°F for up to 9 hours. Nine hours is longer than a shift, so outgrowth is not reasonably likely to occur. Proper employee handling through Written Sanitation SOPs.		
	C: Undeclared allergens	No	This product does not contain allergenic ingredients. LOG from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to verify that each lot of incoming materials does not contain allergenic ingredients. Approved supplier program and ongoing communication with suppliers to verify LOG.		
	P: None				
5. Racking—Seal Roasts in Cook-in Bags and Place on Rolling Oven Racks	B: None				
	C: None				
	P: None				

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
6. Rework	B: Pathogen outgrowth: *Salmonella,* STEC	No	Written Rework Procedures SOP for handling product, including bags punctured for temperature monitoring to be reworked.		
	C: None				
	P: None				
7. Cooking	B: Pathogen outgrowth: *Staphylococcus aureus* Pathogen presence: *Salmonella,* STEC	Yes Yes	Extended heating come-up time could allow excessive *S. aureus* outgrowth and toxin formation. Improper cooking times and temperatures could result in bacterial survival and growth. Relative humidity is addressed through the cook-in-bag process.[22] While monitoring product temperature with a probe thermometer, the bag is punctured which exposes the product to the environment (i.e., post-lethality exposed). Product monitored with a probe thermometer is reworked and recooked before distribution per Written Rework Procedures SOP to ensure no post-lethality exposed product is in commerce.	Limit heating come-up-time (50°F to 130°F) to less than 6 hours to ensure *S. aureus* outgrowth is limited to 2-logs or less (see FSIS Revised Appendix A).[23, 24] Cook to appropriate time and temperature found in FSIS Revised Appendix A to achieve a 6.5 $\log_{10}$ reduction of *Salmonella* as per performance standards in 9 CFR 318.17.[25]	CCP 1
	C: None				

[22] If the product is not cook-in-bag and the establishment uses FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) as support for the lethality treatment/cooking step, relative humidity must be addressed using one of the options on page 26 of the Revised Appendix A or the establishment must provide support for why relative humidity does not need to be addressed (9 CFR 417.5(a)(1)). For a model HACCP plan that addresses relative humidity following one of the options in the Revised Appendix A, see the HACCP Model for Ready-to-Eat, Heat-treated, Shelf-stable (Beef Jerky).

[23] 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 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 must collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological 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).

[24] Establishments producing products with long heating come-up-times due to product size, such as ham and beef brisket, can use the critical operating parameters found on page 48 of the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A). This reference can be used as support for applying FSIS' applicable time-temperature combinations and relative humidity, without considering heating come-up-time as a critical operating parameter.

[25] See FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) for validated times and temperatures. If alternative methods are used, refer to the validation and scientific support for the alternative lethality step as described in the FSIS Compliance Guideline HACCP Systems Validation. Include critical operational parameters for lethality and stabilization in the HACCP plan.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	P: None				
8. Chilling	B: *Clostridium perfringens and Clostridium botulinum*	Yes	Spores can survive the Cooking step (#7), germinate, and grow if not cooled quickly. Product is cook-in-bag and therefore not post-lethality exposed so *Listeria monocytogenes* is not a hazard of concern.[26] Bags that are punctured with a thermometer for monitoring are reworked and recooked before distribution per Written Rework Procedures SOP to ensure no post-lethality exposure.	Chill roasts following appropriate time and temperature in FSIS Revised Appendix B to prevent multiplication of toxigenic microorganisms such as *Clostridium botulinum* and no more than 1-log_{10} multiplication of *Clostridium perfringens* to comply with the performance standard in 9 CFR 318.17(a)(2). [27]	CCP 2
	C: None				
	P: None				
9. Cold Storage Cooked Roasts	B: Pathogen outgrowth: *Clostridium perfringens* and *Clostridium botulinum*	No	Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is stored at temperatures that preclude spore-former growth <50°F, Revised Appendix B.		
	C: None				
	P: None				
10. Packaging and Labeling	B: None				
	C: Undeclared allergens		This product does not contain allergenic ingredients. LOG from suppliers describing quality controls and prevention procedures.		

[26] Product is cooked in a bag and remains in the bag after the cooking step. Therefore, the product is not exposed to the environment after cooking (i.e., not post-lethality exposed) and not covered by 9 CFR 430.4.

[27] See FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) for optional validated time and temperature reported in literature for stabilization processes. If alternative methods are used, validation and scientific support for the alternative lethality step as described in the FSIS Compliance Guideline HACCP Systems Validation. Include critical operational parameters for stabilization in HACCP plan.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
			Written Incoming Material SOP for procedures to verify each lot of incoming packaging material does not contain allergenic compounds. Approved supplier program and ongoing communication with suppliers to verify LOG. Allergen Control SOP ensures ingredient statements on finished product labels match ingredient formulation.		
	P: None				
11. Storage and Distribution	B: Pathogen outgrowth: *Clostridium perfringens* and *Clostridium botulinum*	No	Product stored at improper temperatures can result in outgrowth of pathogens. Product is stored at temperatures that preclude spore germination and *Clostridium* growth (<50°F, Revised Appendix B). Written Final Product SOP for procedures to examine outgoing packaged product. Includes verifying the sanitary condition of the truck, functioning refrigeration unit, and package integrity.		
	C: None				
	P: None				
12. Returned Product	B: None		Returned Product Evaluation 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 at process flow steps 10 or 11 based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted.		
	C: None				
	P: None				

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EXAMPLE ROAST BEEF 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 1 Cooking	(1) Pathogen outgrowth: *Staphylococcus aureus* (2) Pathogen presence: *Salmonella*, STECs,	(1) Product temperature come-up-time, from 50°F to 130ºF, in less than 6 hours. [28], (2) Roasts held for 36 minutes at 135°F internal product temperature. [29], [30]	Internal product temperature and dwell time during heating come-up-time and internal product temperature and dwell time at endpoint.	Designee sets up continuous monitoring device. Designee places product temperature probe in center of largest piece in the batch and held in the oven's coldest spot. Designee will review records from continuous monitoring device at completion of cooking cycle to determine the critical limits are met. [31]	Continuous for each oven load (lot)	Designee	If a deviation from the critical limit occurs, the designee will immediately report to a supervisor. The supervisor will: 1. Hold all product produced since the last acceptable check until appropriate disposition taken (no product injurious to health enters commerce) [32]; 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 observe the designee setting up the continuous monitoring device. Once per week, a manager will observe the designee placing the product temperature probe in center of largest piece in the batch and held in the oven's coldest spot. Once per week, a manager or designee will observe the designee reviewing records from continuous monitoring device. Once per week, a manager or designee calibrates product thermometers per manufacturer's instructions. Once per week a manager or designee will review all records maintained.	Roast Beef Cooking Log from computerized continuous monitoring device Thermometer Calibration Log Direct Observation Log Records Review Log Corrective Action Log

[28] The cooking critical limits used in this plan are derived from the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A). See Appendix A for guidance on implementing this safe harbor and for additional validated time and temperature parameters for lethality cooking processes including parameters for products with heating come-up-times (50°F to 130ºF) longer than 6 hours. For general guidance on establishing critical limits, see the Guidebook for the Preparation of HACCP plans (page 27).

[29] The critical limits in this model assume a thermometer with an accuracy of less than 0.1ºF. Establishments producing cooked meat and poultry products should have sufficient monitoring equipment, including recording devices, to assure that the time, temperature, and relative humidity operating parameters of their processes are being met. With any monitoring equipment, the establishment should take the normal variation of the monitoring equipment into account when designing the critical limits.

[30] Relative humidity is not addressed because moisture is inherently maintained around the product due to cooking in a sealed, moisture impermeable bag.

[31] Establishments may also determine during the initial validation period that the worst-case scenario is the largest roast regardless of location in the oven. In that case, establishments may choose to monitor the internal temperature in the largest roast rather than a roast in the coldest spot in the oven.

[32] See Revised Appendix A guidance on corrective actions to perform when a cooking deviation occurs (page 66).

EXAMPLE ROAST BEEF 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 Chilling	*Clostridium perfringens* and *Clostridium botulinum*	Chill product from 130 °F to 80°F in 1.5 hours or less. Chill product from 80°F to 40°F in 5 hours or less.[33]	Internal product temperature and time.	Designee sets up continuous monitoring device. Designee places product temperature probe in center of largest piece in the batch and held in the cooler's warmest spot. Designee will review records from continuous monitoring device at completion of chilling cycle to determine the critical limits are met.[34]	Each batch (lot)	Designee	If a deviation from the critical limit occurs, the supervisor will: 1. Hold all product produced since the last acceptable check until appropriate disposition taken (no product injurious to health enters commerce); 2. Determine and eliminate the cause of the deviation[35]; 3. Bring the CCP under control; 4. Take measures to prevent recurrence. 9 CFR 417.3	Once per week, a manager will observe the designee setting up the continuous monitoring device. Once per week, a manager will observe the designee placing the product temperature probe in center of largest piece in the batch and held in the cooler's warmest spot. Once per week, a manager or designee will observe the designee reviewing records from continuous monitoring device. Once per week, a manager or designee calibrates product thermometers per manufacturer's instructions. Once per week a manager or designee will review all records maintained.	Roast Beef Chilling Log from computerized continuous monitoring device[36] Thermometer Calibration Log Direct Observation Log Records Review Log Corrective Action Log

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[33] The chilling critical limits used in this plan are Option 1.1 found in the FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) (page 50). See Appendix B for additional guidance on implementing this safe harbor. Appendix B also contains additional validated chilling time and temperature stabilization methods. For general guidance on establishing critical limits see the Guidebook for the Preparation of HACCP plans (page 27).

[34] Establishments may determine during the initial validation period that the worst-case scenario is the largest roast regardless of location in the cooler. In that case, establishments may choose to monitor the internal temperature of the largest roast rather than a roast in the warmest spot in the cooler.

[35] See Revised Appendix B guidance on corrective actions to perform when a cooling deviation occurs (page 71).

[36] The Roast Beef Temperature Cooking and Chilling recordkeeping logs must include monitoring the interim steps for cooling (for this example: record the time required for the product to drop from 130ºF to 80ºF, and the time required for the product temperature to drop from 80ºF to 40ºF).