A Generic HACCP Model for Ready-to-Eat, Heat-Treated, Shelf-Stable (Beef Jerky)

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 <u>Guidebook for the Preparation of HACCP Plans</u> and a generic model for each food processing category defined in the regulation (<u>9 CFR 417.2(b)(1)</u>). 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 of the updated <u>Guidebook for the Preparation of HACCP Plans</u> 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.

The model's critical control points (CCPs) do not necessarily apply to all operations or products in the product category. 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. 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 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 <u>Guidebook for the Preparation of HACCP Plans</u> and the guidance materials available on the FSIS <u>HACCP</u> webpage.

EXAMPLE PRODUCT DESCRIPTION¹

PROCESS / PRODUCT NAME: Beef Jerky (Ready-to-Eat, Heat-Treated, Shelf-Stable)

Process / Product Name	Beef Jerky (Ready-to-Eat, Heat-Treated, Shelf-Stable)
Important Product Characteristics ² (water activity, pH, Preservatives, etc.)	Contains Sodium Nitrite and Sodium Erythorbate Water activity < 0.85
Intended Use	Ready-to-eat ³
Packaging (Durability and storage conditions)	Plastic vacuumed packed single-serve units and stored at ambient temperature
Shelf Life and at what temperature	240 days unopened and not refrigerated
Where it will be sold (specify intended consumers, especially at-risk populations ⁴)	Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI).
Labeling instruction	Product name, inspection legend and establishment number, handling statement, net weight statement, ingredients statement, allergen statement, address line, and nutrition facts.
What special distribution controls are required?	None

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¹ Prior to developing the HACCP plan please read the FSIS <u>Guidebook for the Preparation of HACCP Plans</u> 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 <u>Title 9 Code of Federal Regulations (9 CFR) Part 417</u>. 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 This jerky example is a product cured with sodium nitrite. See the <u>Food Standards and Labeling Policy Book</u> for jerky standards. Examples of jerky standards are products that have a moisture to protein ratio of 0.75:1 or less, they may be cured or uncured, and sodium nitrite is not required. Establishments should gather documentation to support the moisture to protein ratio standard using inplant data collected during initial validation and on-going verification.

³ The intended use or consumer of the product must be identified in accordance with <u>9 CFR 417.2(a)(2)</u>. 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 MATERIAL⁵

Process / Product Name: Beef Jerky (Ready-to-Eat, Heat-Treated, Shelf-Stable)

Meat and Meat by-products	Boneless beef top rounds and top sirloins
Non-Meat food ingredients	Sugar, Salt, Soy Sauce (water, wheat, soybeans, salt, sodium benzoate, brewing starter (Aspergillus Sojae)), Flavor and Spice Mixture
Antimicrobials ⁶ and processing aids	None
Packaging material	Plastic vacuum bags
Restricted ingredients and allergens	Sodium Nitrite, Sodium Erythorbate, Soy Sauce (soy and wheat)
Other	None

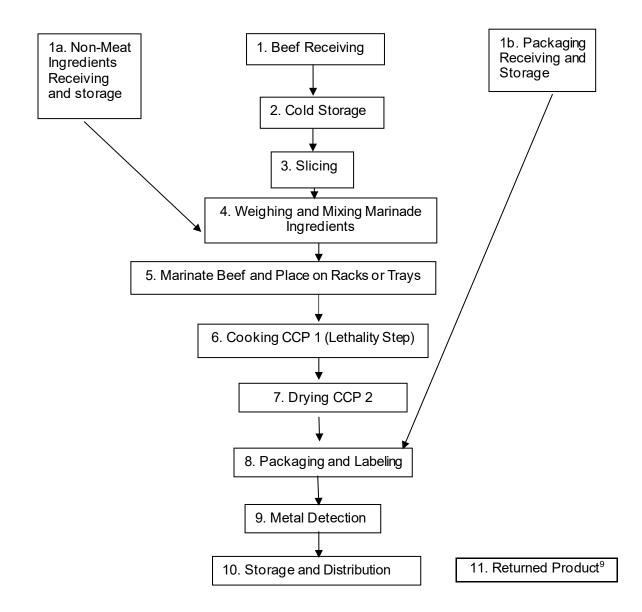
DATE:	APPROVED BY:	

⁴ List all meat, non-meatingredients, 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).

⁶ 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 <u>FSIS Directive 7120.1</u>, <u>Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients</u>.

EXAMPLE PROCESS FLOW DIAGRAM⁷

Process / Product Name: Beef Jerky (Ready-to-Eat, Heat-Treated, Shelf-Stable)⁸



⁶ 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.

⁷ For more information on general processing steps used in jerky production see the <u>FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments</u>. As discussed on pages 6-7, antimicrobial interventions may also be added before, during, or after marinating the strips of raw beef to increase the level of pathogen reduction beyond that achieved by cooking alone.

⁹ The Returned Product step (12) 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, repackaged, or discarded.

EXAMPLE HAZARD ANALYSIS¹⁰

Beef Jerky: Ready-to-Eat, Heat-Treated, Shelf-Stable

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 Reasonabl y Likely to Occur (RLTO)? (Yes or No) ¹²	Justification / Basis for Decision in Column 3 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)?
Receiving	B: Pathogens, Escherichia coli O157:H7 (STEC) ¹⁵ , Salmonella		contaminated with pathogens.	Controlled at the Cooking CCP 1 process step. Written Beef Receiving SOP (Standard Operating Procedure) with purchase specifications that prevent hazards including the temperature of the	No I

⁹ See FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments for suggested best practices and a list of scientific and technical support documents.

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 Shiga toxin-producing Escherichia coli (STEC) includes serogroups O157:H7, O26, O45, O103, O111, O121 and O145).

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 <u>Guidebook for the Preparation of HACCP Plans</u> for more information about hazards identification.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	B: <u>Bovine</u> <u>Spongiform</u> <u>Encephalopathy</u> (BSE) Prions	No	Specified Risk Materials (SRMs) SOP ensures SRMs are not associated with beef products.	product at receiving. Product is received at temperatures that preclude bacterial growth (<45°F, (Tompkin. R.B. 1996). 16 Annual Letter of Guarantee 17 (LOG) is on file for each supplier of incoming beef.	
	C: None		W. ". F . M 100P(
	P: Foreign Material	No	Written Foreign Material SOP for visual inspection of containers and product at receiving.		
1a. Non-Meat Ingredients Receiving and Storage	B: Pathogens, Salmonella	Yes	Spices and flavorings used in the marinade may introduce pathogens.	Controlled at the Cooking CCP 1 process step. Letters of Guarantee from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to examine incoming materials including temperature and sanitary conditions. Non-meat ingredients that are not shelf-stable are received at temperatures that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996). Written Sanitation SOP for procedures used to protect ingredients from environmental contamination.	No

¹⁶ The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F (Tompkin, R.B. 1996).

17 An annual update is not a regulatory requirement. Each establishment must determine the frequency at which the Letters of Guarantee are updated. The frequency should be sufficient to adequately describe the supplier's process.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	ССР
	C: Allergens (soy and wheat) Restricted Ingredients (Sodium Nitrite and Sodium Erythorbate)	No	Soy and wheat are both big 8 allergens. Sodium Nitrite is a restricted ingredient. Letters of Guarantee from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to verify proper identification of allergenic and restricted ingredients for each lot of incoming materials. Approved supplier program and ongoing communication with suppliers to verify Letters of Guarantee. Written Sanitation SOP for procedures to ensure allergen containing products are segregated to prevent contamination of allergen-free products.		
	P: None				
1b. Packaging Receiving	B: Contamination with Pathogens	No	Procedure to protect packaging materials from environment.		
and Storage	C: Non-food grade materials	No	Packaging materials may introduce chemical hazards. Letter of Guarantee 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,	No	Prerequisite Temperature Control SOP (<45°F, Tompkin, R.B. 1996).		

Step	Potential Hazard	RLTO	Justification / Basis	Controls	ССР
	STEC, Salmonella C: None P: None				
3. Slicing	B: Pathogen outgrowth, STEC, Salmonella	No	Written Good Manufacturing Practices to prevent or minimize cross-contamination. The presence and growth of pathogens is prevented or minimized so that the pathogen load is not higher than what the process is designed to reduce. Prerequisite Temperature Control SOP (<45°F, Tompkin, R.B. 1996) to prevent outgrowth of microorganisms.		
	C: None P: Foreign material (metal) contamination	No	Written Equipment Examination and Preventive Maintenance on Slicer SOP to prevent metal contamination from equipment.		
			Written Prerequisite Program for Metal detection for operating and monitoring metal detection equipment at end of packaging line prior to boxing; plant records 18 indicate very low incidence of metal contamination indicating that metal contamination is not a hazard reasonably likely to occur. 19		
4. Weighing and Mixing Marinade Ingredients	B: None C: Restricted Ingredients (Sodium nitrite	No	Incorrect levels of Sodium Nitrite or Sodium Erythorbate added to marinade mix may result in toxic conditions, uncured product. Product		

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 <u>FSIS Meat and Poultry Hazards and Controls Guide</u> which states "Appropriate screening procedure for monitoring equipment or product such as metal detector, screens or X-ray detector" are frequently used controls for foreign material hazards in processing.

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 record keeping and historic data.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	and sodium erythorbate) Soy Sauce (soy and wheat)		containing allergens but not labeled accordingly. Written SOP for determining batches and for weighing marinade spices and restricted ingredients. 20 Written Sanitation SOP to prevent crosscontamination of allergenic ingredients. Written labeling SOP to ensure application of correct label to prevent inadvertent consumption of allergens by consumer.		
	P: None				
5. Marinate Beef and Place on Racks or	B: Pathogen outgrowth STEC, Salmonella	No	Marination performed under refrigeration. Prerequisite Temperature control SOP (<45°F Tompkin, R.B. 1996) to prevent outgrowth of microorganisms.		
Trays	C: Soy Sauce (soy and wheat)	No	Sanitation SOP prevents cross-contamination between products with and without allergens.		
	P: None				
6. Cooking (CCP 1, Lethality	B Pathogens, STEC, Salmonella	Yes	Raw beef may be contaminated with pathogens.	Cook to appropriate time, temperature, and humidity option to achieve at least a 5.0 log ₁₀ reduction of <i>Salmonella</i>	Yes CCP 1

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	ССР
step) ^{21, 22}				species and at least a 5.0 log ₁₀ reduction for STEC. ²³ Dampers are closed within 30 minutes of product being placed in the heated oven to prevent product drying and increased heat-tolerance of <i>Salmonella</i> .	
	C: Soy Sauce (soy and wheat)	No	Sanitation SOP prevents cross-contamination between products with and without allergens.		
7. Drying ²⁴ CCP 2	P: None B: Clostridium perfringens and Clostridium botulinum outgrowth during drying. Staphylococcus aureus outgrowth and	Yes	Drying at low temperatures while the water activity is above the growth limit (<0.93) may allow outgrowth of <i>Clostridium perfringens</i> and <i>Clostridium botulinum</i> . Inadequate drying may allow <i>Staphylococcus aureus</i> outgrowth and enterotoxin formation, and <i>Listeria monocytogenes</i> outgrowth in product during storage.	Drying at oven temperatures ≥ 170°F until water activity decreases below the growth limit of <i>Clostridium</i> perfringens and <i>Clostridium</i> botulinum (<0.93) to prevent outgrowth. Dry to water activity of 0.85 or less to prevent the growth of toxin producing bacteria (<i>Staphylococcus aureus</i>) (≤0.85) and <i>Listeria monocytogenes</i> during storage (<0.92).	Yes CCP 2

²¹ See FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments for information that is more detailed and for scientific support.

²² For time, temperature and humidity combinations, refer to <u>FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Meat and Poultry Products and Revised Appendix A.</u>

If alternative methods are used, see the validation and scientific support for the alternative lethality step as described in the FSIS Compliance Guideline HACCP Systems Validation.

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 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).

²⁴ See FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments for more detailed information and for scientific support. If alternative methods are used, validation and scientific support for the alternative lethality step as described in the FSIS Compliance Guideline HACCP Systems Validation.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	ССР
	enterotoxin formation. Listeria monocytogenes outgrowth during storage.			FSIS Compliance Guideline for Meat and Poultry Jerky Produced in Small and Very Small Establishments. FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products. FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B. 25	
	C: Soy Sauce (soy and wheat)	No	Sanitation SOP prevents cross-contamination between products with and without allergens.		
8. Packaging and Labeling	P: None B: Listeria monocytogenes and growth of toxin-producing molds	No	Listeria monocytogenes is addressed with a prerequisite program for employee hygiene and strict adherence to written Sanitation SOP. The SOP includes testing of food contact surfaces and non-food contact surfaces 26 in the ready-to-eat (RTE) packaging area. The growth of Listeria monocytogenes in the post-lethality environment is not reasonably likely to occur due to CCP 2, as is required to qualify for Alternative 2b.		

²⁵ See FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B for more information on water activity levels that preclude the growth of Clostridium perfringens and Clostridium botulinum.

²⁶ Establishments may choose to test indirect and non-food contact surface samples as part of their Listeria Control Program, although they are not required by the Listeria Rule. Sampling indirect and non-food contact surfaces can give the establishment more information about possible harborage and cross-contamination in the environment. For more information see the FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed RTE Meat and Poultry Products.

SOP for oxygen free packaging makes mold growth unlikely. C: Improperly labeled allergens: Soy Sauce (soy and wheat) P: None	Step	Potential Hazard	RLTO	Justification / Basis	Controls	ССР
labeled allergens: Soy Sauce (soy and wheat) P: None				1 0 0		
B: None C: None P: Metal Fragment Contamination Plant records indicate very low incidence of metal contamination P: None C: None P: None C: None P: None C: None P: None C: None C: None C: None C: None C: None P: None C: None		labeled allergens: Soy Sauce (soy and	No	Written Labeling SOP makes hazard unlikely.		
Detection C: None P: Metal Fragment Contamination Contamination Distribution B: None C: None P: None B: None C: None P: None C: No		P: None				
C: None P: Metal Fragment Contamination P: Metal Fragment Contamination Contamination Plant records indicate very low incidence of metal contamination is not a hazard reasonably likely to occur. 10. Storage and Distribution Distribution B: None P: None P: 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. Notify FSIS personnel when returned product has been accepted.	9. Metal Detection	B: None				
Fragment Contamination for operating and monitoring metal detection equipment at end of packaging line prior to boxing. Plant records indicate very low incidence of metal contamination is not a hazard reasonably likely to occur. 10. Storage and Distribution B: None C: None P: None 11. 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				
And Distribution C: None P: 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.		Fragment	No	for operating and monitoring metal detection equipment at end of packaging line prior to boxing. Plant records indicate very low incidence of metal contamination indicating that metal contamination		
Distribution P: 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.		B: None				
11. Returned Product 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				
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.	Distribution	P: None				
C: None		B: None		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		
		C: None				

Step	Potential Hazard	RLTO	Justification / Basis	Controls	ССР
	P: None				
DATE:			APPROVED BY:		

EXAMPLE BEEF JERKY HACCP Plan ²⁷							7		
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for Each Control Measure	What	Monitoring Pro	Frequency	Who	Corrective Action	Verification	Records
CCP 1 Cooking (Lethality Step)	Escherichia coli O157:H7 (STEC)(E. coli O157:H7, O26, O45, O103, O111, O121 and O145), Salmonella, Listeria monocytogenes	product temperature 145°F for ≥ 4 minutes ≥125°F wet- bulb temperature for ≥ 1 hour ²⁸	Internal product temperature ³⁰ and dwell time, wetbulb temperature, relative humidity, length of time oven is sealed.		for each oven batch (lot)	Designee	critical limit occurs, the designee will immediately report to a manager. 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	Once every two weeks, per smokehouse manual, a manager will calibrate the dry bulb and wet bulb thermometers and the thermometer used for internal product temperatures per manufacturer's procedures. Once per week, a manager will observe the designee reviewing smokehouse records. Once per shift, a manager will observe the designee performing the relative humidity check. Once per week, a manager will review all records maintained.	

²⁷ This information is best suited for small and very small establishments seeking assistance in understanding the requirements in <u>Title 9 Code of Federal Regulations (9 CFR) Part</u> 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.

²⁸ At a minimum, establishments should maintain documentation that supports that when the oven dampers are closed, humidity is maintained in the ovens in addition to documentation that supports the oven dampers are closed for at least one hour or 50% of the cooking time – whichever is longer. Establishments may also choose to target recommended wet-bulb and relative humidity levels as shown in this example. See page 21 of the FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments for specific guidance for using the sealed oven option to introduce relative humidity.

²⁹ In this example the critical limit used is from FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Meat and Poultry Products and Revised Appendix A. If other references are used for the critical limit determination and justification, then the entire research article with accompanying critical parameters must be kept on file for HACCP validation records.

³⁰ Probe placements determined during cold-spot determination conducted under in-plant validation.

EXAMPLE BEEF JERKY HACCP Plan									
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for Each Control Measure	Monitoring Procedures						
			What	How	Frequency	Who	Corrective Action	Verification	Records
CCP 2 Drying ³¹	aureus outgrowth	Oven temperature setting of ≥ 170°F. Dry to water activity (aw) of 0.85 or less.	Measure the temperature in the smokehouse using a dry-bulb thermometer. Measure water activity of product with a water activity meter per manufacturer's instructions.	smokehouse temperature records at the end of drying cycle and before the product is removed from the smokehouse.	batch (lot)		critical limit occurs, the designated employee will immediately report to the manager. 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.	the employee reviewing	Water activity / Drying Log Corrective Actions Log Water Activity Calibration Log Direct Observation Log Records Review Log Thermometer calibration log

DATE:	APPROVED BY:	

³¹ Moisture to protein ration should be checked during validation process to ensure the jerky produced meets the standard of identity. However, water activity is a more accurate measurement for food safety. See <u>FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments</u> for more information.