HACCP Model for Ready-to-Eat Fermented, Salt-Cured, and Dried Products (Not Heat Treated—Shelf Stable)

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, the Food Safety and Inspection Service (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 models to fit the establishment's operation.

The Not Heat Treated-Shelf Stable process category applies to products that are further processed by a curing, drying, or fermenting step as the sole means by which product achieves food safety. To use this model, a low-level heat treatment may be applied if the heat treatment is not used as the sole means to achieve food safety. Products in this category include dried sausage, such as salami and pepperoni (if not heat-treated). Semi-dry sausages may also be in this HACCP category, depending on the process steps. Dried whole muscle products which are mostly dry cured could also fall into this category. These products include dried hams, such as prosciutto, parma, and country ham, and dried intact pieces of meat such as dried pork bellies (Pancetta), dried pork shoulders (coppa), and dried beef rounds (e.g., bresaola, beef prosciutto, and basturma).

The finished products are shelf stable. Several products (not all) in this HACCP category are produced as ready-to-eat (RTE) product. If an establishment produces products such as pepperoni, salami, bresaola, biltong, and droëwors, which are typically RTE, as not ready-to-eat the establishment must have on-file documentation supporting their decisions (9 CFR 417.5(a)(1)). This support must address how the establishment can ensure the consumer will properly cook the product, particularly if there is evidence, such as marketing materials or recipes, commonly indicating the product is RTE. Additional information on these products can be found in the FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline. This model uses RTE dried fermented sausage as the example product.

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 and processing specifications in this model come from

scientific documents or other reliable sources. This model includes references for guidance on the selection of critical limits.

The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP records (9 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.[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.

PRODUCT DESCRIPTION[2]

Dried Fermented Sausage (Not Heat Treated-Shelf Stable)

Product Name and Process Type	Dried Fermented Sausage (Not Heat Treated—Shelf Stable)
Important product characteristics (a_w, pH, preservatives, etc.)	Water activity (a_w), pH, nitrite and nitrate
How it is to be used[3]	Ready-to-eat
Packaging (durability and storage conditions)	Vacuum packed
Shelf-life and at what temperature	180 days non-refrigerated; 365 days 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 instructions	Product name, inspection legend and establishment number, net weight statement, address line, and nutrition facts[5] on retail packages
Special distribution control	none

DATE: _____ APPROVED BY: _____

[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. 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.

[3] The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2).

[4] At risk populations include young children, elderly, and immunocompromised persons.

[5] HRI packages do not require nutrition facts unless the label bears a nutrient content claim (e.g., low sodium, low fat). Nutrition facts may not be required when certain exemptions apply as described in 9 CFR 317.400 including if a business has less than 500 employees or production of less than 100,000 lbs per year.

EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL[6]

Dried Fermented Sausage (Not Heat Treated—Shelf Stable)

Meat	Fresh and frozen raw pork and pork trimmings
Non-meat food ingredients	Dextrose (sugar), salt, flavors, spice mixtures, fermentation starter culture
Antimicrobial[7] interventions and processing aids	None
Packaging material	55mm and 78 mm (3-inch) casings (natural or semipermeable), plastic vacuum bags, waxed paper
Restricted ingredients and allergens	Sodium nitrite and sodium nitrate
Other	None

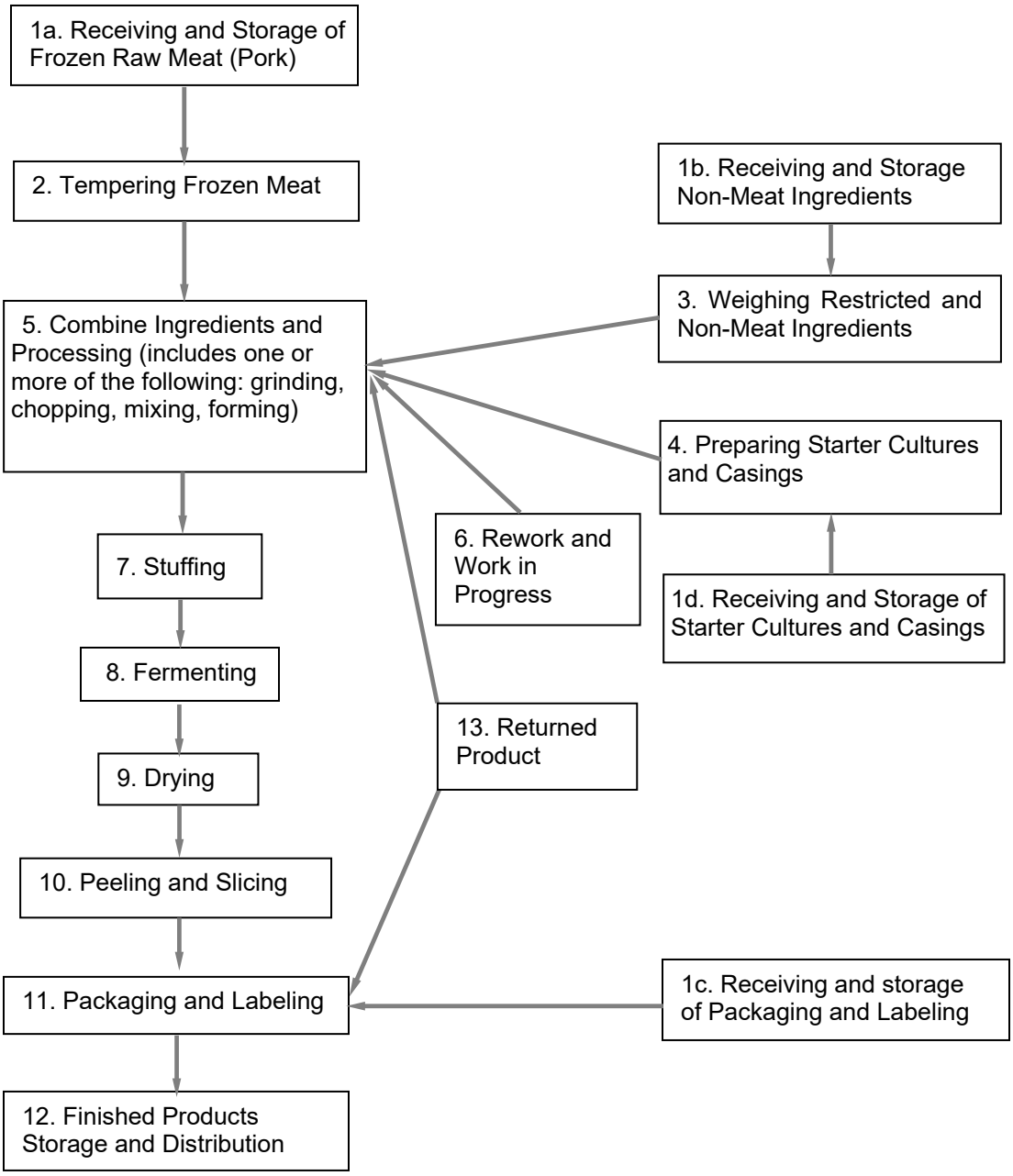
DATE: _____ APPROVED BY:

[6] List all meat, non-meat ingredients, restricted ingredients (for example, nitrite), processing aids, and 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 Guidelines 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).

[7] 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 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 Food, Drug, and 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.

PROCESS FLOW DIAGRAM[8]

Dried Fermented Sausage (Not Heat Treated—Shelf Stable)



[8] 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.

EXAMPLE HAZARD ANALYSIS[9]

Dried Fermented Sausage (Not 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**[10]	**Is the Potential Food Safety Hazard Reasonably Likely to Occur? (RLTO) (Yes or No)**[11]	**Justification / Basis for Decision in Column 3**[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]	**If yes in Column 3 (Hazard RLTO) is this Step a Critical Contro Point (CCP)?**[14]
1a. Receiving and Storage of Frozen Raw Meat (Pork)	B: Presence of pathogens: *Salmonella*, *Listeria monocytogenes*	Yes	*Salmonella* and *Listeria monocytogenes* are known to be present and may cause illness if not controlled. An annual Letter of Guarantee (LOG) is on file for each supplier of incoming pork indicating *Salmonella* controls were applied.	Controlled at CCP 1 Fermenting and CCP 2 Drying	No

[9] For guidance on fermented and dried products, see the FSIS Ready-to-Eat Fermented, Salt-Cured and Dried Products Guideline. The Meat and Poultry Hazards and Controls Guide also contains information on 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 (FSIS Compliance Guideline: HACCP Systems Validation, page 5).

[14] To determine a CCP (column 5), see FSIS Guidebook for the Preparation of HACCP Plans to determine the best CCP to control, reduce, or eliminate a hazard.

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
	B: Outgrowth of pathogens: *Salmonella*, *Listeria monocytogenes*	No	Written SOP to protect ingredients from environmental contamination. Written receiving Standard Operating Procedure (SOP) and written storage temperature control SOP for maintaining product at temperatures that preclude *Salmonella* and limit growth for *Listeria monocytogenes* (Tompkin, R.B. 1996).[15]		
	B: Presence of *Trichinella spiralis*	Yes	The validated Sausage Treatment Method No. 6 drying process in FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork is met by CCP 2.[16]	Controlled at CCP 2 Drying	No
	C: None				
	P: Foreign material	No	Use written Incoming Material SOP to visually evaluate incoming packaged product for foreign material contamination. Records demonstrate no incidents of foreign materials detected in products received.[17]		

[15] 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, Tompkin, R.B. 1996.

[16] See FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork for options used to prevent the control of *Trichinella* in pork and pork products. This HACCP plan is using Sausage Treatment Method No. 6 (2018 revision page 19).

[17] 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 FSIS Meat and Poultry Hazards and Controls Guide. See the guide for frequently used hazard controls.

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
1b. Receiving and Storage of Non-Meat Ingredients	B: Presence of pathogens: *Salmonella*, *Listeria monocytogenes*	Yes	Spices and flavorings may introduce pathogens. Written Receiving SOP includes procedures for examination of non-meat ingredients for sanitary conditions. Written Sanitation SOP includes the procedures used to protect non-meat ingredients from environmental contamination. LOGs[18] from suppliers describe quality controls and prevention procedures.	Controlled at CCP 1 Fermenting and CCP 2 Drying	No
	C: Undeclared allergens	No	This product does not contain allergenic ingredients. Allergenic ingredients are used in other product produced in the establishment. Written allergen program used to protect non-allergenic ingredients and products from cross-contamination with allergenic ingredients. LOG for all non-meat ingredients describe quality controls and contamination prevention procedures. Written Incoming Ingredients SOP procedures to examine incoming non-meat ingredients to verify		

[18] An annual update for LOG is not a regulatory requirement. Each establishment must determine the frequency at which the LOG is updated. The frequency should be sufficient to adequately describe the supplier's process to support the decisions made.

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
			ingredients statement matches the ordered ingredients and sources. Written Sanitation SOP used to protect non-meat ingredients from environmental contamination.		
	P: None				
1c. Receiving and Storage of Packaging and Labeling	B: Contamination with pathogens	No	Procedures to protect packaging materials from pests and environmental contamination. LOG is on file for each supplier of packaging and labeling items.		
	C: Chemical hazards	No	Packaging materials may introduce chemical hazards. LOG for all packaging materials describing quality controls and prevention procedures. Written Packaging Material SOP to examine incoming materials including sanitary conditions. Written Sanitation SOP for procedures used to protect packaging materials from environmental contamination.		
	P: Physical contaminants	No	Written Sanitation SOP used to protect packaging materials from contamination with physical hazards.		
1d. Receiving and Storage of Starter	B: Pathogen presence and outgrowth:	Yes	Natural casings are a known source of pathogens. Casings and starter cultures are stored under refrigeration.	Controlled at CCP 1 Fermenting and CCP 2 Drying	No

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
Cultures and Casings	*Salmonella* and *Listeria monocytogenes*				
	C: None				
	P: None				
2. Tempering Frozen Meat	B: Pathogen outgrowth: *Salmonella* and *Listeria monocytogenes*	No	Tempering is conducted under refrigeration. Written Temperature Control SOP for maintaining product at temperatures that preclude *Salmonella* and limit growth for *Listeria monocytogenes* (Tompkin, R.B. 1996).[15]		
	C: None				
	P: None				
3. Weighing Restricted and Non-Meat Ingredients	B: None				
	C: Sodium nitrite and sodium nitrate, allergens	No	Inappropriate formulation of sodium nitrite and sodium nitrate in the marinade mix may create a toxic or uncured condition. Written SOP for weighing restricted ingredients to ensure the nitrite and nitrate limits are within the allowable limits identified in 9 CFR 424.21(c). Written allergen program used to protect non-allergenic ingredients and products from cross-contamination with allergenic ingredients.		
	P: None				

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
4. Preparing Starter Cultures and Casings	B: Pathogen outgrowth: *Salmonella* and *Listeria monocytogenes*	No	Proper employee handling through Written Sanitation and Formulation SOPs. Follow manufacturer's instruction on the use of starter culture in consistent with the scientific support[23].		
	C: None				
	P: None				
5. Combine Ingredients and Processing (Includes One or More of the Following: Holding, Grinding, Chopping, Mixing, Forming)	B: Pathogen outgrowth: *Salmonella* and *Listeria monocytogenes*	No	Proper employee handling through Written Sanitation and Formulation SOPs. Written Temperature Control SOP for maintaining product at temperatures that preclude *Salmonella* and limit growth for *Listeria monocytogenes* (Tompkin, R.B. 1996).[15]		
	C: Allergens	No	Written allergen program used to protect non-allergenic ingredients and products from cross-contamination with allergenic ingredients and written SOP to ensure there are no undeclared allergenic ingredients.		
	P: Metal contamination	No	No history of findings from daily equipment pre-operational examination and from disassembly and clean up examination (covered in Sanitation SOP)[19].		

[19] 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 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	Hazard	RLTO	Justification / Basis	Controls	CCP
			No history of consumer complaints.		
6. Rework and Work in Progress	B: Pathogen: *Salmonella, Listeria monocytogenes*	No	Proper employee handling through Written Sanitation and Formulation SOPs. Only properly formulated product is reworked to ensure restricted ingredients are within required limits. Written Temperature Control SOP for maintaining product at temperatures that prevent *Salmonella* and limit growth for *Listeria monocytogenes* (Tompkin, R.B. 1996)[15].		
	C: None				
	P: None				
7. Stuffing	B: Pathogen outgrowth: *Salmonella* and *Listeria monocytogenes*	No	Proper employee handling through Written Sanitation SOPs. Written Temperature Control SOP for maintaining product at temperatures that prevent *Salmonella* and limit growth for *Listeria monocytogenes* (Tompkin, R.B. 1996)[15].		
	C: None				
	P: Metal Contamination		Written Sanitation SOP includes procedures for examination of equipment for metal fragments. Employees trained to visually observe product.		

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
			Historical data indicate metal clip contamination is not reasonably likely to occur[19]. No history of consumer complaints.		
8. Fermenting	B: Pathogens: *Staphylococcus aureus*	Yes	Inadequately controlled fermentation may allow pathogen outgrowth and *Staphylococcus aureus* enterotoxin production.	Controlled at CCP 1 Fermenting and CCP 2 Drying	Yes
	Salmonella, Listeria monocytogenes	Yes	The fermentation and drying processes were validated to achieve: ≥ 5-$\log_{10}$ reduction in *Salmonella*, and *Listeria monocytogenes*[20].	Controlled at CCP 1 Fermenting and CCP 2 Drying	Yes
	C. perfringens and *botulinum*	No	The use of a starter culture, dextrose, nitrite and nitrate have been shown to inhibit *C. botulinum* growth[21]. Formulation also contains at least 2.5% salt and at least 100ppm nitrite/nitrate which also controls *C. botulinum* growth during fermentation and drying steps[22].		No

[20] See FSIS Ready-to-Eat Fermented, Salt-Cured and Dried Products Guideline page 40 for recommended lethality targets for *Salmonella*, Shiga-toxin producing *Escherichia coli* and *Listeria monocytogenes* during fermentation and drying.

[21] Christiansen, L.N., Tompkin, R.B., Shaparis, A.B., Johnston, R.W., Kautter, D.A. 1975. Effect of sodium nitrite and nitrate on *Clostridium botulinum* growth and toxin production in a summer style sausage. Journal of Food Science. 488-490.

[22] Canadian Food Inspection Agency (CFIA). 2020. Preventative control recommendations for manufacturing fermented and dried meat products. Available at: https://inspection.canada.ca/preventive-controls/meat/fermented-anddried/eng/1522951036924/1522951037158#control.

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
	Trichinella spiralis	Yes	Prerequisite formulation SOP to ensure sufficient ingredient levels (starter culture, dextrose, salt, nitrite, nitrate).[23, 24]	Controlled at CCP 2 Drying	Yes
	C: None				
	P: None				
9. Drying	B: Pathogens: *Staphylococcus aureus*	Yes	Final pH (≤ 4.5) and a_w (<0.92) combination from CCP1 and CCP2, respectively, results in a shelf-stable product according to Tilkens et al., 2015[25].	Controlled at CCP 1 Fermenting and CCP 2 Drying.	Yes
	Salmonella, Listeria monocytogenes	Yes	The fermentation and drying processes were validated to achieve: ≥ 5-$\log_{10}$ reduction in *Salmonella* and *Listeria monocytogenes*. A Drying Room SOP ensures drying occurs between 67-70°F for the first 24 hours and then	Controlled at CCP 1 Fermenting and CCP 2 Drying	Yes

[23] Deibel Laboratories/https://www.chr-hansen.com/en/. Fate of *Salmonella Spp*., *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Staphylococcus aureus* Inoculated into a Non-Heated and Dried Salami Product. Available from CHR. Hansen Inc. upon request. https://www.chr-hansen.com/en/contact-us.

[24] 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 pH, a_w, temperature, and relative humidity. (FSIS Compliance Guideline: HACCP Systems Validation, page 27).

[25] Tilkens, B.L., King, A.M., Glass, K.A., Sindelar, J.J. 2015. Validating the inhibition of Staphylococcus aureus in shelf-stable, ready-to-eat snack sausages with varying combinations of pH and water activity. J. Food Prot. 78(6): 1215-1220.

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
			between 56-59°F to meet critical operational parameters consistent with scientific support[23]. Smaller diameter (55mm) product is held for a minimum of 30 days to account for the faster drying time as recommended in FSIS Ready-to-Eat Fermented, Salt-Cured and Dried Products Guideline on page 68.		
	C. perfringens and *botulinum*	No	The use of a starter culture, dextrose, nitrite and nitrate have been shown to inhibit *C. botulinum* growth[21]. Formulation also contains at least 2.5% salt and at least 100pm nitrite/nitrate which also controls *C. botulinum* growth during fermentation and drying steps[22]. Prerequisite Formulation SOP to ensure sufficient ingredient levels (starter culture, dextrose, salt, nitrite, nitrate). The parameters control outgrowth through drying.		
	Trichinella spiralis	Yes	The critical limit meets the validated Sausage Treatment Method No 6**Error! Bookmark not defined.**. Prerequisite Formulation SOP to ensure product formula meets conditions in Method No. 6.	Controlled at CCP 2 Drying	Yes
	Molds	No	Adherence to Sanitation SOP prevents undesirable molds growth during processing and reduce airborne mold spores in fermentation and aging rooms[26].		

[26] Quintavalla, S. 2010. Plant Cleaning and Sanitation. In Toldra, F. Handbook of Meat Processing. Blackwell Publishing. 584 pages.

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
	C: None				
	P: None				
10. Peeling and Slicing	B: Pathogen contamination and growth: *Listeria monocytogenes*	No	Post processing contamination is prevented by Sanitation SOPs and *Listeria monocytogenes* Alternative 2 (9 CFR 430.4) because it has a a_w less than or equal to 0.92 which will not support the growth of *Listeria monocytogenes*[27].		
	C: None				
	P: Metal contamination from slicer	No	Written Sanitation SOP includes procedures for examination of slicing equipment for metal fragments, historical records indicate metal contamination is not reasonably likely to occur.		
11. Packaging and Labeling	B: Cross contamination and growth of *Listeria monocytogenes* Outgrowth of undesirable molds	No No	Post processing contamination is prevented by Sanitation SOPs and *Listeria monocytogenes* Alternative 2 (9 CFR 430.4) because it has a a_w less than or equal to 0.92[27]. Vacuum packaging makes molds growth unlikely.		
	C: Allergens	No	Written SOP to ensure there are no undeclared allergenic ingredients or cross contamination between allergenic ingredients used in other products produced at this facility.		
	P: None				

[27] See Table 2.1 page 35 FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products.

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
12. Finished Products Storage and Distribution	B: Outgrowth of undesirable molds	No	Vacuum packaging makes molds growth unlikely.		
	C: None				
	P: None	No	Written Final Product SOP procedures to examine outgoing materials, including sanitary conditions of truck and package integrity.		
13. Returned Product	B: None		Returned Product Evaluation SOP is implemented before accepting returned product. Entity returning the product must demonstrate the product was held 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 step 5 or 11 based on findings of product evaluation. If returned product can be re-sold without reformulation, it may be reboxed (in sealed packages) and sold. Evaluation performed on a case-by-case basis to determine if product should be reworked and, if so, any impact on formulation, allergens, and critical limits. If support to rework a specific return cannot be determined for a specific return, product is destroyed and does not enter the process.		
	C: None				
	P: None				

DATE: _____ APPROVED BY: _____

EXAMPLE HACCP PLAN

Dried Fermented Sausage (Not Heat Treated—Shelf Stable)

Critical Control Point	Significant Hazards	Critical Limits for Each Control Measure	Monitoring Procedures				Corrective Action	Verification	Records
			What	How	Frequency	Who			
CCP 1 Fermenting	*Pathogens: Salmonella, Listeria monocytogenes*[28] *Staphylococcus aureus*[29]	Room temperature: 88-95°F Maximum hours: 28 hours Maximum product pH: 4.9	Measure product pH and record fermentation time Fermentation starts when the first rack is moved into the room Room temperature data log	A designee will measure product pH (center of five pieces from the coldest spots identified in the oven or smokehouse)[30] Review the room temperature data log to verify the room was maintained at a temperature between 88-	In each batch, pH measurement is performed at the start and end of fermentation In each batch, the log is continuous. After each batch is complete, review the log to determine temperatures maintained throughout the 28 hours	Designee	If a deviation from the critical limit occurs, the designee monitoring the CCP will immediately report the critical limit deviation to the production supervisor. The supervisor will per 9 CFR 417.3: 1. Hold all product produced since the last acceptable check until appropriate disposition made (no product injurious to health enters commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; and 4. Take measures to prevent recurrence	Once per week, supervisor will observe the designee perform the pH measurement and review of records Once per week, the supervisor designee will calibrate the pH meter per manufacturer's recommended procedures Once per week designee will replace the room temperature data log paper	Product pH and time Log Corrective Actions Log pH Meter Calibration Log Direct Observation Log Records Review Log Room Temperature data log Thermometer Calibration Log

[28] The ingredient levels (starter culture, dextrose, salt, nitrite, nitrate), and Fermentation Room SOP to ensure fermentation occurs between 88-92°F ensure critical operational parameters are consistent with scientific support: Deibel Laboratories/CHR. Hansen. 2017. Fate of *Salmonella Spp*., *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Staphylococcus aureus* Inoculated into a Non-Heated and Dried Salami Product. Available from CHR. Hansen Inc. upon request. (https://www.chr-hansen.com/en/contact-us).

[29] The fermentation step has been validated to allow no more than 2-logs outgrowth of *Staphylococcus aureus* and a Fermentation Room SOP is used to ensure fermentation occurs between 88-92°F. Using a maximum temperature of 95°F, this process under worst-case conditions has 28 hours to achieve a pH ≤ 5.3 per the scientific support: Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products (American Meat Institute Foundation, October 1997). The critical limit is designed to meet the maximum degree-hours because it demonstrates a pH ≤ 4.9 within 28 hours, ensuring pH was below 5.3 well within the maximum allowable time. See FSIS Ready-to-Eat Fermented, Salt-Cured and Dried Products Guideline page 37 for recommended target for limiting *Staphylococcus aureus* outgrowth during fermentation.

[30] Establishments should conduct a cold-spot determination as part of the data it gathers during initial in-plant validation (9 CFR 417.4(a)(1)). The cold-spot determination can also be used to support monitoring and verification procedures and the frequencies at which those procedures are monitored and verified (9 CFR 417.5(a)(2)).

				95°F throughout fermentation				Once per quarter, designee will calibrate the room temperature thermometer and back up thermometer per the manufacturer's procedures	

Critical Control Point	Significant Hazards	Critical Limits for Each Control Measure	Monitoring Procedures				Corrective Action	Verification	Records
			What	How	Frequency	Who			
CCP 2 Drying	Pathogens; *Salmonella*, *Listeria monocytogenes*[31]	Product final a_w is <0.92. within a minimum of 30 days[16,23] Final pH of product	Check a_w and start and end of drying time Check product pH at the	5 pieces of sample selected from the coldest spots identified in the drying room[30] are cut to expose	Each batch a_w measurement is performed on day 0, day 30 and last day of drying period	Designee	If a deviation from the critical limit occurs, the designee monitoring the CCP will immediately report the critical limit deviation to the production supervisor. The supervisor will, per 9 CFR 417.3: 1. Hold all product produced since the last acceptable	Once per week the supervisor will observe the designee performing the a_w and pH measurements and review the records Once per week designee will calibrate the a_w meter and pH meter per	Product a_w and Time Log Product pH and Time log Calibration Log Corrective Action Log

[31] The fermentation and drying processes were validated to achieve: ≥ 5-$\log_{10}$ reduction in *Salmonella* (why O157:H7 deleted throughout? Not covered?) and *Listeria monocytogenes*. Critical limit and Drying Room SOP to ensure drying occurs between 67-70°F for the first 24 hours and then between 56-59°F to ensure critical operational

	Staphylococcus aureus[32] *Trichinella spiralis*[33]	is 4.5 or less	end of drying	cross-section for a_w and pH measurements The highest pH value is recorded	pH measurement is performed on the last day of drying period		check (no product injurious to health enters commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; and 4. Take measures to prevent recurrence	manufacturer's recommended procedures	Direct Observation Log Records Review Log

DATE: _____ APPROVED BY: _____

parameters are consistent with scientific support: Deibel Laboratories/https://www.chr-hansen.com/en/. 2017. Fate of *Salmonella Spp.*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Staphylococcus aureus* Inoculated into a Non-Heated and Dried Salami Product. Available from CHR. Hansen Inc. upon request. https://www.chr-hansen.com/en/.

[32] Final pH (<4.9) water activity (<0.92) combination from CCP1 and CCP2, respectively results in a shelf-stable product according to the scientific support Tilkens, B.L., King, A.M., Glass, K.A., Sindelar, J.J. 2015. Validating the inhibition of Staphylococcus aureus in shelf-stable, ready-to-eat snack sausages with varying combinations of pH and water activity. J. Food Prot. 78(6): 1215-1220. This paper supports a combination of pH ≤ 5.1 and water activity ≤ 0.92 does not support the growth of S. aureus when products are stored aerobically although molds grew under these conditions in the study. Vacuum packaging makes molds growth unlikely.

[33] The drying step has been validated to eliminate *Trichinella spiralis*. The critical limit meets the validated Sausage Treatment Method No 6 from the scientific support FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork.