Product	Hazard	Process	Critical Operational Parameters[2]	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Poultry Carcass	Biological - *Salmonella*	Final Chiller	Dilution of 15% peracetic acid/10% hydrogen peroxide mixture (PAHP) to a final concentration of 85 ppm peracetic acid in chiller; exposure in chiller for 20 minutes; pH = 4.5; complete carcass coverage	Bauermeister, L.J., J.W.J. Bowers, J.C. Townsend, and S.R. McKee. 2008. Validating the Efficacy of Peracetic Acid Mixture as an Antimicrobial in Poultry Chillers. *J. Food Prot.* 71(6): 1119-1122. Food and Drug Administration Environmental Decision Memo for Food Contact Notification No. 000323: April 10, 2003 FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products	In plant monitoring records for 90 day period recorded on Final Chiller Monitoring Check Sheet (including PAHP concentration, estimation of exposure time, pH, and carcass coverage); Trial report showing consistent operational parameters and microbial analysis, if possible, for 90 days.

[2] Refers to the critical limit or other parameter cited in the scientific support necessary for effective execution of the intervention.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Poultry Carcass	Biological - *Salmonella*	Spraying of carcasses with peroxy-acetic acid prior to chiller	25-230 ppm of peracetic acid (PAA). Pressure or flow rate, pH, contact time, and complete carcass coverage specified in challenge study.	Challenge study from "XYZ" laboratory demonstrating a 1 log reduction *Salmonella* on poultry carcasses after spraying with PAA using critical operational parameters specified. Food and Drug Administration Environmental Decision Memo for Food Contact Notification No. 000323: April 10, 2003. FSIS No Objection Letter for Use of PAA spray, June 12, 2007 on file with company "ABC". FSIS Directive 7120.1	In plant monitoring records for 90 day period confirm that antimicrobial solution was applied consistent with the critical operational parameters (pressure, pH, contact time, and carcass coverage)in the study.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Poultry parts intended for grinding and ground poultry (including mechanically separated poultry)	Biological - *Salmonella*	Acidified sodium chlorite applied to poultry parts as a dip prior to grinding and applied to ground poultry.	1200 ppm acidified sodium chlorite in combination with any GRAS acid at a level sufficient to achieve a pH of 2.5 in accordance with 21 CFR 173.325 and scientific support (*Note: The pH depends on the application, see 21 CFR 173.325)* Contact time of dip and complete coverage.	Chemical manufacturer's pamphlet demonstrating a 1-$\log_{10}$ reduction *Salmonella* on poultry parts following acidified sodium chlorite dip using critical operational parameters specified. 21 CFR 173.325 for poultry parts and acceptability determination for ground poultry. FSIS Directive 7120.1	In plant monitoring records for 90 day period that indicate the antimicrobial was applied to the poultry parts prior to grinding and the mechanically separated poultry prior to mixing according to the appropriate concentration and pH and that indicate contact time and complete coverage were achieved according to scientific support.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Ground Poultry Patties	Biological - *Salmonella*	Validated cooking instructions for consumers	Time and temperature combinations specific to various cooking methods (skillet on electric stove, skillet on gas stove, gas grill, charcoal grill), diameter and thickness of patties produced, formulation of patties produced (80% lean patties vs. 95% lean patties), and state of patties during cooking (frozen and thawed).	Food Safety Inspection Service. 1999. *Appendix A of the Compliance Guidelines for meeting Lethality Performance Standards for Certain Meat and Poultry Products*. Available at: http://www.fsis.usda.gov/wps/wcm/connect/212e40b3-b59d-43aa-882e-e5431ea7035f/95033F-a.pdf?MOD=AJPERES. Cooking trials on-file supporting the time-temperature combination selected from *Appendix A* can be achieved using various cooking instructions provided on the label. Cooking trials should be for the thickest and largest diameter patties produced as these will need the greatest time to achieve the desired endpoint temperature.	In plant monitoring records for 90 day period that demonstrate establishment produces products that are of the thickness, diameter, fat level, and state for which the instructions are validated.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Hog Carcass	Biological - *Salmonella*	Hot Lactic Acid Spray Cabinet	A least a 2% Lactic acid solution at 131°F (55°C) for more than 60 seconds and 13-23 psi. Complete carcass coverage.	Van Netten. P., D.A.A. Mossel, and J. Huis In't Veld. 1995 Lactic acid decontamination of fresh pork carcasses: a pilot plant study. *Int. J. Food Micro.* 5: 1-9. Dormedy, E.S., M.M. Brashears, C.N. Cutter, and D.E. Burson. 2000 Validation of acid washes as critical control points in hazard analysis and critical control point systems. *J. Food Prot.* 63:1676-1680. FSIS Directive 7120.1	In plant monitoring records for 90 day period recorded on Spray Cabinet Monitoring Check Sheet (including parameters for water temperature, and water pressure), records of lactic acid concentration and Trial Reports run under specified critical parameters demonstrating complete coverage of carcass with spray and temperature of the spray at the carcass.
Hog Carcass	Biological - *Salmonella*	Scalding	Scalding in water at 145°F (62°C) for 5 minutes. Complete carcass coverage.	Gill, C.O. and J. Bryant. 1993. The presence of *Escherichia coli, Salmonella,* and *Campylobacter* in pig carcass dehairing equipment. *Food Microbiol.* 10: 337-344. Bolton, D.J., R.A. Pearce, J.J. Sheridan, D.A. McDowell, and I.S. Blair. 2003. Decontamination of pork carcasses during scalding and the prevention of *Salmonella* cross-contamination. *J Appl Microbiol*. 94: 1036-1042.	In plant monitoring records for 90 day period recorded on Scalding Tank Monitoring Check Sheet (including reading for temperature of water and transit time).

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Beef Carcass	Biological - *E. coli* O157:H7, non-O157 STEC	Hot Carcass Wash or Carcass Thermal Treatment	Hot Carcass Wash: Water Temp over 180°F, Pressure over 13 psi. Complete carcass coverage. Contact time: 10 or more seconds. Carcass Thermal Treatment: Ambient steam temp sufficient to achieve 160°F at the surface in five key anatomical locations.	K.R. Davey, M.G. Smith. 1989 A laboratory evaluation of a novel hot water cabinet for the decontamination of sides of beef. *Int J Food Sci Tech.* 24: 305-316. Dorsa, W.J., C.N. Cutter, G.R. Sirgusa, M. Koohmaraie. 1996. Microbial Decontamination of Beef and Sheep carcasses by Steam, Hot water Spray Washes, and a Steam-vacuum Sanitizer. *J. Food Prot.* 59: 127-135. AMI Lethality model, demonstrating lethality at 160°F at carcass surface. Nutsch, A.L., R.K. Phebus, M.J. Riemann, J.S. Kotrola, R.C. Wilson, J.E. Boyer, and T.L. Brown. 1998. Steam pasteurization of commercially slaughtered beef carcasses: evaluation of bacterial populations at five anatomical locations. *J. Food Prot.* 61:571-577. Nutsch, A.L., R.K. Phebus, M.J. Riemann, D.E. Schafer, J.E. Boyer, R.C. Wilson, J.D. Leising, C.L. Kastner. 1997. Evaluation of a Steam Pasteurization Process in a Commercial Beef Facility. *J. Food Prot.* 60:485-492.	In plant monitoring records for 90 day period documenting critical parameters and trial Reports run under specified critical parameters demonstrating complete coverage of carcass with spray and temperature of the spray at the carcass. In plant monitoring records for 90 day period of plant temperature mapping.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Beef carcass	Biological – *E. coli* O157:H7, *Salmonella* Typhimurium	Lactic Acid Spray	2% lactic acid applied within 12 inches of carcass surface and entire carcass covered using a stainless steel spray tank fitted with a pressure gauge and air compressor. Each side of beef should be sprayed for at least 1 minute and sprayed from top to bottom and sufficient lactic acid is applied such that some of it drips off. Note: The entire carcass is sprayed with lactic acid following washing each side of beef from top to bottom for at least 2 minutes with hot water and allowing a 5 minute drip time after the hot water wash.	Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Meat Establishments. Pennsylvania State University. 2005. http://www.meathaccp.wisc.edu/validation/assets/acid_spray_intervention_booklet_from_Penn_State_2005.pdf. FSIS Directive 7120.1	In plant monitoring records for 90 day period recorded on Hot Water and Drip Time Monitoring Check Sheet (including parameters for the time the carcass is sprayed with hot water, carcass coverage, method application (from top to bottom and spray nozzle within 12 inches of carcass), and drip time. Records of lactic acid concentration. Trial Reports run under specified lactic acid critical parameters demonstrating complete carcass coverage, sufficient amount (lactic acid drips off carcass), contact time, method of application (spray nozzle within 12 inches of carcass and from top to bottom).

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Beef carcass	Biological -*E. coli* O157:H7	Lactic Acid Spray	Lactic Acid >2%; Pressure 40 psi (CHAD spray cabinet), Dwell time: minimum of 10 seconds Lactic Acid Temperature: 104°F at point of delivery. Complete carcass coverage. Design of the spray cabinet includes an oscillating (90 rpm) nozzle-header arrangement composed of four spray nozzles.	Gastillo, A, L.M. Lucia, K.J. Goodson, J.W. Savell, G.R. Acuff. 1998. Comparison of Water Washing, Trimming, and combined Hot Water and Lactic Acid Treatment for Reducing Bacteria of Fecal Origin on Beef Carcasses. *J. Food Prot.* 61: 823-828. Hardin, M.D., Acuff, G.R., Lucia, L.M., Oman, J.S., Savell, J.W. 1995. Comparison of Methods for Decontamination from Beef Carcass Surfaces. *J. Food Prot*. 58: 368-374. Delmore, R.J., J.N. Sofos, G.R. Schmidt, K.E. Belk, W.R. Lloyd, G.C. Smith. 2000. Interventions to Reduce Microbiological Contamination of Beef Variety Meats. *J. Food Prot.* 63: 44-50. FSIS Directive 7120.1	In plant monitoring records for 90 day period recorded on Pre-evisceration cabinet worksheet that monitored lactic acid percent, dwell time of the carcass in the cabinet, pressure, carcass coverage and lactic acid temperature at point of delivery.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Raw Ground Beef or Beef Trim for use in Raw Ground Beef	Biological -*E. coli* O157:H7	Prerequisite Program: Supplier Programs	Supplier program to demonstrate a pathogen intervention strategy, including a testing protocol and notification of test results.	Documentation from the supplier assuring that the supplier employs validated interventions addressing *E. coli* O157:H7, certificates of analysis or web based information that conveys same information, records of ongoing communication with supplier and verification data to support the achievement of the first two conditions. Beef Industry Food Safety Council. 2009. Best Practices for Raw Ground Beef Products.	In plant records for 90 day period that show plant employees obtain and review purchase specifications for adequacy at receiving for each lot and any additional verification testing results or web based information on incoming product lots.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Raw Ground Beef or Beef Trim for use in Raw Ground Beef	Biological – *E. coli* O157:H7	Trimmings prior to Grinding	Acetic acid (2%); OR Lactic acid (2%) sprayed on trim for 20s at 20psi and 55°C using a custom-made stainless steel washing apparatus (CHAD spray cabinet). Complete coverage of trimmings.	Carpenter, C.E., Smith, J.V., and Broadbent, J.R. 2011. Efficacy of washing meat surfaces with 2% levulinic, acetic, or lactic acid for pathogen decontamination and residual growth inhibition. *Meat Sci.* 88:256-260. FSIS Directive 7120.1	In plant monitoring records for 90 day period recorded on Trim Spray Cabinet Worksheet demonstrating that the antimicrobial is applied per concentration, pressure, dwell time, and temperature in the article during 90 day period. Records demonstrating that complete coverage of trimmings is consistently achieved.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Beef Jerky	Biological – *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*	Cooking and Drying	(For the Type 1-A Process) Stage 1* – 170°F (oven must reach 145°F within 10 minutes and 170°F within 25 minutes. Stage 2 – Choose either: Dry-bulb at 170°F and wet-bulb at 125F for at least 60 minutes; OR Dry-bulb at 170°F and wet-bulb at 130°F for at least 60 minutes; OR Dry-bulb at 170°F and wet-bulb at 135°F for at least 30 minutes; OR Dry-bulb at 170°F and wet-bulb at 140°F for at least 10 minutes. Stage 3- Dry at 170°F dry-bulb to doneness Relative humidity during wet-bulb temperature spike at Stage 2, water activity of the product at the end of wet-bulb temperature spike, and total drying time.	Critical limit summary for shelf stability of beef jerky and related products: http://www.meathaccp.wisc.edu/validation/assets/CLSummary_WMJerkyJune2013.pdf. Buege, D.R., Searls, G., and Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against *Salmonella* Serovars and *Escherichia coli* O157:H7. *J. Food Prot*: 69(9): 2091-2099.	In plant monitoring records for 90 day period demonstrating Time and dry-bulb and wet bulb temperature data. Use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor to measure relative humidity during wet-bulb temperature spike and compare test results with relative humidity results in Table 2 of article. Test beef jerky product for water activity at the end of wet-bulb temperature spike and compare test results with water activity results in Table 2 of article.

*This example is for the Type 1-A process. Note that Type 1-A processes with a higher dry-bulb temperature in Stage 1, a higher wet-bulb temperature or longer time in Stage 2, or a higher dry-bulb temperature in Stage 3, as long as the oven reaches the minimum temperature as outlined in Stage 1.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Post-lethality exposed ready-to-eat meats	Biological - *Listeria monocytogenes*	Prerequisite program – SSOPs	*Listeria* control program for food contact surfaces. Sanitary design of equipment and sanitary zone concept. Frequency for collecting samples and number of samples that should be collected per line.	Joint Industry Task Force on Control of Microbial Pathogens in Ready-to-Eat Meat and Poultry Products. 1999. Interim Guidelines: Microbial Control During Production of Ready-to-Eat Meat and Poultry Products, Controlling the Incident of Microbial Pathogens. Sanitary Design Assessment Fact Sheet http://www.sanitarydesign.org/pdf/Sanitary%20Design%20Fact%20Sheet.pdf. Tompkin, R.B. 2004. Environmental Sampling – A tool to verify the effectiveness of preventative hygiene measures. *Mitt Lebens Hyg*. 95:45-51. Tompkin, R.B. 2002. Control of *Listeria monocytogenes* in the food processing environment. *J Food Prot*. 65: 709-725. FSIS. 2012. Compliance Guidelines to *Control Listeria monocytogenes* in Post-lethality Exposed Ready-to-eat Meat and Poultry Products. http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling_LM_RTE_guideline_0912.pdf?MOD=AJPERES.	In plant records for 90 day period mapping food contact surface swab results for *Listeria spp.* collected on different processing dates and at different times and locations a 90-day period to potentially find hard-to-control areas in the plant and to support ongoing verification testing frequency after the initial validation period*. Assessment of sanitary design of equipment in the post-lethality environment using the AMI Sanitary Equipment Design worksheet and changes to *Listeria* control program based on assessment. Identification of all possible food contact surfaces.

*__NOTE:__ Establishments may also collect environmental swab samples on different processing dates and at different times during the 90-day initial validation period to potentially find hard-to-control areas and niches within the establishment.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Post-lethality exposed ready-to-eat meats	Biological - *Listeria monocytogenes*	Storage - Time and Temperature GMP's	Storage temperature ≤ 50°F. Product remains in storage ≤ 24 hours.	Tompkin Paper. Table 2. http://www.meathaccp.wisc.edu/Model_Haccp_Plans/assets/raw_ground/TompkinPaper.pdf.	In plant records for 90 day period demonstrating ambient air temperature does not exceed 50°F and that product is not held during storage at that temperature for more than 24 hours.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Raw beef products (e.g., beef carcasses, beef manufacturing trimmings)	Biological -*STEC*	Sanitary dressing procedures prerequisite program (same question as above)	Employee procedures associated with each station as defined in the written sanitary dressing program (e.g., specific steps employees take at each station to prevent contamination during hide removal, evisceration, etc.)	BIFSCO. 2009. Best Practices for Slaughter. http://www.bifsco.org/CMDocs/BIFSCO/Best%20Practices/BestPracslaught%20Sept%2009.pdf FSIS. 2002. Guidance for Minimizing the Risk of *Escherichia coli* O157:H7 and *Salmonella* in Beef Slaughter Operations. FSIS. 2012. Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* (STEC) Organisms or Virulence Markers. http://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-9026-4e1e-a0c2-1ac60b836fa6/Compliance_Guide_Est_Sampling_STEC_0512.pdf?MOD=AJPERES	In plant records for 90 day period demonstrating employees consistently perform the sanitary dressing procedures as written. Review of additional records generated during the 90 day period as part of the HACCP system that support that the procedures are effective (e.g., carcass audits, generic *E. coli* test results, and any other microbial test results).

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Post-lethality exposed ready-to-eat smoked turkey deli meat with skin on*	Biological -*Listeria monocytogenes*	Hot water Pasteurization	Hot water temperature at 195°F; product submersed for at least 6 minutes.	Muriana, P.M., Quimby, W., Davidson, C.A., Grooms, J. 2002. Postpackage pasteurization of ready-to-eat deli meats by submersion heating for reduction of *Listeria monocytogenes*. *J. Food Prot*. 65(6): 963-969.	In plant monitoring records for 90 day period demonstrating time and temperature can be consistently achieved. In plant monitoring records for 90 day period in which temperature of water is mapped and measured at increased frequencies to support monitoring procedures and frequencies.

*__NOTE:__ Reduction of *Lm* was found to be less for smoked turkey deli meat with skin-on using these time/temperature parameters than smoked turkey deli meat without skin, although the log reduction was > 1 log. For products subject to 9 CFR 430, the post-lethality treatment should be designed to achieve at least a 1-log lethality of *Lm* before the product leaves the establishment.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Semi-dry sausage	Biological - *Staphylococcus aureus*	Fermentation	Ferment product to a pH<5.3 within fewer than 1000 degree-hours*. Shrink to an MPR of 3.1:1 or less (which equates to <11% product shrink) and achieve a pH of 5.0 or less to be considered a shelf stable dry or semi-dry fermented sausage.	American Meat Institute. 1995. Interim Good Manufacturing Practices for Fermented Dry and Semi-Dry Products. Degree Hour Calculation - Degree-hours to reach a pH of 5.3 or less for a process when the highest chamber temperature is between 90 and 100°F = 1000 degree-hours or less. FSIS Food Standards and Labeling Policy Book and Ingham et al. 2005. Fate of *Staphylococcus aureus* on Vacuum-Packaged Ready-to-Eat Meat Products Stored at 21°C. Journal of Food Protection. 68:1911-1915.	In plant monitoring records for 90 day period demonstrating Degree Hour Calculation per GMP conducted and demonstrating Degree-hours are < 1000. For example on 10/24/99: Establishment process = (95°F-60°F) multiplied by 12 = 420 degree hours to a pH of 4.9, well within the guidelines for control of *Staphylococcus aureus.* In plant monitoring records for 90 day period indicating pH is ≤ 5.3 for the Degree Hours Calculation and ≤5.0 and a MPR of 3.1:1 or less for shelf stability.

*__NOTE:__ The limit for degree-hours will depend on the highest chamber temperature.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Roast Beef (uncured)	Biological -*C. perfringens* and *C. botulinum*	Stabilization	Chilling should begin within 90 minutes after the cooking cycle is completed. All product should be chilled from 120°F to 55°F in no more than 6 hours. Chilling should then continue until the product reaches 40°F. Chilling between 120°F to 80°F should take no more than 1 ½ hours. pH = 6.2, salt concentration = 3%	*Appendix B: Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)* available at: http://www.fsis.usda.gov/wps/wcm/connect/a3165415-09ef-4b7f-8123-93bea41a7688/95-033F_Appendix_B.pdf?MOD=AJPERES Results (including screen shots of the predicted growth) from the ComBase Perfringens Predictor model demonstrating no more than 1 log growth *C. perfringens* is achieved using the establishment's custom stabilization schedule and intrinsic factors. *Perfringens* Predictor User Manual (http://modelling.combase.cc/HelpPerPredictor/Perfringens_Predictor_Manual.pdf) supporting that the model has been validated for cured and uncured meat and poultry products.	In plant monitoring records for 90 day period showing each batch of product cooled from 120°F to 55°F in no more than 6 hours, and that all batches reached 40°F. In plant monitoring records for 90 day period demonstrating product chilling for each batch produced was between 120°F to 80°F in less than 1 ½ hours. Product testing results for pH at 6.2 and salt concentration at 3 %.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Semi-dry Sausage (Lebanon Bologna)	Biological - *Salmonella*, *E. coli* O157:H7	Fermentation and intermediate heating step	Diameter:115 mm ± 23 mm Starter culture: Pediococcus, Lactobacillus, and Micrococcus spp. Casing: Cellulose Smokehouse Schedule: Stage 1: Come-up to 80°F – 5 hours Hold at 80°F – 8 hours Relative humidity – 88 ± 2% Stage 2: Come-up to 100°F – 4 hours Hold at 100°F – 25 hours Relative humidity – 80 ± 2% Stage 3: Come-up to 110°F – 2 hours Hold at 110°F – 24 hours Relative humidity – 80 ± 2% During the last 2 hours at 110°F hickory smoke applied Product Composition: pH = 4.39 a_w = 0.94 % salt = 4.77 % fat = 10.43	Getty, K.J.K, Phebus, R.K, Marsden, J.L., Schwenke, J.R., and Kastner, C.L. 1999. Control of *Escherichia coli* O157:H7 in Large (115 mm) and Intermediate (90 mm) Diameter Lebanon-style Bologna. *J of Food Sci*. 64(6): 1100-1107.	In plant monitoring records for 90 day period recording time and dry-bulb and wet bulb temperature data. Use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor to measure relative humidity during wet-bulb temperature spike and compare test results with relative humidity results in article. Cold-spot determination in smokehouse to support monitoring procedures and frequencies. Records assessing variability in sausage diameter. Records supporting product composition data. Decision-making document showing that starter culture and casing used in actual process are the same as those used in support documents.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Fully Cooked Not Shelf Stable Poultry Fillets	Biological - *Salmonella*	Impingement Oven Cooking	$D_{62°C}/_{145°F}$ -values for chicken with between 2 and 6.3% fat ($D_{62°C}/_{145°F}$ = 1.14 min). Cook to internal temp of ≥145°F, hold for ≥ 8 minutes. Product formulation: salt and phosphate concentration (%) and in-going sodium nitrite level (ppm); pH of the product. Thickness of the fillets; arrangement of fillets on the belt; conveyor belt speed; and air flow rate. Wet-bulb and dry-bulb temperature.	American Meat Institute Process Lethality Spreadsheet. Available at http://www.amif.org/process-lethality/. Juneja, V.J., B.S. Eblen, and H.M. Marks. 2001. Modeling non-linear survival curves to calculate thermal inactivation of Salmonella in poultry of different fat levels, *Int J Food Microbiol.* 70: 37-51. Documentation supporting that the D- and z-values of the product are comparable to the values used in the AMI spreadsheet. Factors that can impact D- and z-values include the salt and phosphate concentration (%), the in-going sodium nitrite level (ppm), the pH of the product, and the fat level.	In plant monitoring records generated during 90 day period demonstrating that process can achieve time and temperature. Records documenting that variability in thickness of the fillets; arrangement of fillets on the conveyor belt; conveyor belt speed; and the air flow rate used in the process will consistently meet time and temperature parameters. Records supporting that the % fat of product is consistently between 2 and 6.3%. Records generated during 90 days demonstrating the dry-bulb and wet-bulb temperatures meet those in the scientific support.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Fully Cooked Roast Beef	Biological - *Salmonella*, *E. coli* O157:H7	Product Cooking	Internal temperature of 130°F for a minimum of 112 minutes. Relative humidity >90% for at least 25% of the cooking time and in no case less than one hour.	Food Safety Inspection Service. 1999. *Appendix A of the Compliance Guidelines for meeting Lethality Performance Standards for Certain Meat and Poultry Products*. Available at: http://www.fsis.usda.gov/wps/wcm/connect/212e40b3-b59d-43aa-882e-e5431ea7035f/95033F-a.pdf?MOD=AJPERES. Doyle, M.P., and J.L. Schoeni. 1984. Survival and growth characteristics of *Escherichia coli* associated with hemorrhagic colitis. *Appl. Environ. Microbiol*. 48:855-856.	In plant monitoring records for 90 day period indicating a minimum internal temperature of 130° F for 112 minutes is achieved. In plant monitoring records for 90 day period demonstrating use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor to measure relative humidity during cooking. Records should indicate that humidity can be maintained >90% for at least 25% of the cooking time and in no case less than one hour by use of steam injection for 90 days.