A Generic HACCP Model for Heat-Treated, Not Fully Cooked (Bacon)

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 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 updated 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". FSIS recommends that establishments tailor the model(s) to fit the establishment's operation.

This generic model uses bacon to illustrate the Heat-Treated, Not Fully Cooked processing category. Bacon is a cured and smoked pork product. Bacon is made with salt as a curing agent. Nitrite is the other most frequently used additive. Bacon may also contain sugars, wood smoke, flavorings, and spices. Bacon receives a heat processing step but the application of heat is not adequate to achieve food safety. Therefore, bacon is not ready-to-eat, it must be kept refrigerated or frozen, and it is cooked before consumption.

This model's critical control point (CCP) does not necessarily apply to all operations or bacon products. HACCP plans may require more CCPs depending on the product and 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. This model includes references for guidance on the selection of critical limits.

The selection of this processing category and bacon HACCP model are preliminary steps to completing a hazard analysis. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP records ((CFR 417.5(a)). Ensure you maintain the documents produced while developing a HACCP plan.

For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP plans and the guidance materials available on the FSIS HACCP webpage.

EXAMPLE PRODUCT DESCRIPTION[1]

Product Name and Process Type: Bacon (Heat-Treated, Not Fully Cooked)

Product Name and Process Type	Bacon; Heat-Treated, Not Fully Cooked
Important product characteristics (A_w, pH, Preservatives, etc.)	Contains Sodium Nitrite (120 ppm)[2]
How it is to be used[3]	Intended for cooking
Packaging (durability and storage conditions)	Vacuum packaged
Shelf life and at what temperature[4]	1 month at 40ºF or less or 6 months frozen at 0ºF
Where it will be sold (specify intended consumers, especially at-risk populations)[5]	Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI).
Labeling instructions and requirements	Product name, nutrition facts, ingredients statement, allergen statement, establishment number, keep refrigerated, keep frozen, cooking instructions, safe handling instructions
Special distribution control	Keep refrigerated or frozen

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[1] Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.
[2] Pumped bacon has a regulatory requirement for 120 ppm ingoing Sodium Nitrite or an equivalent amount of potassium nitrite (148 ppm ingoing) and 550 ppm Sodium Ascorbate or Sodium Erythorbate (9 CFR 424.22(b)).
[3] The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product's intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2).
[4] Each establishment may have their own defined shelf life.
[5] At-risk populations include young children, the elderly, and immunocompromised persons.

EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL[6]

Product Name and Process Type: Bacon (Heat-Treated, Not Fully Cooked)

Meat and Meat by-products	Pork belly
Non-Meat food ingredients	Sugar, Salt, Flavor and Spice mixture
Antimicrobial interventions[7] and processing aids	Sodium Nitrite
Packaging material	Plastic vacuum bags
Restricted ingredients and allergens	Sodium Nitrite, Sodium Erythorbate
Other	None

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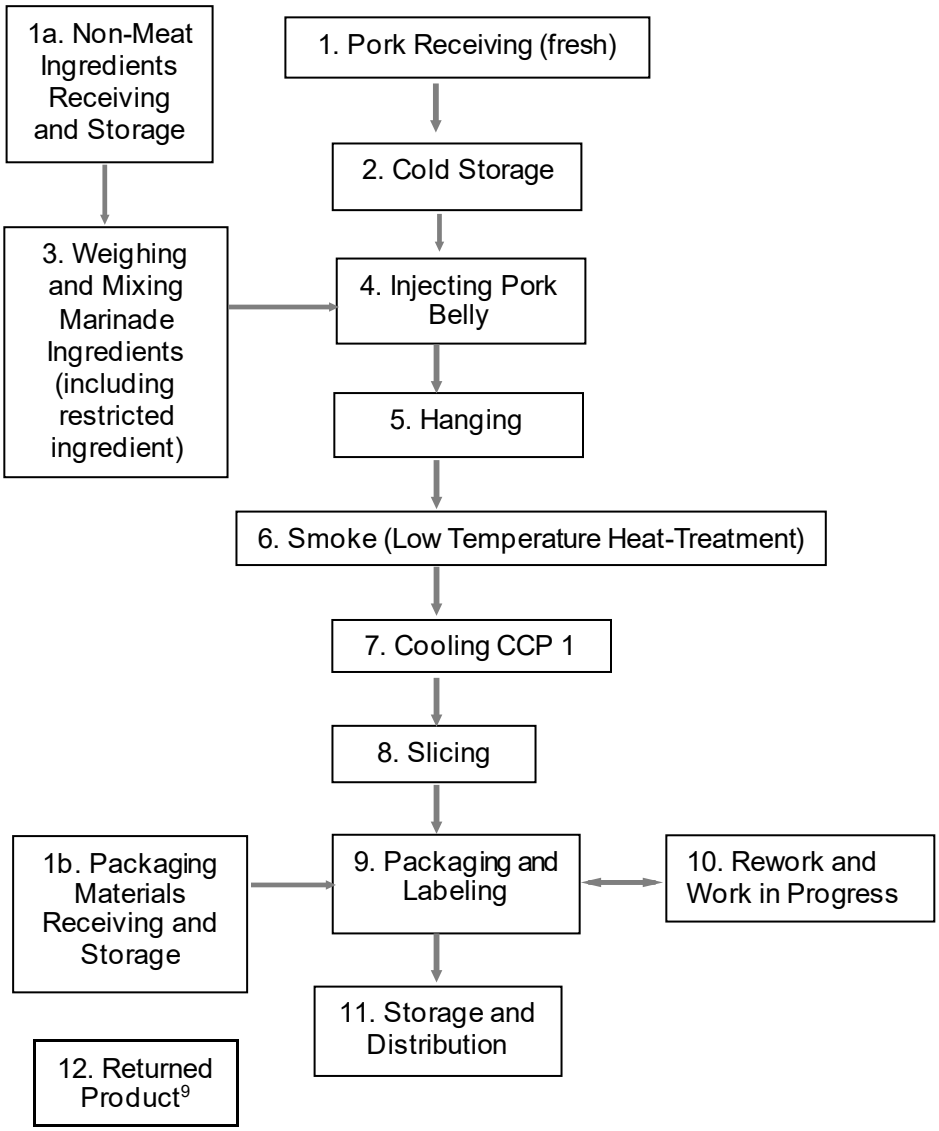
[6] List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens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

[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 (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients.

EXAMPLE PROCESS FLOW DIAGRAM[8]

Product Name and Process Type: Bacon (Heat Treated, Not Fully Cooked)



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[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.

[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 problem. Returned product may be relabeled, discarded, etc.

EXAMPLE HAZARD ANALYSIS[10]

Product Name and Process Type: Bacon (Heat Treated, Not Fully Cooked)

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 Reasonably Likely to Occur? (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)?[15]**
1. Pork Receiving (fresh)	B: *Salmonella*	No	It is well documented that raw pork may be contaminated with pathogens. Bacon (like other forms of not ready-to-eat pork products, including all forms of fresh pork) is customarily well-cooked in the home or elsewhere before being served to the consumer and the product bears safe handling		

[10] See FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products for suggested best practices and a list of scientific and technical references.

[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 Guidebook for the Preparation of HACCP Plans for more information about hazards identification.

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

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	Trichinella spiralis[16]	No	instructions. Written Pork Receiving Standard Operating Procedure (SOP) to establish controls to prevent hazards.[17] Written Pork Receiving SOP followed to establish controls for purchase specifications, ensure only qualified pork products are received and that product has been prepared and handled by the supplier in a manner that minimizes or eliminates the possibility of pathogen contamination. Written Temperature Control SOP for maintaining product at temperatures that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996).[18] Letter of Guarantee (LOG) is on file for each supplier of incoming pork. Bacon (like other forms of not ready-to-eat pork products, including all forms of fresh pork) is customarily well-cooked in the home or elsewhere before being served to the consumer. The product bears safe handling instructions.		
	C: None				

[16] See FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork for more information regarding *Trichinella spiralis*.

[17] Prerequisite programs (SOP, Sanitation SOP, GMP) used as controls must be written procedures or protocols. The name of the program (for example, Receiving Trim SOP) must be listed, and the program and plant data become part of recordkeeping. These programs must have a description of controls and on-going verification used to prevent hazards from occurring.

[18] FSIS recognizes the author's work since it was presented at a public hearing on a proposed regulation. The full title of the document is: *Tompkin, R.B. 1996. The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F. Presented during the Joint FSIS/FDA Conference on Time/Temperature. November 18, Washington, DC.*

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	P: Foreign Material	No	Written Foreign Material SOP[19] for visual inspection of containers and product at receiving.		
1a. Non-Meat Ingredient Receiving and Storage	B: Presence and growth of pathogens *e.g.*, *Salmonella, E. coli, Listeria monocytogenes*	No	Spices and flavorings may introduce pathogens. LOGs from suppliers describing quality controls and prevention procedures. Written Incoming Ingredients SOP for procedures to examine incoming non-meat ingredients including temperature (<45°F, (Tompkin, R.B. 1996) and sanitary conditions. Written Sanitation SOP for procedures used to protect ingredients from environmental contamination.		
	C: Allergens, Sodium Nitrite, Sodium Erythorbate	No	The product formulation does not include an allergenic compound (Big 8). Allergenic ingredients are in other product formulations. Written Sanitation SOP for procedures used to protect non-allergenic ingredients and products from cross-contamination with allergenic ingredients. LOG for all non-meat ingredients describing quality controls and prevention procedures. Written Incoming Ingredients SOP for procedures to examine incoming non-meat ingredients including sanitary conditions. Written Sanitation SOP for procedures used to protect non-meat ingredients from environmental contamination.		
	P: None				

[19] This Foreign Material SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historic data.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
1b. Packaging Materials Receiving and Storage	B: Contamination with Pathogens	No	Procedures to protect packaging materials from pests and environmental contamination.		
	C: Chemical hazards	No	Packaging materials may introduce chemical hazards. Letter of Guarantee for all packaging materials describing quality controls and prevention procedures. Written Packaging 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: Physical contaminants	No	Written Sanitation SOP for procedures used to protect packaging materials from contamination with physical hazards.		
2. Cold Storage	B: Pathogen outgrowth	No	Written Sanitation SOP for condition of use in coolers to prevent outgrowth of microorganisms. Written Temperature Control SOP for maintaining product at temperatures that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996).		
	C: None				
	P: Physical contaminants	No	Written Sanitation SOP for procedures used to protect packaged product from contamination with physical hazards.		
	B: None				

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
3. Weighing and Mixing Marinade Ingredients (including restricted ingredient)	C: Sodium Nitrite, Sodium Erythorbate, Allergens	No	Inappropriate levels of Sodium Nitrite or Sodium Erythorbate added to marinade mix creating potential toxic or uncured condition. Written SOP for Weighing Marinade Spices and Restricted Ingredients. Brine (concentration) records maintained for lots and batching. Written Sanitation SOP for procedures used to protect non-allergenic ingredients and products from cross-contamination with allergenic ingredients.		
	P: None				
4. Injecting Pork Belly	B: Pathogen outgrowth	No	Duration of this step (Injecting Pork Belly) is short enough that pathogen outgrowth is not reasonably likely to occur. According to Tompkin, R.B. 1996, *Salmonella* growth is limited to < 1-log if product temperatures are no more than 70˚F for up to 9 hours. This would be longer than a shift, so outgrowth is not reasonably likely to occur. Bacon (like other forms of not ready-to-eat pork products, including all forms of fresh pork) is customarily well-cooked in the home or elsewhere before being served to the consumer and the product bears safe handling instructions.		
	C: Sodium Nitrite, Sodium Erythorbate	No	Written SOP for injection process ensures restricted ingredient limits are not exceeded and minimum levels of Sodium Nitrite are achieved.		
	P: Metal from injector needles	No	Written SOP for equipment inspection during operations. No history of findings from daily equipment pre-operational inspections (covered in Sanitation		

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
			SOPs).[20] No history of consumer complaints.		
5. Hanging	B: Pathogen outgrowth		Duration of this step (Hanging) is short enough that outgrowth is not reasonably likely to occur. According to Tompkin, R.B. 1996, *Salmonella* growth is limited to < 1-log if product temperatures are no more than 70°F for up to 9 hours. This would be longer than a shift, so outgrowth is not reasonably likely to occur. Bacon (like other forms of not ready-to-eat pork products, including all forms of fresh pork) is customarily well-cooked in the home or elsewhere before being served to the consumer and the product bears safe handling instructions.		
	C: None				
	P: None				
6. Smoke (Low Temperature Heat-Treatment)[21]	B: *Clostridium perfringens, Clostridium botulinum,* and	No	Pathogens present on raw meat. Pre-requisite formulation SOP to ensure sufficient ingredient levels (salt, brine, sodium nitrite, sodium erythorbate, sodium phosphate) for preventing outgrowth of *Staphylococcus aureus*, *Clostridium perfringens* and *Clostridium botulinum* during smoking.[22]		

[20] Note: this "historical data" must be supported with evidence from the establishment through the establishment's history or validation data. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide which states "appropriate screening procedure for monitoring equipment" is a frequently used control for foreign material hazards in processing.

[21] See FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A for information that small and very small establishments can use to produce safe products with respect to *Salmonella* and other pathogens.

[22] If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. (FSIS Compliance Guideline HACCP Systems Validation, page 27).

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	Staphylococcus aureus		Pre-requisite smoking SOP to ensure heating come up-time is met (heat to 120 °F within 6 hours) while natural smoke applied: for preventing outgrowth of *Staphylococcus aureus*, *Clostridium perfringens* and *Clostridium botulinum* during smoking.		
	C: None				
	P: None				
7. Cooling[23]	B: *Clostridium perfringens, Clostridium botulinum, Staphylococcus aureus*	Yes	Bacteria can grow and spores can survive the smoke step (#6) and can germinate and grow if not cooled quickly. Bacterial outgrowth can occur if product temperature reduction times are not met. Rapid and controlled cooling ensures no multiplication of toxigenic microorganisms such as *Clostridium botulinum* and no more than 1-Log multiplication of *Clostridium perfringens*.	CCP 1 Cooling. Pre-requisite formulation SOP to ensure sufficient ingredient levels (salt, brine, sodium nitrite, sodium erythorbate, sodium phosphate) for preventing outgrowth of *Staphylococcus aureus*, *Clostridium perfringens* and *Clostridium botulinum* during cooling.[24,25]	Yes, CCP 1
	C: None				
	P: None				
8. Slicing	B: Growth and recontamination of pathogens.	No	Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is sliced at temperatures		

[23] 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 the Appendix B for suggested best practices and a list of scientific and technical references.

[24] 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 that 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.

[25] Taormina, P.J. and Bartholomew, G.W. 2005 Validation of Bacon processing Conditions to Verify Control of Clostridium perfringens and Staphylococcus aureus. Journal of Food Protection. 68(9): 1831-1839

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
			that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996). Written Sanitation SOP controls potential cross-contamination of product from slicer.		
	C: None				
	P: Metal	No	Written SOP for equipment inspection during operations. No history of findings from daily equipment pre-operational inspections (covered in Sanitation SOPs). No history of consumer complaints.		
9. Packaging and Labeling	B: Growth of pathogens.	No	Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is packaged at temperatures that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996).		
	C: Allergens	No	Allergenic ingredients are present in this facility and used in other products. Written SOP for procedure used to ensure products are correctly labeled.		
	P: None				
10. Rework and Work in Progress	B: Growth of pathogens.	No	Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is reworked at temperatures that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996).		
	C: None				
	P: None				

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
11. Storage, Distribution	B:Growth of pathogens	No	Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is stored at temperatures that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996). Written Final Product SOP for procedures to examine outgoing materials including sanitary conditions of truck, functioning refrigeration unit, and package integrity.		
	C: None				
	P: None				
12. Returned Product	B: None		Reinspection SOP implemented before accepting returned product. Entity returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted.		
	C: None				
	P: None				

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EXAMPLE HACCP PLAN for Bacon (Heat-Treated, Not Fully Cooked)									
Critical Control Point (CCP)	**Significant Hazard(s)**	**Critical Limits for Each Control Measure**	**Monitoring Procedures**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
CCP 1 Cooling	B: *Clostridium perfringens*, *Clostridium botulinum,* and *Staphylococcus aureus*	Cooling: from 120°F to 80°F in 5 hours and 80°F to 45°F in 10 hours (15 hours total cooling time)[26]	Measure product temperature and the time taken to determine the number of hours product is held in the 120°F to 80°F and 80°F to 45°F temperature zones.	Measure product temperature in center of largest piece in the batch and held in the cooler's warmest spot, and record times between critical temperatures at regular intervals.	Each batch	Designee	If a deviation from the critical limit occurs, the supervisor will: 1. Hold all product produced from last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence 9 CFR 417.3.	Once per week a supervisor observes designee perform chill temperature checks. Once per week, a supervisor calibrates thermometers to be used for product and coolers as per the manufacturer's instructions. A manager performs records review once per week.	Temperature Smoke / Cool Log. Thermometer Calibration Log. Direct Observation Log Records Review Log. Corrective Actions Logs.

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[26] Taormina, P.J. and Bartholomew, G.W. 2005 Validation of Bacon processing Conditions to Verify Control of Clostridium perfringens and Staphylococcus aureus. Journal of Food Protection. 68(9): 1831-1839