A Generic HACCP Model for Fresh Ground Pork Sausage Patties

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 of 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.

The model's critical control points (CCPs) do not necessarily apply to all operations or products in the product category. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources to meet regulatory validation requirements. Each model includes references for guidance on the selection of critical limits.

To select the model that will be most useful for the products produced, consider the production activity occurring (slaughter, cutting, grinding, smoking, cooking, etc.), the product (beef, pork, chicken, etc.), and the food safety characteristics of the final product produced (intact or non-intact, raw or ready-to-eat, requires refrigeration or is shelf-stable, etc.). Examine the list of processing categories (9 CFR 417.2(b)(1)) and group similar products according to the categories. Many similar products may be grouped under the same category and HACCP plan. Selection of the processing categories reveal which of the generic models might be useful.

Selecting the most appropriate model to work from will save the establishment time and personnel resources. Deciding on a generic model is an important achievement for your establishment.

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

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

EXAMPLE PRODUCT DESCRIPTION[1]

Process / Product Name: Fresh Ground Pork Sausage Patties

Process / Product Name	Non-intact pork product (sausage patties)
Important product characteristics (A_w, pH, preservatives, etc.)	None
How it is to be used	Intended to be thoroughly cooked.
Packaging (durability and storage conditions)	Tray packs
Shelf-life and at what temperature	3 – 6 months at 0˚F or below; 7 days at 40˚F
Where it will be sold (specify intended consumers, especially at-risk populations)[2]	Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI).
Labeling instructions	Product name, inspection legend and establishment number, handling statement, net weight statement, ingredients statement, address line, nutrition facts, the statement "Cook to an internal temperature of 160 degrees Fahrenheit as measured by a food thermometer" on the principle display panel, and safe handling instructions.
Special distribution control	Keep frozen, keep refrigerated

DATE: _____ APPROVED BY: _____

[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. 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.

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

EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL[3]

Process / Product Name: Fresh Ground Pork Sausage Patties

Meat and meat by-products	Fresh or frozen raw pork trimmings from in-house production. Purchased fresh or frozen raw pork trimmings.
Non-meat food ingredients	Sugar, Salt, Spices
Antimicrobial interventions[4] and processing aids	None
Packaging material	Tray packs and shrink wrap
Restricted ingredients or allergens	None
Other	None

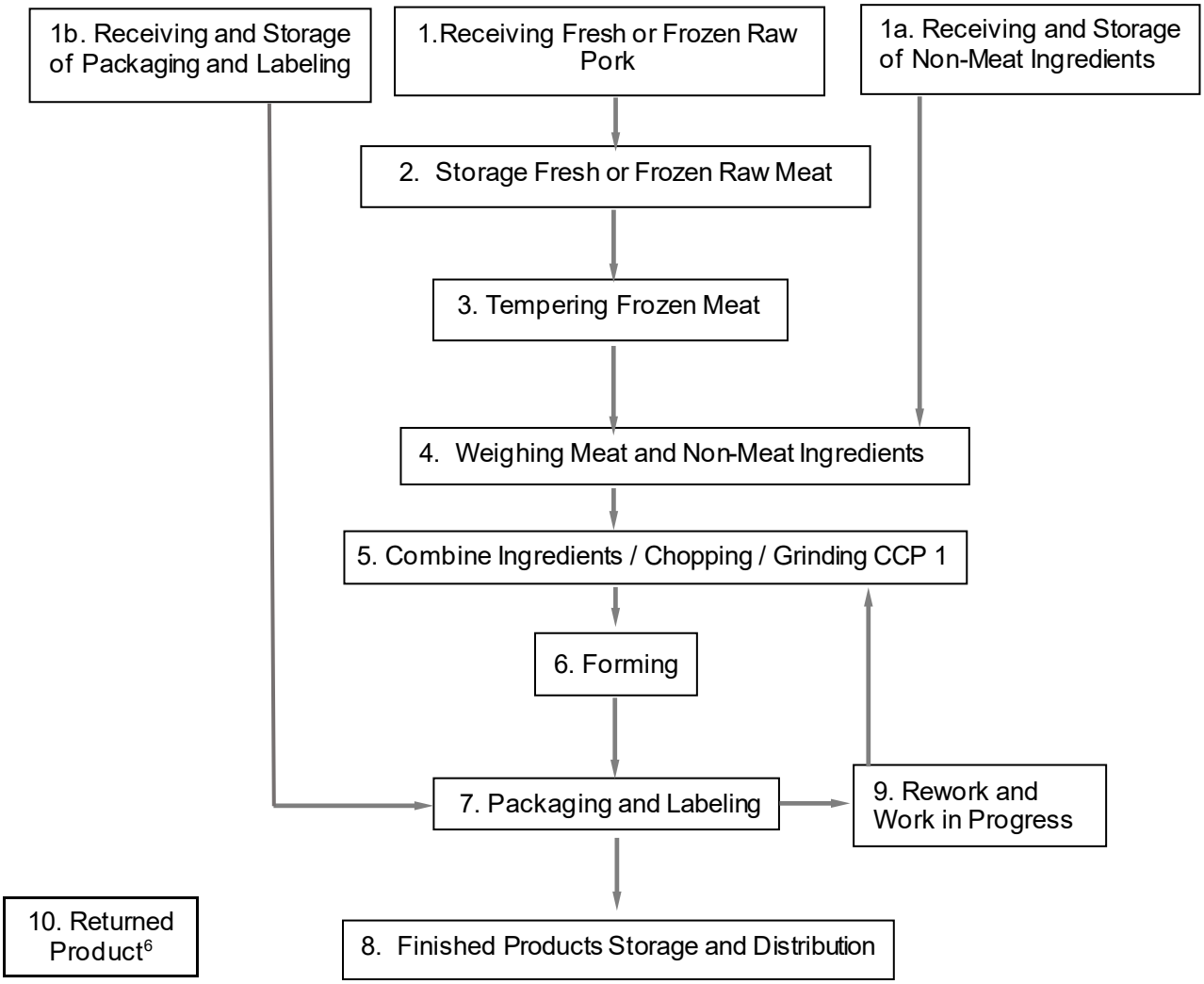
DATE: _____ APPROVED BY: _____

[3] List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), antimicrobials, processing aids, and packaging material used in production of this product. This step is important to help identify special ingredients or processes to address in the HACCP plan.

[4] 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 FD&C 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[5]

Fresh Ground Pork Sausage Patties



[5] 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.
[6] The Returned Product step (10) 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, re-ground, discarded, tempered, etc.

EXAMPLE HAZARD ANALYSIS[7]

Fresh Ground Pork Sausage Patties

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Ingredient / Process Step	Potential Hazards (introduced or controlled) at this Step[8]	Is the Potential Food Safety Hazard Reasonably Likely to Occur (NRLTO)? (Yes or No)[9]	Justification / Basis for Decision in Column 3[10]	If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels[11]	Is this Step a Critical Control Point (CCP)?[12]

[7] This is an example hazard analysis. Establishments' hazard analyses for the same product may be different. Establishments determine which hazards are applicable to their process.

[8] 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.

[9] 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.

[10] Scientific references are important in making decisions and providing justifications. 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 scientific or technical support is needed, and these non-FSIS supporting documents must be kept for the life of the HACCP plan.

[11] 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).

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

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
1. Receiving Fresh or Frozen Raw Pork	B: Pathogens: *Salmonella* outgrowth	No	Pathogens known to be present and likely to cause illness if not controlled. Pork trimmings are either sourced from in-house production or purchased. Pork trimmings may be processed fresh or placed in frozen storage for later use. Written Temperature Control SOP for maintaining product temperatures to prevent outgrowth of micro-organisms (The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F (Tompkin, R.B. 1996)). Letter of Guarantee is on file from the originating slaughter facility of purchased product. The blanket LOG is updated annually.		
	Trichinella spiralis[13]	No	Not ready-to-eat pork products, including all forms of fresh pork, do not need to be treated to destroy *Trichinella* because they are customarily well-cooked in the home or elsewhere before being served to the consumer. Product label principle display panel includes the statement "Cook to an internal temperature of 160 degrees Fahrenheit as measured by a food thermometer" to clearly indicate the products require additional treatment by the consumer.		
	C: Allergens	No	Letter of Guarantee is on file from the originating slaughter facility of purchased product. The blanket LOG is updated annually.		

[13] This HACCP model uses option 3 *Label NRTE pork products, including all forms of fresh pork to clearly indicate the products require additional treatment by the consumer* described in the FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork.

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
	P: Foreign material	No	Written Foreign Material SOP[14] for visual inspection of product in containers at receiving. Records generated from the Foreign Material SOP demonstrate no incidents of foreign materials detected in products received.		
1a. Receiving and Storage of Non-Meat Ingredients	B: Pathogens: *Salmonella*	No	Spices and flavorings may introduce pathogens. Written Incoming Material SOP include procedures used to examine materials including temperature and sanitary conditions. Written Sanitation SOP for procedures used to protect ingredients from environmental contamination. Letters of Guarantee from suppliers describing quality controls and prevention procedures. Only irradiated spices are purchased.		
	C: Allergens	No	Written Incoming Material SOP for procedures to examine incoming materials including allergen declarations.		
	P: Extraneous materials	No	Letters of Guarantee from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP includes procedures to examine integrity of packaging material.		
1b. Receiving and Storage of Packaging and Labeling	B: None				

[14] 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	Hazard	RLTO	Justification / Basis	Controls	CCP
	C: Allergens and pesticides	No	Written Sanitation SOP for procedures used to protect packaging materials from environmental contamination. Letter of Guarantee for all packaging materials describing quality controls and prevention procedures.		
	P: None	No	Written Sanitation SOP for procedures used to protect packing materials from physical contamination and debris.		
2. Storage Fresh or Frozen Raw Meat	B: Outgrowth of Pathogens: *Salmonella*	No	Written Sanitation SOP for refrigerated or frozen product storage to maintain sanitary environment. Written Temperature Control SOP for maintaining product temperatures in refrigerated and frozen product storage to prevent outgrowth of micro-organisms. (Tompkin, R.B. 1996)		
	C: None				
	P: None				
3. Tempering Frozen Meat	B: Outgrowth of Pathogens: *Salmonella*	No	Written Tempering SOP to maintain time and temperature to prevent outgrowth of pathogens (Tompkin, R.B. 1996).		
	C: None				
	P: None				
4. Weighing Meat and Non-Meat Ingredients	B: None				
	C: Cross-contamination of allergens or chemicals	No	Written Good Manufacturing Practices (GMPs) to prevent and minimize the likelihood of cross-contamination with allergens and chemicals.		

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
	P: None				
5. Combine Ingredients / Chopping / Grinding	B: Outgrowth of Pathogens: *Salmonella*	Yes	Pathogen outgrowth may occur during processing procedures due to equipment generated heating of product.	CCP 1 is a measure of the product temperature as it emerges from the grinder. Ingredients Temperature Control SOP is for monitoring the temperatures of ingredients batched for grinding (Tompkin, R.B. 1996) Temperature Control SOP for production room temperature control.	Yes CCP 1
	C: Cross-contamination with allergens	No	Equipment Maintenance SOP to ensure equipment used for processing products containing allergens are properly labeled and not used for non-allergen containing product.		
	P: Metal contamination	No	No history of findings from daily equipment pre-operational inspections (Sanitation SOPs). No history of consumer complaints. Equipment Inspection SOP. Metal Detector Prerequisite Program.		
6. Forming	B: Outgrowth of Pathogens: *Salmonella*	No	Pathogen outgrowth is a potential during processing procedures. Temperature Control SOP for production room temperature control. Proper employee handling through Sanitation SOP		
	C: None				

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
	P: None				
7. Packaging and Labeling	B: Outgrowth of Pathogens: *Salmonella*	No	Pathogen outgrowth is a potential during processing procedures. Temperature Control SOP for production room temperature control. Proper employee handling through Sanitation SOP.		
	C: None				
	P: None				
8. Finished Products Storage and Distribution	B: Outgrowth of Pathogens: *Salmonella*	No	Written Sanitation SOP for product holding coolers to maintain sanitary environment. Written Temperature Control SOP for maintaining cooler and product temperatures to prevent outgrowth of micro-organisms. Written Final Product SOP for procedures to examine outgoing products including sanitary condition of trucks, functioning transport refrigeration unit, and package integrity.		
	C: None				
	P: None				
9. Rework and Work in Progress	B: Outgrowth of pathogens: *Salmonella.*	No	Temperature Control SOP for production room temperature control. Written Sanitation SOP for product holding coolers to maintain sanitary environment. Written Temperature Control SOP for maintaining cooler and product temperatures to prevent outgrowth of micro-organisms. Proper employee handling through Sanitation SOP		

Step	Hazard	RLTO	Justification / Basis	Controls	CCP
	C: None				
	P: None				
10. Returned Product	Reinspection SOP implemented before accepting returned product. Product enters the appropriate step of the production system based on findings of product evaluation. Opened packages are not accepted. Notify FSIS personnel when product has been returned.				

DATE: _____ APPROVED By: _____

EXAMPLE HACCP PLAN[15]

Fresh Ground Pork Sausage Patties

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 Combine Ingredients / Chopping / Grinding	*Pathogen: Salmonella*	Temperature of product as it emerges from the grinder will measure at 40˚F or less.	Measure ground product temperature	Calibrated handheld thermometer	Once per hour during grinding operations.	Quality Control Technician or designee	If a deviation from the critical limit occurs, the supervisor will: 1. Hold all affected product until appropriate disposition taken (no product injurious to health will be sold); 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 shift, supervisor will observe technician measure product temperature. Once per shift, supervisor will review records. Once per week, supervisor will calibrate thermometer per manufacturer's procedures.	Preshipment Records Review Form Product Temperature Form Thermometer Calibration Form

DATE: _____ APPROVED By: _____

[15] 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.