HACCP Model for Raw Intact Beef

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, 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 model(s) to fit the establishment's operation.

The raw intact[1] beef 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 selected must come from scientific documents or other reliable sources. Each model includes references for guidance on the selection of critical limits.

This model illustrates how establishments might include beef intended for intact use in the production of steaks and roasts. The sources of beef in this model are purchased product intended for intact use and product from in-house slaughter operations.

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.[2]

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[1] FSIS considers raw products to be intact unless they have undergone any of the processes associated with the raw non-intact process category. Processes common to the non-intact category include grinding, comminuting, injecting product with solutions, or mechanical tenderization by needling, cubing, pounding devices or other means of creating non-intact product.

[2] 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.

EXAMPLE PRODUCT DESCRIPTION[3]

Process Type and Product Name: Raw Intact Beef

Process Type and Product Name	Raw Intact Beef: steaks and roasts.
Important product characteristics (Aw, pH, preservatives, etc.)	None
How it is to be used[4]	The products are to be cooked intact while using the validated cooking instructions.[5]
Packaging (durability and storage conditions)	Tray packages, vacuum sealed packages or in butcher paper.
Shelf Life and at what temperature[6]	Shelf life is 7 days when held at ≤40°F and paper wrapped; 60 days when held at ≤40°F and vacuum packed.[7] Vacuum packed product can be held for 180 days at ≤10°F.
Where it will be sold (specify intended consumers, especially at-risk populations[8])	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, address line, nutrition facts, and safe handling instructions. Validated cooking instructions.[9]
What special distribution controls are required?	None

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[3] 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.
[4] 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).
[5] Establishments are required to identify the intended use of the product (9 CFR 417.2(a)(2)); they are also required to maintain decisionmaking documents associated with the HACCP plan (9 CFR 417.5(a)(2)). See the Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts FSIS knowledge article for additional information.
[6] Each establishment's products may have their own defined shelf life.
[7] See Beef Shelf-life.
[8] At-risk populations include young children, the elderly and immunocompromised persons.
[9] See the FSIS Labeling Overview and Generic Label Approval guideline for information on required labeling features.

EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL[10]

Process Type and Product Name: Raw Intact Beef

Meat and Meat by-products	In-house slaughtered beef primals and sub-primals intended for intact use. Purchased beef sub-primals intended for intact use.
Non-meat food ingredients	None
Antimicrobial[11] Interventions and processing aids	None
Packaging Material	Plastic, foam, or paper.
Restricted Ingredients and Allergens	None
Other	None

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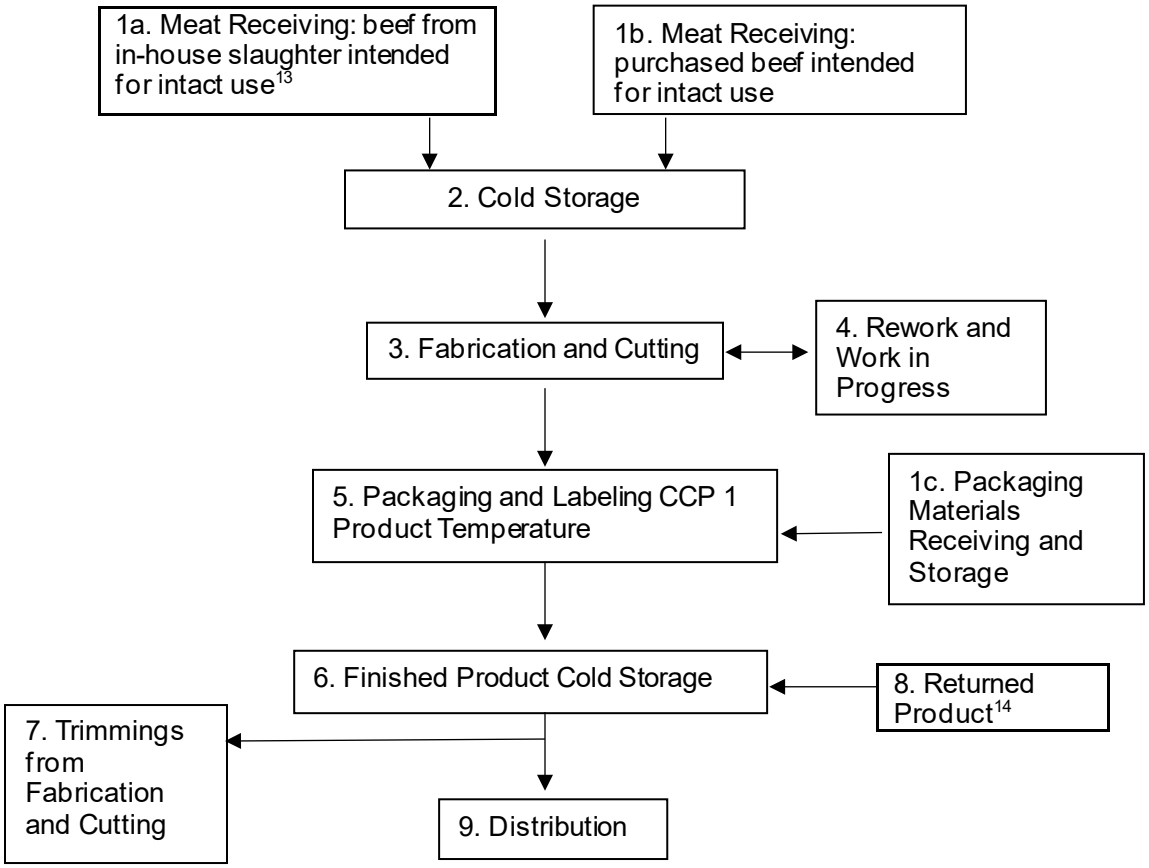
[10] List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens 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).

[11] 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[12]

Process Type and Product Name: Raw Intact Beef



[12] 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.

[13] The flow diagram and hazard analysis demonstrate the use of two differently sourced beef products. They are from in-house slaughter production (step 1a) that underwent interventions as part of the slaughter HACCP plan, and purchased product intended for intact use (without a COA) (step 1b).

[14] The Returned Product step (9) is shown connected to the Finished Product Cold Storage step. Returned product may re-enter the production system at different process steps depending on condition or food safety concerns. Returned product may be relabeled, repackaged, or discarded.

EXAMPLE HAZARD ANALYSIS

Process Type and Product Name: Raw Intact Beef

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6

Ingredient / Process Step	Potential Hazards (introduced or controlled at this Step[i]	Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No)[ii]	Justification / Basis for Decision[iii]	If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels[iv]	Is this Step a Critical Control Point (CCP)?
1a. Meat Receiving: beef from in-house slaughter intended for intact use	B: Presence of pathogens: Shiga-toxin producing *Escherichia coli* (STEC) (*E. coli* O157:H7, O26, O45, O103, O111, O121 and O145), and *Salmonella*	No	STEC and *Salmonella* are known to be present and may cause illness if not controlled. In-house product from slaughter operations was subjected to slaughter sanitary dressing procedures, a Zero Tolerance CCP, and an Organic Acid CCP. STEC is not an adulterant on intact products intended for intact use as the contamination is limited to the exterior of the product whereby customary consumer cooking practices will destroy the pathogen on the exterior surface even if the interior of the product is consumed in a rare or medium rare state.[15]		
	B: Outgrowth of pathogens: STEC and *Salmonella*.	No	Temperature Control Standard Operating Procedure (SOP) for maintenance of cold storage room temperature.		

[15] STEC is an adulterant in raw non-intact beef products. When STEC is present on the meat's exterior, the pathogen may be translocated to the interior of the product during processing (e.g., grinding, tenderizing). In such cases, normal cooking to a rare or medium-rare internal state may not be sufficient to destroy STEC that is present throughout the product. See the Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations (page 8) for additional information.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	B: Bovine Spongiform Encephalopathy (BSE) Prions associated with Specified Risk Materials (SRM) (9 CFR 310.22).	No	Written Cold Storage Program to receive product ≤44.6°F to prevent outgrowth (Tompkin, R.B. 1996).[16,17] Written SRM Program to remove, segregate and dispose of SRMs (9 CFR 310.22).		
	C: None				
	P: None				
1b. Meat Receiving: purchased beef intended for intact use	B: Presence of pathogens: STEC and *Salmonella*.	No	An annual Letter of Guarantee[18] (LOG) from each supplier indicating the STEC and *Salmonella* controls were applied, and the products are intended for intact use.		
	B: Outgrowth of pathogens STEC and *Salmonella*.	No	Written Receiving Program to receive product ≤44.6°F to prevent outgrowth (Tompkin, R.B. 1996).		
	B: BSE / SRMs	No	SRMs are required to be removed by supplier prior to receipt. Only boneless beef received and supplier LOG on file.		

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

[17] If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameters (FSIS Compliance Guideline HACCP Systems Validation, page 27).

[18] A LOG is a document that provides details for components that are used in the areas of food processing, handling, and storage. Generally, a LOG contains: supplier name and address, brand name, statement that the material is safe and effective under intended conditions of use and will not adulterate the food product, and signature of an official of the supplier. The LOG may be attached to an invoice or may be a continuing LOG that does not accompany each shipment. An annual update for Letters of Guarantee (LOG) is not a regulatory requirement. Each establishment must determine the frequency at which the LOG are updated. The frequency should be sufficient to adequately describe the supplier's process to support the decision(s) made.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	C: None				
	P: None				
1c. Packaging Materials Receiving and Storage	B: Contamination with Pathogens	No	Procedure to protect packaging materials from pests and environmental contamination.		
	C: Non-food grade materials	No	LOG for packaging materials (9 CFR 317.24) and the materials are safely stored.		
	P: Foreign materials	No	Foreign Material SOP with visual evaluation for foreign material.[19] Protect packaging materials from environment.		
2. Cold Storage	B: Outgrowth of pathogens: STEC and *Salmonella*	No	Written Cold Storage Program to maintain product ≤44.6°F to prevent outgrowth (Tompkin, R.B. 1996).		
	C: None				
	P: None				
3. Fabrication and Cutting	B: Outgrowth of pathogens: STEC and *Salmonella*.	No	Temperature Control SOP for maintenance of production room temperature.[20]		
	C: None				
	P: None				
4. Rework and Work in Progress	B: Outgrowth of pathogens, STEC and *Salmonella*.	No	Temperature Control SOP for production room temperature.		
	C: None				
	P: None				

[19] This Foreign Material SOP (prerequisite program) should have details on how this procedure (such as metal prevention controls) is preventing the hazard from occurring 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 historical data.

[20] Establishments may decide to add an organic acid treatment to be applied during fabrication. The organic acid treatment functions as a component of a multi-hurdle approach to pathogen control in ground product because trimmings are frequently used in ground beef production.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
5. Packaging and Labeling CCP 1 Product Temperature	B: Outgrowth of pathogens: STEC and *Salmonella*.	Yes	Processing activities may result in product temperatures >44.6°F. Product temperatures >44.6°F may facilitate pathogen outgrowth. Product temperature taken at packaging.	CCP 1 Product Temperature at Packaging and Labeling. Temperature Control SOP for production room temperature.	CCP 1 Product Temperature at Packaging and Labeling
	C: None				
	P: None				
6. Finished Product Cold Storage	B: Outgrowth of pathogens, STEC and *Salmonella*.	No	Written (and implemented) Cold Storage Program to maintain product ≤44.6°F to prevent outgrowth (Tompkin, R.B. 1996).		
	C: None				
	P: None				
7. Trimmings from Fabrication and Cutting	B: Outgrowth of pathogens: STEC and *Salmonella*.	No	Trimmings are processed into ground beef. Steaks and roasts may be mechanically tenderized, or needle injected. Mechanically tenderized, needle injected products and beef trimmings are packaged and then further processed under the Raw Non-Intact Beef HACCP plan which contains a Written Raw Beef Testing SOP for verification of STEC and *Salmonella* controls. Temperature Control SOP for production room temperature.	.	
	C: None				
	P: None				
8. Returned Product	B: None		Returned Product Evaluation SOP implemented before accepting returned product. Person(s) or		

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
			business 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				
9. Distribution	B: None				
	C: None				
	P: None				

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EXAMPLE HACCP PLAN for Raw Intact Beef									
Critical Control Point (CCP)	**Significant Hazard(s)**	**Critical Limits for Each Control Measure**	**Monitoring Procedures**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
Packaging and Labeling CCP 1 Product Temperature	Pathogen outgrowth: STEC (*E. coli* O157:H7, O26, O45, O103, O111, O121 and O145), and *Salmonella*.	Internal product temperature is ≤44.6°F at packaging.	Internal product temperature is measured after the product is placed in its packaging and before the package is closed. Observations documented.	Employee measures product internal temperature at the thickest part of 5 pieces with a handheld digital thermometer. Record results on the Product Temperature Form.	To be performed one time during each 2 hours of production.	Designee	If a deviation from the critical limit occurs, a supervisor will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence 9 CFR 417.3	Once per week, a supervisor will directly observe the monitoring activity, conduct the records review and calibrate the thermometer (per manufacturer's calibration instructions).	Product Temperature Form Verification Form Corrective Action Form Pre-shipment Review Form Thermometer Calibration Form

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[i] 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.

[ii] Place the justification for your decision in column 4. Control measures for hazards not reasonably likely to occur are entered in column 4. Control measures for hazards reasonably likely to occur are entered in column 5. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See the Meat and Poultry Hazards and Controls Guide for a list of frequently used controls.

[iii] 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.

[iv] 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).