A Generic HACCP Model for a Thermally Processed, Commercially Sterile Product

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 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 operations.

Thermally processed, commercially sterile (TPCS) products are commonly referred to as canned products although the containers can be metal cans, glass jars, flexible pouches, paperboard, and other types of hermetically sealed containers. Processors of TPCS products must identify their biological, physical, and chemical food safety hazards when performing their hazard analysis. Under 9 CFR 417.2(b)(3) of the HACCP regulations, establishments do not have to address the microbiological food safety hazards identified in its hazard analysis if the product is produced in accordance with the requirements of 9 CFR Part 431. However, canning establishments that identify chemical or physical food safety hazards as reasonably likely to occur (RLTO) are to address those hazards in their HACCP plan.

The regulations provide that canning establishments do not have to address microbiological hazards in their HACCP plan because FSIS recognized that the canning regulations were based on HACCP concepts and provide for the analysis of thermal processing systems and controls to exclude biological food safety hazards. However, a canning establishment may choose to address the microbiological food safety hazards in its HACCP plan. In either case, the requirements in 9 CFR parts 431 and 417 must be met through the establishment's HACCP system.

This HACCP model illustrates the scenario when the establishment does not address microbiological hazards in a HACCP plan and does not identify chemical or physical food safety hazards as reasonably likely to occur. Thus, this model does not include any critical control points (CCP). This model does contain the required product description, list of product ingredients and materials, flowchart, and hazard analysis. The model may not necessarily apply to all operations or products. Products or operations may require 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 records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP records (9 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]

Thermally Processed, Commercially Sterile: Beef Stew	
Process or Product name	Beef Stew
Important product characteristics (A_w, pH, Preservatives, etc.)	None
Intended use[2]	Ready-to-eat; typically heated before consumption.
Packaging (durability and storage conditions)	3-piece metal, double seamed ("Sanitary") can.
Shelf life and at what temperature[3]	3 years under cool (e.g., 75 °F or lower) and dry conditions; Protected from freezing.
Where it will be sold (specify intended consumers, especially at-risk populations)[4]	Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI).
Labeling instructions and requirements	Product name, inspection legend and establishment number, heating instructions, net weight statement, address line, nutrition facts, and ingredients list.
Special distribution control	None

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[1] Prior to developing the HACCP plan please read the 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 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] 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).
[3] Each establishment's products may have their own defined shelf life. Thermally Processed, Commercially Sterile products must be shelf stable per 9 CFR 431.1.
[4] At-risk populations include young children, the elderly, and immunocompromised persons.

EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL[5]

Thermally Processed, Commercially Sterile: Beef Stew	
Meat and meat by-products	Frozen beef
Non-meat food ingredients	Water, Frozen diced celery, Frozen sliced carrots, Frozen tomato puree, Modified food starch, Textured soy protein, Spice mix, Salt, Sugar.
Antimicrobial interventions[6] and processing aids	None
Packaging material[7]	3-piece double seamed ("Sanitary") cans with capacities of 7 oz, 11.5 oz, 12 oz and 20 oz.
Restricted ingredients or Allergens	Texturized soy protein
Other	None

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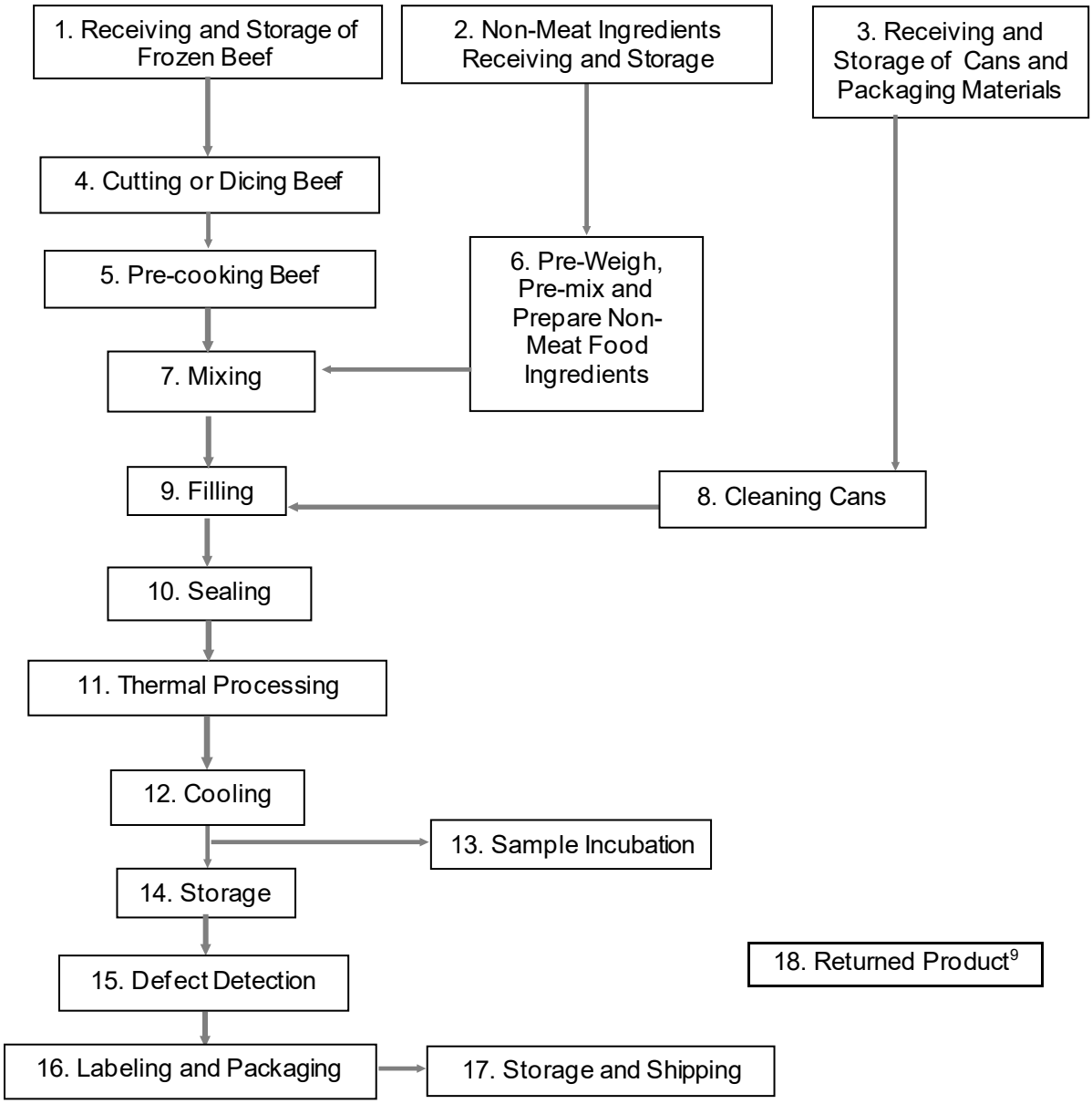
[5] List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, and packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline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

[6] 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.

[7] Establishments will follow different process schedules developed by a processing authority for the product packaged in different container sizes.

EXAMPLE PROCESS FLOW DIAGRAM[8]

Thermally Processed, Commercially Sterile: Beef Stew



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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 (18) 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 food safety concerns. Returned product may be relabeled, repackaged, or discarded.

EXAMPLE HAZARD ANALYSIS

Thermally Processed, Commercially Sterile: Beef Stew				
Potential Hazards[10]	**Is the Hazard Reasonably Likely to occur (RLTO)?**[11]	**Justification or Basis for Decision**[i]	**If yes in Column 2 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels**[ii]	**Is this Step a Critical Control Point (CCP)?**
1. Receiving and Storage of Frozen Beef				
B: Presence and outgrowth of pathogens, Shiga-toxin producing *Escherichia coli* (STEC) (*E. coli* O157:H7, O26, O45, O103, O111, O121 and O145), *Salmonella* and *Clostridium botulinum*	No	Beef may be contaminated with Shiga-toxin producing *Escherichia coli* (STEC) (*E. coli* O157:H7, O26, O45, O103, O111, O121 and O145), *Salmonella* and *Clostridium botulinum.* 9 CFR 417.2(b)(3) exempts establishment from having to address microbiological food safety hazards in the HACCP plan if the product is produced in accordance with the requirements in 9 CFR Part 431. Written receiving program to ensure product specifications, temperature, and package integrity. Written Sanitation Standard Operating Procedure (SOP), including temperature control and maintenance of sanitary conditions. The product is thermally processed during the thermal process step in accordance with 9 CFR Part 431.		

[10] Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification.

[11] Place the justification for your decision in column 3. Control measures for hazards not reasonably likely to occur are entered in column 3. Control measures for hazards reasonably likely to occur are entered in column 4. 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.

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
BSE (Prions)	No	Bovine Spongiform Encephalopathy (BSE) Prions associated with specified risk materials (SRM) is a potential hazard in beef products. Only boneless beef received from approved suppliers according to company purchasing program. SRMs are required to be removed by supplier prior to release into commerce. Letters of Guarantee (LOGs) from suppliers describing SRM controls.		
C: Antibiotic and pesticide residues	No	Letters of Guarantee (LOG) from suppliers describing quality controls and prevention procedures. The blanket LOG is updated annually. Approved supplier program and ongoing communication with suppliers to verify LOGs.		
P: Foreign materials, i.e., metal, rubber, plastic, and wood.	No	Visual examination procedures in the Foreign Material SOP.[12] Establishment Foreign Material SOP records demonstrate no incidents of foreign materials detected in products received.		
2. Non-meat Ingredients Receiving and Storage				
B: Presence and outgrowth of pathogens, e.g., STEC, *Salmonella* and *Clostridium botulinum*	No	9 CFR 417.2(b)(3) exempts establishment from having to address microbiological food safety hazards in the HACCP plan if the product is produced in accordance with the requirements in 9 CFR 431. Written receiving program to ensure product specifications, temperatures, and package integrity. Purchasing program to ensure microbiological specifications for non-meat ingredients are met. Written Sanitation SOP including storage temperature control and		

[12] 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.

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
		maintenance of sanitary conditions.		
C: Pesticide residues and undeclared allergens	No	Written receiving program to ensure product specifications. Allergen Control SOP to verify proper identification of allergenic containing ingredients for each lot. Approved supplier program and ongoing communication with suppliers to verify LOGs. Establishment records demonstrate no incidents of chemical hazards detected in products received.[13] Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1.		
P: Foreign materials, i.e., metal, rubber, plastic, and wood.	No	Visual examination procedures in the Foreign Material SOP. Approved supplier program and ongoing communication with suppliers to verify LOGs. Establishment Foreign Material SOP records demonstrate no incidents of foreign materials detected in products received.		

[13] Note: this "historical data" must be supported with evidence from the establishment through the establishment's history or validation data with reference to the actual SOP or prerequisite program. 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 "letters of guarantee, certificate of analysis, approved supplier program and proper storage to prevent contamination of allergen-free products" as frequently used controls for the receiving and storage of pesticides and allergens.

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
3. Receiving and Storage of Cans & Packaging Materials				
B: Post-process contamination due to container defects	No	Packaging materials are stored, handled, and conveyed according to SOP to prevent damage that could affect the hermetic condition of the sealed container (9 CFR 431.2).		
C: Chemicals	No	LOGs for all packaging materials describing the material's intended use complies with the Federal Food, Drug, and Cosmetic Act (FFDCA) and all applicable food additive regulations. Incoming packaging material examination procedures per 9 CFR 431.2. Approved supplier program.		
P: Foreign material	No	Cans are inverted and washed with hot water at step 8 in accordance with 9 CFR 431.2		
4. Cutting or Dicing Beef				
B: Pathogen outgrowth	No	Written Sanitation SOP to prevent or minimize cross-contamination. Temperature control SOP in the processing area to prevent the outgrowth of pathogens. Beef is cut into sizes in accordance with the process schedule developed by a processing authority (9 CFR 431.3(a) &(b)). The product is thermally processed during the thermal process step in accordance with 9 CFR Part 431.		
C: None				
P: Foreign materials, i.e., metal from	No	Metal fragments could come from processing equipment. Daily equipment examination and preventive maintenance SOP on equipment and conveyor to prevent foreign materials, i.e., metal, rubber,		

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
processing equipment		plastic from contaminating the product.		
5. Pre-cooking Beef				
B: Presence and outgrowth of pathogens: e.g., STEC, *Salmonella* and *Clostridium botulinum*	No	Written Sanitation SOP to prevent or minimize cross-contamination. Beef is pre-cooked according to the procedures defined by a processing authority (9 CFR 431.3). The product is thermally processed during the thermal process step in accordance with 9 CFR Part 431.		
C: None				
P: None				
6. Pre-Weigh, Pre-mix and Prepare Non-Meat Food Ingredients				
B: Presence and outgrowth of pathogens	No	Written Sanitation SOP to prevent or minimize cross-contamination. Non-meat ingredients are pre-mixed according to the written formulation SOP. Temperature control SOP to prevent the outgrowth of pathogens.		
C: Undeclared allergen	No	Formulation is conducted in accordance with established process schedules. Allergen Control SOP ensures ingredient statements on finished product labels match ingredient formulation. Written Good Manufacturing Practices (GMPs) prevent and minimize the likelihood of cross-contamination with allergens and chemicals.		

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
P: Foreign materials	No	Daily equipment examination and preventive maintenance SOP on equipment and conveyor to prevent foreign materials, i.e., metal, rubber, plastic from contaminating the product.		
7. Mixing				
B: *Clostridium botulinum*	No	9 CFR 417.2(b)(3) exempts establishment from having to address microbiological food safety hazards in the HACCP plan if the product is produced in accordance with the requirements in 9 CFR Part 431. Improper formulation may cause process deviation and survival of *Clostridium botulinum* spores. Written formulation SOP defined by a processing authority.[14]		
C: Undeclared allergens	No	Formulation is conducted in accordance with established process schedules. Allergen Control SOP ensures ingredient statements on finished product labels match ingredient formulation. Written Good Manufacturing Practices (GMPs) to prevent and minimize the likelihood of cross-contamination with allergens and chemicals.		
P: Metal fragments	No	Metal fragments could come from processing equipment. Daily equipment examination and preventive maintenance SOP on equipment and conveyor to prevent foreign materials, i.e., metal, rubber,		

[14] 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 parameter (FSIS Compliance Guideline HACCP Systems Validation, page 27).

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
		plastic from contaminating the product.		
8. Cleaning Cans				
B: None				
C: None				
P: Foreign materials	No	Cans are inverted and cleaned per 9 CFR 431.2		
9. Filling				
B: *Clostridium botulinum*	No	Improper fill may cause process deviation and survival of *Clostridium botulinum* spores. Fill-in weight[15] checked by inline scale monitoring SOP. Written formulation and filling procedure defined by a processing authority (9 CFR 431.3).		
C: None				
P: None				
10. Sealing				
B: Container defects causing spoilage of product due to defective	No	Routine visual and teardown examinations during the operation and seamer per 9 CFR 431.2. Reject non-conforming products in accordance with closure and teardown examinations SOP.		

[15] The process schedule developed by a processing authority determines whether the fill-in weight is a critical factor. Establishment is required to measure, control, and record the critical factors specified in the process schedule per 9 CFR 431.4.

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
seaming Formation of Staphylococcal enterotoxins	No	Daily equipment examination and preventive maintenance SOP. The maximum time lapse between closure of containers and initiation of thermal processing is controlled to be less than 2 hours per 9 CFR 431.2(f)(2).		
C: None				
P: None				
11. Thermal Processing				
B: *Clostridium botulinum*	No	Proper application of process schedule developed for the product by a processing authority (9 CFR 431.3). Operation procedures in accordance with requirements in 9 CFR part 431.		
C: None				
P: None				
12. Cooling				
B: Post-process contamination	No	Containers are cooled using potable water per 9 CFR 431.6(h) and cooling water is not reused in the retort system.		
C: None				
P: None				

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
13. Sample Incubation				
B: Spoilage of product due to process deviation or post-process deviation	No	At least one container per load[16] of product will be selected for 10 days incubation per 9 CFR 431.10(b).		
C: None				
P: None				
14. Storage				
B: Spoilage of product due to process deviation or post-process contamination	No	The lot will be on hold during the 10 days incubation period. Written SOP for the handling of abnormal containers to ensure only normal-appearing safe and stable product are released per 9 CFR 431.10(a). Written GMPs to prevent and minimize container defects due to rough handling (9 CFR 431.2(f)(1)).		
C: None				
P: None				
15. Defect Detection				
B: Spoilage of product due to container	No	Visual examination of containers to ensure only normal appearing containers are labelled and released (9 CFR 431.10(c)). Written Container Examination SOP including procedures for, and records		

[16] In this HACCP model, the establishment is using a steam-still, batch-type retort. If the establishment is using a continuous-type retort system, such as continuous rotary retorts or hydrostatic retorts, it will select at least one container per 1000 for incubation per 9 CFR 431.10(b).

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
defects or process deviation		of, container examinations and handling of abnormal containers.		
C: None				
P: None				

16. Labeling and Packaging

B: None				
C: Undeclared Allergens	No	Formulation is conducted in accordance with established process schedules (9 CFR 431.3(a)). Allergen Control SOP ensures ingredient statements on finished product labels match ingredient formulation.		
P: None				

17. Storage and Shipping

B: None				
C: None				
P: None				

18. Returned Product

B: None		Reinspection SOP implemented before accepting returned product. Person(s) or 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		

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
		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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[i] Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced articles 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.

[ii] 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, or 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).