HACCP Model for Unpasteurized Liquid Egg (Raw Non-Intact Processing Category)

The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule (PR/HACCP rule) in July 1996, mandating all USDA inspected meat and poultry establishments implement a HACCP system. Hazard Analysis and 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) required meat and poultry 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.

On October 29, 2020, the USDA published a final rule that updated the egg products inspection regulations. The USDA amended the egg products inspection regulations to require official plants that process egg products to develop and implement Sanitation Standard Operating Procedures (Sanitation SOPs) to meet other sanitation requirements consistent with USDA's meat and poultry regulations (effective date: October 29, 2021) and develop and implement HACCP Systems (effective date: October 31, 2022).

With the PR/HACCP 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.

This generic HACCP model illustrates the Raw Non-Intact processing category with an unpasteurized liquid egg product. The model's critical control points (CCPs) do not necessarily apply to all egg products 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. This model includes references for guidance on the selection of critical limits.

The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP decisionmaking 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 Egg Products Hazards and Controls Guide, the FSIS Food Safety Guideline for Egg Products, the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP Guidance webpage. Visit the State HACCP Contacts and Coordinators webpage for a list of contacts who provide technical advice, assistance, resources and conduct activities to support HACCP implementation in small and very small plants.[1]

[1] 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[2]

Product Name and Process Type: Unpasteurized Liquid Egg

(Raw Non-Intact Processing Category)

Process Type and Product Name	Raw Non-Intact Liquid Egg Product (Whole Egg, Yolk, Whites)
Important product characteristics (A_w, pH, Preservatives, etc.)	None
How it is to be used[3]	Further processed into pasteurized liquid or dried egg product.
Packaging (durability and storage conditions)	Bulk container (e.g., tanker, totes)
Storage condition and at what temperature[4]	Perishable, not shelf stable - Keep refrigerated (≤45°F)
Where it will be sold (specify intended consumers, especially at-risk populations[5])	Official egg products plants for further processing.
Labeling instructions and requirements	"Date of loading" is displayed, indicating the date the container, tanker truck, or portable tank is loaded, along with product name, the statement 'For Further Processing in an Official USDA Plant' and the producing establishment number. [6]
What special distribution controls are required?	Controls are in place to secure the product during transportation.

[2] 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.

[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 9 CFR 417.2(a)(2).

[4] Each establishment's products may have their own defined shelf life. A specific shelf life may not be applicable for intermediate products.

[5] At-risk populations include young children, the elderly and immunocompromised persons.

[6] See the FSIS Labeling Overview and Generic Label Approval guideline for information on required labeling features. Not all labeling features are required for products moving between official establishments under company control.

EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIALS[7]

Product Name and Process Type: Unpasteurized Liquid Egg (Raw Non-Intact Processing Category)

Eggs	Shell eggs
Non-Egg food ingredients	Salt, sugar
Antimicrobials[8] or processing aids	None
Packaging material	Product transported with tanker trucks or plastic portable totes
Restricted Ingredients/Allergens	Allergens - Egg
Other	None

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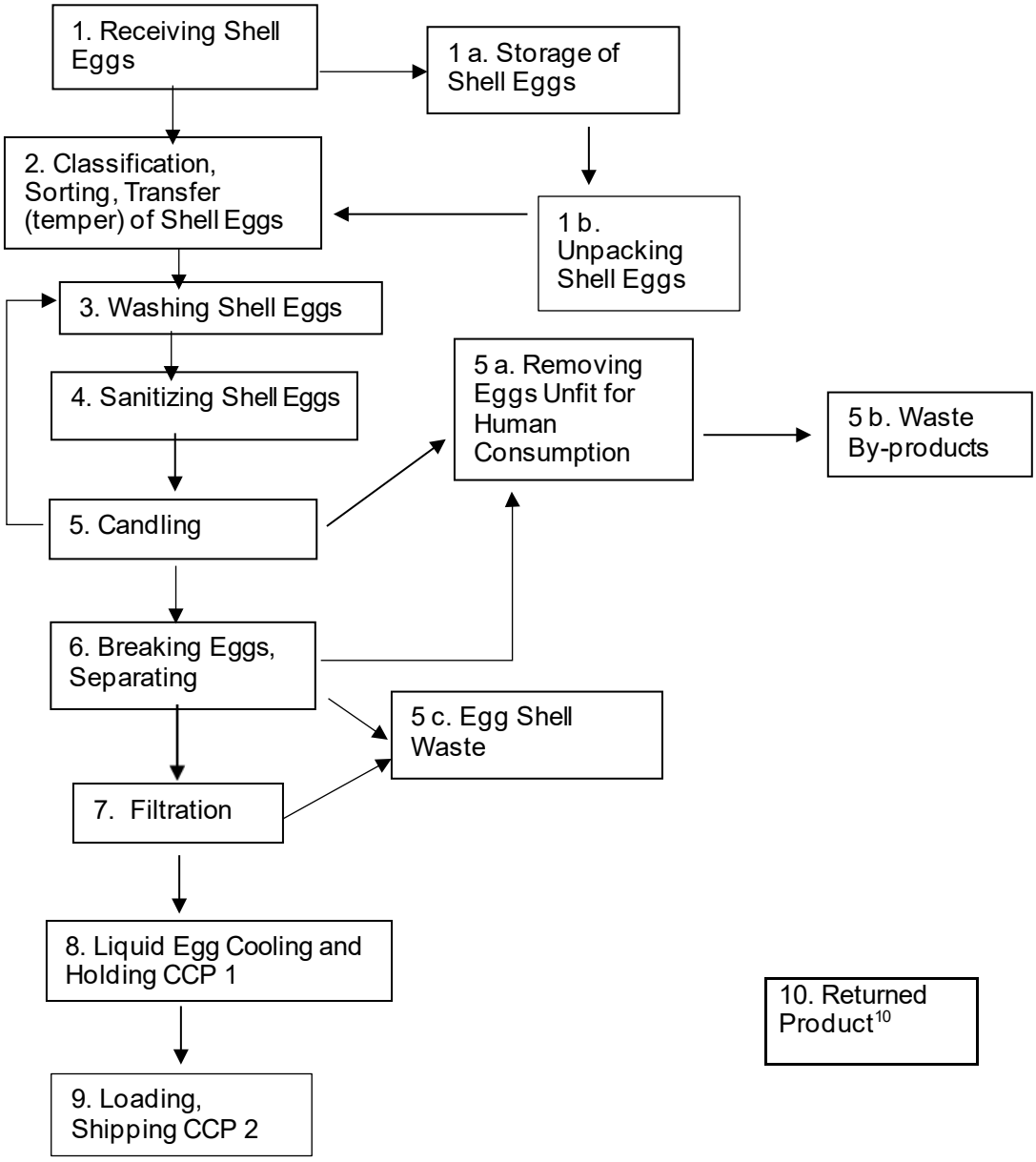
[7] List all egg, non-egg ingredients, restricted ingredients (for example, nitrites), processing aids, and packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens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

[8] 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 CHART[9]

Product Name and Process Type: Unpasteurized Liquid Egg

(Raw Non-Intact Processing Category)



[9] 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.

[10] 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 re-processed, discarded, etc.

EXAMPLE HAZARD ANALYSIS[11]

Product Name and Process Type: Unpasteurized Liquid Egg (Raw Non-Intact Processing Category)

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, (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)?**
1. Receiving Shell Eggs	B: Presence of pathogens: (e.g., *Salmonella)*	No	Pre-harvest measures, ambient temperature compliance, proper sanitation of equipment. Subsequent steps ensure final packaged unpasteurized liquid egg product is appropriately labeled and will be shipped and maintained under company control to FSIS-regulated official egg products plant for pasteurization or heat treatment.		
	C: Residues (pesticides, antibiotics)	No	Residue control program or approved supplier program.		
	P: None				
1 a. Storage	B: Presence of pathogens: (e.g.,	No	Pre-harvest measures, ambient temperature compliance, proper sanitation of equipment.		

[11] This is an example hazard analysis. Each establishment's flow chart, hazards analysis, hazards, decision-making, and support may be different. An establishment can determine what "steps" are included in the overall process if all of the hazards are considered in the hazard analysis. The FSIS Egg Products Hazards and Controls Guide (starting on page 5) describes the usual process steps for egg product processing.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
of Shell Eggs	*Salmonella)*		Subsequent steps ensure final packaged unpasteurized liquid egg product is appropriately labeled and will be shipped and maintained under company control to FSIS-regulated official egg products plant for pasteurization or heat treatment.		
	C: Residues (pesticides, antibiotics)	No	Residue control program or approved supplier program.		
	P: None				
1 b. Unpacking Shell Eggs	B: Presence of pathogens: (e.g., *Salmonella)*	No	Proper handling and employee hygiene.		
	C: None				
	P: Foreign material (plastic, wood)	No	Proper handling and employee hygiene. Foreign Material SOP.[12]		
2. Classification, Sorting, Transfer (temper) of Shell Eggs	B: Presence of pathogens: (e.g., *Salmonella)*	No	Restricted or ineligible eggs are properly segregated. Eggs with strong odors are segregated and processed separately. Soiled eggs are segregated for washing.		
	C: None				
	P: None				

[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.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
3. Washing Shell Eggs	B: Presence of pathogens: (e.g., *Salmonella)*	No	Maintain wash water temperature, monitor water quality to minimize cross contamination, monitor pH and concentration.		
	C: Washing compounds	No	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 (FCN# [insert number]).[13]		
	P: None				
4. Sanitizing Shell Eggs	B: Presence of pathogens: (e.g., *Salmonella)*	No	Maintain wash water temperature, monitor water quality to minimize cross contamination, monitor pH and concentration.		
	C: Washing compounds	No	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 (FCN# [insert number]).		
	P: None				
5. Candling	B: Presence of pathogens: (e.g., *Salmonella)*	No	Proper segregation and sorting of ineligible eggs. Soiled eggs are segregated for resorting and rewashing. Proper cleaning of		

[13] 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 egg products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) 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.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
			equipment and effective Sanitation SOP's.		
	C: None				
	P: None				
5 a. Removing Eggs Unfit for Human Consumption	B: Presence of pathogens: (e.g., *Salmonella)*	No	Proper disposal, denaturing, and labeling and segregation of inedible product.		
	C: None				
	P: None				
5 b. Waste By-products	B: Presence of pathogens: e.g., *Salmonella)*	No	Proper disposal, segregation, and labeling of waste products.		
	C: None				
	P: None				
5 c. Egg Shell Waste	B. Presence of pathogens: (e.g., *Salmonella)* (exterior of egg)	No	Proper disposal, segregation, and labeling.		
	C: None				
	P: None				
6. Breaking Eggs, Separating	B: Presence and outgrowth of Salmonella	No	Sanitation SOPs address proper cleaning and sanitation of rooms and equipment. Proper hygienic practices in place. Adequate air movement to ensure organoleptic examination for product wholesomeness. Use of sanitizers, frequency of equipment cleaning, and control of room temperature adequate to inhibit		

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
			growth of pathogenic bacteria on food contact surfaces. Proper candling to prevent ineligible eggs from entering breaking room; line speed adjusted to maintain process control.		
	C: Cleaning chemicals and sanitizers	No	Sanitation SOPs address proper cleaning, sanitation, and use of cleaning chemicals/compounds.		
	P: Foreign material (eggshell fragments)	No	Maintain liquid egg pumps and shell egg filters for effective performance. Adjustments to breaking equipment to minimize shell fragmentation. Lack of historical findings from visual inspection during egg processing.[14]		
7. Filtration	B: Outgrowth of pathogens (e.g., *Salmonella*)	No	Proper sanitation and maintenance of pipes, liquid egg pumps, and shell egg filters for effective removal of fragments.		
	C: None				
	P: Foreign material (eggshell fragments)	No	Proper sanitation and maintenance of equipment.		
8. Liquid Egg Cooling and	B: Outgrowth of pathogens (e.g.,	Yes	Improper cooling of product may lead to pathogen growth. Cooling occurs in a period of time which precludes pathogen outgrowth.	Monitor time and temperature to ensure proper cooling of product	Yes CCP 1

[14] 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 Egg Products Hazards and Controls Guide which states "liquid egg pumps and shell filters working properly" is a frequently used control for foreign material hazards in egg breaking.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
Holding CCP 1	*Salmonella*)			is attained. CCP #1 – Cold Storage/Silo Temperature Log.[15] Maintain product at Safe Harbor holding time and temperature combination to minimize pathogen outgrowth (Table 2 – Cooling Operations within FSIS Food Safety Guideline for Egg Products, 9/9/2020)	
	C: None				
	P: None				
9. Loading, Shipping CCP 2	B: Outgrowth of pathogens (e.g., *Salmonella*)	Yes	Improper product temperature during loading or transport may lead to pathogen growth.	Monitor temperature upon completion of loading product prior to shipping. CCP #2 Bulk Container Shipping Temperature Log. Maintain product at Safe Harbor holding time and	Yes CCP 2

[15] 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 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 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).

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
				temperature combination to minimize pathogen outgrowth (Table 2 – Cooling Operations within FSIS Food Safety Guideline for Egg Products, 9/9/2020)	
	C: None				
	P: None				
10. Returned Products	B. Outgrowth of pathogens (e.g., *Salmonella*)	No	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 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 Unpasteurized Liquid Egg (Raw Non-Intact Processing Category)									
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 Liquid Egg Cooling and Holding	B: Outgrowth of pathogens, *Salmonella*	≤45°F for product held less than 8 hours.* ≤40°F for product held more than 8 hours.* *Product temperature must be met within two hours of breaking	Product temperature is measured via temperature gauge on silo continuous monitoring log. Observations documented.	Read thermometer and verify on continuous monitoring log sheet. Record results on Silo Storage Temperature CCP Form.	Every cold storage unit (each silo container)	Designee	If a deviation from the critical limit occurs, the supervisor will: 1. Hold product in cold storage unit until appropriate disposition taken (no product injurious to health will be shipped into 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 thermometers (per manufacturer's instructions).	Silo Storage Temperature Form Verification Form Corrective Action Form Pre-Shipment Form Thermometer Calibration Form

EXAMPLE HACCP PLAN Unpasteurized Liquid Egg (Raw Non-Intact Processing Category)									
Critical Control Point (CCP)	**Significant Hazard(s)**	**Critical Limits for Each Control Measure**	**Monitoring Procedures**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
CCP2 Loading, Shipping	B: Outgrowth of pathogens, *Salmonella*	Internal product temperature is ≤45°F (for product held less than 8 hours) ≤40°F (for product held more than 8 hours) at packaging	Product temperature is measured at packaging prior to shipping.	Measure product temperature with handheld probe thermometer.	Each bulk container of unpasteurized liquid egg product intended for further processing into edible product (e.g., tanker).	Designee	If a deviation from the critical limit occurs, the supervisor will: 1. Hold product in cold storage unit until appropriate disposition taken (no product injurious to health will be shipped into 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 thermometers (per manufacturer's instructions).	Bulk Container Shipping Temperature Log Verification Form Corrective Action Form Pre-Shipment 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 FSIS Egg Products 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 document, 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 (NRLTO) because the implementation of a prerequisite program (e.g., Sanitation Standard Operating Procedure (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).