HACCP Model for Pasteurized Liquid Egg (Fully Cooked – Not Shelf Stable 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) require 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 to require establishments 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, the Food Safety and Inspection Service (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 Fully Cooked – Not Shelf Stable processing category with a pasteurized 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 and meet 9 CFR 417 regulations. 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 decision making 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.

Step 3a: EXAMPLE PRODUCT DESCRIPTION[2]

Process/Product Name(s)/HACCP Category:

Process/Product Type Name	Not Shelf Stable Pasteurized Liquid Egg Products (includes pasteurized liquid whole egg, pasteurized liquid egg white, pasteurized liquid egg yolk, pasteurized scrambled egg mix products)
Important product characteristics	None
How it is to be used[3]	Ingredient for further processing, Ready to Eat (RTE) product at restaurants and institutions, retail RTE products
Packaging (durability and storage conditions)	Bulk containers (e.g., tanker), wax coated totes, plastic lined totes, plastic pouches, cartons, boxes, etc.
Storage condition and at what temperature[4]	Perishable – keep refrigerated (≤ 45°F)
Where it will be sold (specify intended consumers, especially at-risk populations[5])	Retail, Restaurants, Institutions, Commercial outlets
Labeling instructions and requirements	Product name, inspection legend and establishment number, handling statement, net weight statement, ingredients statement, allergen statement, address, and nutritional facts[6]
What special distribution controls are required?	Refrigerated or frozen distribution

[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.

Step 3b: EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIALS[6]

Process/Product Name(s)/HACCP Category:

Eggs/Egg Products	Whole egg, egg yolk, egg whites
Non-egg food ingredients[7]	Salt, sugar, citric acid, other food-grade ingredients Generally Recognized as Safe (GRAS)
Antimicrobial Interventions	N/A
Packaging Material	Wax coated totes, boxes, cartons, plastic pouches, bulk container (e.g., tanker)
Restricted Ingredients/Allergens	N/A
Other	

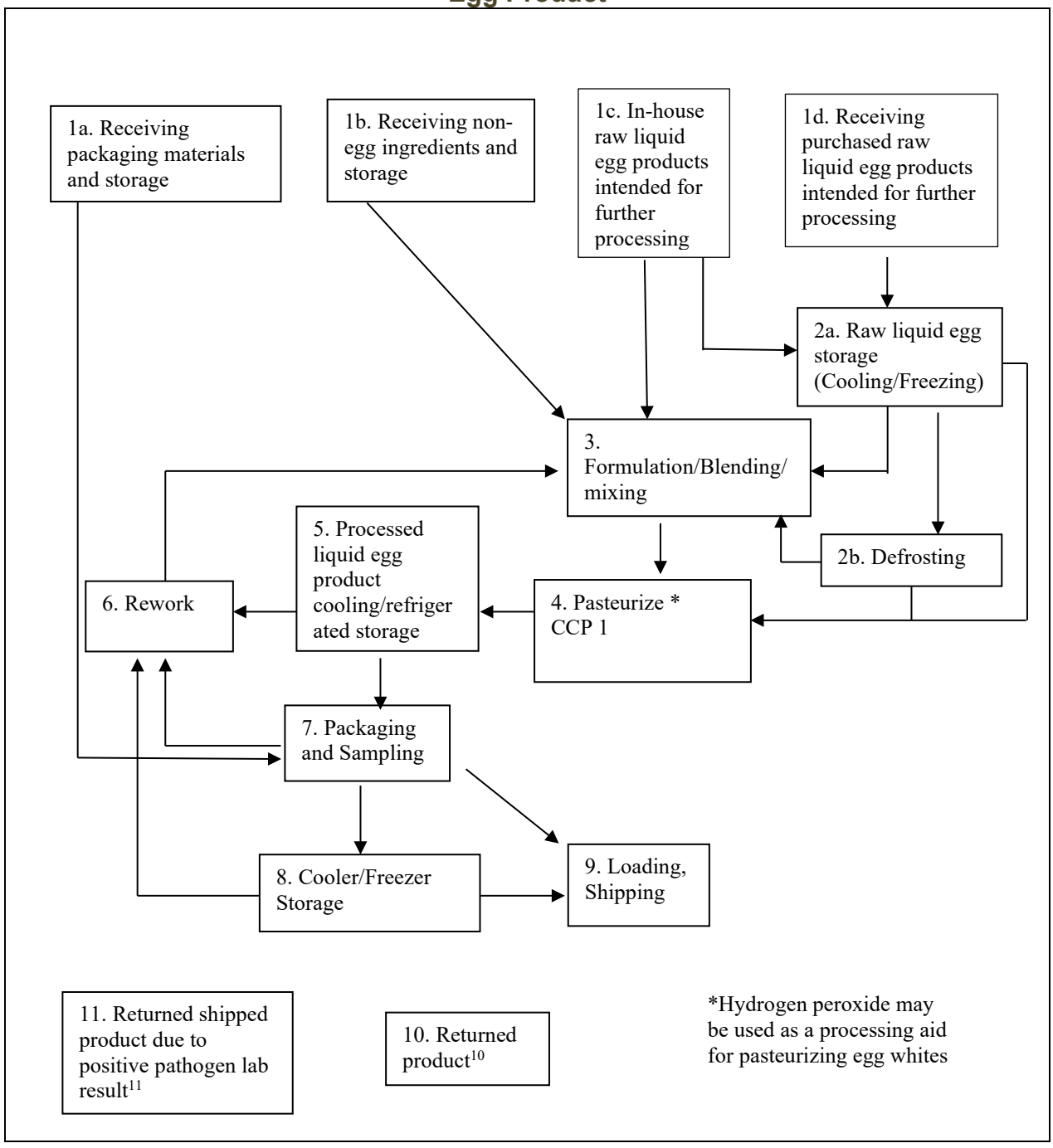
DATE: _____ APPROVED BY: _____

[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 the Production of Meat, Poultry, and Egg Products* for the list of suitable ingredients.

Step 4: EXAMPLE PROCESS FLOW CHART[8]

Process/Product Name(s)/HACCP Category: Fully Cooked-Not Shelf Stable Pasteurized Egg Product



[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 discarded or reintroduced at a point in the process for reprocessing and undergo lethality.

[11] Returned shipped product due to positive pathogen lab result may re-enter the production system at different process steps depending on the establishment's evaluation of any sanitation, misbranding, or food safety hazards related to that finding. Returned product may be discarded or reintroduced at a point in the process for reprocessing and undergo lethality.

Principle 1: HAZARD ANALYSIS[12]

Process/Product Name(s)/HACCP 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)?**
1a. Packaging Materials Receiving and Storage	Biological: Contamination with pathogens (e.g., *Salmonella*)	No	Procedure to protect packaging materials from pests and environmental contamination.		
	Chemical: Non-food grade materials	No	Letter of Guarantee (LOG) for packaging materials (9 CFR 590.435) and materials are safely stored.		
	Physical: Foreign material (e.g., metal, plastic)	No	Foreign material SOP with visual evaluation for foreign material. Protecting packaging		

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

			materials from environment.		
1b. Non-egg Ingredients Receiving and Storage	B: Contamination with pathogens (e.g., *Salmonella*)	No	Procedure to protect non-egg materials from pests and environmental contamination that ensures product integrity and sanitary conditions are maintained.		
	C: Allergens	No	LOG, approved supplier program, proper storage/handling/separate equipment/tools to prevent cross-contamination of allergen-free products. Allergen properly identified in ingredients statement on finished product label.		
	P: Foreign material (e.g., metal, plastic)	No	Foreign material SOP with visual evaluation for foreign material.		
1c. In-house Raw Liquid Egg Products Intended for Further Processing	B: Contamination/outgrowth of pathogens (e.g., *Salmonella*)	Yes	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)	Product subject to pasteurization at a later step to achieve lethality. Controlled at CCP 1.	No
	C: Residues, pesticides, cleaners, antibiotics	No	Residue control program or approved supplier program under Raw Non-Intact HACCP plan. Sanitation SOPs address proper		

			cleaning, sanitation, and use of cleaning chemicals/compounds.		
	P: Foreign materials (e.g., 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.		
1d. Receiving Purchased Raw Liquid Egg Products Intended for Further Processing	B: Contamination/outgrowth of pathogens (e.g., *Salmonella*)	Yes	Improper product temperature during transport may lead to pathogen growth. Maintain product at Safe Harbor holding time and temperature combination to minimize pathogen growth (Table 2 – Cooling Operations within FSIS Food Safety Guideline for Egg Products, 9/9/2020). Product properly handled prior to acceptance (e.g., LOG, product temperature records, bill of lading).	Product subject to pasteurization at a later step to achieve lethality. Controlled at CCP 1.	No
	C: Residues, cleaners, pesticides, antibiotics	No	Prerequisite Supplier Residue control program, letters of guarantee that ingredients are free of		

			hazards.		
	P: Foreign materials (e.g., eggshell fragments)	No	Supplier controls, letters of guarantee that materials are free of hazards when received.		
2a. Raw Liquid Egg Product Storage (Cooling/Freezing)	B: Contamination/outgrowth of pathogens (e.g., *Salmonella*)	Yes	Maintain product at Safe Harbor holding time and temperature combination to minimize pathogen growth (Table 2 – Cooling/Freezing Operations within FSIS Food Safety Guideline for Egg Products, 9/9/2020)	Product subject to pasteurization at a later step to achieve lethality. Controlled at CCP 1.	No
	C: None				
	P: None				
2b. Defrosting	B: Outgrowth of pathogens (e.g., *Salmonella*)	No	Sanitation SOPs or address proper cleaning and sanitation of rooms and equipment. Proper hygienic practices in place. Adequate air movement to ensure organoleptic examination for product wholesomeness. Sanitation SOPs, Good Manufacturing Practices (GMPs), SOPs address proper tempering procedures to prevent outgrowth and not cause the adulteration of product prior to processing or drying.		
	C: None				

	P: Foreign material (e.g., metal)	No	Proper sanitation and maintenance of equipment.		
3. Formulation/Blending/Mixing	B: Contamination/outgrowth of pathogens (e.g., *Salmonella*)	No	Maintain product at time/temperatures that minimize pathogen growth. Maintaining product at Safe Harbor holding time and temperature combination (specify combination) to minimize pathogen growth (Table 2 – Cooling/Freezing Operations within FSIS Food Safety Guideline for Egg Products, 9/9/2020). Sanitation SOPs address proper cleaning and sanitation of room and equipment. Ingredients are acceptable under conditions of use (e.g., LOG). GMPs and proper processing procedures ensure proper identification, storage, and weighing of ingredients.		
	C: Cross-contamination with allergens	No	Allergens properly identified in formulation, so accurate ingredients statement on		

			finished product label. Sanitation SOPs address proper cleaning and sanitation of room and equipment. Products containing allergens are processed and stored separately from allergen-free products. Written Allergen Program to monitor allergens, labels, and prevent cross-contamination.		
	P: None				
4. Pasteurization	B. Pathogens (e.g., *Salmonella, Listeria monocytogenes* (*Lm*))	Yes	Improper pasteurization could lead to survival of *Salmonella* or other pathogens. Salted or sugared egg products may require higher pasteurization times and temperatures.	Monitor time and temperature to ensure proper pasteurization of product is attained. CCP 1 Pasteurization Temperature Log. Maintain product at Safe Harbor holding time and temperature combination (specify combination) to achieve required lethality. Example: Pasteurize at 142°F for 4.46 minutes (see Appendix III: Pasteurization Time and Temperature Tables	Yes CCP 1

				within FSIS Food Safety Guideline for Egg Products, 9/9/2020).[13]	
	C: Chemicals, sanitizers, cross-contamination with allergens	No	Sanitation SOPs address proper cleaning and sanitation of room, equipment, and use of cleaning chemicals and compounds. Written Allergen Program to monitor allergens, labels, and product flow to prevent cross-contamination.		
	P: Foreign material, plastic, rubber, metal (e.g., gaskets)	No	Pre-operational inspections, implementing proper sanitation and maintenance of equipment (Sanitation SOPs).		
5. Processed Liquid Egg Product Cooling/Refrigerated Storage	B: Outgrowth of pathogens (e.g., *Salmonella*)	No	Improper product handling and subsequent temperature abuse during storage may lead to pathogen growth. Maintain product at Safe Harbor holding time and		

[13] 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 must 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 parameters (FSIS Compliance Guideline HACCP Systems Validation, page 27).

			temperature combination to minimize pathogen growth (Table 2 – Cooling/Freezing Operations within FSIS Food Safety Guidelines for Egg Products).		
	C: Allergens	No	Proper sanitation and maintenance of equipment. Written Allergen Program to monitor allergens, labels, and prevent cross-contamination.		
	P: None				
6. Rework	B: Outgrowth of pathogens (e.g., *Salmonella*)	No	Reinspection SOP implemented before reworking product. Sanitation SOPs, GMPs, SOPs address proper storage conditions, product handling, ensure product is held under appropriate temperatures to prevent pathogen growth and not cause the adulteration of product.		
	C: Allergens	No	Written Allergen Program to monitor allergens, labels, and prevent cross-contamination.		
	P: None				
7. Packaging and	B: Outgrowth of pathogens (e.g.,	No	Proper sanitation of packaging equipment and		

Sampling	*Salmonella*)		implementation of Sanitation SOPs. Good employee hygiene and product handling procedures. Maintenance of packaging equipment and proper sealing of finished product containers. Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is packaged at temperatures that prevent bacterial growth. Product Lab Sampling SOP for pathogens to ensure compliance with 9 CFR 590.580 requirements.		
	C: Allergens	No	Written Allergen Program to monitor allergens, labels, and prevent cross-contamination.		
	P: None				
8. Cooler/Freezer Storage	B: Outgrowth of pathogens (e.g., *Salmonella*)	No	Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Design of freezing rooms and		

			implement proper storage capable of solidly freezing or reducing to a temperature of 10 °F or lower, all liquid egg products.		
	C: None				
	P: None				
9. Loading, Shipping	B. Outgrowth of pathogens (e.g., *Salmonella*)	No	Improper product temperature during loading or transport may lead to microbial growth. Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is packaged, loaded, and shipped at temperatures that prevent bacterial growth. Written Final Product SOP for procedures to examine outgoing packaged product. Includes verifying the sanitary condition of tanker, truck, functioning refrigeration unit, and package integrity.		
	C: None				
	P: None				
10. Returned Product	B: None	No	Reinspection SOP implemented before accepting returned product.		

			Persons 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, including open tankers, 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				
11. Returned Shipped Product Due to Positive Pathogen Lab Result	B: Pathogens (e.g., *Salmonella, Lm*)	Yes	Reinspection SOP implemented before accepting returned product. Persons 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, including open tankers, are not accepted.	Product subject to pasteurization to achieve lethality. Controlled at CCP 1.	No

			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				

DATE: _____ APPROVED BY: _____

Example HACCP PLAN

Process/Product Name(s)/HACCP Category:

HACCP Plan									
CCP	Significant Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
CCP1 Pasteurization	B: Pathogens (e.g., *Salmonella, Lm*)	Pasteurize plain whole egg at 142°F for 4.46 minutes to align with the Safe Harbor holding time and temperature combination to minimize pathogen outgrowth dependent on product. (See Appendix III – Pasteurization Time/Temperature within FSIS Food Safety Guideline for Egg Products).	Product temperature and holding time/flow rate is recorded via pasteurization recording chart on continuous monitoring log.	An employee will review records hourly from pasteurization recording chart on continuous monitoring log sheet for each pasteurization run. Record results on Pasteurization Temperature CCP Form.	Continuous for every pasteurization run.	Designee	If a deviation from a critical limit occurs, the supervisor will: 1. Hold product until appropriate disposition is 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(a)).	Once per week, a supervisor will directly observe the monitoring activity, conduct the records review. Once per quarter, a supervisor or designee calibrates pasteurization thermometers per manufacturer's instructions (e.g., quarterly). Once daily, a supervisor or designee conducts manual flow rate checks (e.g., calculating holding time)	Pasteurization Temperature CCP Form Verification Form Thermometer Calibration Log Corrective Action Form Pre-Shipment Form

[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 reasonably 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 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 (SSOP), 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).