United States Department of Agriculture
Food Safety and Inspection Service

Egg Products FSA Tool VS1 – DO NOT IMPLEMENT THIS TOOL UNTIL OCTOBER 31, 2022

This FSA tool is for plants that produce **EGG PRODUCTS** that are considered to fall under the following HACCP processing categories:

RAW, NON-INTACT
HEAT TREATED, SHELF STABLE
FULLY COOKED, NOT SHELF STABLE

The FSA tool contains the following main sections:

- HACCP (E1-E22)
- Shell Eggs (E23)
- Lethality Treatments (E24)
- Stabilization and Other Enzyme-Modified Products (E25–E26)
- Packaging (E27 – E29)
- Non-Egg Ingredients (E30)
- Sampling (E31-E45)
- Egg Products Tool Summary (E46)

In responding to questions in this tool, the EIAO is to focus on documenting any vulnerability and noncompliance, not making positive editorial findings.

A vulnerability is an identified weakness in the establishment's process that does not rise to the level of noncompliance but that could impact the establishment's ability to produce safe and wholesome meat, poultry, or egg products in accordance with FSIS statutory and regulatory requirements (i.e., the Acts and 9 CFR).

References:

1. FSIS Directive 5100.1, *Food Safety Assessment (FSA) Methodology*
2. FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*
3. FSIS Directive 5000.2, *Review of Establishment Testing Data by Inspection Personnel*;
4. FSIS Food Safety Guideline for Egg Products
5. Egg Products Hazards and Control Guide

For all questions in this FSA tool, please note that some FSA tool questions are not applicable questions for the processes being assessed and will only appear based on the answer responses provided. EIAOs are to copy and paste information into a text field if that answer was provided in a previous text field question within the tool, or another tool.

HACCP (E1-E22)

This section is designed to assess the establishment's HACCP system. The HACCP system includes hazard analysis, any supporting documentation, including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records.

The EIAO is to document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool.

E1 Has the establishment considered the relevant food safety hazards throughout the HACCP system? Briefly describe any noncompliances and vulnerabilities (limit 4,000 characters).

☐Yes
☐No

E2 Does the HACCP system include a prerequisite program or supporting documentation for any hazard that the establishment determines is "not reasonably likely to occur" (NRLTO) (9 CFR 417.5(a)(1))? Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 4,000 characters).

☐Yes
☐No

E3 Has the establishment properly developed and implemented a written HACCP plan to address each food safety hazard determined to be "reasonably likely to occur" (RLTO) (9 CFR 417.5(a)(2))? Describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 4,000 characters).

☐Yes

☐No

E4 Does the establishment address chemical residues in its hazard analysis?

☐Yes

☐No

E5 Did a significant development occur in the last 60 days that affects the hazard analysis such as major process or product change, categorization change, or unforeseen hazard?

NOTE: Answer this question based on your review of the selected records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1.

☐Yes – If selected, answer the following question(s)

☐No

E5a Briefly describe how the hazard analysis and/or HACCP plan was reassessed in response to the change. Briefly describe any vulnerability and noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 5,000 characters).

E6 Does the establishment apply antimicrobial treatments or additives that support decisions in the hazard analysis (e.g., CCPs, pre-requisite programs, or other programs)?

☐Yes – If selected, answer the following question(s)

☐No

E6a Does the supporting documentation show the antimicrobial treatments or additives are safe and suitable (FSIS Directive 7120.1) for their intended use, including cleaning shell eggs (9 CFR 590.516), facilitating the lethality treatment, stabilization additives, or the enzyme-modification process (limit 4,000 characters)? Briefly describe any vulnerability and noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.

☐Yes

☐No

E7 Reprocessing: Does the establishment have reprocessing or reconditioning procedures in place and implemented (if observed) that prevent cross contamination of product?

☐Yes – If selected, answer the following question(s)

☐No

E7a Briefly describe the establishment's procedures for reprocessing or reconditioning. Include any vulnerability and any noncompliance with how the establishment's food safety system addressed reprocessing (limit 20,000 characters).

E8 Allergens: Does the establishment produce products that contain any of the "Big 9" allergens or other ingredients of public health concern? Big 9 allergens include: Wheat, Crustacean shellfish (e.g., crab, lobster, shrimp), Eggs, Fish, Peanuts, Milk, Tree nuts (e.g., almonds, pecans, walnuts), Soy, and Sesame.

☐Yes – If selected, answer the following question(s)

☐No

E8a Briefly describe any vulnerability and any noncompliance with how the establishment's food safety system addressed the identification, prevention and control, and declaration of allergens/ingredients. If applicable, address if the establishment has had a recall for undeclared allergens/ingredients in the past 6 months, and the corrective actions taken (limit 20,000 characters).

HACCP System Validation

This section is designed to assess the establishment's validation of its HACCP system.

E9 Does the establishment maintain adequate scientific or technical support that relates to the establishment's actual process, product, and hazard identified in the hazard analysis (1st part of validation – design)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No, support does not relate

☐No, establishment does not have support

E10 Does the establishment's scientific support demonstrate the process meets the performance standards or targets (i.e., pathogen reduction level) identified in the hazard analysis for each food safety system? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No, the support does not demonstrate that it meets the performance standards or targets

☐No, the establishment does not identify performance standards or targets

E11 Does the establishment receive shell eggs diverted for processing under FDA's Prevention of *Salmonella* Enteritidis in Shell Eggs?

For additional information, review FDA Guidance for Industry *Prevention of* Salmonella *Enteritidis in Shell Eggs During Production, Transportation, and Storage*

☐Yes – If selected, answer the following question(s)

☐No

E11a Does the establishment's scientific support demonstrate the products receive appropriate pasteurization to achieve a 5-log reduction of *Salmonella* Enteritidis (21 CFR 118.6(f))?

☐Yes

☐No, the support does not demonstrate that it meets the targets

☐No, the establishment does not identify targets

☐N/A, the establishment is a breaking establishment only and ships unpasteurized egg products under seal to an FSIS-regulated establishment for further processing

E12 Does the establishment incorporate the critical operating parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No

E13 Does the establishment maintain in-plant validation data demonstrating the control measures, as written in the HACCP system, achieve the intended food safety outcome (2nd part – execution)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No

E14 Briefly describe any vulnerability or noncompliance finding with the establishment's HACCP system (i.e., HACCP plan, prerequisite program, or another program) validation that affect the establishment's ability to produce safe, wholesome, and unadulterated food not described above (limit 20,000 characters).

HACCP Monitoring, Verification, and Corrective Actions

This section is designed to assess the establishment's monitoring, verification, and corrective action procedures of those CCPs, prerequisite programs, or other programs.

E15 Does the establishment conduct the monitoring and verification (procedure and frequency) as written in its HACCP program (i.e., HACCP plan, prerequisite program, or another program)? Noncompliances and vulnerabilities are to be described in E17.

☐Yes

☐No, the establishment does not conduct monitoring and verification as written

☐No, the monitoring and verification are not written in its HACCP program

E16 Does the establishment maintain support for the selected monitoring and verification procedures and frequencies? Noncompliances and vulnerabilities are to be described in E17.

☐Yes

☐No

E17 Briefly describe any vulnerability and noncompliance finding with the establishment's monitoring and verification procedures and frequencies, including the support for its monitoring and verification procedures and frequencies in its program (i.e., HACCP plan, prerequisite program, or another program) (limit 20,000 characters).

E18 Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or another program)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No

E19 Has the establishment taken corrective actions as appropriate in response to deficiencies as required by 9 CFR 417.3 over the last 60 days?

*If yes, note whether all applicable parts of 9 CFR 417.3 were met. If no, note why the establishment did not take appropriate corrective actions (limit 4,000 characters).

☐Yes

☐No

☐N/A – The establishment has not had any deficiencies over the last 60 days.

E20 Do the records include the actual times, temperatures, or other quantifiable values, and include the product code(s), product name or identity, or production lot? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No

E21 Based on your review of records and observation of operations, briefly describe any vulnerability and noncompliance findings not described in previous questions with the implementation of monitoring and verification procedures that affect the establishment's ability to produce safe, wholesome, and unadulterated products. Note if the records accurately reflect the process (limit 20,000 characters).

E22 HACCP Summary: Describe any HACCP design findings not described in the previous questions and how your findings impact the establishment's food safety system (limit 20,000 characters).

Shell Eggs (E23)

E23 Does the establishment receive shell eggs for breaking?

☐Yes – If selected, answer the following question(s)

☐No

E23a What is the source of shell eggs used in the breaking process?

☐On-site houses (e.g., inline)

☐Off-site – contract farms

☐Off-site – open market, broker, etc.

☐Other – Describe (limit 200 characters).

E23b Does the establishment have effective procedures to ensure the shell eggs presented for breaking are of edible interior quality and free of adhering dirt and foreign material (9 CFR 590.510(c))? Noncompliances and vulnerabilities are to be described in E23g.

☐Yes

☐No

E23c When an inedible egg is broken, does the establishment properly remove the inedible egg, and clean and sanitize all affected surfaces prior to reuse (automated cup washer, tray manual sprayer, etc.)? Noncompliances and vulnerabilities are to be described in E23g.

☐Yes

☐No

E23d Does the establishment have effective procedures to remove blood and meat spots, shell particles, and other foreign materials from the raw liquid egg product (9 CFR 590.510 (c))? Noncompliances and vulnerabilities are to be described in E23g.

☐Yes

☐No

E23e Does the establishment ensure that all unpasteurized and/or *Salmonella* positive egg products shipments are sent only to other official establishments or plants (9 CFR 590.504(d)(2))? Note: The EPIA requires unpasteurized or *Salmonella* positive egg products to be sent to only FSIS-regulated establishments. Noncompliances and vulnerabilities are to be described in E23g.

☐Yes

☐No

☐N/A, establishment does not ship unpasteurized and/or *Salmonella*-positive egg products

E23f Has the establishment experienced any breaches in control over the past 60 days for product found to have a violative residue or a positive microbiological sampling result? Establishments are required to maintain control over product if it is being sampled for pathogens per 9 CFR 590.504(d)(2). Establishments are encouraged but not required to hold product for FSIS residue testing. Noncompliances and vulnerabilities are to be described in E23g.

☐Yes

☐No

E23g Briefly describe any vulnerability and any noncompliance concerning the establishment's ability to present shell eggs for breaking that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

Lethality Treatments (E24)

This section is limited in its focus to just the unique aspects of egg product lethality treatments. While most egg products are subjected to heat as a form of lethality (pasteurization in holding tubes, heat treatment of dried egg whites), the EIAO is to be aware that establishments may elect to use other forms of lethality, such as high-pressure processing, irradiation, etc.

E24 Does the plant conduct lethality treatments of egg products?

☐Yes – If selected, answer the following question(s)

☐No

E24a What form of lethality treatment is used?

☐Flow Pasteurization

☐Batch Pasteurization

☐Heat Treatment of dried egg whites

☐High-Pressure Processing

☐Irradiation

☐Other – Describe (limit 200 characters)

E24b Are controls and procedures in place to ensure all product receives adequate lethality treatment (automatic flow diversion valves; temperature recording devices; support for monitoring temperature methods and locations for dried egg whites. etc.)? Noncompliances and vulnerabilities are to be described in E24c.

☐Yes

☐No

E24c Briefly describe any vulnerability and any noncompliance concerning the establishment's HACCP lethality treatment that can affect the establishment's ability to produce safe, wholesome, and unadulterated product, if not previously discussed (limit 20,000 characters).

Stabilization and Other Enzyme-Modified Products (E25–E26)

This section is designed to assess the establishment's stabilization and other enzyme-modification processes, such as emulsification. Stabilization is the process of removing sugar from egg products.

E25 Does the plant stabilize liquid egg products?

☐Yes – If selected, answer the following question(s)

☐No

E25a What method is used to achieve a stabilized egg product (21 CFR 160.105(b); 21 CFR 160.145(b); or 21 CFR 160.185(b))?

☐Enzyme Procedure

☐Controlled Yeast Fermentation

☐Bacterial Procedures

☐Other – Describe (limit 200 characters)

E25b Does the establishment have effective controls to prevent microbial growth during the stabilization process? Noncompliances and vulnerabilities are to be described in E25c.

☐Yes

☐No

E25c Briefly describe the stabilization process and any vulnerability and any noncompliance concerning the establishment's stabilization process, limits selected, the associated monitoring records, and any corrective actions taken over the past 60 days that can affect the plant's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

E26 Does the establishment conduct enzyme-modification processes other than for stabilization (i.e., emulsification)?

☐Yes – If selected, answer the following question(s)

☐No

E26a Does the establishment have support for the enzyme-modification process, to include support that the enzyme-modification process addresses the cumulative growth of spore-formers (e.g., *Bacillus cereus, Clostridium botulinum*)? Noncompliances and vulnerabilities are to be addressed in E26b.

☐Yes

☐No

E26b Briefly describe the enzyme-modification process and any vulnerability and any noncompliance concerning the enzyme-modified processes, limits selected, the associated monitoring records, and any corrective actions taken over the past 60 days (limit 20,000 characters).

Packaging (E27 – E29)

E27 Does the establishment have effective controls to prevent microbial contamination and foreign material in the pasteurized egg product? Noncompliances and vulnerabilities are to be described in E29.

☐Yes

☐No

☐N/A, the establishment is a breaking establishment only and ships unpasteurized egg products under seal to an FSIS-regulated establishment for further processing

E28 For breaking only establishments, does the establishment appropriately label all unpasteurized egg products to be shipped to a FSIS-regulated establishment for further processing? Noncompliances and vulnerabilities are to be described in E29.

☐Yes

☐No

☐N/A, the establishment is not a breaking only establishment

E29 Briefly describe any vulnerability and any noncompliance concerning the packaging and the potential for cross contamination (limit 20,000 characters).

NOTE: Egg products are not subject to 9 CFR 430 and are not required to implement any of the alternatives listed in the *Listeria* Rule.

Non-Egg Ingredients (E30)

E30 Does the establishment add non-egg ingredients (e.g., binders, color agents, anti-caking agents, etc.) to any egg products? This does not include fortification agents, such as vitamins and minerals.

☐Yes – If selected, answer the following question(s)

☐No

E30a Does the establishment ensure non-egg ingredients are safe and suitable and intended for that use (FSIS Directive 7120.1)?

☐Yes

☐No

E30b Briefly describe the non-egg ingredients and any vulnerability and any noncompliance with the addition of non-egg ingredients (limit 20,000 characters).

Sampling (E31-E45)

This section is designed to assess whether the plant's sampling and testing programs that are part of the plant's HACCP system (e.g., as ongoing verification for a CCP or prerequisite program), are designed appropriately and performed under validated conditions, and that the plant reacts appropriately to sampling results.

As instructed in FSIS Directive 5100.1, the EIAO is to:

- Directly observe the plant collecting samples according to its supporting documentation if the plant conducts sampling during the FSA;
- Review plant sampling results from the previous 60 days;
- Document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool; and
- Review the Foodborne Pathogen Test Kits Validated by Independent Organizations database to determine whether the method used by the plant is fit for purpose and performed under validated conditions.

E31 Does the plant conduct sampling and testing for *Salmonella* (9 CFR 590.580)?

☐Yes

☐No

E32 Does the plant conduct sampling and testing of product for other organisms, such as *Listeria* or indicator organisms (e.g., Aerobic Plate Count (APC) or Aerobic Count (AC), Enterobacteriaceae (EB), Pseudomonas)?

☐Yes

☐No

E33 Does the plant conduct sampling and testing for residues?

☐Yes

☐No

E34 Does the establishment retain control of the product, pending residue test results (FSIS testing or establishment testing)?

Note: It is encouraged for establishments to maintain control over the product, but it is not required.

☐Yes

☐No

E35 Does the establishment maintain adequate support for the sample collection method (sampling frequency, sampling method, sampling portion, aseptic technique, etc.)? Noncompliances and vulnerabilities are to be described in E41.

☐Yes

☐No

E36 Does the establishment maintain adequate support for the testing method (test portion, fit for intended use, validation, etc.)? Noncompliances and vulnerabilities are to be described in E41.

☐Yes

☐No

E37 Do the establishment employees perform the sampling as described in the establishment's sampling protocol (aseptic technique, sample size and type, lab methods)? Noncompliances and vulnerabilities are to be described in E41.

☐Yes

☐No

☐N/A, the establishment did not conduct sampling during the FSA

E38 Has the plant had any *Salmonella* positive tests (FSIS or plant testing) in the previous 60 days? Noncompliances and vulnerabilities are to be described in E44.

☐Yes

☐No

E39 Has the plant had any *Listeria* positive tests (FSIS or plant testing) in the previous 60 days? Noncompliances and vulnerabilities are to be described in E44.

☐Yes

☐No

E40 Does the establishment sample equipment or processing areas for indicator organisms?

☐Yes – If selected, answer the following question(s)

☐No

E40a Briefly describe what equipment or processing areas the establishment samples. Describe trends, corrective actions, noncompliances, and vulnerabilities (limit 20,000 characters).

E41 Briefly describe the sampling methodology, testing methodology, and your observation of the sampling collection. If the establishment performs sample analysis in-house, your assessment should include whether the lab methodology is validated, and the establishment is performing as described in the validation. Briefly describe any vulnerability and any noncompliance that can affect the plant's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

E42 Sampled Lot Definition: Considering rework, returned product, carry-over, commingling, and cross-contamination during processing, does the establishment have a supportable basis for its sampled lot definition (microbiological independence)?

☐Yes

☐No

E43 Describe the establishment's sample lot definitions, the support and rationale for lot independence, and any flaws in the process that would question the establishment's microbiological independence determination (limit 20,000 characters).

E44 Summarize how the plant addresses positives, identifies trends and how the sample results are used for decision making within the HACCP system. Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

E45 Based on the products the establishment produces and a review of the laboratory sampling results obtained from the PHRE report, is the in-plant team receiving the appropriate sampling tasks through PHIS according to the establishment's products and production volume?

NOTE: If the EIAO identifies that the appropriate sampling tasks are not being assigned to the in-plant team, they are to contact the FLS.

☐Yes

☐No

Egg Products Tool Summary (E46)

This question is designed to focus on the most significant noncompliance or vulnerability findings that can affect the plant's ability to produce safe, wholesome, and unadulterated product. Summarize the findings that bear most directly on the FSA recommendation with respect to what action, if any, is necessary with respect to the plant's HACCP system. The answer to this question is to be used to construct the Executive Summary.

E46 Summarize any vulnerability or noncompliance findings identified in the Egg Products tool that have an impact on the establishment's ability to produce safe, wholesome, unadulterated product and are critical to determine an FSA recommendation (limit 20,000 characters). Limit your response to three to five bullet points total.