

Egg Products FSA Tool

Introduction: The Egg Products FSA Tool contains the following main sections:

Shell Eggs - Receiving and Storage (Questions E1-E6)
Shell Eggs - Washing (Questions E7-E13)
Shell Eggs - Breaking (Questions E14-E20)
Liquid Egg - Shipping and Receiving (Questions E21-E28)
General Sanitation (Questions E29-E37)
Formulation/Blending Liquid Egg - Pasteurization (Questions E38-E49)
Cooling, Freezing, Defrosting and Holding Liquid Unpasteurized or Pasteurized Egg Products (Questions E50-E53)
Egg Whites/Yellow Egg Products Stabilization (De-sugaring) (Questions E54-E60)
Pasteurizing Stabilized Dried Egg Whites or Stabilized Dried Yellow Egg Products (Questions E61- E68)
Egg Drying (Questions E69-E71)
Packaging of Egg Products (Liquid and Dried Egg) (Questions E72-E78)
Pasteurized Egg Products - Sampling Program (Questions E79-E94)
Miscellaneous (Questions E95-E105)

In responding to questions in this tool, the EIAO is to focus on documenting any vulnerability and noncompliance, not making positive editorial findings. EIAOs are to be mindful of regulatory waivers and alternative procedures, and document their impact on food safety, if encountered.

A vulnerability is an identified weakness in the plant's process that does not rise to the level of noncompliance but that could contribute to the plant's ability to produce safe and wholesome egg products in accordance with FSIS statutory and regulatory requirements (i.e., the EPIA and 9 CFR 590).

Add a note about the use of alternative procedures. Typically, FSIS will not take enforcement actions based on the lack of the original letter unless there are actual findings to support that the product may be adulterated. If there are no issue with the procedures other than the letter, than they should contact new technology and seek approval.

NOTE: For all questions in this FSA tool, please note that some FSA tool questions are not required questions and will only appear based on the answer responses provided. Also, it is not necessary to copy and paste information into a text field that you've provided in a previous text field question within the tool.

Section: Shell Eggs - Receiving and Storage

E1 (Multiple Choice) What is the source of shell eggs used in the breaking process?

- On-site houses (inline)
- Off-site (contract farms)
- Off-site (open market, broker, etc.)
- Other (please specify)

E2 (Single Choice) Does the plant receive shell eggs diverted for processing under FDA's Prevention of Salmonella Enteritidis in Shell Eggs, and have controls in place to ensure the products receive appropriate pasteurization? 21 CFR 118.6(f)

- Yes
- No
- N/A, the plant does not receive these diverted shell eggs.

E3 (Single Choice) Does the plant use shell eggs that are not of current production (:S60 days old) and have measures to ensure the eggs are appropriately identified during receiving, storage, processing, and on the product label? 590.411(c)(6)

- Yes
- No
- N/A, the plant only receives eggs of current production.

- E4** (Yes/No) Does the plant appropriately identify and handle restricted eggs, including during receiving, storage and production?
- E5** (Yes/No) Does the plant store the shell eggs under acceptable conditions per 590.504(g)?
- E6** (Free Text) Briefly describe any vulnerability and noncompliance concerning the diverted eggs and restricted eggs, and procedures used to identify or segregate shell eggs at receiving, during storage and production that was not mentioned in a previous answer. Describe the impact your findings have on food safety.

Section: Shell Eggs - Washing

- E7** (Single Choice) Does the plant wash incoming shell eggs prior to breaking, regardless of their incoming status (clean, dirty, nest-run, etc.)? 590.515 & 590.516(a)
- Yes
- No
- No, they are clean sound eggs
- E8** (Yes/No) Does the plant remove leakers, loss, dirties, or otherwise inedible eggs immediately following washing? 590.506(a) & (d), & 590.510(c)
- E9** (Yes/No) Are the implemented procedures effective to ensure the shell eggs presented for breaking are of edible interior quality (sound shell and free of adhering dirt and foreign materials)? 590.510(c)
- E10** (Yes/No) Does the system prevent eggs from standing, soaking, or being immersed in water? 590.515(a)(7)
- E11** (Yes/No) Does the plant maintain the appropriate documents to demonstrate all antimicrobials, detergents, wetting agents and other chemical are approved for manner in which they are being used? 590.504(h)
- E12** (Yes/No) Does the plant maintain the washing operations in a manner to meet the general sanitation requirements of 590.504?
- E13** (Free Text) Describe the plant's ability to present shell eggs for breaking that are of clean and edible interior quality, and history of corrective actions. Briefly describe any vulnerability and any noncompliance concerning the shell egg handling and washing, and the effectiveness of the washing operation that were not mentioned in a previous answer. Describe the impact your findings have on food safety.

Section: Shell Eggs – Breaking

- E14** (Yes/No) Does the plant maintain the breaking facility per 590.520 and meet the general sanitation requirements per 590.522?
- E15** (Single Choice) Does the plant sanitize all shell eggs prior to breaking using chlorine (100 ppm to 200 ppm) or its equivalent? 590.516(a)
- Yes
- Yes, the plant uses an alternative procedure per 590.516(a)
- No

- E16** (Single Choice) If the egg-breaking machine does not present the shell at the time of organoleptic inspection of the egg meat, does the plant only break only Grade B or better shell eggs? 590.522(f) & 590.100
- Yes
- No
- N/A, shell and met are presented at the same time.
- E17** (YesNo) Does the plant adequately clean and sanitize the breaking equipment every 4 hours? 590.522
- E18** (YesNo) When an inedible egg is encountered on the breaking equipment, does the plant properly remove the inedible egg cleaned and sanitized all affected surfaces are prior to reuse (automated cup washer, manual sprayer of trays, etc.)? 590.522(h)
- E19** (YesNo) Does the plant reexamine the eggs prior to entering the tank or churn, and have a process in place to ensure the immediate removal of blood and meat spots, shell particles and foreign materials? 590.504(m), 590.522(f), 590.522(g) & 590.522(aa)(1)
- E20** (Free Text) Briefly describe any vulnerability and any noncompliance concerning the plant's ability to present shell eggs for breaking that are of clean and edible interior quality, and history of corrective actions, and the effectiveness of the procedures in place to maintain sanitary conditions. Include any concerns not mentioned in a previous answer. Describe the impact your findings have on food safety.
- Section:** Liquid Egg - Shipping and Receiving
- E21** (Single Choice) Does the plant ensure that all unpasteurized and/or Salmonella positive egg products shipments are sent to other official establishments or plants? 590.504(o)(2) and 590.410(b)
- Yes
- No
- N/A, not unpasteurized and/or Salmonella positive eggs are shipped.
- E22** (YesNo) Has the plant experienced any breaches in custody over the past 60 days?
- E23** (YesNo) Does the plant have controls to ensure the shipping containers and pumping equipment is sanitary prior to their use? 590.504(k) 590.522(y) 590.532(a)
- E24** (YesNo) Does the plant maintain the liquid egg temperature in accordance with 590.530(c) for egg shipped and received?
- E25** (YesNo) In the last 60 days, has the plant shipped or received product above the temperature limit? 590.530(b)
- E26** (YesNo) Does the plant accept returned product? 590.424(a) and 590.504(d)
- E27** (YesNo) Does the plant examine returned product to determine whether it is sound, wholesome, or unadulterated and fit for human consumption? 590.424(b)
- E28** (Free Text) Briefly describe any vulnerability and any noncompliance concerning the adequacy of control measures in place for shipped and received products, the temperatures limits selected, and corrective actions over the last 60 days, and any breaches in custody that were not mentioned in a previous answer. Describe the impact your findings have on food safety.

Section: General Sanitation

- E29 (YesNo) Does the plant maintain the facility in a sanitary manner? 590.500, 590.520, 590.549 & 500.552**
- E30 (YesNo) Does the plant maintain egg storage areas in a clean manner, free of odors? 590.504(g)**
- E31 (YesNo) Do the plant personnel follow proper health and hygiene practices? 590.560**
- E32 (YesNo) Does the plant restrict cross utilization of equipment or have sanitation procedures that prevent cross-contamination (pasteurized v. unpasteurized, or ingredients, blends, etc.)? 590.504(a).**
- E33 (Single Choice) Does the plant demonstrate the cleaned-in place system (CIP) is equivalent to that obtained through manual washing and sanitizing of dismantled equipment? 590.552(a)(3)**
- Yes
 - Yes, the plant uses alternative procedures
 - No
 - No, no CIP methods are used
- E34 (Single Choice) If the plant reuses packaging containers (tankers, unlined combos, pails, etc.) for pasteurized or unpasteurized egg product, does the plant ensure the container is clean prior to use? 590.419**
- Yes
 - No
 - N/A, the plant does not reuse packaging containers
- E35 (Free Text) Briefly describe any vulnerability and any noncompliance concerning the hygiene, sanitation, effectiveness of the CIP measures, drying unit cleaning, container re-use, history of corrective actions, and potential for product cross-contamination that was not mentioned in a previous answer. Include whether the plant has developed any written sanitation or operating procedures in response to a noncompliance. Describe the impact your findings have on food safety.**

Section: Formulation/Blending Liquid Egg - Pasteurization

- E36 (Single Choice) If the plant does not process eggs in their natural proportions, does the formulated egg product meet the standards of identity? 21CFR 160 and 590.580 (a)**
- Yes
 - No
 - N/A, the plant only processes eggs in natural proportions
- E37 (YesNo) Does the plant confirm, through laboratory analysis, that the egg products have met the standards of identity? 590.580(d)**
- E38 (Single Choice) Do the records generated and maintained by the plant demonstrate compliance with the standards of identity (if any) and with the product label? 590.580(a)**
- Yes
 - No
 - N/A, the plant only processes eggs in natural proportions.

- E39** (Single Choice) If the plant has written procedures for liquid egg pasteurization, are the procedures being followed?
 Yes
 No
 N/A, plant does not have written pasteurization procedures.
- E40** (Yes/No) Does each pasteurizer include a functioning automatic flow diversion valve thermal controls and a recording device? 590.570(a)
- E41** (Yes/No) Does the plant have knowledge of the system specifications (volume, length, capacity, rate, etc.) to assure they are achieving adequate holding time? 590.570(b)
- E42** (Single Choice) Do the liquid egg pasteurization limits meet the requirements of 590.570 (Table 1) (whites, whole egg and yolk, etc.)?
 Yes
 Yes, the plant uses alternative procedures
 No
- E43** (Free Text) How does the plant monitor the flow rate, to include the time and temperature of the pasteurization cycle? 590.570 (b) and Table I Pasteurization Requirements
- E44** (Yes/No) In the last 60 days, has the plant failed to meet the pasteurization limits?
- E45** (Single Choice) Does the plant add any of the following substances or additives to the product before, during or after pasteurization?
Hydrogen Peroxide
Lactic Acid
Citric Acid
Aluminum Sulfide
Other, please identify
Plant does not add any substance or additives before, during or after pasteurization.
- E46** (Single Choice) Does the plant maintain documents that support the substance is safe under the conditions of use in human food? 590.435(c)(1) and (2)
 Yes
 No
 N/A, Plant does not add any substances or additives are added during pasteurization.
- E47** (Free Text) Briefly describe any vulnerability and any noncompliance concerning the formulation, blending, and pasteurization systems, and test results to demonstrate the standard of identity is met and label is correct. Describe any concerns that were not mentioned in the previous answer, including repasteurizing stabilized yellow egg products. Describe the impact your findings have on food safety.
- Section:** Cooling, Freezing, Defrosting and Holding Liquid Unpasteurized or Pasteurized Egg Products
- E48** (Single Choice) Has the plant had a process deviation regarding the liquid egg cooling requirements per 590.530 Table I?
 Yes, cooling deviation from 590.530 Table I
 Yes, cooling deviation from the plant's alternative procedures
 No cooling deviations

- E49** (Single Choice) Has the plant had a deviation regarding freezing egg products following breaking or pasteurization, per 590.536(b) (solid frozen or $\leq 10^{\circ}\text{F}$ within 60 hours)?
- Yes, freezing deviation from 590.536(b)
 - Yes, freezing deviation from plant's waiver
 - No freezing deviation
 - N/A, the plant does not freeze product following breaking or pasteurization.
- E50** (Single Choice) Has the plant had a deviation regarding defrosting egg products per the temperature requirements of 590.539(d)?
- Yes, defrosting deviation from 590.539(d)
 - Yes, defrosting deviation from plant's waiver
 - No defrosting deviation
 - N/A, the plant does not defrost eggs.
- E51** (Free Text) Briefly describe any vulnerability and any noncompliance concerning the adequacy of the plant's cooling, freezing, defrosting and holding methods, and any process deviation trends. Include any concerns that were not mentioned in a previous answer. Describe the impact your findings have on food safety.
- Section:** Egg Whites/Yellow Egg Products Stabilization (De-sugaring)
- E52** (Multiple Choice) What method is used to achieve a stabilized egg product? Title 21 Part 160 Subpart B 160.105 (b), 160.145(b) or 160.185(b)
- Enzyme Procedure
 - Controlled Yeast Fermentation
 - Bacterial Procedures
 - Other
 - N/A, plant does not stabilize egg products
- E53** (YesNo) Does the plant have support for the stabilization process and limits selected in safe and suitable levels?
- E54** (Single Choice) Does the plant have support for the stabilization process and limits selected in safe and suitable levels?
- Yes
 - No
 - N/A, no written stabilization procedures
- E55** (YesNo) Does the plant maintain records to document the stabilization?
- E56** (YesNo) In the last 60 days, has the plant failed to meet the stabilization limits?
- E57** (YesNo) Does the plant maintain a negative airflow in the stabilization areas?
- E58** (Free Text) Briefly describe any vulnerability and any noncompliance concerning the stabilization process, limits selected, the associated monitoring records and any corrective actions taken over past 60 days. Include any concerns that were not mentioned in a previous answer. Describe the impact your findings have on food safety

Section: Pasteurizing Stabilized Dried Egg Whites or Stabilized Dried Yellow Egg Products

E59 (Single Choice) Do the selected pasteurization heat treatment limits for dried stabilized egg products meet the requirements of 590.575(b)?

- Yes
- Yes, the plant uses alterative procedures
- No

E60 (YesNo) Does the plant's process, including monitoring method and monitoring location ensure all associated products achieve adequate pasteurization during the stabilization and heat treatment ? 590.575(a)

E61 (YesNo) In the last 60 days, has the plant failed to meet the pasteurization limits for heat treatment of dried egg products in 590.575(b)?

E62 (Single Choice) Did the plant take measures to reprocess the product? 590.504(o)(1)

- Yes
- No
- No, product was denatured and labeled unfit for human food.

E63 (Single Choice) If reprocessed, did the plant determined whether the reprocessed product was Salmonella negative? 590.580(b)

- Yes
- No
- No, product was denatured and labeled unfit for human food.

E64 (YesNo) Are the records maintained for 1 year, and include the product type, lot number, heat treatment room temperatures, product temperatures, length of time in the heat treatment room, and Salmonella test results? 590.575(d)

E65 (Free Text) Briefly describe any vulnerability and any noncompliance concerning the pasteurization of the stabilized egg products and any corrective actions taken over the past 60 days. Include any concerns not mentioned in a previous answer. Describe the impact your findings have on food safety.

Section: Egg Drying

E66 (Multiple Choice) What type of drying system is used?

- Box Dryer
- Cyclone Dryer
- Pan Dryer
- Refractant (a waiver has been granted)
- Other (a waiver has been granted)
- Other (please specify)

E67 (Multiple Choice) Which type of egg products does the plant dry?

- Yes, pasteurized yolk
- Yes, pasteurized whole egg
- Yes, unpasteurized whites (albumen)
- Yes, pasteurized whites (albumen)
- Yes, pasteurized egg blends
- Other (please specify)

- E68** (Yes/No) Does the plant have a dryer cleaning program?
- E69** (Yes/No) Has the plant initiated cleaning of their systems when wet powder or other conditions are encountered in the drying units, including sifters, conveyors, powder coolers or packaging system? 590.542
- E70** (Free Text) Briefly describe any vulnerability and any noncompliance concerning the adequacy of the drying process, records, and storage, and any corrective actions taken over past 60 days. Include any concerns not mentioned in a previous answer. Describe the impact your findings have on food safety.

Section: Packaging of Egg Products (Liquid and Dried Egg)

- E71** (Multiple Choice) How does the plant package and distribute the pasteurized egg products?

- Bulk (Tanker)
- Combo Bin / Tote
- Boxes (dried egg)
- Sealed Bags Carton
- Aseptic or Automatic Packaging System (complete next 4 questions)
- Other (please specify)

Section: For Aseptic or Automatic Packaging System

- E72** (Yes/No) Does the aseptic packaging system include an antimicrobial treatment (solution, gas, heat, steam, etc.) to rid the system and packaging materials of microorganisms? 590.522(b)
- E73** (Yes/No) Does the plant maintain adequate support for the antimicrobial's use? 590.552(b)
- E74** (Yes/No) Is the product exposed to any non-aseptic surfaces prior to being sealed
- E75** (Free Text) Briefly describe the packaging system design, the effectiveness of the control measures applied, and the adequacy of the support on file for the antimicrobial's use.
- E76** (Yes/No) Does the plant have effective controls to prevent foreign material in the egg product (dried product and liquid egg)? 590.504(g)
- E77** (Free Text) Briefly describe any vulnerability and any noncompliance concerning the packaging and the potential for cross-contamination. Include any concerns not mentioned in a previous answer. Describe the impact your findings have on food safety.

Section: Pasteurized Egg Products - Sampling Program, Identify the plant's Salmonella sample category for each pasteurized product, based on the last completed 60-sample lot: (590.504(o)(1) & 590.580

- E78** (Single Choice) Whites (with or without added ingredients)

- Product not produced
- 100%
- Level 1 - 1 lot sampled for every 2 lots produced.
- Level 2 - 1 lot sampled for every 4 lots produced.
- Level 3 - 1 lot sampled for every 8 lots produced.

- E79 (Single Choice) Whole eggs or yolks (with less than 2 percent-added ingredients or no added ingredients)**
- Product not produced
 - 100%
 - Level 1 - 1 lot sampled for every 2 lots produced.
 - Level 2 - 1 lot sampled for every 4 lots produced.
 - Level 3 - 1 lot sampled for every 8 lots produced.
- E80 (Single Choice) Whole eggs (or yolks or blends thereof with 2 percent or more added ingredients other than salt or sugar)**
- Product not produced
 - 100%
 - Level 1 - 1 lot sampled for every 2 lots produced.
 - Level 2 - 1 lot sampled for every 4 lots produced.
 - Level 3 - 1 lot sampled for every 8 lots produced.
- E81 (Single Choice) Whole eggs, yolks or blends thereof (with 2 percent or more salt or sugar added)**
- Product not produced
 - 100%
 - Level 1 - 1 lot sampled for every 2 lots produced.
 - Level 2 - 1 lot sampled for every 4 lots produced.
 - Level 3 - 1 lot sampled for every 8 lots produced.
- E82 (YesNo) Do the past sampling results support sampling frequency selected for each product?**
- E83 (YesNo) Does the plant have adequate support for the Salmonella product sampling methodology? (Sample portion, unbiased collection technique, sampling location, aseptic handling, etc.)**
- E84 (YesNo) Does the plant have adequate support for the Salmonella product testing methodology? (Test portion, appropriately validated for egg products, integrity of results, aseptic handling, etc.)**
- E85 (YesNo) In the last 6 months, has any pasteurized products tested positive for Salmonella from either plant or FSIS testing?**
- E86 (Free Text) For each positive, describe the situation, the cause of the positive, whether trends exist and plant's corrective actions, including the actions taken on the Salmonella positive lot and results of follow-up sampling.**
- E87 (YesNo) Does the plant conduct any sampling for other indicator organisms? (APC, Enterobacteriaceae, Pseudomonas, etc.)**
- E88 (Free Text) If yes, list the specific indicator organisms and the results from the past 6 months.**

- E89** (Multiple Choice) Does the plant sample product, equipment or processing areas for microbial indicator organisms (e.g. generic *E. coli*, coliforms, ATP, APC or Enterobacteriaceae)?
- No
 - Yes, product
 - Yes, equipment surfaces (e.g. scoops/cups, piping, pasteurizer or cooling plates, etc.)
 - Yes, containers (e.g. tankers, totes, etc.)
 - Yes, processing area (i.e., environment)
 - Yes, other
 - Other (please specify)
- E90** (YesNo) In the last 6 months, has any pasteurized product tested positive for *Listeria monocytogenes* or *Listeria* species from either plant or FSIS testing?
- E91** (Free Text) For each positive, describe the situation, the cause of the positive, whether trends exist and plant's corrective actions, including the actions taken on the *Listeria monocytogenes* or *Listeria* species positive lot and results of follow-up sampling.
- E92** (YesNo) Does the plant consider individual sample results in addition to whether there are trends in the results?
- E93** (YesNo) Do all the test result records appear authentic, unaltered and credible?
- E94** (Free Text) Briefly describe any vulnerability and any noncompliance concerning microbial sampling and testing procedures, methods, results, and corrective actions. Include any concerns not mentioned in a previous answer. Describe the impact your findings have on food safety.
- Section:** Miscellaneous
- E95** (Single Choice) If the plant has a shelf-life claim, does the plant have microbial data to support its shelf life claim (*Salmonella*, *Listeria monocytogenes*, or other microbial testing data)?
- Yes
 - No
 - No shelf life claims apply
- E96** (YesNo) Does the plant sample product for microbial indicator organisms (e.g. generic *E. coli*, coliforms, ATP, APC or Enterobacteriaceae)?
- E97** (Free Text) Describe any additional questions that came up during the FSA that you sought answers to, based on the unique characteristics of the plant's process.
- E98** (Free Text) Summarize in up to three bullets of any vulnerability or noncompliance findings identified in the Egg Products Tool that have an impact on the plant's ability to produce safe, wholesome, unadulterated product and are critical to determine a FSA recommendation. Describe the impact the findings have on the plant's food safety system.
- Instruction:** HACCP is not currently required in Egg Products plants, however, many egg plants have developed HACCP systems. The following HACCP questions are designed to report on the plant's usage of HACCP principles so that FSIS can develop useful HACCP assistance materials for possible future outreach efforts.

EIAOs should not allocate significant time or resources to conduct a review of the hazard analysis, HACCP plan and supporting documents but rather focus time on assessing whether the food safety system is designed and executed in compliance with the 9 CFR 590 regulatory requirements.

E99 (Single Choice) Does the plant have a written HACCP system (written hazard analysis, HACCP plan, and supporting documents) that they are willing to share with FSIS?

NOTE: Answer E96-105 only if "Yes" is selected and the plan is shared with FSIS

- Yes
- No
- Yes, but plan is not shared with FSIS

E100 (YesNo) Has the plant conducted a hazard analysis to determine the food safety hazards reasonably likely to occur?

E101 (Multiple Choice) Where does the establishment implement a CCP to control a hazard?

- Shell egg sanitizer (ppm)
- Process control for egg ineligible for breaking (EIFB) entering breaker
- Time/temperature following breaking
- Temperature during storage
- Temperature at shipping/receiving
- Time/Temperature at liquid pasteurization, based on egg solids
- Time/Temperature at hot room pasteurization
- Temperature during freezing/defrosting
- Egg Solids - Drying
- Pasteurized product sample results
- Other (please specify)

E102 (Multiple Choice) Where does the establishment prevent a hazard with a prerequisite program?

- Shell egg sanitizer (ppm)
- Process control for egg ineligible for breaking (EIFB) entering breaker
- Time/temperature following breaking
- Temperature during storage
- Temperature at shipping/receiving
- Time/Temperature at liquid pasteurization, based on egg solids
- Time/Temperature at hot room pasteurization
- Temperature during freezing/defrosting
- Egg Solids - Drying
- Pasteurized product sample results
- Other (please specify)

E103 (YesNo) Does the plant implement the HACCP plan as written?



E104 (Multiple Choice) Indicate the types of scientific or technical support on file for the CCPs or pre-requisite programs.

- Regulations
- Peer-reviewed scientific or technical data or information (e.g., journal articles)
- Expert advice from processing authority
- A challenge or inoculated pack study
- Pathogen Modeling program
- Data gathered by the establishment in-plant
- Waiver
- Regulatory Performance Standard
- Best Practices Guideline
- Other (please specify)

E105 (Single Choice) In the last 60 production days, has the plant taken corrective actions for deviations or unforeseen hazards?

- Yes
- No
- N/A, no deviations or unforeseen hazard in the previous 60 days