



United States  
Department of  
Agriculture



# Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



# EGG PRODUCTS INSPECTION REGULATIONS FINAL RULE

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# Food Safety and Inspection Service:

## Egg Products Inspection Regulations Final Rule – Overview of Webinar

- ✓ Amendments to the Egg Products Inspection Regulations
  - ✓ General Requirements
  - ✓ Sanitation Standard Operating Procedure Regulations to be Implemented by October 29, 2021
  - ✓ Hazard Analysis and Critical Control Point Requirements to be Implemented by October 31, 2022
  - ✓ Egg Product Regulatory Oversight Changes to be Implemented by October 30, 2023
  - ✓ Egg Products Guidance
  - ✓ Implementation
  
- ✓ Exports
  - ✓ Use of the FSIS PY-200 Form
  
- ✓ Imports
  - ✓ Imported Egg Products Stamped With the Import Mark of Inspection “U.S. Inspected and Passed”
  - ✓ Weight Limits Extended for Small Importations for Importers Personal Use, Display, or Laboratory Analysis
  - ✓ Amount of Time Extended for Importers to Dispose of Egg Product Identified as “Refused Entry”



## Food Safety and Inspection Service: Egg Products Inspection Regulations

- ❑ On February 13, 2018, FSIS proposed to amend the egg products inspection regulations. The rule proposed to:
  - ❑ Require plants to develop and implement Hazard Analysis and Critical Control Point (HACCP) systems and Sanitation Standard Operating Procedures (Sanitation SOPs) and meet all sanitation requirements already applicable to meat and poultry products.
  - ❑ Specify that egg products are required to be processed to edible without additional preparation to achieve food safety.
  - ❑ Provide for generic label approvals and amend the required labeling features.
  - ❑ Bring egg products under the “Rules of Practice” that govern administrative enforcement actions initiated by the Agency.
  - ❑ Reinterpret the Agency’s interpretation of continuous inspection.
  - ❑ Exercise jurisdiction over egg substitutes and freeze-dried egg products.
- ❑ On October 29, 2020, the rule finalizing these regulations was published in the *Federal Register*.

## Food Safety and Inspection Service: General Requirements

- ❑ For importers and exporters, relevant regulations that were amended include:
  - 9 CFR 590.200 Recordkeeping requirements
  - 9 CFR 590.411 Label approval
  - 9 CFR 590.412 Approval of generic labels
  - 9 CFR 590.570(b) Control of pathogens in pasteurized egg products



Food Safety and Inspection Service:

## General Requirements: Recordkeeping

- ❑ Persons engaged in the transporting, shipping, or receiving of any egg products in commerce, or holding such articles received must maintain records documenting the following for 2 years:
  - The date of production and quantity of egg products delivered and sold, and to whom
  - The date of receipt and quantity of egg products purchased or received, and from whom
- ❑ All records required to be maintained must be made available to an authorized representatives of the Secretary for official review and copying
- ❑ These requirements were effective December 28, 2020



## Food Safety and Inspection Service: General Requirements: Labeling

- ❑ FSIS has revised 9 CFR 590.411 to require that plants must comply with the requirements of 9 CFR 412.1 (label approval).
- ❑ Only labels that meet the following criteria need to be submitted for approval:
  - Intended for Temporary Approval
  - Products Exported with Labeling Deviations
  - Special Statements and Claims as described in 9 CFR 412.1(e)
- ❑ FSIS has revised the requirements of 9 CFR 590.412 to state that plants, including official plants certified under a foreign inspection system in accordance with 9 CFR 590.910, may comply with the requirements of 9 CFR 412.2 (approval of generic labels).
- ❑ Egg products plants may use generically approved labels without submitting them to the Agency provided the label displays all the required mandatory features in a prominent manner and is not otherwise false or misleading.



## Food Safety and Inspection Service: Egg Products are Ready-to-Eat

- ❑ The presence of pathogenic organisms in egg products (e.g., *Salmonella*, *Listeria monocytogenes*, etc.) render those products adulterated and FSIS treats them like ready-to-eat products.
- ❑ On October 30, 2022, FSIS will remove the prescriptive time/temperature requirements in 9 CFR 590.570(b) and require egg products to be processed such that they do not require additional preparation to ensure food safety.
- ❑ Plants that do not develop new or modified procedures under HACCP can continue to follow the set of pasteurization time and temperature combinations found in the *Food Safety Guideline for Egg Products* and incorporate them into their HACCP plans.



Food Safety and Inspection Service:

# **Sanitation Standard Operating Procedures to be Implemented on October 29, 2021**



## Food Safety and Inspection Service:

### Sanitation Standard Operating Procedures (Sanitation SOPs)

- ❑ The Sanitation SOPs will become effective on October 29, 2021, one year from the date of publication in the final rule.
- ❑ Sanitation SOPs define the results to be achieved by sanitation, but not the specific means to achieve those results.
- ❑ Sanitation SOPs describe all the procedures a plant will conduct daily, before, and during operations sufficient to prevent direct contamination or adulteration of product(s).
- ❑ Plants can meet the sanitation requirements in different ways, but the required results are the same for all plants.

**Hazard Analysis and Critical Control Point  
Requirements to be Implemented on  
October 31, 2022**



## Food Safety and Inspection Service:

### Hazard Analysis and Critical Control Point (HACCP) Systems

- ❑ The HACCP requirements will take effect on October 31, 2022, two years from the date of publication of the final rule.
- ❑ HACCP is a flexible system that will enable plants to tailor their control systems to the needs of their particular plants and processes.
- ❑ Plants will be required to develop and implement a HACCP system for food safety that is designed to prevent, eliminate, or reduce to an acceptable level the occurrence of biological, chemical, and physical hazards that are reasonably likely to occur in the plant's process.
- ❑ Specifically, plants will have to develop and implement HACCP plans that incorporate controls that are necessary to produce safe egg products.

# **Egg Product Regulatory Oversight Change: October 30, 2023**



## Food Safety and Inspection Service: Egg Substitutes and Freeze-Dried Egg Products

- ❑ October 30, 2023, FSIS will be assuming regulatory authority over egg substitutes and freeze-dried egg products, including those that are imported. These products:
  - Pose the same risk as egg products and will be inspected in the same manner; and
  - Are similar, if not identical, to currently amenable egg products and subject to the same food safety risks during processing.

## Food Safety and Inspection Service: Egg Products Inspection Regulations

- ❑ Products remaining under FDA jurisdiction under the new rule:
  - Imitation egg products
  - Dietary foods
  - Dried no-bake custard mixes
  - Egg nog mixes
  - Acidic dressings
  - Noodles
  - Milk and egg dip
  - French toast
  - Sandwiches containing eggs or egg products
  - Cooked eggs or cooked egg products

# **Egg Products Guidance**





## Food Safety and Inspection Service: Food Safety Guideline for Egg Products

### **FSIS Food Safety Guideline for Egg Products**

**September 9, 2020**

- The guideline does not impose new regulatory requirements, but rather provides guidance
- Establishments can continue to use former regulations, and includes
  - No objection letters to various egg product formulations and pasteurization time-temperatures
  - Waivers to extended freezing times
  - Waivers to enzyme-modification processes
  - Calculated time-temperature tables to achieve lethality

Available at <https://www.fsis.usda.gov/wps/wcm/connect/372cc535-5efc-43c9-9dae-02285052ef61/food-safety-guideline-egg-products.pdf?MOD=AJPERES>



Food Safety and Inspection Service:  
Egg Products Hazards and Controls Guide

Helps in identifying:

- *relevant processing steps*
- *potential hazards for each of the steps*
- *controls frequently used to address these hazards*

Process Step	Potential Hazards	Frequently Used Controls
Receiving and storage of packaging materials and non-egg ingredients	Biological—Contamination with pathogens (e.g., <i>Salmonella</i> or <i>Listeria monocytogenes</i> )	<ul style="list-style-type: none"><li>• Letters of guarantee.</li><li>• Packing materials and non-egg ingredients are transported and stored in a manner that ensures product integrity and proper conditions are maintained.</li><li>• Dry goods are protected from pests and environmental contamination.</li></ul>
	Chemical—Allergens	<ul style="list-style-type: none"><li>• Letters of guarantee; approved supplier program.</li></ul>

Available at <https://www.fsis.usda.gov/wps/wcm/connect/2d097b2f-4cb6-4dd9-aee2-891fba39d45d/egg-products-hazards-controls-guide.pdf?MOD=AJPERES>

Food Safety and Inspection Service:  
**Implementation of New Rule**

# Implementation

## Food Safety and Inspection Service: Implementation of New Rule



- ☐ Early opt in plants
- ☐ Staffing
- ☐ Patrol Assignments

Food Safety and Inspection Service:

## Exports



## Food Safety and Inspection Service: December 28: PY-200 Egg Product Exports

- ❑ Issuance of FSIS Directive 5030.1 Revision 2, has cancelled FSIS Directive 5040.1, Uses of FSIS Form PY – 200 *Egg Products Inspection Certificate*, 1/22/13.
- ❑ The labeling requirements in 9 CFR 590.410(c) replace the requirement for the PY-200, *Egg Products Inspection Certificate* to accompany the shipment and the need to apply government seals.
- ❑ European Union currently requires a PY – 200 to accompany shipments for sampling by AMS.



## Food Safety and Inspection Service: December 28: PY-200 Egg Product Exports

- ❑ EU samples for certification are submitted under the Voluntary Egg Products Inspection Program (9 CFR part 592) to the USDA/Agricultural Marketing Service, Science and Technology National Science Laboratory for analysis.
- ❑ Upon receipt of results of laboratory analyses, IPP are to determine that the lot of product tested is eligible for certification. Each shipment consigned to a destination within the European Union must be accompanied by FSIS Form 9060-5EP, Egg Products Export Certificate of Wholesomeness, the FSIS Letterhead Certificate, and a copy of the PY-200 that identifies lab results.

Food Safety and Inspection Service:

**Imports**



## Food Safety and Inspection Service:

December 28, 2020: Applying the Official Import Mark of Inspection

### New Regulation

- ❑ Imported egg products found acceptable upon reinspection must be stamped with the official import mark of inspection, “U.S. Inspected and Passed” as described in 590.940(a).
- ❑ The requirement does not apply to egg products from Canada.





## Food Safety and Inspection Service:

December 28, 2020: Pre-stamping Imported Egg Products

### New Regulation

- ❑ The inspection legend may be placed on containers of egg products before completion of the official import inspection as described in 590.940(e).
- ❑ The official import inspection establishment must have:
  - Submitted a pre-stamping procedure for egg products to the Front Line Supervisor for approval; and
  - Received a signed letter from the District Manager approving the pre-stamping procedure.
- ❑ FSIS Directive 9900.3, *Pre-Stamping Imported Product*, contains information on pre-stamping imported products.

## Amended Regulation

- ❑ Imported egg products that are “Refused Entry” into the United States must be disposed of within 45 days as described in 9 CFR 590.945(a)(3).
- ❑ The amended regulation extends the amount of time allowed for disposal from 30 days.

UNITED STATES  
REFUSED ENTRY



## Food Safety and Inspection Service:

December 28, 2020: Small Importations

### Amended Regulation

- ❑ Small importations of liquid, frozen or dried egg product for importers personal use, display, or laboratory analysis cannot exceed 50 lbs. (22.7kg) for each type of product as described in 9 CFR 590.960.
- ❑ The amended regulation extends the amount of liquid and frozen egg products from 30 lbs. (13.6kg)



## Food Safety and Inspection Service:

December 28, 2020: Imported Egg Products Seal Requirement

### Regulation Reference Change

- ❑ All conveyances containing imported liquid egg products must be sealed by inspection authorities in the exporting country as per 590.935(b).
- ❑ Examples Include: Bulk Tanker Shipments, Trailers Containing Packaged Liquid and Frozen Egg Product, and Undenatured Inedible Liquid and Frozen Egg Product.



## Food Safety and Inspection Service:

December 28, 2020: Date of Loading Placard Not Required

### Imported Unpasteurized Egg Products

- ❑ A foreign inspection certificate is required for bulk shipments of imported unpasteurized egg products.
- ❑ A placard with the “Date of Loading” as described in 9 CFR 590.410(c) does not apply to bulk shipments of imported unpasteurized egg products.



## Food Safety and Inspection Service: Imported Egg Product Guidance

### Additional Policy References

- ❑ FSIS Import Compliance Guide

<https://www.fsis.usda.gov/wps/wcm/connect/be330a39-20de-43ee-b84a-6be8a5d20178/Import-Compliance-Guide.pdf?MOD=AJPERES>

- ❑ 9000 Series: Export/Import Directives

<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/9000-series>



## Food Safety and Inspection Service: Imported Egg Product Guidance

### Questions

- ❑ Refer questions on imported egg products regulatory compliance through askFSIS.
- ❑ askFSIS - <https://www.fsis.usda.gov/contact-us/askfsis> or contact askFSIS by telephone at 1-800-233-3935