



United States
Department of
Agriculture



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service:

EGG PRODUCTS INSPECTION REGULATIONS FINAL RULE

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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 final rule was published in the *Federal Register*.

Food Safety and Inspection Service:

**Regulations to be
Implemented on
December 28, 2020**

December 28: Previously Exempted Products

- ❑ FSIS has eliminated the exemption from inspection for the following products:
 - Freeze-Dried Products
 - Egg Substitutes
- ❑ What this means:
 - These products now fall under FSIS jurisdiction.
 - Production of these products will require "*continuous inspection.*"

Food Safety and Inspection Service:

December 28: Accommodations and Equipment Changes

- ❑ Egg products plant are no longer required to provide specific pieces of equipment to inspection program personnel (IPP). Instead, they must provide:
 - Furnishings
 - Heat
 - Light
 - Janitor service
 - A room or area suitable for sampling product; and a stationary or adequately secured storage box or cage that can be locked only by FSIS for holding official samples
- ❑ Office space must meet FSIS approval and:
 - Be conveniently located
 - Be properly ventilated
 - Include lockers or file cabinets suitable for the protection and storage of supplies
- ❑ Office space must have accommodations suitable for IPP to change clothing.

Food Safety and Inspection Service:

December 28: Record Requirement Changes

- ❑ Persons engaged in the transporting, shipping, or receiving of any eggs or egg products in commerce, or holding such articles received, as well as all egg handlers, must maintain records documenting the following for 2 years, as applicable:
 - Date of lay, date and time of refrigeration, date of receipt, quantity and quality of eggs purchased and received and from whom. Process records documenting that time and temperature requirements have been met must also be kept.
 - Date of packaging, ambient air temperature surrounding product stored after processing, quantity and quality of eggs delivered or sold, and to whom.
 - If a consecutive lot numbering system is not employed to identify individual eggs, containers of eggs, or egg products, records explaining the alternative code system used, in accordance with § 590.411(c)(3).
 - Date of disposal and quantity of restricted eggs, including inedible egg product or incubator rejects, sold or given away for animal food or other uses or otherwise disposed of, and to whom.

Food Safety and Inspection Service:

December 28: Record Requirement Changes

- ❑ FSIS has revised the requirements of 9 CFR 590.411 to require that the individual or composite record of restricted egg sales to household consumers be kept. Records must show number of dozens sold on a daily basis. The name and address of the consumer is not required.
- ❑ The date of production and quantity of egg products delivered or sold, and to whom.
- ❑ The date of receipt and quantity of egg products purchased or received, and from whom.
- ❑ The production records by categories of eggs such as graded eggs, nest run eggs, dirties, checks, etc., and bills of sale, inventories, receipts, shipments, shippers, receivers, dates of shipment and receipt, carrier names, etc.

Food Safety and Inspection Service:

December 28: Record Requirement Changes

- ❑ All records require to be maintained must be made available to an authorized representatives of the Secretary for official review and copying.
- ❑ Records of all labeling, including product formulations and processing procedures, as prescribed in §§ 590.410-412, must be kept by every person processing, except processors exempted under § 590.100.
 - Poultry processors who process and sell eggs of their own flock's production when sold exclusively for the use by the consumer and members of the household and its nonpaying guests and employees
 - Non-official plants, including but not limited to bakeries, restaurants, and other food processors of certain categories of food products which contain eggs or egg products as an ingredient

Food Safety and Inspection Service:

December 28: Labeling and Other Consumer Protection Requirements

- ❑ FSIS has revised the requirements of 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 412.1(e)

Food Safety and Inspection Service:

December 28: Labeling and Other Consumer Protection Requirements

- ❑ FSIS has revised the requirements of 9 CFR 590.412 to state that plants 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:

Labeling and Other Consumer Protection Requirements

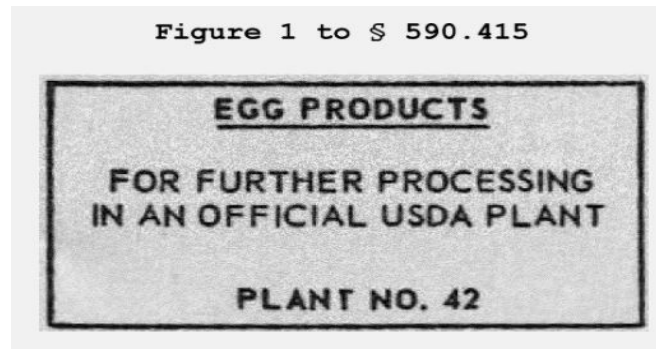
- ❑ Bulk shipments of unpasteurized egg products produced in official plants must bear a label containing the words “date of loading,” followed by a suitable space in which the date the container, tanker truck, or portable tank is loaded must be inserted.
- ❑ The label must be:
 - Conspicuously located
 - Printed and affixed on material that cannot be detached or effaced due to exposure to weather
 - Removed or obliterated by carrier before the truck or tank is removed from the place where it is unloaded

Food Safety and Inspection Service: December 28: PY-200

- ❑ The PY-200 was used as an official certificate on bulk shipments of liquid egg products transported from one official plant to another for further processing.
- ❑ Under the new rule (9 CFR 590.420(c)), bulk shipments of unpasteurized egg products need not move to from one official plant to another with an official certificate.
- ❑ Instead, such shipments must bear a label containing the words "date of loading," followed by a suitable space in which the date the container, tanker truck, or portable tank is loaded must be inserted.
- ❑ The label must be conspicuously located and printed and affixed on or in material that cannot be detached or effaced due to weather. Labels may be made of plastic, cardboard, or heavy paper stock, or other materials, provided they are appropriately protected from the elements.

Food Safety and Inspection Service:
December 28: PY-200

- ❑ The identification set forth in Figure 1 to 9 CFR 590.415 must also appear on the label.



- ❑ The label must be removed or obliterated from the truck or tank at the place where it is unloaded.

Food Safety and Inspection Service:
December 28: Reinspection

- ❑ The operator of an official plant must identify egg products brought into the plant at the time of receipt.
- ❑ Such egg products are subject to reinspection by IPP at the plant in such manner and at such times as may be deemed necessary to ensure compliance with the regulations in Part 590.

Food Safety and Inspection Service:
December 28: Testing of Egg Products

- ❑ Under 9 CFR 590.504(d) of the egg product regulations, IPP have been permitted to allow egg products to be shipped from a plant prior to the receipt of laboratory results for *Salmonella*, provided they did not otherwise suspect noncompliance with the regulations.
- ❑ 590.504(d) has been redesignated as 590.504(e) and now makes clear that egg products plants that move product that has already been sampled by the Agency or the plant before receiving test results must maintain control of the products represented by the sample, pending the test results.

December 28: General Testing Information

- ❑ Samples analyzed by plants must be analyzed for the presence of *Salmonella* spp. with such frequency and using such laboratory methods as is sufficient to ensure that product is not adulterated. For each category of product, sampling should be conducted on a rotating basis.
- ❑ Samples must be drawn from the final packaged form.
- ❑ Results of all partial and completed analyses performed must be provided to IPP promptly upon receipt by the plant. Positive test results must be provided to IPP immediately upon receipt by the plant.

Food Safety and Inspection Service:

**New Sanitation Standard Operating
Procedures (Sanitation SOPs) and
Hazard Analysis and Critical Control
Point (HACCP) Requirements**

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.

Food Safety and Inspection Service: Hazard Analysis and Critical Control Point Systems

- ❑ The HACCP requirements will take effect on October 30, 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.

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: Continuous Inspection

- ❑ The Agency believes that egg products operations are more like meat and poultry processing operations than they are meat and poultry slaughter operations
- ❑ FSIS now interprets “continuous inspection” to require inspection in egg products plants at least once per shift, instead of during all processing operations.
- ❑ FSIS has removed the exemption under 9 CFR 590.100(b) that allowed plants to operate with periodic inspection.
 - As a result, FSIS has removed the regulations for exempted plants (9 CFR 590.600 – 9 CFR 590.680).

Food Safety and Inspection Service:

Hazard Analysis and Critical Control Point (HACCP) Systems Overview



Food Safety and Inspection Service: HACCP Seven Principles

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping & Documentation
7. Establish Verification Procedures



Food Safety and Inspection Service: Conducting a Hazard Analysis



- ❑ Identify Reasonably Likely To Occur (RLTO) hazards at each process step
 - Biological
 - Chemical
 - Physical
- ❑ Identify preventive measures – forms the basis for CCPs
- ❑ Unique to each establishment

Food Safety and Inspection Service: Thought Process for Hazard Analysis

- ❑ Is there a potential hazard at **this step**?
 - Biological? Chemical? Physical?
- ❑ Is it reasonably likely to occur?
 - **Yes** – CCP
 - **No** – What basis for this decision?
 - Supporting documentation
 - Prerequisite program / other supporting program



Food Safety and Inspection Service: Prerequisite Programs

- ❑ Procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food.
- ❑ Become part of the HACCP system if used to support a decision in the hazard analysis.
- ❑ Common examples
 - Temperature control programs
 - Sanitation SOPs
 - Purchase specifications
 - Allergen control programs
 - Antimicrobial interventions



Food Safety and Inspection Service: Verification Procedures

❑ Validation

- Element 1: Scientific and Technical Support
 - Support that an intervention operating at specified critical operating parameters (critical limits) achieves certain log reduction
- Element 2: In-plant Validation Data (90 calendar days)
 - The plant operations can meet the critical operating parameters

Food Safety and Inspection Service: Verification Procedures

- ❑ Ongoing verification (monitoring, corrective action, documentation)
- ❑ Reassessment
- ❑ Government verification

Food Safety and Inspection Service:
HACCP Training (§ 417.7)

- ❑ Once the HACCP regulations take effect, only an individual trained to develop HACCP plans and reassess and modify such plans will be permitted to do so.
 - Need not be plant employee
 - Needs to have successfully completed a course of instruction in the application of the seven HACCP principles to meat, poultry, or egg products processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Food Safety and Inspection Service:

Sanitation Standard Operating Procedures (Sanitation SOP) and Sanitation Performance Standards (SPS)



Food Safety and Inspection Service: Sanitation

- ❑ Plants will be required to follow all parts of 9 CFR 416.
 - This includes the Sanitation SOP requirements (9 CFR 416.11 – 416.17).
 - This includes Sanitation Performance Standards (9 CFR 416.1 – 416.6).
 - These regulations will replace many of the current egg products sanitation regulations.

Food Safety and Inspection Service: Sanitation Standard Operating Procedures

- ❑ **Sanitation SOPs** are written procedures that a plant develops and implements to prevent direct contamination or adulteration of product.
- ❑ Sanitation SOPs consist of two sets of activities:
 - Pre-operational Sanitation
 - Operational Sanitation



Food Safety and Inspection Service: Sanitation Standard Operating Procedures

- ❑ Development (416.12)
- ❑ Implementation (416.13)
- ❑ Maintenance (416.14)

Sanitation

Standard

Operating

Procedures

Food Safety and Inspection Service:
Sanitation Standard Operating Procedures

- ❑ Corrective Actions (416.15)
- ❑ Record Keeping (416.16)
- ❑ Agency Verification (416.17)

Sanitation

Standard

Operating

Procedures

Food Safety and Inspection Service: Sanitation

- ❑ The SPS can be broken down into the following categories:
 - 416.1 – General Rules
 - 416.2 – Establishment Grounds and Facilities
 - 416.3 – Equipment and Utensils
 - 416.4 – Sanitary Operations
 - 416.5 – Employee Hygiene
 - 416.6 – Tagging Insanitary Equipment, Utensils, Rooms or Compartments

GUIDELINES

Food Safety and Inspection Service:
Food Safety Guideline to Assist Establishments

FSIS Food Safety Guideline for Egg Products

September 9, 2020

The guideline does not impose new regulatory requirements, but rather provides guidance

Food Safety and Inspection Service:
Former Regulations as “Safe Harbors”

Establishments can continue
to use former regulations



- ✓ *Pasteurization Operations
(formerly 9 CFR 590.570)*
- ✓ *Cooling Operations
(formerly 9 CFR 590.530)*
- ✓ *Freezing Operations
(formerly 9 CFR 590.536)*
- ✓ *Defrosting Operations
(formerly 9 CFR 590.539)*
- ✓ *Heat Treatment Operations
(formerly 9 CFR 590.575)*

Food Safety and Inspection Service:
Additional “Safe Harbors”

Additional safe harbors

- ✓ *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*



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">• Letters of guarantee.• Packing materials and non-egg ingredients are transported and stored in a manner that ensures product integrity and proper conditions are maintained.• Dry goods are protected from pests and environmental contamination.
	Chemical—Allergens	<ul style="list-style-type: none">• Letters of guarantee; approved supplier program.

Food Safety and Inspection Service:

Rules of Practice

Food Safety and Inspection Service: Rules of Practice

- ❑ FSIS has replaced 9 CFR 590.160(a), (b), (c), and (f)(1) with the rules of practice contained in 9 CFR part 500.
- ❑ FSIS has amended 9 CFR 500.2(c) to include 9 CFR 590.310 to the list of regulatory citations under which an establishment may appeal a regulatory control action.
- ❑ FSIS has amended 9 CFR 500.3(a)(7) to allow FSIS to take a withholding action or to impose a suspension without providing an establishment prior notification because the establishment did not destroy a condemned egg product that has been found to be adulterated and has not been reprocessed, in accordance with 9 CFR part 590, within three days of notification.

Food Safety and Inspection Service: Rules of Practice

- ❑ FSIS has amended 9 CFR 500.5(a)(5) and (c) to add 9 CFR 590.310 to the list of regulatory citations under which it must advise an establishment that it may appeal a withholding action or suspension, and under which an establishment may appeal a withholding action or suspension.
- ❑ FSIS has amended 9 CFR 500.6 by adding section 18 of the EPIA (21 U.S.C. 1047) to the statutory citations under which the FSIS Administrator may file a complaint to withdraw a grant of Federal inspection because a recipient of inspection, or anyone responsibly connected to the recipient, is unfit to engage in any business requiring inspection.

Food Safety and Inspection Service: Rules of Practice

- ❑ FSIS has amended paragraphs (a)(3) and (5) of 9 CFR 500.7 to permit the FSIS Administrator to refuse to grant Federal inspection because an applicant has not demonstrated that adequate sanitary conditions exist in the establishment as required by the egg products inspection regulations, or because the applicant is unfit to engage in any business requiring inspection as specified in 21 U.S.C. 1047.
- ❑ FSIS has amended 9 CFR 500.8(a) to allow FSIS to rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any egg product under sections 7 or 14 of the EPIA (21 U.S.C. 1036 and 1043).

Food Safety and Inspection Service: Rules of Practice

- ❑ Under 9 CFR 500.8(c), FSIS will provide for an opportunity for a hearing, in accordance with the Uniform Rules of Practice, 7 CFR subtitle A, part 1, subpart H, if FSIS rescinds or refuses approval of false or misleading marks, labels, or sizes or forms of any container for use with any egg product.
- ❑ As an aside, for the purposes of Part 500 (and Parts 416 and 417) an official establishment includes an official plant (9 CFR 591.1(c))

Food Safety and Inspection Service: Rules of Practice

- ❑ FSIS would take a withholding action or impose a suspension without providing the plant prior notification because:
 - The official plant does not have a HACCP plan as specified in 9 CFR 417.2;
 - The official plant does not have Sanitation Standard Operating Procedures as specified in accordance with 9 CFR 416.11 and 416.12;
 - The official plant does not maintain sanitary conditions (9 CFR 500.3(a)(4)); or
 - Plant personnel assault, intimidate, or interfere with Federal inspection service (21 U.S.C. 1047).
- ❑ FSIS would also refuse to grant inspection when facilities apply for a grant of inspection and the applicant or recipient, or anyone responsibly connected with the applicant or recipient, is unfit to engage in business because of prior criminal convictions

Food Safety and Inspection Service:
Implementation of New Rule

IMPLEMENTATION

Food Safety and Inspection Service: Implementation of New Rule

- ❑ The rule was published on October 29, 2020
 - The 60-day effective date is December 28, 2020
 - Rules of practice, and recordkeeping and labeling requirements
 - Sanitation SOPs are effective October 29, 2021
 - HACCP is effective October 31, 2022
 - Plants that produce egg substitutes and freeze-dried egg products must meet the requirements of the final rule on October 30, 2023

Food Safety and Inspection Service: Implementation of New Rule

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