UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

5030.1
Revision 4

10/26/22

LABELING AND IMPORT VERIFICATION IN AN OFFICIAL EGG PRODUCTS PLANT

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL OCTOBER 31, 2022.

I. PURPOSE

This directive instructs inspection program personnel (IPP) how to verify labeling requirements and how to conduct import reinspection on shipments of imported unpasteurized liquid egg products received at an official egg products plant. This directive is being reissued to remove instructions related to egg products food safety verification tasks since food safety verification for egg products is now done under the Hazard Analysis and Critical Control Points (HACCP) tasks. This change reflects the implementation of the HACCP and Rules of Practice portions of the final rule Egg Products Inspection Regulations (85 FR 68640). IPP are to refer to FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, for instructions related to food safety verification activities under HACCP and Rules of Practice in egg products plants.

KEY POINTS:

- *Provides regulations and instructions to IPP for verification of PHIS Labeling tasks*
- *Provides instructions on IPP responsibilities when imported unpasteurized liquid egg products are received at official egg products plants*

II. CANCELLATION

FSIS Directive 5030.1, Revision 3, *Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants,* 10/22/21

III. BACKGROUND

A. FSIS conducts inspection activities at egg products plants as required under the Egg Products Inspection Act (EPIA). FSIS egg products inspection regulations are in 9 CFR part 590. Under the EPIA, an egg product is adulterated if, among other things, it has "been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health" (21 U.S.C. 1033(a)). Under the EPIA, an egg product is misbranded if it is not labeled and packaged in accordance with FSIS regulations (21 U.S.C. 1033(l)). FSIS IPP verify that egg products plants meet the regulations to ensure that egg products are not adulterated or misbranded.

B. IPP perform reinspection on all amenable egg products offered for import into the United States. IPP verify that the certification and application is complete and accurate and access the Public Health Information System (PHIS) to obtain the reinspection assignment. IPP are to follow the instructions in this directive on how to determine whether the product offered for import meets United States import requirements and FSIS standards and is not adulterated or misbranded.

IV. VERIFICATION OF THE LABELING REGULATORY REQUIREMENTS

A. IPP are to verify that plants comply with regulatory requirements designed to protect the consumer in ways other than ensuring food safety.

B. When PHIS schedules a routine labeling task, IPP are to perform the appropriate labeling verification task. This task includes verifying that plants:

1. Comply with labeling requirements (9 CFR 590.410-418, 412.1, and 412.2);

2. Ensure that all loss and inedible eggs or inedible egg products meet labeling and handling requirements (9 CFR 590.504(c)(1));

3. Ship undenatured or inedible egg products from official egg products plant and meet the labeling, packaging, segregation, and inventory controls (9 CFR 590.504(c)(2));

4. Label products containing ova in accordance with 9 CFR 590.411 (9 CFR 590.440); and

5. Receive, segregate, process, and dispose of restricted shell eggs in accordance with 9 CFR 590.720(a).

NOTE: Shell egg producers/packers shipping shell eggs destined for further processing at egg product plants are to comply with labeling and handling requirements in accordance with 9 CFR 590.720. IPP are to verify that the egg products plant ensures these shell eggs are appropriately segregated, processed, and properly disposed of.

C. IPP are to perform a directed labeling task when, during the performance of food safety verification activities, they observe conditions or activities that cause them to suspect that the plant is not meeting labeling regulatory requirements. Similarly, if while performing a scheduled labeling verification task IPP have food safety concerns, they are to perform the appropriate HACCP system verification task as a directed task and take any necessary enforcement actions. For example, if an inspector is performing a labeling verification task and upon organoleptic examination determines that the product is off-condition or has an unsatisfactory odor (9 CFR 590.5 (Adulteration) and 590.504(b)), he or she is to perform the applicable HACCP system verification task directed as instructed in FSIS Directive 5000.1 to verify the applicable regulatory requirements and to determine whether the product is adulterated and document noncompliance if appropriate.

D. IPP are to examine product (9 CFR 590.424) to determine whether the product complies with regulatory requirements such as product standards (21 CFR part 160), regulatory minimum or maximum limits of ingredients or components (FSIS Directive 7120.1, *Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products*), or whether product meets the labeling requirements. If IPP find that product exceeds any of the maximum limits, falls below the minimum requirements, or fails to meet any of the other labeling, there is regulatory noncompliance.

NOTE: The applicable labeling verification tasks include: General Labeling, Labeling – Product Standards, Labeling – Net Weights, and Other Inspection Requirements.

V. VERIFICATION ACTIVITIES UNDER GENERAL LABELING, PRODUCT STANDARDS/IDENTITY, AND NET WEIGHTS

A. IPP are to select one or more products in current production and verify that the applicable labels, containers, portable tanks, bulk shipments of edible egg products, and packaging material bearing USDA identification meet the requirements in 9 CFR 590.411-415.

NOTE: As of December 28, 2020, the Labeling and Policy Delivery Staff (LPDS) will no longer issue the PY-221 form nor provide an egg products approval number. IPP are to be aware that plants are to comply with the label approval provisions of 9 CFR part 412.1 and are responsible for obtaining label approval by submitting those requests to LPDS or generic label approval as described in 9 CFR 412.2. IPP are also to be aware that the plant is required to make these records available to IPP upon request to review and substantiate compliance with applicable labeling requirements as per 9 CFR part 412, 590.220, and 590.411.

B. IPP are to review plant records and product labels and observe plant operations to verify that the product complies with the regulations by determining whether:

1. The plant maintains records of product formulation and processing procedures, as prescribed in 9 CFR 590.410 through 412, (9 CFR 590.200(c)), to establish that the labels meet the applicable approval labeling requirements under 9 CFR 412.2 for generic approval and 9 CFR 412.1(e) for labels that require sketch approval;

2. The product meets any applicable product standards of identity to ensure that the label is not false or misleading;

NOTE: 9 CFR 590.411(c) includes, by reference, the requirements for specific standardized egg products under U.S. Food and Drug Administration regulations implementing the Federal Food, Drug, and Cosmetic Act, found in 21 CFR part 160.

3. The net weight of the product is accurately reflected on its label (9 CFR 590.411(c));

4. All ingredients have been added in amounts that come within the maximum or minimum level specified (e.g., color preservatives);

5. Ingredients are accurately declared on the product label in order of descending proportions by weight;

6. All required labeling features listed in 9 CFR 590.411(c) are displayed on the label (e.g., product name, ingredients statement, address line, lot number, net contents, official identification, plant number, and nutritional labeling, unless an exemption applies);

7. Product formulations and processing procedures are documented to ensure that labels conform to the requirements (9 CFR 590.411(c));

8. Labels of packages of egg products produced from shell eggs treated with ionizing radiation reflect that treatment in the ingredient statement on finished product labeling (9 CFR 590.410(a)(3));

9. Containers, portable tanks, and bulk shipments of edible egg products meet the labeling requirements per 9 CFR 590.411 through 590.414 and bear the official identification shown in Figure 1 of 9 CFR 590.413; and

10. Bulk shipments of unpasteurized egg products (including shell eggs from *Salmonella enteriditis* (SE) positive flocks diverted for treatment) or microbial pathogen-positive egg products meet the labeling requirements per 9 CFR 590.410(c). The label must be conspicuously located and printed and affixed on material that cannot be detached or effaced due to exposure to weather and bear the official identification per 9 CFR 590.415. IPP are to also verify that such products:

    a. Are not released into consumer channels until subjected to pasteurization, heat treatment, or other method of treatment sufficient to produce egg products that are edible without additional preparation to achieve food safety; and

    b. After pasteurization or treatment, the product may bear the official inspection mark as shown in 9 CFR 590.413.

NOTE: 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. Egg products plants may include a statement on the company's bill of lading for bulk shipments of unpasteurized egg products (e.g., tanker) that indicates the sourced shell eggs used were from SE positive flocks.

C. IPP are to verify the presence and accuracy of plant records (9 CFR part 412 and 590.411(c)) substantiating that each lot produced:

1. Complies with applicable standards of identity or product identity;

2. Contains ingredients, including non-egg ingredients, that are food grade;

3. Meets egg solids requirements;

4. Has batch records that correspond with the volume of packaged product produced; or

5. Meets other requirements as indicated on the product label (e.g., special claims, shelf-life claims).

D. IPP are to issue a noncompliance record (NR) when product does not comply with a non-food safety regulatory requirement and are to notify the plant orally of the finding. IPP are to consider all relevant factors when determining the amount of affected product. Factors IPP are to consider include such items as the plant's lot identification procedures, receiving records, and production records, as well as the average amount of product produced per shift or per production line. When necessary, IPP are to consult with their supervisor for assistance in determining the amount of affected product.

E. IPP are to take appropriate regulatory control actions (9 CFR 590.426), such as retention of product, rejection of equipment or facilities, stopping lines, or refusing to allow the processing of specifically identified product, if they determine that misbranded or adulterated product would enter commerce. Additionally, FSIS may rescind or refuse approval of false or misleading marks, labels, or forms of any container for use with egg products.

F. IPP are to issue an NR when they determine that the process is out of control, resulting in economically adulterated or misbranded product. IPP are to associate the NRs when noncompliances are related, as described in FSIS Directive 5000.1.

VI. IPP RESPONSIBILITIES FOR IMPORTED UNPASTEURIZED LIQUID EGG PRODUCT RECEIVED AT AN OFFICIAL EGG PRODUCTS PLANT

A. Unpasteurized egg products are not required to stop at an import establishment prior to proceeding directly to an official egg product processing plant in the U.S. that conducts a pasteurization process. IPP are to coordinate with the egg plant to monitor and track incoming shipments of imported unpasteurized liquid egg products prior to arrival at the official egg products plant.

B. IPP are to follow the instructions in FSIS Directive 9900.1, *Imported Product Shipment Presentation* for performing document review (9 CFR 590.915), proper presentation, and assignment of Types of Inspections (TOIs) in PHIS when the egg plant has notified IPP that a shipment of imported unpasteurized liquid egg product has arrived.

C. IPP are to refer to FSIS Directive 9900.4, *Import Applications* for information on the types of import applications and instructions on how to enter, submit, and review import applications in PHIS. When IPP are provided with a paper application (FSIS Form 9540-1), IPP are to follow the instructions in FSIS Directive 9900.4 to retrieve, review, and complete the application in PHIS. For electronic applications filed through the PGA Message Set, IPP are to review the applications in PHIS along with the certificate prior to receiving the lots as referenced in FSIS Directive 9900.4.

D. When IPP are notified by egg processing plant management that a shipment is presented, IPP are to access PHIS, search for the lot, access the Lot Manager screen, receive the lot which will simultaneously assign Types of Inspection (TOI), and then proceed with completion of the TOIs and verification of the lots. IPP are to refer to FSIS Directive 9900.2, *Import Reinspection of Meat, Poultry, and Egg Products,* for guidance.

NOTE: Currently Canada is the only country that is eligible to ship unpasteurized liquid egg product into the United States.

E. To complete data entry for egg product the lot IPP are to:

1. Enter all TOI findings and results into PHIS;

2. Ensure that all of the information necessary to complete the assignment is entered into PHIS;

3. Ensure that the assignment is properly completed and closed in the system;

4. Follow FSIS Directive 9900.8 for all refused entry instructions; and

5. Consult the DO on any problems with data entry or questions related to completing the data entry and closing the case file.

NOTE: IPP can access the PHIS Imports Inspectors User Guide and Imports Tutorials via FSIS Applications in the PHIS Help menu for additional guidance.

VII. DOCUMENTING VERIFICATION RESULTS IN PHIS

IPP are to use PHIS to document the results of their verification tasks, including findings of regulatory compliance and regulatory noncompliance. For additional instructions on how to use PHIS to document inspection results, please refer to the IPP Help, selecting the PHIS Help icon to access the Domestic Tutorials user guides and FSIS Directive 13,000.1, *Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)*. IPP are to follow the instructions in FSIS Directive

5000.1 for instructions on how to document and associate noncompliances.

VIII. QUESTIONS

Refer questions regarding this directive to your supervisor or as needed to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select Import for the inquiry type for import questions and Labeling for the inquiry type for labeling questions.

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.

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