

Egg Products Plants and the Rules of Practice

Objectives

After completing this module, participants will be able to do the following:

1. Describe the Rules of Practice (ROP).
2. Explain the enforcement actions that FSIS may take in egg products plants.
3. Identify circumstances where prior notice of enforcement action is not required.
4. Identify circumstances where prior notice of enforcement action is required.

References

1. FSIS Directive 5030.1, *Inspection Methodology Utilizing the PHIS for the Verification of Regulatory Compliance in Egg Products Plants*
2. 9 CFR 500, *Rules of Practice*
3. FSIS Notice 70-20, *Egg Products Inspection Regulatory Changes*
4. Final Rule Egg Products Inspection Regulations, *85 FR 68640*
5. 9 CFR 590, *Egg and Egg Products Inspection Regulations*

Egg Products Inspection Regulatory Changes

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.

On October 29, 2020, FSIS published a final rule, *Egg Products Inspection Regulations* (85 FR 68640). The final rule has staggered effective dates. Some provisions became effective on December 28, 2020. Provisions related to the implementation of Sanitation SOPs will become effective on October 29, 2021 or the egg products plants may opt in early. Provisions related to the implementation of HACCP systems will become effective on October 31, 2022 or the egg products plants may opt in early. Plants that produce egg substitutes or freeze-dried egg products and imports of these products will be regulated by FSIS on October 30, 2023.

Rules of Practice, 9 CFR 500, in Egg Products Plants

As of December 28, 2020, the FSIS Rules of Practice in 9 CFR part 500 apply to egg products plants. These rules of practice authorize FSIS to take certain actions against products or plants under certain conditions. FSIS actions under the rules of practice can

include regulatory control actions, such as retaining potentially adulterated products, rejecting insanitary equipment, suspending inspection, or withdrawing a plant's grant of inspection. IPP are to take regulatory control actions in accordance with 9 CFR 500.2 to prevent adulterated or misbranded products from entering commerce or to prevent adulteration of products by exposure to insanitary conditions. The egg products plants may appeal a regulatory control action, as provided in 9 CFR 590.310. When IPP believe that their findings may warrant additional administrative actions because of ongoing trends of noncompliance or other conditions described in 9 CFR part 500, they are to discuss their findings with the FLS.

Egg products plants are subject to 9 CFR 500.3. FSIS may take a withholding action or impose a suspension without providing the eggproducts plant prior notification, if the plant produced and shipped adulterated or misbranded product as defined in 21 U.S.C 1033 or the plant did not destroy adulterated egg product or did not reprocess adulterated product in accordance with 9CFR 590, within three days of notification.

Egg products plants will be subject to the provisions of 9 CFR 500.4(b) and (c) on October 29, 2021 when implementation of Sanitation Standard Operating Procedures become effective or earlier if egg products plants opt-in to early compliance with Part 416. Egg products plants will be subject to the provisions of 9 CFR 500.4(a) when implementation of HACCP systems becomes effective on October 31, 2022 or earlier if egg products plants opt-in to early compliance with Part 417.

Previously, the egg products regulations did not provide specific timelines for FSIS to provide notice to egg products plants that it was going to initiate a withholding action or impose a suspension. As per 9 CFR 500.5, IPP are to notify an egg products plant orally, and as promptly as circumstances permit, in writing, if FSIS takes a withholding action or imposes a suspension. IPP are to advise the egg products plant that it may appeal the action, as provided in 9 CFR 590.310 and 9 CFR 500.5.

Under the Rules of Practice, 9 CFR 500.6, the FSIS Administrator may file a complaint to withdraw a grant of Federal inspection, if a recipient of inspection or anyone responsibly that is connected to the recipient is unfit to engage in any business requiring inspection as specified in the Egg Products Inspection Act (EPIA).

Under 9 CFR 500.7, the FSIS Administrator may refuse to grant Federal inspection because an applicant has not demonstrated that adequate sanitary conditions exist in the establishment as required by 9 CFR part 590, or is unfit to engage in any business requiring inspection as specified in section 18 of the EPIA.

Under 9 CFR 500.8, FSIS may rescind or refuse to approve false or misleading marks, labels, or sizes or forms of container for use with any egg product under Sections 7 and 14 of the EPIA. If FSIS rescinds or refuses to approve false or misleading marks, labels, or sizes or forms of any container for use with any egg product, an opportunity for a hearing will be provided in accordance with the Uniform Rules of Practice, 7 CFR subtitle A, part 1, subpart H.

The FLS will correlate with District Office personnel to determine if enforcement actions are appropriate in accordance with FSIS Directive 5100.3, *Administrative Enforcement Action Decision-Making and Methodology*. IPP are to refer to FSIS Directive 5000.1, Rules of Practice, 9 CFR part 500 for instructions regarding the various steps of enforcement actions.

