



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 416, 417, 500, 590 and 591

[Docket No. FSIS-2005-0015]

RIN 0583-AC58

Egg Products Inspection Regulations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the egg products inspection regulations by requiring official plants that process egg products (herein also referred to as "egg products plants" or "plants") to develop and implement Hazard Analysis and Critical Control Point (HACCP) Systems and Sanitation Standard Operating Procedures (Sanitation SOPs) and to meet other sanitation requirements consistent with the meat and poultry regulations. FSIS is proposing to eliminate those current regulatory provisions that are inconsistent with HACCP, Sanitation SOPs, and the proposed sanitation requirements. FSIS is also proposing to specify in the regulations that official plants are required to process egg products to be edible without additional preparation to achieve food safety.

In addition, FSIS is proposing to: provide for generic approval as part of the prior label approval system for egg products; make changes to labeling requirements for shell eggs consistent with those in the Food and Drug Administration's (FDA's) regulations; require special handling instructions on egg products; eliminate the requirements for prior approval by FSIS of egg products plant drawings, specifications, and equipment; incorporate egg products plants into the coverage of the "Rules of Practice" that the Agency follows when initiating administrative enforcement actions; and change the Agency's interpretation of the requirement for continuous inspection in agency law.

FSIS is also announcing that it is seeking public comment on draft guidance designed to help small and very small plants producing egg products to meet the new regulatory requirements being proposed in this rulemaking. Should the rule become final, FSIS intends to finalize this guidance.

DATES: Comments must be received on or before (INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER). FSIS is providing a longer comment period than typical for this proposed rule because of the magnitude of

the proposed action and the need to provide for possible public meetings on the proposed action.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule and the draft guidance.

Comments may be submitted by any of the following methods:

- **Federal eRulemaking Portal:** This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.
- **Mail, including CD-ROMs, etc.:** Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.
- **Hand- or Courier-Delivered Submittals:** Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163B, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2005-0015. Comments received in response to this docket will be made available for public inspection

and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Victoria A. Levine, Program Analyst, Issuances Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 6079, South Agriculture Building, Washington, DC 20250-3700; telephone (202) 720-5627; fax (202) 690-0486.

SUPPLEMENTARY INFORMATION:

Executive Summary

FSIS is proposing to amend the egg products inspection regulations (9 CFR part 590) to require that official plants¹ that process egg products develop and implement Hazard Analysis and Critical Control Points (HACCP) systems and Sanitation Standard Operating Procedures (Sanitation SOPs), in accordance with the regulations in 9 CFR parts 416 and 417, and to meet proposed sanitation requirements (proposed 9 CFR part 591). The Agency is proposing to eliminate those regulations that are incompatible with the

¹ As defined in the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). Exempted plants, as defined in 9 CFR 590.5, are also official plants, per the statute.

regulations for HACCP and Sanitation SOPs and to convert prescriptive, command-and-control requirements to general sanitation standards.

Existing regulations that FSIS is proposing to revise or eliminate include those relating to egg products plant grounds and pest management; plant sanitation; plant construction, including rooms, doors, and windows; lighting; ventilation and odors; plumbing; sewage disposal; water supply and solution re-use; and dressing rooms, lavatories, and toilets. The Agency is proposing to replace all of these with general sanitation requirements, as it has previously done with the requirements on the same subjects in the meat and poultry products regulations.

The Agency is also proposing to specify in the regulations that official plants are required to process egg products to be edible without additional preparation to achieve food safety (proposed 9 CFR 590.570). This will ensure that the products are free of detectable pathogens. The proposed regulations will require egg product plants to maintain control of egg products that have been sampled and tested for public health hazards, e.g., *Salmonella*, until the test results become available (proposed amendments to 9 CFR 590.504). The proposed amended regulations will provide for the use of irradiated shell eggs in the

processing of egg products and food products containing them (proposed 9 CFR 590.590).

The Agency is proposing to make the egg products labeling and "other consumer protection" requirements, including requirements for generically approved labeling, more like the labeling requirements for meat and poultry products (proposed 9 CFR 590.412).

FSIS is proposing to align the import requirements for eggs and egg products more closely with the import requirements for meat and poultry products (proposed 9 CFR 590, Subpart B).

FSIS is proposing to change organizational terms and job titles that appear in the regulations but that are no longer used in FSIS (proposed amendment of 9 CFR 590.5).

FSIS is also proposing to change the Agency's interpretation of the requirement for continuous inspection in 21 U.S.C. 1034(a). Inspection will no longer be conducted during all processing operations, but may instead be provided at least once per shift.

Finally, FSIS is proposing to replace the rules of practice governing enforcement procedures for egg product plants with those that apply to meat and poultry product establishments (proposed amendments to 9 CFR part 500).

Costs attributable to the proposed rule are those associated with the development and implementation of HACCP plans and Sanitation SOPs and the need for new product labels with safe-handling instructions. The impact of the costs is somewhat mitigated by the fact that 93 percent of egg products plants already use a written HACCP plan to address at least one production step in their process.

FSIS will continue to test for *Salmonella* and *Listeria monocytogenes* (Lm) in egg products. If FSIS detects the pathogens in the product, under HACCP, plants will be required to take corrective actions to prevent recurrence of the problem, if the plant has determined the pathogen is reasonably likely to occur in its production process (9 CFR 417.3(a)). If FSIS detects the pathogen and the plant has not determined that the hazard is reasonably likely to occur, the plant will be required to take corrective actions and also will be required to reassess its HACCP plan (9 CFR 417.3(b)). FSIS also will continue to require that egg product plants test pasteurized egg products for pathogens. Plants must ensure that egg products that test positive for pathogens are condemned or reprocessed (9 CFR 590.422).

The proposed rule will provide greater flexibility and incentives for innovation through reductions in paperwork

and unnecessary approvals. In addition, plants voluntarily meeting HACCP requirements and also complying with current prescriptive regulations would reduce costs because they would be operating entirely under HACCP requirements.

Table 1: Summary of Estimated Costs and Benefits

Discussion of Benefits and Costs			
	Low	Mid	High
Benefits (\$1,000) ^a	5,585	5,585	5,585
Costs (\$1,000)	2,195.0	4,235.2	6,287.8
Net Benefits (\$1,000)	3,389.7	1,349.5	-703.1
Industry Benefits	<ul style="list-style-type: none"> • Long-term efficiency gains, as shown in academic literature derived from producing egg products in a HACCP system. • Less burdensome or elimination of waiver, blueprints, no objection letter, changes to production equipment, and label approval submissions to FSIS. • Cost savings from the elimination of overtime and holiday pay paid to FSIS inspectors for inspection. 		
Agency Benefits	<ul style="list-style-type: none"> • Long-term benefits from improved inspection personnel coverage. Egg products inspection personnel will now be trained under a HACCP system and can be positioned for inspection in traditional meat and poultry establishments. • Salary savings for the reduction in inspection at egg products plants. • Savings from the reduction or elimination of waiver, blueprints, no objection letter, changes to production equipment, and label approval submissions to FSIS from industry. 		
Industry Costs	<ul style="list-style-type: none"> • Cost to the plant to create HACCP plans and Sanitation SOPs. • Costs to the plant for additional 		

	<ul style="list-style-type: none"> recordkeeping and monitoring. • Cost to the plant for training personnel in the HACCP system.
Agency Costs	<ul style="list-style-type: none"> • Costs for training inspection program personnel in HACCP and egg products inspection. • Costs to the Agency to provide relief inspectors while egg products plants inspectors are being trained. • Additional travel costs for inspection personnel on patrol assignments in egg products plants. • Loss of overhead paid to the Agency by industry.

^a **Costs were annualized over 10 years at the 7 percent discount rate.**

A copy of each document referenced in this notice of proposed rulemaking is available for viewing in the FSIS Docket Room, on the FSIS Web site as a related document associated with this docket, and on www.regulations.gov, unless otherwise noted.

Table of Contents

I. Background

FSIS's Regulatory Jurisdiction over Egg Products

1. What Products Are Covered under the EPIA

2. Product Amenability Determinations under the EPIA

II. Proposed Changes to Specific Regulations

A. Part 591

B. HACCP

C. Sanitation SOPs

D. Sanitation Requirements

E. Egg Products are "Ready-To-Eat"

F. Not Applying the Mark of Inspection Pending Test

Results

G. Irradiated Shell Eggs

H. Preparing for Implementation of Regulatory

Requirements

I. Labeling and Other Consumer Protection Regulatory

Requirements

J. Rules of Practice

K. Other Regulatory Changes

1. Elimination of Egg Products Plant Equipment and
Facility Prior Approval Requirements

2. Import Requirements

3. Changes to Defined Terms
4. Conditions for Receiving Inspection
5. Miscellaneous Changes
6. Reinterpreting the Requirement for Continuous Inspection in 21 U.S.C. 1034(a)

III. Executive Orders 12866 and 13563 and the Regulatory Flexibility Act

IV. Paperwork Reduction Act

V. Executive Order 12988

VI. E-Government Compliance

VII. Executive Order 13175

VIII. USDA Nondiscrimination Statement

IX. Additional Public Notification

I. Background

FSIS's Regulatory Jurisdiction over Egg Products

FSIS carries out its food safety responsibilities with respect to eggs and egg products under the provisions of the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031-1056).

To prevent the entry into commerce of any egg product that is capable of use as human food and is misbranded or adulterated, the Secretary of Agriculture regulates the processing of egg products under 21 U.S.C. 1034. Section

1034(a) states that the Secretary "shall, whenever processing operations are being conducted, cause continuous inspection to be made, in accordance with the regulations promulgated under this Act, of the processing of egg products, in each plant processing for commerce, ..."

Therefore, under FSIS's current interpretation of the EPIA, an inspector needs to be on the premises during all such operations. The Secretary has also been authorized to make inspections, as appropriate, of the facilities of egg handlers (including transport vehicles) to determine whether shell eggs destined for the ultimate consumer are being held under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit after packing and contain labeling that indicates that refrigeration is required (21 U.S.C. 1034(e)).

Under 21 U.S.C. 1043, the Secretary of Agriculture has the authority to promulgate such rules and regulations as he deems necessary to carry out the purposes or provisions of the Act. The Secretary is also responsible for the administration and enforcement of the EPIA, except as otherwise provided in 21 U.S.C. 1034(d).

1. What Products Are Covered Under the EPIA

Under the EPIA, FSIS regulates egg products. FSIS also has been delegated the authority to establish

temperature and labeling requirements applicable to shell eggs destined for the ultimate consumer (see 21 U.S.C. 1034(e)(1)).

Under 21 U.S.C. 1033(f), the term "egg product" means any "dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products." The EPIA does not define "relatively small proportion," nor does it provide additional guidance as to what criteria the Secretary should take into consideration when determining what egg products consumers consider to be products of the egg food industry.

Under 21 U.S.C. 1034(a), the Secretary requires continuous inspection to be made of the processing of egg products in each plant processing for commerce. There are currently 77 such official plants that are under FSIS jurisdiction. Under the EPIA, "processing" means "manufacturing egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing,

cooling, freezing, drying, or packaging egg products” (21 U.S.C. 1033(w)). Thus, egg products processing operations, such as mixing, pasteurizing, freezing, packaging, or relabeling, must be conducted under continuous Agency inspection.

The definition of “egg product” in the egg products inspection regulations (9 CFR 590.5) includes a list of specific products that have been exempted as not being “egg products.” These exempted products include freeze-dried products; imitation egg products; egg substitutes; dietary foods; dried no-bake custard mixes; egg nog mixes; acidic dressings; noodles; milk and egg dip; cake mixes; French toast; and sandwiches containing eggs or egg products. Such products must, however, be prepared from inspected egg products or from eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs.² Exempted products are subject to the jurisdiction of the Food and Drug Administration (FDA).

As stated above, products that contain eggs only in a relatively small proportion are exempted from the definition of “egg product” and thus not amenable under the

² See the United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56.216(c).
http://www.ams.usda.gov/sites/default/files/media/Shell_Egg_Standard%5B1%5D.pdf

EPIA. Several of the products listed in the preceding paragraph have been exempted from the coverage of "egg products" for this reason, including dried no-bake custard mixes; egg nog mixes; acidic dressings; noodles; milk and egg dip; cake mixes; and French toast. The egg product ingredients in these foods are not easily distinguished in the food and are used simply to add flavor. Other products that include eggs but are not subject to FSIS jurisdiction are closed-face sandwiches containing eggs or egg products and balut, a Philippine delicacy. These products are subject to the jurisdiction of FDA.

Cooked egg products, such as cooked egg patties, cooked omelets, and freeze-dried cooked eggs, also fall under FDA's jurisdiction because they are produced from USDA-inspected and passed egg products. To eliminate confusion as to who has statutory authority over these types of products, FSIS is proposing to amend the definition of "egg product" in 9 CFR 590.5 to include cooked egg products as not being egg products under FSIS jurisdiction.

2. Product Amenability Determinations Under the EPIA

FSIS considers a product to be amenable under the EPIA if it consists of dried, frozen, or liquid eggs, with or without added ingredients. Examples include Pasteurized

Frozen Whole Egg with citric acid; plain Pasteurized Frozen Whole Egg without added ingredients; Pasteurized Liquid Yolk with 10% salt; Pasteurized Frozen Scrambled Egg Mix with Whole Egg and pepper, starch, and dried milk; Frozen Yolks with 10% sugar added; Frozen Egg Whites with whipping aids (such as sodium sulfate or triethyl citrate); Pasteurized Enzyme Modified Dried Egg Product with Egg Yolks and xanthan gum and citric acid to preserve color, and less than 1% silicon dioxide as an anticaking agent and phospholipase; Spray Dried Albumin; and Spray Dried Egg Whites with calcium citrate and salt (or other added ingredients).

FSIS has determined that some of the products on the list of specific products that have been exempted as not being "egg products" are incorrectly categorized as such. FSIS believes that these products, egg substitutes and freeze-dried egg products, are, in fact, egg products, and should therefore no longer be exempt from inspection by FSIS under the EPIA. FSIS is seeking comment on the number of facilities that might become dual jurisdiction facilities, that is, regulated by FSIS and FDA, if egg substitutes and freeze-dried egg products are no longer exempt from FSIS inspection.

Egg substitutes

Egg substitutes are low-cholesterol products that are characterized by yolk replacement by other non-egg ingredients such as vegetable oil, nonfat dry milk, soy protein, gums, food coloring, artificial flavors, and vitamins and minerals (for nutritional fortification). The fundamental ingredient in these products is egg white, but they may also include added egg-white solids or a small amount of yolk. When the EPIA and the egg products inspection regulations were written, the production of egg substitutes was exempted from United States Department of Agriculture (USDA) inspection in the egg products inspection regulations.

As a result, egg substitutes are under the jurisdiction of FDA. FDA has overseen the formulation, packaging, labeling, storage, and transportation of egg substitutes under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301-399). Egg substitutes do not undergo continuous inspection during processing (unless the starting ingredient is unpasteurized egg white), and most egg substitutes do not bear a USDA inspection legend.

However, FSIS tentatively finds that egg substitutes should no longer be exempt from inspection by FSIS under the EPIA. Egg substitutes are similar, if not identical,

in some cases, in formulation to egg products. Indeed, the egg product ingredient is distinctive and significantly contributes to the basic nature of egg substitutes by characterizing the food. The only substantive difference among these categories of products is color and nutrients. When a color additive is mixed with pasteurized egg whites, the resulting product is called an "egg substitute." The application of color to pasteurized egg whites has generally not been conducted under FSIS inspection.

The processing of egg substitutes is also similar to that of other egg products, and the contamination risks associated with these types of products are the same. Egg products and egg substitutes are manufactured using the same process, though egg substitutes processed in an FDA facility do not have to re-pasteurized; where CCPs exist in the manufacture of egg products, they exist in the production of egg substitutes, e.g., during mixing, blending, pasteurization, if applicable, cooling, and packaging. The fact that egg substitutes are formulated with pasteurized egg whites does not mean that all food safety risks associated with the products are eliminated. Some egg substitutes are not re-pasteurized after production, even though they have been further processed in the FDA facility. To produce egg substitutes,

manufacturers need to reprocess pasteurized egg whites because of the risk of product contamination post-pasteurization.

Because the risks associated with egg substitutes are the same as those associated with egg products, and because the reprocessing step presents a point in the process where contamination of egg substitutes might occur, under the EPIA, the processing of egg substitutes needs to take place within the framework of HACCP and Sanitation SOP preventive control measures. Furthermore, the addition of color and other ingredients does not materially change the products such that the jurisdiction over the inspection of the products should be different than for other egg products. In an effort to be more transparent about the roles and responsibilities of FSIS and FDA regarding eggs, and after consulting with FDA, FSIS is proposing to assert jurisdiction over egg substitutes.

In addition, FSIS is proposing to assert jurisdiction over freeze-dried egg products. Under 9 CFR 590.5, these are exempted from being egg products. However, FSIS tentatively finds this categorization to be incorrect. Freeze-dried egg products are amenable under the EPIA because they consist of a pasteurized egg product that is flash frozen and placed in a vacuum chamber where ice

particles are removed. The food safety risks associated with freezing the product and contemplated by the EPIA are the same whether the process takes place in an FSIS-inspected egg products plant or an FDA-inspected facility. As a result, if this proposal is adopted, freeze-dried egg products will no longer be exempt and will be subject to FSIS's jurisdiction. Therefore, FSIS is proposing to amend the list of products exempted as not being egg products in 9 CFR 590.5 to eliminate freeze-dried products and egg substitutes.

II. Proposed Changes to Specific Regulations

A. 9 CFR part 591

Under proposed 9 CFR 591.1(a), all official plants will have to comply with the requirements contained in 9 CFR parts 416, Sanitation, and 417, HACCP Systems. For the purposes of these parts, as well as 9 CFR part 500, Rules of Practice, an "official establishment" or "establishment" will include a plant that processes egg products (proposed 9 CFR 591.1(b)).

B. HACCP

FSIS is proposing to adopt HACCP as the organizing structure for its egg products food safety program because HACCP has been proven to be an optimal framework for building science-based process control into food production

systems to prevent food safety hazards. Under proposed 9 CFR 590.149(b) and 591.1(a), official plants will be required to comply with 9 CFR part 417, the Agency's regulation on HACCP, as a condition of receiving inspection.

HACCP is a flexible system that will enable official plants to tailor their control systems to the needs of their particular plants and processes. Under proposed 9 CFR 590.149(b) and 591.1 and 9 CFR part 417, each egg products plant 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. Plants will be responsible for developing and implementing HACCP plans that incorporate the controls that are necessary to produce safe egg products. Given the requirements in 9 CFR part 417, FSIS is proposing to amend or eliminate many of the processing and facility requirements contained in 9 CFR 590.500-575.

Under 9 CFR part 417, when developing a HACCP plan (9 CFR 417.2(b)), a plant conducts a hazard analysis to identify and list the biological, chemical, or physical food safety hazards that are reasonably likely to occur in

its production process for a particular product and the measures necessary to prevent, eliminate, or reduce the occurrence of those hazards to an acceptable level. The plant then identifies the points in each of its processes at which control is necessary to achieve this goal (9 CFR 417.2(c)(2)). These points are called "critical control points" (CCPs). The plant would have to establish critical limits for the preventive measures associated with each identified CCP. A critical limit is the maximum or minimum value to which a hazard must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. Critical limits are most often based on process parameters such as temperature, time, water activity, pH, or humidity.

FSIS is proposing to treat egg products similarly to the way it treats ready-to-eat (RTE) meat and poultry products. FSIS will require that official plants produce egg products to be edible without additional preparation to achieve food safety. Pathogens detected in or on RTE egg products would adulterate those egg products under 21 U.S.C. 1033(a)(1)) because they would contain a poisonous or deleterious substance which may render them injurious to health.

For example, FSIS regards any amount of Lm in an RTE product as a product adulterant (9 CFR 430.4). Because the product is RTE, it is likely to be consumed without any effort to kill the pathogen, and the presence of the pathogen may render the product injurious to health (21 U.S.C. 601(m)(1), 453(g)(1)) and would cause the product to be unhealthful.³ The same would be true of an RTE egg product containing *Salmonella* or Lm. While egg products may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes, they are produced to be edible without additional preparation to achieve food safety. The presence of *Salmonella* or Lm, therefore, would render the product injurious to health (21 U.S.C. 1033(a)(1)) and would cause it to be unhealthful.

FSIS has also addressed shiga-toxin producing E. coli (STEC) in certain raw beef products (non-intact or intended for non-intact use) in this manner. FSIS considers an acceptable reduction for STEC to be a reduction to an undetectable level (i.e., a level that would not be detectable using the FSIS testing method or a method with a

³ Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products; Final Rule (68 FR 34208, Jun. 6, 2003).

sensitivity at least equivalent to FSIS's method).⁴ This means that an establishment producing RTE meat or poultry products or certain raw beef products needs to address the pathogens so that they will not be detected by FSIS or other equivalent testing. FSIS has recommended that establishments do their own testing to verify that their HACCP systems address the pathogens of concerns.⁵ While establishments can use their own testing methods, those methods should be at least as sensitive as FSIS's.⁶ FSIS has also said that establishments can address the pathogen in their HACCP plan or Sanitation SOPs or other prerequisite program.⁷ This same guidance would apply to egg products plants.

Under the Agency's verification testing program, egg products are broken into seven product categories – four liquid and three dried. Each month, inspectors collect one egg product sample per process from each plant that produces egg products. Thus, inspectors could sample an egg products plant as many as seven times per month depending on the number of plant production processes occurring

⁴ E. coli O157:H7 Contamination of Beef Products (67 FR 62325, October 7, 2002) (available at: <http://www.fsis.usda.gov/wps/wcm/connect/ad259bcd-5b85-4696-9888-89872bee39ee/00-022N.pdf?MOD=AJPERES>)

⁵ Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products; Final Rule (68 FR 34214, Jun. 6, 2003).

⁶ FSIS. 2013. Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory (available at: <http://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651-b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab-062013.pdf?MOD=AJPERES>)

⁷ HACCP Systems Validation (80 FR 27557, May 14, 2015)

during the month. After inspectors collect the samples, FSIS Field Service Laboratories analyze the samples for the presence of *Salmonella* and Lm using the protocols listed in the Microbiology Laboratory Handbook.^{8,9}

Once a plant has established critical limits for the measures associated with each identified CCP, it will need to monitor the identified CCPs to assess whether the CCP is within the established critical limit (9 CFR 417.2(c)(4)). Monitoring is an integral part of HACCP, and monitoring frequencies must be sufficient to ensure that each CCP is under control. The plant's HACCP plan would also have to include corrective action to be taken when monitoring indicates that there is a deviation from a critical limit at a CCP, because the existence of a HACCP plan does not guarantee that problems will not arise (9 CFR 417.2(c)(5)). For example, corrective action plans must be in place to identify and correct the cause of a deviation and to determine the disposition of potentially adulterated product.

⁸ Isolation and Identification of *Salmonella* from Meat, Poultry, Pasteurized Egg, and Siluriformes (Fish) Products and Carcass and Environmental Sponges. January 2, 2017 (available at: <https://www.fsis.usda.gov/wps/wcm/connect/700c05fe-06a2-492a-a6e1-3357f7701f52/MLG-4.pdf?MOD=AJPERES>)

⁹ Isolation and Identification of *Listeria Monocytogenes* from Red Meat, Poultry, Ready-To-Eat Siluriformes Fish and Egg Products, and Environmental Samples January 2, 2017 (available at: <https://www.fsis.usda.gov/wps/wcm/connect/1710bee8-76b9-4e6c-92fc-fdc290dbfa92/MLG-8.pdf?MOD=AJPERES>)

Plants will also have to develop and maintain effective recordkeeping procedures that document the entire HACCP system (9 CFR 417.2(c)(6)). Finally, plants will need to list the verification procedures, and the frequency with which those procedures will be performed, that the plant will use to ensure that the HACCP system is in compliance with the HACCP plan (9 CFR 417.2(c)(7)). Periodic verification will help the plant to ensure that it is operating in accordance with its HACCP plan. The occurrence of unforeseen hazards evidences that the HACCP plan needs to be reassessed. If this proposal is adopted, individuals developing, reassessing, and modifying HACCP plans in accordance with 9 CFR 417.2(b) and 417.3 will have 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 (9 CFR 417.7(b)).

Under this proposal, if an egg products plant fails to develop and implement a HACCP plan that complies with proposed 9 CFR 590.149(b) and 591.1 and 9 CFR 417.2, or to operate in accordance with other 9 CFR part 417 requirements, FSIS is likely to file a complaint to withdraw or refuse inspection services, pursuant to 9 CFR

500.6 or 500.7. As with official meat and poultry products establishments, FSIS will verify that the plant's HACCP plans comply with the requirements of proposed 9 CFR 590.149(b) and 591.1 and 9 CFR part 417; that these plans have been validated by the facility; and that plants are producing egg products to be edible without additional preparation to achieve food safety. In other words, these products must be free of detectable pathogens.

Hazard analysis

If this proposal is adopted, each egg products plant will be required to conduct a hazard analysis to determine the food safety hazards reasonably likely to occur in its production processes and to identify the preventive measures that it needs to take to control those hazards (proposed 9 CFR 590.149(b) and 591.2 and 9 CFR 417.2(a)(1)). The analysis must include a flow chart that describes the steps of the process and that identifies the intended use or consumers of the finished product (9 CFR 417.2(a)(2)).

Contamination with *Salmonella* spp. can be a food safety hazard that is reasonably likely to occur in the production of egg products. Therefore, as part of its hazard analysis, each egg products plant should consider addressing this food safety hazard in its HACCP system.

Consistent with the application of HACCP in meat and poultry operations, plants may determine that the Sanitation SOP or a prerequisite program is an appropriate and suitable means to effectively prevent the occurrence of certain food safety hazards and thus make them not reasonably likely to occur.

HACCP plan

Under this proposed rule, each egg products plant will be required to develop and implement a HACCP plan covering each product produced whenever the hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. Note that a single HACCP plan may encompass multiple products within a single processing category (see proposed 9 CFR 590.149(b) and 591.2 and 9 CFR 417.2(b)(1)) if the food safety hazards, CCPs, critical limits, and procedures identified within are essentially the same.

Once completed, the HACCP plan must be signed and dated by a responsible official, that is, the individual with overall authority on-site or a higher level official of the plant. This signature signifies that the plant accepts and will implement the HACCP plan. The HACCP plan must be signed and dated not only upon initial acceptance by the processor but also upon any modification to the plan

and at least annually, as required by 9 CFR 417.4(a)(3) (9 CFR 417.2(d)).

Corrective actions

Under this proposed rule, the HACCP plan must identify the corrective actions that the plant will take when responding to a deviation from a critical limit and assign responsibility for taking corrective action. Corrective actions must ensure that no product that is injurious to health or that is otherwise adulterated as a result of the deviation enters commerce; that the cause of the deviation is identified and eliminated; that the CCP will be under control after the corrective action is taken; and that measures to prevent recurrence are established (proposed 9 CFR 590.149(b) and 591.2 and 9 CFR 417.3).

Because pre-established corrective actions may not cover every contingency, and unforeseen hazards or deviations may occur, 9 CFR 417.3(b) provides a series of steps that must be taken in such situations. These steps include segregating and holding affected product and conducting a review to determine the acceptability of the product for distribution, ensuring that any adulterated product or product otherwise injurious to health does not enter commerce, and reassessing HACCP plans to determine whether any modification is needed.

Validation, verification, and reassessment

Under this proposed rule, every egg products plant will be required to validate its HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis. Once the plant has determined that the HACCP plan is functioning as intended, it will have to validate that the plan is being effectively implemented (proposed 9 CFR 590.149(b) and 591.1 and 9 CFR 417.4(a)).¹⁰ FSIS will provide additional guidance to plants on how to validate their HACCP systems.

Upon completion of the hazard analysis and the development of the HACCP plan, the plant will conduct its initial validation, which consists of the activities the plant must perform to determine whether the plan is functioning as intended. During this initial validation, the facility repeatedly tests the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records, routinely generated by the HACCP system, in the context of other validation activities. Plants may use independent consultants, process authorities, or employees trained in

¹⁰ On May 14, 2015, FSIS announced the availability of the final revision of its Compliance Guideline for Hazard Analysis Critical Control Point (HACCP) systems validation (80 FR 27557).

accordance with 9 CFR 417.7 for plan development and validation.

The data used to validate a HACCP plan may be derived from various sources, including the scientific literature, product testing results, experimental research results, scientifically-based regulatory requirements, FSIS compliance guidelines, computer-modeling programs, and data developed by process authorities (a process authority is a person or organization with expert knowledge in the relevant products, process controls, and regulations). However, validation data must include at least 90 days of in-plant data or information reflecting the plant's experience in implementing the HACCP plan during plant operations. These data are needed because validation must demonstrate not only that the HACCP plan is scientifically sound, but also that this particular egg products plant can implement the HACCP plan and make it work.

To ensure that the HACCP plan is functioning as intended on a continual basis, the plant would conduct ongoing verification activities (proposed 9 CFR 590.149 and 591.1 and 9 CFR 417.4(a)(2)). Verification is intended to show that the HACCP system is working effectively on a day-to-day basis, resulting in the production of safe food. Verification is distinct from ongoing plant monitoring,

which is designed to provide a record showing that the written HACCP plan is being followed.

Verification includes repeatedly reviewing and evaluating the various components of the HACCP system. Verification activities should provide practical results specific to the operation of the given HACCP plan and could include, but would not be limited to, checking the adequacy of critical limits; reviewing CCP-monitoring records; reviewing monitoring and recordkeeping procedures; calibrating process-monitoring instruments; collecting in-line or finished product samples for biological (e.g. *Salmonella* spp.), chemical, or physical analysis; and directly observing and evaluating the adequacy of corrective actions.

Under this proposed rule, plants will also be required to reassess the adequacy of their HACCP plans at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Examples of such changes include changes in raw materials or the source of raw materials; product formulation; production volume; packaging; or the intended use or consumers of the finished product (proposed 9 CFR 590.149, 591.1, and 591.2, and 9 CFR 417.4(a)(3)). This reassessment must be conducted by an individual who has successfully completed a course of

instruction in the application of the seven HACCP principles, including a segment on the development of a HACCP plan for a specific product, for example, liquid egg product, and on record review (9 CFR 417.7(b)).

By periodically monitoring its HACCP plan, a plant can ensure that the plan is continuously effective in controlling and preventing food safety hazards. It also provides a plant the opportunity to apply relevant experiences to improving process controls.

Records

Under this proposed rule, plants will have to maintain records regarding their operations under HACCP. These records include the written hazard analysis and all supporting documentation, the written HACCP plan and all decision-making documents associated with the development of CCPs and critical limits, and documents supporting the monitoring and verification procedures selected and the frequency of those procedures. Records documenting the monitoring of CCPs and critical limits, corrective actions, verification procedures and results, product codes, and product name or identity will also have to be maintained. Each entry on a record maintained under the HACCP plan will have to be made at the time the specific event occurred and

include the date and time recorded, and be signed or initialed by the employee making the entry.

Prior to shipping product, the plant will have to review the processing and production records associated with the HACCP plan to ensure that they are complete, all critical limits were met, and, if applicable, that corrective actions were taken (proposed 9 CFR 590.149 and 591.1 and 9 CFR 417.5(c)). This pre-shipment review will have to be conducted by someone other than the person who produced the records, where practicable, and preferably by an individual trained in accordance with 9 CFR 417.7 or the responsible plant official.

C. Sanitation Standard Operating Procedures (Sanitation SOPs)

General

Proper sanitation is an important and integral part of every food process and a fundamental requirement under the law. Insanitary facilities and equipment, and poor food handling and personal hygiene practices among employees, create an environment in which pathogens can flourish. Furthermore, the law is quite clear: eggs or egg products that have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth, or whereby they may have been rendered injurious to

health are deemed adulterated (21 U.S.C. 1033(a)(4)). FSIS inspection program personnel are expressly charged with ensuring that product is produced and held under sanitary conditions.¹¹ For these reasons, FSIS is proposing to require that all plants that process egg products develop, implement, and maintain written Sanitation SOPs to prevent direct contamination or adulteration of product before and during operations (9 CFR 416.11). Under this proposed rule, plants will be required to maintain daily records to document adherence to the SOPs (§ 416.16). FSIS is proposing to cross-reference 9 CFR part 416 in 9 CFR 591.1 rather than duplicate the regulatory text.

Sanitation SOPs are necessary because they clearly define each plant's responsibility to consistently follow effective sanitation procedures to minimize the risk of direct product contamination and adulteration. This proposal is based on FSIS's determination for meat and poultry plants that effective sanitation is essential for food safety and for the successful implementation of HACCP. FSIS is not aware of any reason why the same determination should not be made for egg products plants.

¹¹ Under 21 U.S.C. 1035, official plants must be operated in accordance with such sanitary practices and have such premises, facilities, and equipment as are required by regulations promulgated by the Secretary to effectuate the purposes of the EPIA.

Well-run plants have effective quality control and sanitation programs, including written Sanitation SOPs. Such programs are based, in large part, on the plants' recognition of the link between the existence of insanitary conditions during the processing and production of egg products and the likelihood that bacteria, including pathogenic bacteria, will contaminate the finished product. Some plants, however, do not have adequate programs and do not consistently maintain good sanitation. In fact, poor sanitation is the most frequently cited problem identified by FSIS inspection program personnel in egg products plants.

If FSIS finalizes this proposal, all official plants will be required to develop, implement, and maintain written Sanitation SOPs, as well as comply with the Sanitation requirements (9 CFR 416.1-6), in accordance with 9 CFR part 416. As a result, FSIS is proposing to amend or replace many of the current sanitary requirements contained in 9 CFR 590.500-575. The plant's Sanitation SOPs will need to describe all procedures the plant conducts daily to prevent direct contamination or adulteration of products (proposed 9 CFR 591.1(a) and 9 CFR 416.12(a)). The Sanitation SOPs will also need to specify the frequency with which each procedure in the Sanitation SOPs is to be

performed and identify the plant employees responsible for implementing and maintaining the procedures (9 CFR 416.12(d)). The Sanitation SOPs will have to be signed and dated, upon initiation and any modification, by "the individual with overall authority on-site or a higher level official of the plant." The signature will signify that the plant will implement and maintain the Sanitation SOPs in accordance with 9 CFR part 416 (proposed 9 CFR 591.1 and 9 CFR 416.12(b)). Official plants will also have to identify their pre-operational sanitation procedures in their written Sanitation SOPs, distinguishing them from sanitation activities to be carried out during operations (proposed 9 CFR 591.1 and 9 CFR 416.12(c)).

Under this proposal, each plant will be required to conduct the pre-operational and operational procedures as specified in the Sanitation SOPs, monitor the conduct of the procedures, and routinely evaluate the effectiveness of the SOPs and modify the Sanitation SOPs as necessary, in light of changes to the facility, personnel, or operations, to ensure that they remain effective in preventing direct product contamination and adulteration (proposed 9 CFR 591.1 and 9 CFR 416.13 and 416.14).

Plants will have to take corrective action when either the plant or FSIS determines that the Sanitation SOPs, or

their implementation, may have failed to prevent direct product contamination or adulteration (9 CFR 416.15(a)). Corrective actions include "procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOPs and the procedures specified therein ..." (proposed 9 CFR 591.1 and 9 CFR 416.15(b)).

If this proposed rule is adopted, plants will have to keep daily records documenting that the sanitation and monitoring procedures listed in the Sanitation SOPs are performed and maintain records documenting any corrective actions taken to prevent direct contamination or adulteration of products, or when the plant determines or FSIS notifies it that its Sanitation SOPs are inadequate (proposed 9 CFR 591.1 and 9 CFR 416.16(a)). Under this proposal, records may be maintained on a computer, provided that plants implement controls to ensure the integrity of the electronic data (9 CFR 416.16(b)). Records could be retained off-site, provided that they are not removed from the plant for at least 48 hours following their completion,

and that they can be provided to FSIS personnel within 24 hours of being requested (9 CFR 416.16(c)).

Under the proposed Sanitation SOPs, FSIS inspection program personnel will verify that plant management is conducting its operations in a sanitary environment and manner. Failure to comply with the Sanitation SOPs provides presumptive evidence of insanitation. As is now the case, inspection program personnel will act to prevent a facility from operating under insanitary conditions.

D. Sanitation Requirements

In addition to Sanitation SOP requirements, FSIS is proposing to remove the current sanitation requirements discussed below for egg products plants from its regulations. Some of the existing plant sanitation requirements will no longer be needed in light of the proposed HACCP and Sanitation SOP requirements. Further, some of the existing plant sanitation requirements impede innovation and blur the distinction between plant and inspector responsibilities for maintaining sanitary conditions. Should these regulations become final, they will provide official plants with more flexibility to innovate with regard to facility design, construction, and operations.

The sanitation requirements proposed in this rule will not only provide plants with the flexibility to innovate in facility design, construction, and operations but will also articulate the standards for good sanitation and for food product safety that must be met by egg products processors. All sanitation requirements have the same intent: A plant that processes egg products must operate under sanitary conditions, in a manner that ensures that the product is not adulterated and that does not interfere with FSIS inspection and its enforcement of such standards. However, because the proposed sanitation requirements define the results to be achieved by sanitation, but not the specific means to achieve those results, plants can meet the sanitation requirements in different ways. Regardless of the means by which plants comply with the standards under this proposed rule, the required results will be the same for all egg products plants.

FSIS is proposing to replace most of the current sanitation regulations in 9 CFR 590.500 through 590.560 with the general sanitation requirements set out in 9 CFR 416.1 through 416.6, which the Agency is proposing to incorporate by reference (proposed 9 CFR 591.1(a)). This proposed change will significantly reduce the number of egg and egg products sanitation regulations and consolidate

most sanitation requirements for eggs and egg products with those for meat and poultry products.

General Sanitation-9 CFR 416.1 and proposed 9 CFR 591.1

The current sanitation regulations for eggs and egg products require that plants, including rooms, windows, and floors, be kept clean and reasonably dry, and free from objectionable odors, flies, insects, and rodents. Section 416.1 of 9 CFR, which applies to meat and poultry establishments, provides greater flexibility: "Each official establishment must be operated and maintained in a sanitary manner sufficient to ensure that product is not contaminated, adulterated, or misbranded." Unlike command-and-control regulations, examples of which are cited below, 9 CFR 416.1 will provide facilities with the maximum possible flexibility to innovate in facility design, construction, and operation.

Examples of current requirements to be replaced by the general standards are: § 590.500(d), which states that materials and equipment not currently needed shall be handled or stored in a manner so as not to constitute a sanitary hazard; § 590.500(e), concerning doors and windows leading to rooms where exposed edible product is handled; § 590.522(a) concerning breaking room operations; and §

590.539(a), concerning the defrosting of frozen egg product in a sanitary manner.

The proposed rule would also provide flexibility to industry in facility design, construction, and operation by the replacement of the following regulations with the general standards in 9 CFR 416.1:

§ 590.506(c), which requires the installation of an approved exhaust system for the continuous removal directly to the outside of any steam, vapors, odors, or dust in the candling and transfer room; § 590.508(a), which states that candling and transfer rooms and equipment shall be kept clean, free from cobwebs, dust, objectionable odors, and excess packing materials; and § 590.546(b), which requires that the air intake source in albumen flake process drying facilities be free from foul odors, dust, and dirt.

Establishment Grounds and Pest Management-9 CFR 416.2(a)

The current egg products plant requirements for facility grounds are unnecessarily prescriptive. For example, 9 CFR 590.500(b) requires that the premises be free from refuse, waste, and other materials and conditions that constitute a source of odors or a harbor for insects, rodents, and other vermin, while § 590.500(g) states that drains and gutters shall be properly installed with approved traps and vents. Several other sections (§§

590.542(a), 547(a), and 548(a)) require that rooms be kept free of flies, insects, and rodents.

The other prescriptive establishment grounds regulations are 9 CFR 590.500(a) and (c), which require that the plant be free from objectionable odors, dust, and smoke-laden air and state that the buildings shall be of sound construction and kept in good repair to prevent the entrance or harboring of vermin, and § 590.522(a), which states that the breaking room shall be kept in dust-free clean condition and free from flies, insects, and rodents. In addition, 9 CFR 590.522(a) requires that the plant keep the floor clean and reasonably dry during breaking operations and free of egg meat and shells.

The general sanitation requirements in 9 CFR 416.2(a) preserve the intent of these requirements that grounds be maintained to prevent conditions that could lead to the contamination or adulteration of product, and that establishments implement and maintain an integrated pest control program to eliminate the harborage of pests on the grounds and within the plant facilities. This regulation, however, provides the flexibility and leave to innovate that the Agency is proposing to incorporate into the egg product regulations.

Establishment Construction-9 CFR 416.2(b)

The egg products inspection regulations concerning construction of egg products plants are very prescriptive and inflexible. For example, 9 CFR 590.500 prescribes numerous, specific requirements for different areas within an official plant, e.g., dressing rooms, toilet facilities, and refuse rooms. Other regulations containing prescriptive construction requirements include § 590.506, candling and transfer-room facilities and equipment; § 590.520, breaking room facilities; § 590.546, albumen flake process drying operations, § 590.560, concerning personnel facilities; and § 590.570(a), concerning pasteurization facilities.

Section 416.2(b) of 9 CFR sets out construction sanitation requirements that will allow for increased flexibility in regard to facility operation construction and maintenance if adopted by reference through proposed 9 CFR 591.1. Plants will be able to design facilities and equipment in the manner that they deem best to maintain the required sanitary environment for food production.

In addition to the six prescriptive egg products construction regulations listed above, there are seven more construction requirements that will be replaced by 9 CFR 416.2(b) if this proposal is finalized. They are 9 CFR

590.146(b) (5) and (d), concerning the requirements for floor plans and revised blueprints submitted prior to receiving inspection service or making changes or revisions to an official plant; § 590.500(i), (j), (l), and (o), concerning structure construction materials, maintenance requirements for rooms in which shell eggs or egg products are handled, and toilet and refuse room requirements; § 590.532(a), concerning liquid egg holding tank requirements; § 590.534(a), concerning freezing room requirements; § 590.548(c), which addresses heat treatment room construction requirements; § 590.550, dealing with washing and sanitizing room or area facility requirements; and § 590.560(a) and (b), concerning the health and hygiene of plant personnel and the construction of personnel facilities.

Light-9 CFR 416.2(c)

The lighting requirements for breaking rooms in official plants in § 590.520(a) prescribe specific light intensities for all working surfaces in the room and at breaking and inspection stations. For example, all working surfaces must have at least 30 foot-candles of light intensity, while breaking and inspection stations must have at least 50 foot-candles of light intensity. Other egg products regulations do not contain specific lighting

requirements, stating only that rooms shall be adequately or well-lighted (see §§ 590.500(1)(i), 548(a), and 550(a)).

The intent of the lighting requirements is to ensure that there is enough light of adequate quality to monitor sanitary conditions and processing operations and to examine product for evidence of adulteration or misbranding. Section 416.2(c) of 9 CFR has codified this intent as a general sanitation requirement, and it will be applicable to plants that process egg products if this proposed rule is finalized. Under 9 CFR 416.2, which requires that lighting be of good quality and of sufficient intensity to ensure that sanitary conditions are maintained, and that product is not adulterated, plants will have the flexibility to determine what light intensities are appropriate to ensure sanitation in different operational contexts. Therefore, FSIS is proposing to remove §§ 590.500(1)(1), 520(a), 548(a), and 550(a) from the egg products inspection regulations.

Ventilation-9 CFR 416.2(d)

The egg products inspection regulations addressing ventilation generally require that ventilation provide for a positive flow of outside filtered air through rooms and air of suitable working temperature during operations, and that rooms be kept free from objectionable odors and

condensation (see §§ 590.500, 590.504(p), 590.506(c), 590.520(d), 590.550(a)). Objectionable odors or condensation are to be reduced to the extent possible or eliminated because they can adulterate product. FSIS has codified a single sanitation requirement, 9 CFR 416.2(d), which preserves the intent of the current egg products regulations. This codification will simplify FSIS's egg products ventilation regulations by consolidating them into 9 CFR 416.2(d).

In addition to the regulations discussed above, FSIS is proposing to remove the following regulations from 9 CFR part 590 because they will be replaced by proposed 9 CFR 416.2(d) if this rule is finalized: 9 CFR 590.435(d), which states that containers and packing or packaging materials in which shell eggs are received into the official plant shall be free from odors and materials which could contaminate or adulterate the eggs or egg products; § 590.508(b), requiring the removal of containers for trash and inedible eggs at least once daily and their cleaning and treatment in such a manner as to prevent odors or objectionable conditions in the plant; § 590.530(a), which states that liquid egg storage rooms, including surface coolers and holding tank rooms, shall be kept clean and free from odors and objectionable odors and condensation;

and § 590.536(a), concerning the conditions in which freezing rooms are to be kept.

Other regulations to be replaced by 9 CFR 416.2(d) will be: 9 CFR 590.540(d), which states that air drawn into the drier in spray process drying facilities be free from foul odors, dust, and dirt; § 590.546(b), requiring that intake air sources in albumen flake process drying facilities be free from foul odors, dust, and dirt; § 590.549, requiring that dried egg storage be sufficient to adequately handle the production of the plant and be kept clean, dry, and free from objectionable odors; and § 590.560(b), requiring that toilets and dressings be kept clean and that toilet rooms be ventilated to the outside of the building.

Plumbing-9 CFR 416.2(e)

The design, installation, and maintenance of an adequate plumbing system are key responsibilities of an egg products plant. Because plumbing systems carry water into plants and convey water, sewage, and other waste from plants, problems with plumbing systems can easily cause product contamination or adulteration. The plumbing sanitation requirements in 9 CFR 416.2(e) set out the essential condition plants must achieve with their plumbing systems: plumbing systems cannot cause adulteration of

product and must ensure sanitary operating conditions. Plants otherwise will be allowed to build plumbing systems suitable to the nature and volume of their production. Therefore, FSIS is proposing to eliminate the requirement in § 590.500(g) that drains and gutters with approved traps and vents be installed. The Agency is also proposing to eliminate the prescriptive requirements regarding lavatory accommodations in § 590.500(l) and (m).

Sewage Disposal-9 CFR 416.2(f)

The current regulations require any person desiring to process egg products under continuous inspection to submit drawings and specifications before receiving approval of a plant and facilities as an official plant. Information that must be submitted includes how the plant intends to dispose of sewage (§ 590.146(b)(7)). Section 590.504(q) states that all liquid and solid material in the official plant shall be disposed of in a manner approved by the Administrator to prevent product contamination and in accordance with acceptable environmental protection practices.

Section 416.2(f) of 9 CFR, sewage disposal, will replace both of these regulations by requiring that sewage be disposed into a sewage system separate from all other drainage lines or disposed of through other means

sufficient to prevent backup of sewage into areas where product is processed, handled, or stored.

Water Supply and Reuse-9 CFR 416.2(g)

The current regulations regarding water supply and reuse in plants require that the water supply be ample, clean, and potable, with adequate pressure and facilities for its distribution throughout the plant or portion thereof utilized for egg processing and handling operations and protected against contamination and pollution (§ 590.500(h)). Section 590.500(h) also requires that the applicant for inspection obtain and furnish to the Administrator, at the Administrator's request, a water report, issued under the authority of a State or municipal health authority, certifying to the potability of the water supply. When ice is used as an emergency refrigerant by being placed directly into the egg meat, § 590.530(f) requires that the source of the ice be certified by the local or State board of health and that the ice be handled in a sanitary manner.

Section 416.2(g)(1) of 9 CFR sets out a transparent water supply performance standard concerning potable water. The water must comply with Environmental Protection Agency (EPA) National Primary Drinking Water regulations. These EPA regulations are applicable to public water systems.

Because these regulations already apply to potable water used by egg products plants, the reference in the sanitation requirements would not constitute a new requirement for these plants. The sanitation requirement also restates the current requirement that plants must make available to FSIS, upon request, State or local certificates attesting to water quality.

The egg products industry uses large quantities of water for processing products and for cleaning. Water and water based (aqueous) solutions are widely used for prewetting, washing, and rinsing eggs, product formulation, and cleaning and sanitizing equipment. Reuse of water solutions, therefore, can offer significant economic advantages.

Section 590.515(a), for example, sets forth the requirements for washing shell eggs to be presented for breaking. They include changing the wash water every four hours or more often if needed to maintain sanitary conditions and at the end of each shift (paragraph (a)(4)); adding replacement water to the wash water of washers continuously to maintain a continuous overflow (paragraph (a)(5)); piping waste water from the egg washing operation directly to drains (paragraph (a)(6)); and completing continuous washing operation as rapidly as possible

(paragraph (a) (7)). Section 590.516(a) requires that all shell eggs be spray rinsed with potable water containing an approved sanitizer of not less than 100 ppm but no more than 200 ppm of available chlorine or its equivalent immediately prior to breaking.

Section 590.552 establishes cleaning and sanitizing requirements for equipment used in egg processing operations that comes in contact with liquid eggs or exposed edible products. While such equipment may be cleaned by any sanitary means, it is preferable to use water to do so. Paragraph (b) (2) requires that shell eggs that have been sanitized and equipment that comes in contact with edible products be rinsed with clean water after sanitizing if other than hypochlorites are used as sanitizing agents.

Section 416.2(g) (2) through (6) of 9 CFR sets forth sanitation requirements for the reuse of water in meat and poultry establishments. If this proposal is adopted, plants will also be able to use reuse water in their operations, as appropriate.

Prior to the implementation of 9 CFR 416.2(g), reuse water was permitted in meat and poultry establishments only under certain circumstances, and any other reuse situation had to be approved by the Agency in advance. However, once

technologies were developed that can recondition water for safe and effective reuse in various applications, the Agency recognized that reuse water may be used safely and effectively in certain food processing situations.

Under 9 CFR 416.2(g), reuse water can be treated to render it free of biological, chemical, and physical hazards. Some of the general treatment options used include filtration, chlorination, ozonation, ultraviolet (UV) radiation, and heating. Use of these procedures can usually return water to a level of quality appropriate to its intended use. After treatment, however, such water should be tested regularly to ensure continual freedom from biological, chemical, or physical hazards.

Depending upon the original use, the intended use, and the duration of reuse, a wide range of acceptable biological, chemical, or physical contaminant levels are possible in reuse water. The previous degree of exposure or potential exposure to contaminants dictates the appropriate reconditioning treatment and the allowable reuse.

FSIS requires official egg products plants to produce pasteurized, RTE products that are free of pathogens. Therefore, reuse water that is used to chill or cook pasteurized, RTE egg products must be free of fecal

coliforms because their presence would indicate that the water was contaminated, possibly with pathogenic organisms (9 CFR 416.2(g)(2)). Other types of contamination will also have to be reduced sufficiently to prevent adulteration of product.

Section 416.2(g)(3) of 9 CFR deals with the use and reuse of water, ice, and solutions used to chill or wash raw product. In response to questions raised at public meetings in Columbus, OH, and Sacramento, CA, on March 30 and April 6, 2000, and Washington, DC, on July 31, 2001, held to obtain comments on FSIS's and FDA's thinking at the time on approaches to ensure egg safety from farm to table, FSIS has tentatively concluded that unprocessed shell eggs, i.e., eggs that have not yet been washed, sized, or candled, are more like raw product than RTE product. As a result, FSIS has determined that the provisions of 9 CFR 416.2(g)(3), which regulate the use of reuse water to wash raw product, will apply to official plants. Consequently, water used to wash unprocessed shell eggs may be reused for the same purpose, provided that measures are taken to reduce biological, chemical, and physical contamination so as to prevent contamination or adulteration of the eggs. Such reused water from use on raw eggs may not come into contact with processed shell eggs.

Paragraph (g) (4) of 9 CFR 416.2 will allow plants that recondition their water through an advanced wastewater treatment facility to use such reconditioned water on raw product, except in product formulation and throughout the plant in edible and inedible production areas. This water is not, however, potable, and it may not have ever contained human waste. Product, facilities, and equipment coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in 9 CFR 416.2(g)(1). The reuse water described above would most likely be used to wash solid waste from equipment and floors.

Paragraph (g) (5) of 9 CFR 416.2 will permit plants to use any water for any purpose in edible or inedible product areas, provided that it has never contained human waste, has been conditioned to be free of pathogenic organisms, and does not contact edible product. Finally, paragraph (g) (6) states that any water not meeting the conditions of 9 CFR 416.2(g) (1) through (5) may not be used, except in areas where no edible product is handled or prepared, and may not be used in any manner which would allow it to contaminate or adulterate edible product.

Moving the egg products water supply and reuse regulations into 9 CFR 416.2(g) will consolidate them with

those for meat and poultry. The proposed sanitation requirements in 9 CFR 416.2(g) are intended to and should account for every allowable water reuse situation in official plants, including those covered by the following egg products inspection regulations, which will be replaced by 9 CFR 416.2(g) if this proposal is finalized: § 590.520(e), which requires adequate and easily accessible hand washing facilities in an official plant; § 590.539(d)(1), which permits frozen eggs packed in metal or plastic containers to be placed in running tap water (70 degrees F or lower) without submersion to speed defrosting; and § 590.552(a) and (b)(2), concerning equipment cleaning and sanitizing requirements.

Dressing Rooms, Lavatories, and Toilets-9 CFR 416.2(h)

The current regulations concerning dressing rooms, lavatories, and toilets in egg products plants are highly prescriptive. For example, § 590.500(1)(2) provides a formula that serves as the basis for determining the toilet facilities required in an official plant, the intent being to ensure that plants provide an adequate number of toilet bowls, thus maintaining related sanitary conditions. The sanitation requirement in 9 CFR 416.2(h) gives plants the responsibility and flexibility to determine how many dressing rooms, lavatories, and toilets it needs. Of

course, plants will have to meet any applicable State and local codes concerning the number of lavatories and toilets in the workplace.

There are also other requirements for dressing rooms, lavatories, and toilets currently in the egg products regulations (see § 590.520(e), concerning hand washing facilities in breaking rooms, § 590.560(a) and (b), concerning health and hygiene of personnel, and § 590.146(b) (5), requiring floor plans to show the locations of hand-washing facilities and toilets). The proposed sanitation requirement in 9 CFR 416.2(h) eliminates the need for these requirements because it renders them redundant.

Equipment and Utensils-9 CFR 416.3

The egg products inspection regulations concerning equipment and utensils are unduly prescriptive and can deprive official plants of the flexibility to innovate in regard to equipment and utensil sanitation. The equipment and utensil sanitation requirement that FSIS is proposing to adopt for plants not only provides flexibility but also clarifies plant responsibility for selecting and maintaining equipment and utensils in a manner that effectively prevents product contamination or adulteration.

If this proposal is adopted, plants will no longer have to install and use equipment that complies with the applicable 3-A or E-3-A Sanitary Standards and accepted practices currently in effect for such equipment (§ 590.502(b)). Instead, equipment and utensils used for processing or otherwise handling edible product or ingredients will only have to be of such material and construction as to facilitate thorough cleaning and be durable and suitable for its intended use. Plants will need to ensure that product is not contaminated, adulterated, or misbranded during processing, handling, or storage. Equipment and utensils will still need to be maintained in sanitary condition so as not to contaminate or adulterate product. In addition to 9 CFR 590.502(b), FSIS is also proposing to remove the following sections from 9 CFR part 590 because 9 CFR 416.3 will make them redundant:

- § 590.500(n), requiring suitable facilities for cleaning and sanitizing utensils and equipment at convenient locations throughout the plant
- § 590.504(f) and (n), requiring personnel handling utensils or containers which may come into contact with egg products to wash their hands and maintain them in a clean condition and requiring most utensils and equipment to be

clean and sanitized at the beginning of processing operations and kept clean and sanitary during all processing operations

- § 590.506(a), which states that the equipment shall be arranged to facilitate cleaning and the removal of refuse and excess packing material from the candling and transfer room

- § 590.508(c) and (d), requiring the handling of shell eggs in a manner to minimize sweating prior to breaking and placing shell eggs with extensively damaged shells, unless otherwise prohibited, into leaker trays

- § 590.515(a) (1) and (b), requiring that shell egg cleaning equipment be kept in good repair and be cleaned after each day's use or more frequently, if necessary, and requiring that the temperature of wash water be maintained at 90 degrees F or higher, and shall be at least 20 degrees F warmer than the temperature of the eggs to be washed, throughout the cleaning cycle

- § 590.520(g), states that a suitable container conspicuously identified shall be provided for the disposal of rejected liquid

- § 590.522(d), (h), (s), (t), (u), (v), (y), (aa) (1)-(3), containing prescriptive requirements for the cleaning

of breaking machines and equipment, including mechanical breaking machines, as well as other equipment used in the processing of egg products, such as cups, knives, racks, etc., dump tanks, drawoff tanks, and churns, strainers, filtering devices, etc., and containers used for transporting liquid eggs products

- § 590.538, concerning the construction and cleaning of defrosting facilities

- § 590.539(f), concerning the cleaning of crushers and other equipment used in defrosting operations

- § 590.540(h), requiring the construction of powder conveying equipment as will facilitate thorough cleaning

- §590.542(b)(2) and (c)(1), requiring the sanitizing of spray process drying equipment within 2 hours prior to resuming spray drying operations and the clearing of sifters and conveyers used for other than dried albumen powder when such equipment is not to be used for 24 hours or longer

- § 590.548(b)(3)-(5), which requires that equipment and utensils used in dried eggs be kept off the floor and be kept clean at all times and whenever contaminated be cleaned and sanitized. It also requires that all equipment

used to mechanically package dried egg products be vacuum cleaned daily

- § 590.560(c) and (d), prohibiting personnel affected with any communicable disease in a transmissible stage or a carrier of such disease, or affected by a list of other health conditions, from coming into contact with equipment used to process eggs. Paragraph (d) requires workers coming in contact with equipment to wear clean outer uniforms

Food-Contact Surface Cleaning and Sanitation-9 CFR 416.4(a)

The egg products inspection regulations require that egg products plants clean food contact surfaces at the start of processing operations, and that they keep equipment and utensils clean and sanitary during all processing operations (9 CFR 590.504(n)). Section 590.522(aa)(3) of 9 CFR states that mechanical egg breaking equipment shall be clean and sanitized prior to use, and during operations the machines shall be cleaned and sanitized approximately every 4 hours or more often if needed to maintain them in a sanitary condition. It also requires that the equipment be cleaned at the end of each shift. See also 9 CFR 590.552(a).

The objective of the food-contact surface cleaning requirements has always been to mitigate biological,

chemical, and physical contamination that could adulterate product. The proposed food-contact surface cleaning sanitary operations requirement in 9 CFR 416.4(a) embodies this objective and clarifies plant responsibility for determining how best to achieve it. The advantage of this proposed standard is that it would provide plants with the flexibility to innovate when determining how to mitigate biological, chemical, and physical contamination that could adulterate product. For this reason, therefore, FSIS is proposing to remove the egg products inspection regulations discussed above, as well as following sections, and replace them with the sanitary operations requirement in 9 CFR 416.4(a):

- § 590.504(i) and (k), requiring the removal, cleaning, and sanitizing of utensils and equipment that are contaminated during the course of processing egg products and containing the admonition that all reasonable precautions be taken to avoid soiling or contaminating the surface of any package or container liner which is or will be in direct contact with egg products

- § 590.515(a)(4), which states that wash water will be changed every four hours or more often, if needed, to maintain sanitary conditions and at the end of each shift

- § 590.522(x), (z), and (aa)(2), requiring that containers for holding egg products variously be washed, rinsed, sanitized, and drained immediately prior to use and cleaned after each use. The pipelines of systems for pumping egg liquid directly from egg breaking machines must be cleaner or flushed as often as necessary to maintain them in a sanitary condition, and they must be cleaned and sanitized at the end of each shift. Other pumping system equipment must be cleaned and sanitized at least every four hours or sooner to maintain it in sanitary condition

- § 590.539(e), which states that sanitary methods will be used in handling containers and removing egg product

- § 590.542, which includes prescriptive requirements for maintaining sanitary conditions in spray process drying operations

- § 590.544(c) and (d), which states that dry blending must be done in accordance with § 590.548 or in a closed blending system and in accordance with clean, sanitary practices. Edible dried egg powder may be reconstituted, repasteurized, and redried when accomplished in a clean, sanitary manner

- § 590.548(b)(4), which includes prescriptive requirements for maintaining sanitary conditions in drying,

blending, packaging, and heat treatment rooms and facilities.

Non-food-Contact Surface Cleaning and Sanitation-9 CFR 416.4(b)

If this proposed rule (proposed 9 CFR 591.1) is adopted, official plants that process egg products will have to keep, in accordance with 9 CFR 416.4(b), non-food-contact surfaces, such as floors and walls, free of any biological contaminants, chemical contaminants, or physical contaminants that could adulterate egg products. FSIS is proposing to remove the following sections and replace them with the sanitary operations requirement in 9 CFR 416.4(b) because this requirement will give plants greater flexibility and responsibility for developing sanitary procedures specific to the nature of their operations:

- § 590.500(j) and (l)(1), requiring rooms and compartments in which shell eggs or egg products are handled or processed to be maintained in a clean and sanitary condition
- § 590.504(g) and (h), prohibiting the storage of products or materials that create objectionable conditions in any room, compartment, or place where shell eggs or egg products are processed, stored, or handled and permitting only compounds approved by the Administrator that will not

deleteriously affect shell eggs or egg products when used in an approved manner to be used in an official plant

- § 590.515(b), prohibiting shell eggs from being washed in the breaking room or any room where edible products are processed

- § 590.522(m), stating that ingredients used in, or for, processing egg products, must be handled in a clean and sanitary manner

§ 590.546(b), requiring that intake air sources be free from foul odors, dust, and dirt

- § 590.548(b)(3), requiring that dry blending equipment and supplies be kept off of the floor

Cleaning Compounds and Sanitizers-9 CFR 416.4(c)

Section 590.504(h) of 9 CFR requires that FSIS approve detergents, wetting agents, or other similar compounds, among other things, before they can be used within an official plant. Section 590.552(b) of 9 CFR states that sanitizing shall be accomplished by such methods as approved by the Administrator and requires the approval of chemicals and compounds used for sanitizing by the Administrator before use. These requirements are intended to ensure that egg products are not adulterated with chemicals or any injurious substance.

FSIS is proposing to replace 9 CFR 590.504(h) and 552(b) with proposed 9 CFR 591.1 and the single sanitary operations requirement in 9 CFR 416.4(c), which states that cleaning compounds and sanitizing agents must be safe and effective under the conditions of use, and that plants would not be required to obtain prior approval from FSIS. If this proposed rule becomes final, plants that process egg products would be able to use cleaning compounds and sanitizing agents that are safe and effective under the conditions of use. They would have to use, handle, and store them in a manner that would not adulterate product or create insanitary conditions and maintain documentation to support that these compounds and agents are safe and effective. Plants would, however, have to meet the use requirements for the substances promulgated by other regulatory agencies, such as FDA and EPA, who are responsible for ensuring that these substances are safe for their intended uses.

Operational Sanitation-9 CFR 416.4(d)

The egg products requirements for operational sanitation (sanitation measures carried out during operations) are spread through a number of regulations. (See 9 CFR 590.515 concerning egg cleaning operations; § 590.516 concerning sanitizing and drying of egg shells

prior to breaking; and § 590.522 concerning breaking room operations.)

These requirements are unnecessarily prescriptive. For example, § 590.515(a)(4) requires an official plant to change wash water approximately every 4 hours or more often if needed to maintain sanitary conditions and at the end of each shift. Section 590.522(s) requires the cleaning and sanitizing of cups, knives, racks, separators, trays, spoons, liquid egg pails, and other breaking equipment every 2½ hours.

If adopted, the sanitary operations requirement in 9 CFR 416.4(d) will consolidate the concepts in all of these operational sanitation requirements (which are discussed in this preamble and are currently spread throughout §§ 590.500-575) in a single place and remove them from the egg products inspection regulations. Plants will be required to protect egg products from adulteration during processing, handling, storage, loading, and unloading at and during transportation from their premises.

Employee Hygiene-9 CFR 416.5(a)

The current egg products inspection regulations mandate specific employee hygiene practices which egg products plants must adopt. For example, plant personnel handling exposed edible product must wash their hands

before beginning work and upon returning to work after leaving the work room (§ 590.560(e)). Section 590.560(f) states that expectorating or other unsanitary practices are not permitted in official plants.

The proposed sanitation requirement in 9 CFR 416.5(a) requires that all persons working in contact with product, food-contact surfaces, and product-packaging materials adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions. It would, if adopted, allow plants to develop alternative or innovative means to ensure that employee hygiene practices do not result in product adulteration, without being as prescriptive and restrictive as the current egg products inspection regulations. Therefore, FSIS is proposing to remove § 590.560 and replace it with the proposed sanitation requirement in § 416.5(a).

Employee Clothing-9 CFR 416.5(b)

The requirements regarding employee clothing are prescriptive. For example, § 590.560(d) states that workers coming into contact with liquid or dried eggs, containers, or equipment shall wear clean outer uniforms, while paragraph (h) of that section requires all persons in breaking and packaging rooms to properly wear hair nets or caps. Section 590.560(g) prohibits the use of tobacco in

any form or the wearing of jewelry, nail polish, or perfumes in any area where edible products are exposed.

As stated in the previous section, FSIS is proposing to remove § 590.560 and replace it with the sanitation requirement in 9 CFR 416.5(b) and proposed 9 CFR 591.1(a). If the proposed rule is finalized, cleanliness in employee hygiene would be required without the prescriptiveness of § 590.560. Under 9 CFR 416.5(b), aprons, frocks, and other outer clothing worn by persons in plants processing egg products who handle product must be made of material that is disposable or readily cleaned. Clean garments will also have to be worn at the start of each working day, and garments will have to be changed during the day as often as necessary to prevent adulteration of product and creation of insanitary conditions.

Employee Disease-9 CFR 416.5(c)

The sanitation requirement in 9 CFR 416.5(c) is similar to the requirements for employee health in § 590.560(c) to prevent transmission of communicable diseases. FSIS is proposing to remove § 590.560(c) and adopt proposed 9 CFR 591.1 and 416.5(c) for egg products plants.

Tagging Insanitary Equipment, Rooms, or Compartments-9 CFR
416.6

Retention tags or other devices and methods as may be approved by the Administrator are used for the control and identification of equipment, utensils, rooms, or compartments in official plants that are found to be unclean or otherwise in violation of the egg products inspection regulations (§ 590.426). This requirement is similar to the sanitation requirement articulated in 9 CFR 416.6, which requires the attachment of a "U.S. Rejected" tag to any equipment, utensil, room, or compartment at an official establishment that is insanitary, or the use of which could cause the adulteration of product. Both regulations prohibit the use of tagged equipment, utensils, rooms, or compartments until they have been made acceptable and require the removal of tags by program employees. Therefore, FSIS is proposing to replace § 590.426 with 9 CFR 416.5(c) and proposed 9 CFR 591.1. This proposed sanitation requirement for plants that process egg products would serve to provide consistency between the egg products requirements and the meat and poultry requirements.

Sanitation Performance Standards Compliance Guide

To meet the sanitation requirements proposed in this document, egg products plants may develop and employ

sanitation or processing procedures customized to the nature and volume of their production. However, FSIS has developed a Sanitation Performance Standards Compliance Guide (Compliance Guide) that presents or references methods already proven to be effective in maintaining sanitary conditions in meat and poultry products establishments, which is posted on the Agency's Web page: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/sanitation-performance-standards>. If this proposed rule is adopted, and before it takes effect, FSIS will update the Compliance Guide to include methods that are effective in maintaining sanitary conditions in egg products plants. Past FSIS regulations and guidance, as well as recommendations from the current Model Food Code issued by FDA and other technical sources, will be included or cited.

Plants that follow the recommendations in the Compliance Guide could be reasonably certain that they will be meeting the sanitation requirements. They would need to be mindful, however, that each processing environment is unique, and that in some cases, the methods presented in the Compliance Guide might require validating the adequacy to ensure sanitary conditions or to prevent the adulteration of egg products.

E. Egg Products are "Ready-To-Eat"

21 U.S.C 1036(a) requires that egg products inspected at an official plant and found to be not adulterated be pasteurized before they leave the official plant, except as otherwise permitted by the regulations of the Secretary. Any detectable pathogen would adulterate egg products under 21 U.S.C. 1033(a) (1) because it would contain a poisonous or deleterious substance which may render them injurious to health. Pasteurized egg products are ready-to-eat; that is, they have been prepared so that they can be consumed as is, without any additional cooking.

In 2005, FSIS undertook a quantitative microbial risk assessment to assist Agency risk managers in evaluating possible pasteurization performance standards for reducing the likelihood of *Salmonella* spp. contamination in liquid and dried egg products, and, subsequently, for reducing the risk of human illness, hospitalization, and death associated with egg products.¹² However, while the risk assessment showed that pasteurization resulting in a 6-log₁₀ reduction of *Salmonella* was predicted to be effective for reducing illnesses from *Salmonella* spp. in egg products, FSIS has chosen to propose a standard for egg products that

¹² FSIS. 2005. Risk Assessments of *Salmonella* Enteritidis in Shell Eggs and *Salmonella* spp. in Egg Products. (<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments>).

requires them to be produced to be edible without additional preparation to achieve food safety. FSIS has chosen this approach because in-plant inspectors cannot effectively verify whether a plant has met a specific lethality standard. The Agency can, however, effectively verify whether *Salmonella* is present in an egg product through testing. Overall, this approach is simpler than that of log₁₀ pasteurization performance standards and is consistent with the approach used by FSIS in establishing requirements for most RTE meat and poultry products.

Meat and poultry establishments produce the vast majority of their RTE products without needing to meet FSIS-specified time and temperature combinations or lethality performance standards codified in the regulations. The only FSIS regulations that include specific times and temperatures for ready-to-eat products are for cooked uncured meat patties, which must meet or exceed the times and temperatures listed in 9 CFR 318.23, and for pork, and products containing pork, which must meet or exceed the times and temperatures listed in 9 CFR 318.10. Cooked beef and poultry products must meet the lethality performance standards listed in 9 CFR 318.17 and 381.150. FSIS previously removed prescriptive time and temperature requirements for other ready-to-eat meat and

poultry products from the meat and poultry regulations. Such prescriptive time and temperature requirements are not necessary because under the statutes, establishments need to produce ready-to-eat products (including egg products) so that no detectable pathogens exist in the final products.

Therefore, FSIS is proposing to amend the egg products inspection regulations by removing the prescriptive regulations on the pasteurization of egg products (9 CFR 590.570 and .575). If this proposed rule is finalized, 9 CFR 590.570 would be replaced by a new regulation specifying that egg products are ready-to-eat and do not require additional steps to ensure food safety, consistent with the definition of "ready-to-eat" product in 9 CFR 430. Egg products must be produced such that the finished product is free of detectable pathogens. In addition, egg products would not be required to bear a safe-handling instruction or other labeling that directs that the product must be cooked or otherwise treated for safety.

The current requirements for egg products mandate step-by-step processing measures and specifically prescribe minimal time and temperature combinations for the pasteurization treatment of various egg products. Under HACCP, these prescriptive requirements are not necessary.

Under HACCP, egg products plants are required to produce product by controlling, eliminating, or reducing microbial hazards so that the finished product has no detectable pathogens.

Plants that choose not to develop new or modified procedures will be able to continue to follow a set of pasteurization time and temperature combinations for products that have been validated as achieving the intended pathogen reduction, such as those in the current regulations. FSIS has developed a draft compliance guideline document that includes these procedures. The draft guideline document can be found at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index>. An official plant would then need to validate that it is properly applying the FSIS time and temperature combinations provided in the guidance material and conduct monitoring and verification activities to demonstrate proper execution of the selected combinations.

The pasteurization time and temperature compliance guidelines specifically will assist small and very small businesses in identifying validated procedures. The materials will be posted on the Agency's Web site.

F. Not Applying the Mark of Inspection Pending Test Results

As discussed previously, egg products inspected at an official plant and found to be not adulterated must be pasteurized before they leave the official plant, except as otherwise permitted by the regulations of the Secretary. They must also bear the official inspection legend and official plant number of the plant where the products were processed.¹³

9 CFR 590.504(o) requires that egg products be pasteurized in accordance with the egg products inspection regulations before being released into consuming channels, while paragraph (o)(1) requires that they be sampled and tested for the presence of *Salmonella* to ensure that they were adequately pasteurized. 9 CFR 590.580 sets forth the specific testing requirements, and in this proposal, FSIS has rewritten this section for clarity.

While FSIS does not require final product testing for *Salmonella* in RTE meat and poultry products, the Agency is continuing to require testing for *Salmonella* for RTE egg products by official plants. An egg products plant's *Salmonella* testing data continues to be important in

¹³ 9 CFR 411(c)(5) requires that containers of product bearing official identification display that identification and the plant number. Official identification means the official inspection mark or any other symbol prescribed by the regulations in part 590 to identify the status of any article. See 9 CFR 590.5.

monitoring process control.^{14,15} As part of its control verification effort, FSIS also will continue to collect and analyze samples from egg product processes for *Salmonella* and Lm.

While 9 CFR 590.504(o) states that egg products must be pasteurized before being released into consuming channels, 9 CFR 590.504(d) does permit inspection program personnel to allow egg products to be moved from an official plant before the plant receives laboratory results for *Salmonella*, or any other test results, if the plant retains control of the product. The plant must ensure that the product will be returned to the plant for reprocessing if the test results show that the product is positive for *Salmonella*.

FSIS allows meat and poultry establishments to move product to locations other than the production facility prior to the receipt of FSIS test results so long as the establishment maintains control of the product. It also permits them to package and label products sampled and tested for adulterants with the mark of inspection pending negative test results, provided those products do not enter

¹⁴ The current *Salmonella* sampling levels that egg products plants must meet are provided in FSIS Directive 10,230.4, *Salmonella* Surveillance Program for Liquid and Frozen Egg Products.

¹⁵ The USDA, FSIS Pasteurized Egg Products Lab (PEPRLab) Program is a program for laboratories performing *Salmonella* analysis on official surveillance samples of pasteurized egg products.

commerce, i.e., the products remain under the establishment's control until negative test results become available. The product does not, however, actually receive the mark of inspection until negative test results have been returned.

The egg products regulations are the same. Egg products plants may move product pending test results only under circumstances that will ensure the return of the product to the plant for reprocessing, or under such other conditions as the Administrator may determine to ensure compliance with part 590. FSIS's practice of allowing egg products to be moved pending receipt of results of tests done by FSIS or the plant is codified in 9 CFR 590.504(d).

Failure of an egg products plant to hold or maintain control of product pending Agency or plant test results endangers public health. Therefore, FSIS is proposing to revise paragraph (e) to 9 CFR 590.504 to make clear that egg products plants that move product that has 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.

The Agency is not requiring the use of any particular control measures to ensure that product is not used or distributed for sale before test results are known.

Instead, egg products plants may continue to use, or develop, their own new, effective methods of control.

G. Irradiated Shell Eggs

Shell eggs that are subjected to ionizing radiation may be used in the production of egg products because when applied at sufficient doses, irradiation can be a means of destroying disease-producing bacteria in food and result in a pasteurized product. Specifically, food irradiation is the process of exposing food to high levels of radiant energy. Forms of radiant energy include: microwave and infrared radiation that heat food during cooking; visible light or ultraviolet light used to dry food or kill surface microorganisms; and ionizing radiation, resulting from cobalt-60, cesium-137, x-ray machines, or electron accelerators, that penetrates deeply into food, killing insect pests and microorganisms without significantly raising the temperature of the food. Food is most often irradiated commercially to extend shelf life, eliminate insect pests, or reduce pathogenic microorganisms. Food irradiation for these purposes is practiced in many countries, including the United States.

Irradiation is subject to the food additive provisions of the FFDCFA. FDA has the primary responsibility for determining whether food additives are safe for particular

uses. FDA lists uses of food additives it has concluded are safe in 21 CFR parts 172 through 179. Under section 201(s) of the FFDCA (21 U.S.C. 321(s)), a source of radiation used to treat food is defined as a food additive. A source of radiation is used to process or treat food such that, analogous to other food processes, its use can affect the characteristics of the food.

In a notice published in the *Federal Register* on March 20, 1998 (63 FR 13675), FDA announced that a food additive petition (FAP 8M4584) had been filed by Edward S. Josephson, University of Rhode Island, Food Science and Nutrition Research Center, 530 Liberty Lane, West Kingston, RI 02892-1802, to amend the food additive regulations to provide for the safe use of ionizing radiation for the reduction of *Salmonella* in fresh shell eggs.

The petitioner submitted published articles and other study reports containing data and information related to eggs and other kinds of food in the areas of radiation chemistry, nutrition, toxicology, and microbiology. FDA considered the data and studies submitted in the petition, as well as other information in its files relevant to the safety and nutritional adequacy of eggs treated with ionizing radiation.

Based on the totality of evidence from all evaluated

data and studies, FDA determined that: (1) the proposed use of irradiation on fresh shell eggs at levels not to exceed 3.0 kGy is safe, (2) the irradiation can achieve its intended technical effect of reducing the numbers of *Salmonella* in fresh shell eggs, and, therefore, (3) it should amend 21 CFR 179.26 to provide for the use of irradiation on fresh shell eggs. Consequently, on July 21, 2000 (65 FR 45280), FDA approved the use of ionizing radiation on eggs in the shell to reduce the internal level of *Salmonella*. It also amended its regulations by expanding the list of products (21 CFR 179.26(b)) for which ionizing irradiation may be safely used to include fresh shell eggs. (While FDA does not define the word "egg," FSIS has included the definition contained in the EPIA in 9 CFR 590.5.)

While the irradiation of fresh shell eggs at the doses approved by FDA will reduce the level of microorganisms in shell eggs (65 FR 45281, July 21, 2000), the irradiation treatment of shell eggs to be processed as liquid egg product will not sufficiently eliminate pathogens of public health concern from this form of egg. As a result, treating shell eggs used to process egg products only with ionizing radiation will not result in a final egg product that is completely pasteurized, i.e., RTE. Because the

irradiation treatment approved by FDA is insufficient to produce a ready-to-eat product based on the maximum approved irradiation dose specified in 21 CFR 179.26, it must be used in combination with other lethality treatments to complete the total lethality required to result in a pasteurized, RTE egg product.

Under proposed 9 CFR 590.590, the irradiation treatment must precede the heat or other lethality treatment because FDA has not approved the use of irradiation on egg products. Irradiated shell eggs or the use of the irradiated contents of fresh shell eggs for inclusion in pasteurized egg products must be reflected in the ingredient statement on the finished product labeling (proposed 9 CFR 590.410(a)(3)).

H. Implementation of Regulatory Requirements

Domestic Plants

All official plants will be subject to the requirements put forth in this proposal if it is adopted. FSIS intends to phase in the HACCP requirements in this proposal over a 2-year period after publication of a final rule, both as a means to reduce the impact for small and very small businesses and to ensure that FSIS inspection program personnel are properly trained and equipped with

the tools to carry out the new requirements for inspection. FSIS intends to enforce the Sanitation SOP measures and the sanitation requirements one year after publication of a final rule because these regulations should involve less significant changes for the plants, and these regulations provide the plant increased flexibility.

FSIS intends to enforce the requirement that egg products be processed to be edible without additional preparation to achieve food safety on the effective date of the rule. This requirement is consistent with current regulatory and statutory requirements; FSIS tests samples from all egg products for *Salmonella* and Lm. FSIS will continue to do so should this rule become final.

Under this proposal, FSIS would no longer control design specifications for buildings and equipment. Instead, FSIS would focus its regulatory attention on determining whether an official plant is successfully meeting sanitation requirements. Should this rule become final, plants would be required to ensure that the design of buildings and equipment is appropriate for sanitary food production and for maintaining good sanitary conditions in accordance with broad sanitation principles. In addition, official plants adopting Sanitation SOPs of their own design would identify the elements of good sanitation

required to prevent direct product contamination, carry out their Sanitation SOPs on a daily basis, and achieve acceptable sanitation results.

Foreign Plants

Under 9 CFR 590.910, to export egg products to the United States, foreign countries will have to have a system of inspection that is equivalent to the system in the United States. Should this rule become final, as HACCP and other regulatory provisions are implemented in the American domestic market, foreign countries that export egg products to the United States would be evaluated to ascertain whether their inspection systems provide equivalent food safety protection, including adequate levels of enforcement.

I. Labeling and Other Consumer Protection Regulatory Requirements

Official plants are responsible for ensuring that labeling used on egg products is truthful and not false or misleading (21 U.S.C. 1036). They are also responsible for ensuring that all labeling complies with the EPIA and the egg products inspection regulations. To ensure that official plants comply with applicable statutory and regulatory labeling requirements, FSIS conducts a prior approval program for labels used on federally-inspected egg

products (9 CFR 590.411). Examples of label features that FSIS evaluates include the standardized, common or usual, or descriptive name of the product; an ingredients statement containing the common or usual name of each ingredient listed in descending order of predominance; and handling statements if the product is perishable.

To obtain label approval, egg products plants must submit sketch labels to FSIS before they print the labels, containers, or packaging materials that bear official identification (9 CFR 590.411(a)). The information submitted is evaluated by the FSIS Labeling and Program Delivery Staff (LPDS) for conformance with the EPIA and the regulations adopted under it.

Before July 1996, FSIS conducted a prior approval program for meat and poultry labels used on federally-inspected meat and poultry products. As with egg products, the meat and poultry prior approval program was intended to ensure that the labels applied to those products complied with the labeling and standards requirements of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and their implementing regulations.

Effective July 1, 1996, FSIS modified its prior label approval program for meat and poultry products by eliminating the need for submitting final labels to the

Agency. The Agency changed the previous program by requiring the submission of only sketch labels (i.e., printer's proofs) and by expanding the types of labels that are generically approved and that could be applied to products in final form without first submitting such labels to the Agency for evaluation and approval (60 FR 67443, Dec. 29, 1995). FSIS took this action to improve the label approval system by eliminating the need for industry to re-submit sketches in final label form, thereby reducing the number of labels being submitted to the Agency for approval.

On November 7, 2013, FSIS published a final rule that amended the meat and poultry products inspection regulations to expand the circumstances under which the labels of meat and poultry products would be deemed to be generically approved by the Agency. Effective January 6, 2014, FSIS regulations only require four categories of meat and poultry product labels to be submitted to LPDS for approval, as described in 9 CFR 412.1. FSIS requires the submission of labels: 1) intended for temporary approval; 2) for products produced under religious exemption; 3) for products for export with labeling deviations; and 4) with special statements and claims as described in § 412.1(c).

All labels that do not fit into one of the four categories are eligible for generic approval.

As part of its effort to make the egg products inspection regulations as consistent as possible with the Agency's meat and poultry products regulations, FSIS is proposing to modify the prior label approval program for egg products labeling. If finalized, the program will be consistent with the prior label approval system that is in place for meat and poultry products, including the regulations that permit generically approved labeling. Under this system, only labeling that meets the criteria described in 9 CFR 412.1 will have to be submitted to FSIS for evaluation and approval.

Therefore, FSIS is proposing to revise 9 CFR 590.411 to require all official plants, including those certified under a foreign inspection system in accordance with 9 CFR 590.910, to comply with the requirements contained in 9 CFR 412.1. As a result, egg products plants will have to submit only four categories of product labels to FSIS for approval, including labels: 1) intended for temporary approval; 2) for products produced under religious exemption; 3) for products for export with labeling deviations; and 4) with special statements and claims as described in 9 CFR 412.1(c).

In addition, FSIS is proposing to revise 9 CFR 590.412 to require that all official plants, including those certified under a foreign inspection system in accordance with § 590.910, comply with the requirements in 9 CFR 412.2. Under this section, egg products plants would be authorized to use generically approved labels and thus would be free to use such labels without submitting them to the Agency for approval, provided the label displays all of the required mandatory features in a prominent manner and is not otherwise false or misleading in any particular.

As with meat and poultry products, FSIS would select samples of generically approved labels from the records maintained by official plants and plants certified under foreign inspection systems to determine compliance with label requirements (9 CFR 412.2(a)(2)). If the Agency finds that an official plant is using a false or misleading label, it would institute the proceedings prescribed in 9 CFR 500.8 to revoke the approval for the label.

Current 9 CFR 590.50 requires shell eggs that are packed into containers destined for the ultimate consumer to be labeled to state that refrigeration is required. However, on December 5, 2000, FDA amended 21 CFR part 101 to require that all shell eggs bear a safe handling statement. This statement, which is intended to inform

consumers that there may be a risk associated with the consumption of eggs, and of the ways that they can properly handle and prepare eggs in order to reduce such risks, specifically instructs consumers to keep eggs refrigerated (21 CFR 101.17). As a result, FSIS's labeling requirement essentially duplicates FDA's, which became effective on September 4, 2001. Since it is FSIS's intention not to unnecessarily burden any parties with its regulatory requirements, FSIS is proposing to state in its regulations that shell eggs packed into containers destined for the ultimate consumer must be labeled in accordance with 21 CFR 101.17(h).

Meat and poultry products that require special handling to maintain their wholesome condition are required to bear handling statements. To ensure that the egg products inspection regulations will be as consistent as possible with the Agency's meat and poultry products regulations, FSIS is proposing a similar requirement for certain egg products, 9 CFR 590.410(a). Under this proposal, packaged egg products that require special handling to maintain their wholesome condition would have to bear the statement "Keep Refrigerated," "Keep Frozen," "Perishable Keep Under Refrigeration," or a similar statement. This statement would have to be prominently

displayed on the principal display panel. Similarly, egg products that are distributed frozen and thawed before or during display for sale at retail would have to bear the statement "Keep Frozen" on the shipping container.

Consumer-sized containers for such egg products would have to bear the statement "Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated."

J. Rules of Practice

Under the EPIA, FSIS ensures that egg products are wholesome, not adulterated, and properly marked, labeled, and packaged. FSIS has broad authority to issue regulations to carry out the provisions of the EPIA, including the authority to prescribe terms and conditions under which inspection will be provided and maintained (21 U.S.C. 1035(b) and 1043).

Currently, when FSIS refuses to inaugurate inspection in a plant, seeks to withdraw inspection, or refuses to approve egg products markings, labels, or containers, the Agency initiates an administrative action under 9 CFR 590.160. FSIS is proposing to replace 9 CFR 590.160(a)-(c) and (f)(1) with the supplemental rules of practice contained in 9 CFR part 500. These supplemental rules already apply to meat and poultry products establishments. Should this proposed rule become final, 9 CFR part 500,

Rules of Practice, would apply to egg products plants, as an official establishment or establishment would include an official plant under proposed 9 CFR 591.1(b).

FSIS is proposing to amend 9 CFR 500.2(c) to add 9 CFR 590.310 to the list of regulatory citations under which an establishment¹⁶ may appeal a regulatory control action.

FSIS is also proposing to amend 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.

FSIS is proposing to amend 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 is also proposing to amend 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

¹⁶ For the purposes of Part 500, Rules of Practice, an official establishment or establishment includes an official plant. See proposed § 591.1(b).

connected to the recipient, is unfit to engage in any business requiring inspection.

FSIS is proposing to amend 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 is also proposing to amend 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). If this proposal is adopted, 9 CFR 500.8(c) 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.

Should this rule become final, FSIS would take a withholding action or impose a suspension without providing the plant prior notification because: (1) the official plant does not have a HACCP plan as specified in 9 CFR

417.2; (2) the official plant does not have Sanitation Standard Operating Procedures as specified in accordance with 9 CFR 416.11 and 416.12; or (3) the official plant does not maintain sanitary conditions (9 CFR 500.3(a)). FSIS would also take these actions 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, or when plant personnel assault, intimidate, or interfere with Federal inspection service (21 U.S.C. 1047).

The proposed rules of practice will ensure that enforcement procedures are fair; identify situations that may lead FSIS to take enforcement action that may include refusing to apply or withholding the marks of inspection from product or suspending or withdrawing inspection from facilities; provide an opportunity for official plants to address and correct problems before the Agency files a formal administrative complaint to suspend or withdraw inspection; establish the procedures FSIS will follow in taking such actions; and consolidate the rules of practice applicable to official plants with those applicable to meat and poultry products establishments.

K. Other Regulatory Changes

1. Elimination of Official Egg Products Plant Equipment and Facility

Prior Approval Requirements

The egg products inspection regulations require that official egg products plants applying for inspection submit to FSIS multiple sets of drawings of and specifications for the facilities for approval before inspection can be granted (§ 590.146). The regulations require plans to be submitted to the Agency for approval before any remodeling of facilities, and they require that prior approval by FSIS be obtained for equipment and utensils proposed for use in preparing edible product or product ingredients in official plants (§§ 590.146(d), 590.502, 590.504).

The prior-approval process is a feature of the traditional "command-and-control" regulatory approach. While prior approval provides assurance that equipment, facilities, and processes, as designed, meet certain requirements that are intended to ensure food safety or quality, it also reflects the emphasis of the current egg products inspection system on dictating the way in which official plants maintain sanitation and produce safe food. This feature of the current system is inconsistent with FSIS's view of the appropriate allocation of responsibility

between the Agency and official plants. It is an obstacle and too often a deterrent to innovation by official plants seeking to improve operations, and it contributes to unproductive use of FSIS resources both in managing the approval system and policing official plants' compliance with approved facility and equipment specifications.

Experience has shown that FSIS prior approvals are of limited value in ensuring good sanitation. They are limited in both scope, in that they deal only with official plant facilities as presented in drawings, and time, in that they are given once, on the condition that official plants will maintain a sanitary operating environment after their facilities are approved. Ultimately, an official plant's implementation of good Sanitation SOPs on a continuing basis is more critical than the actual design of a facility. Plant-operated sanitation procedures will achieve, without prior approval, the same objectives as the FSIS prior approvals, thereby rendering the prior approval procedures unnecessary. Thus, under HACCP-based inspection, the FSIS prior approvals could no longer be considered an efficient and cost-effective means to achieve sanitation objectives.

Under this proposal, although there will no longer be a requirement for an official plant to submit facility

drawings and specifications when applying for a grant of inspection, FSIS will continue to use a specific process to determine whether to grant inspection. This process will still include an on-site review, or "walk-through," of the plant's facilities by FSIS inspection program personnel as part of the pre-decisional review of the facility's capability to produce complying product. However, the decision-making process will no longer include the review and prior approval of facility blueprints and specifications by the Agency. The on-site review will not involve matching items on the blueprints with the actual facilities represented. Instead, the focus of the review will be on the extent to which the facility is able to maintain a sanitary environment for food production and not impede government inspection.

Prior approval by FSIS of equipment and utensils proposed for use in preparing edible egg products or product ingredients will also be eliminated under this proposal. FSIS's one-time approval does not address daily operational issues such as proper maintenance and adjustment of equipment to prevent product contamination. Such issues are covered by the requirement in 9 CFR 416.3 that equipment and utensils be of such material and construction that they can be thoroughly cleaned and

sanitized, as well as by other general sanitation requirements.

While facilities will be required to meet the general sanitation requirements prescribed in the regulations, they will have the flexibility to determine the specific steps to be taken to comply with those requirements. Facilities will be able to use equipment based on their own evaluation of their ability to utilize the equipment in a sanitary way.

In its inspection activities, FSIS will verify that plant equipment meets those general standards. FSIS inspection program personnel will act if they find that the equipment that a facility is using creates an insanitary condition that may render product injurious to health.

2. Eggs and Egg Products Import Requirements

FSIS is proposing to amend the regulations governing the importation and inspection of foreign eggs and egg products to align them more closely with the regulations governing the importation of foreign meat and poultry products. Historically, significant differences have existed in how FSIS makes determinations of eligibility for the import of meat and poultry products to the United States as opposed to determinations for imported egg products. Similarly, requirements and procedures for the

reinspection of imported products presented for entry into domestic commerce have been applied differently to meat and poultry products than to egg products. In this proposal, therefore, to improve import program efficiency and food safety controls, FSIS is seeking to harmonize the requirements and procedures applicable to imported eggs and egg products with those applicable to imported meat and poultry products.

FSIS is proposing to amend 9 CFR part 590 by adding a new subpart B, Imports (9 CFR 590.900 *et seq.*), that will contain the imported egg products regulations. FSIS is proposing to amend these regulations by adding 9 CFR 590.900, which includes paragraphs that define certain basic terms, Import (Imported) and Offered for entry, and for product from eligible countries: Entry (Entered). FSIS is also proposing to add the term Official Import Inspection Establishment consistent with the definition in the meat inspection regulations.

FSIS is proposing to add a new 9 CFR 590.901 to 9 CFR part 590 to establish the identity of inspected and passed imported egg products as domestic products. In so doing, the Agency seeks to ensure that imported egg products that bear the mark of inspection may be combined with inspected

and passed domestic products for purposes of further processing or sale in domestic commerce.

FSIS is proposing to amend 9 CFR 590.910 to establish the process and criteria that the Agency will follow to evaluate the equivalence of the inspection programs of foreign countries interested in gaining eligibility to export egg products to the United States. This section also delineates the manner in which foreign governments will be required to maintain the equivalence of their egg products inspection programs, including their certification of eligible establishments, separation of certified from uncertified establishments, and audits to verify the ongoing equivalence of food safety and HACCP controls in certified establishments. FSIS is also proposing to prescribe the manner in which foreign governments are to certify eligible establishments to FSIS. Finally, proposed 9 CFR 590.910 includes provisions for the public notification of determinations of equivalence made by FSIS of foreign egg products inspection programs.

FSIS is addressing those circumstances in which a shipment of imported egg products may be rejected for container defects, but are otherwise found to be acceptable, by proposing to add a new paragraph (d) to 9 CFR 590.945 to identify the conditions under which imported

egg products consignments with damaged containers may be reoffered for inspection.

For the handling of imported egg products, FSIS is proposing to amend 9 CFR 590.930 to require official import inspection establishments that re-inspect egg products to meet the sanitation requirements in 9 CFR part 416. The sanitation requirements in 9 CFR part 416 address conditions within establishments, such as facility and equipment sanitation, employee hygiene, and the development and implementation of sanitation standard operating procedures and associated recordkeeping requirements.

FSIS is proposing to amend 9 CFR 590.940 to establish official inspection marks for imported egg products. Current regulations require only that egg products found to be acceptable for importation be properly labeled and bear the inspection mark of the country of origin. FSIS is proposing that imported egg products bear the same mark of inspection that is applied to imported meat and poultry products. Additionally, this section outlines a procedure for the pre-stamping of official marks of inspection on product containers prior to the completion of an inspection assignment. These changes are intended to help to facilitate the clearance of inspected product during the

examination process when the product is not being held pending the receipt of laboratory test results.

FSIS is proposing to amend 9 CFR 590.945 to clarify the procedures for the treatment and handling of imported egg products identified as "U.S. Refused Entry." Paragraph (a)(5) of that section states that if the owner or importer fails to take the required action within the time specified under paragraph (a)(4) of this section, the Department will take such actions as may be necessary to effectuate its order to have the product destroyed for human food purposes. The Department shall seek court costs and fees, storage, and proper expenses in the appropriate forum.

FSIS is proposing to amend 9 CFR 590.955 to include shipping or identification marks among the list of required items for the labeling of imported egg products shipping containers. Shipping and identification marks are identifiers included on product container labels to distinguish product contained in a particular shipment from other product shipped elsewhere from the same production lot. Including shipping and identification marks on the shipping container labels facilitates identification of the product in the event of a recall or compliance investigation.

9 CFR 590.956 permits the relabeling of all egg products eligible for importation with an approved label under the supervision of an FSIS inspector at an official egg products plant or other location. Under proposed 9 CFR 590.411(f)(1), if the Administrator has reason to believe that any labeling, including the size or form of any container in use or proposed for use, with respect to egg products is false or misleading in any way, the Administrator may direct that such use be withheld unless the labeling or container is modified so that it will not be false or misleading, or the formulation of the product is altered so that it is not adulterated or would not cause misbranding.

While 9 CFR 590.956 permits the relabeling of all egg products eligible for importation with an approved label, proposed 9 CFR 590.411(f)(1) would permit only those products whose containers, labels, or packaging materials are false or misleading to be modified so that the containers or labels are not adulterated or would not be misbranded. Therefore, FSIS is proposing to amend 9 CFR 590.956 to permit only those egg products that have been refused entry into the United States solely because of misbranding to be brought in compliance with the labeling requirements of 9 CFR chapter III. An authorized

representative of the Secretary will have authority to supervise any such compliance activities.

Under 9 CFR 590.965, egg products that have been inspected and marked by USDA may be returned from foreign countries. They are not considered importations within the meaning of 9 CFR part 590. Because such products are inspected and passed U.S. product, they are handled in the same manner as domestic products. FSIS is proposing to amend 9 CFR 590.965 to permit the re-entry of inspected and passed egg products from foreign countries if they are not adulterated or misbranded at the time of such return. The product may be subject to reinspection in an official plant before it can be released into commerce. Such products would be exempted from further requirements under 9 CFR part 590, and returned shipments must be reported to the Administrator by letter prior to their arrival at the United States port of entry. The proposed language will be consistent with that for returned United States inspected and marked poultry products (9 CFR 381.209).

9 CFR 590.960 provides an exemption from foreign export certification and import inspection requirements for imported egg products that are intended for an importer's personal use, display, or laboratory analysis or that are not intended for sale or distribution in domestic commerce.

FSIS is proposing to extend the 50 pound exemption for dried egg products to liquid or frozen egg products, which may currently not exceed 30 pounds in weight. This proposed change is consistent with the personal exemption provisions for imported meat and poultry products, which permit any product in a quantity of 50 pounds or less which was purchased by the importer outside of the United States for his/her own consumption to be imported into the United States from any country without compliance with the provisions of chapter III of title 9.

On September 19, 2014, FSIS published a final rule amending 9 CFR 590.915 and 590.920 to provide an electronic alternative to the paper-based import inspection application and the foreign inspection and foreign plant certificate processes (79 FR 56220). It also removed from the regulations the discontinued "streamlined" import inspection procedures for Canadian product. The Agency is reproducing the amended regulatory text in the codified text of this rule for context and clarity. It is not, however, amending that text.

3. Changes to Defined Terms

FSIS is proposing to amend the egg and egg products inspection regulations by updating the terminology used to refer to Agency personnel and the definitions of various

terms. FSIS is proposing to remove the undesignated paragraphs of 9 CFR 590.5 that define *Chief of the Grading Branch, Inspector/Grader, National Supervisor, Regional Director, and Service* because such positions/entities do not exist within FSIS. As mentioned previously, FSIS assumed responsibility for conducting the egg products inspection program from AMS on May 28, 1995. Therefore, 9 CFR part 590 references should refer to FSIS and its officials. FSIS is also proposing to remove the term *Sanitize* from 9 CFR 590.5. As discussed earlier in this document, the Agency is proposing to consolidate the current sanitation regulations applicable to official plants into 9 CFR 590.1 and part 416. While not explicitly defined, the concept underlying the term "sanitize" is explained in 9 CFR part 416. Therefore, to eliminate this difference between the meat and poultry inspection regulations and the egg and egg products inspection regulations, FSIS is proposing to remove the term *Sanitize* from 9 CFR 590.5.

FSIS is also proposing to remove the definition for the term *Eggs of current production*. "Eggs of current production" are those eggs that have moved through the usual marketing channels since the time they were laid and

are not in excess of 60 days old.¹⁷ AMS uses the concept of "eggs of current production" to maintain the integrity of its quality standards and the AMS grade shield. It is a quality, not a food safety, indicator. Therefore, FSIS is proposing to remove the term because continued application of the regulatory requirement may unduly restrict the availability of edible eggs. However, FSIS is requesting comments on whether it should keep the term "eggs of current production," and any support that the term is still necessary.

Finally, FSIS is proposing to remove the definition for the term "plant." Under this definition, the term "plant" can refer to an exempted plant, i.e., a plant where the Administrator has determined that the facilities and operating procedures meet the standards prescribed in part 590, and where the eggs received or used in the manufacture of egg products contain no more than restricted eggs than are allowed by the official standards of U.S. Consumer Grade B for shell eggs, and where an exemption has been granted, or an official plant, which means any plant in which the plant facilities, methods of operations, and sanitary procedures have been found suitable and adequate for the continuous inspection of egg products in accordance

¹⁷ On April 19, 2006, AMS amended its definition of "eggs of current production" to mean shell eggs that are no more than 21 days old (71 FR 20288).

with part 590 and in which inspection service is carried on. FSIS is proposing to remove this definition because it is proposing to eliminate the exempted plant regulations, which is discussed later in this document. FSIS is proposing to add, in alphabetical order, an undesignated paragraph to 9 CFR 590.5 defining "official plant." An "official plant" will be any plant in which the plant facilities, methods of operation, and sanitary procedures have been found suitable and adequate by the Administrator for the inspection of egg products pursuant to the regulations in this part and in which inspection service is carried on.

FSIS is proposing to revise the undesignated paragraphs of 9 CFR 590.5 that define the terms *Administrator*, *Egg*, *Egg product*, *Pasteurize*, *Processing*, and *Shell egg packer*. FSIS is proposing to revise the definition for the term *Administrator* to make reference to the FSIS Administrator instead of the AMS Administrator. This change reflects the fact that the authority for inspecting egg products under the EPIA's food safety provisions was delegated by the Secretary of Agriculture to FSIS from AMS in November 1994.

Because the term *Dirty egg* or *Dirties* is defined twice in 9 CFR 590.5, once as an undesignated stand alone term

and once as a definition under the term *Egg* (paragraph c)), FSIS is proposing to eliminate this redundancy by removing the undesignated stand-alone term and its definition of *Dirty egg* or *Dirties*. While the definition of *Dirty egg* or *Dirties* in paragraph (c) of the term *Egg* is properly located, FSIS is proposing to revise it. The definition includes prominent stains as a criterion for classifying an egg as "dirty," but the EPIA's definition of the term does not include this criterion (21 U.S.C. 1033(g)(3)). In addition, rather than being called "dirties," dirty eggs are referred to as "dirts" in 7 CFR 59.720, which the Agency is proposing to add to the egg products inspection regulations. Consequently, FSIS is proposing to delete the words "prominent stains" from the definition of *Dirty egg* or *Dirties* in the regulations.

Also in 9 CFR 590.5, FSIS is proposing to replace the term *Official standard* with the term *Official standards*, correcting a typographical error made when the term was transferred from 7 CFR chapter 1, part 59 to 9 CFR chapter III, part 590 on December 31, 1998 (63 FR 72352).

FSIS is also proposing to amend the definition of *Processing*, to make clear that official plants may not repackage pasteurized dried egg products unless inspection program personnel are available to provide inspection

oversight during the process. FSIS is proposing to amend the definition of *Pasteurize* to eliminate the requirement that only lethality treatments prescribed in the egg products inspection regulations may be used to destroy harmful viable microorganisms.

FSIS is also proposing to amend the term *Shell egg packer (grading station)* by removing the phrase *(grading station)*. *Grading station* is a term used by AMS to differentiate between the two primary types of egg handlers: (1) producer-packers, who pack only their own production, and (2) grading stations, which are all other facilities that segregate and pack eggs. While FSIS also distinguishes between producer-packers and all other packing facilities in its regulations, the phrase *(grading station)*, when included as part of the defined term itself, causes confusion because FSIS does not perform any grading functions.

FSIS is proposing to add to 9 CFR 590.5 an undesignated paragraph that defines *Program employee* because it is specific to FSIS and refers to Agency personnel. FSIS is also proposing to define the phrase *Shipped for retail sale*. *Shipped for retail sale* means eggs that are forwarded from the processing facility for distribution to the ultimate consumer.

4. Conditions for Receiving Inspection

FSIS is proposing a 9 CFR 591.1(a) which, by cross-reference, will require that official plants, before receiving Federal inspection, develop written sanitation Standard Operating Procedures, in accordance with 9 CFR part 416, conduct a hazard analysis, and develop and implement a HACCP plan, in accord with 9 CFR part 417. Conditional inspection may be provided for a period not to exceed 90 days, during which period the plant will have to validate its HACCP plan.

5. Miscellaneous Changes

FSIS is proposing to amend the following egg products inspection regulations to match the text in the meat and poultry products inspection regulations:

9 CFR 590.118 Identification.

9 CFR 590.120 Financial interest of inspectors.

9 CFR 590.136 Accommodations and equipment to be furnished by facilities for use of program employees in performing service.

9 CFR 590.146 Survey and grant of inspection.

9 CFR 590.310 Appeal inspections.

FSIS is also proposing to eliminate the issuance of appeal certificates (9 CFR 590.360) and the cost of an appeal to a plant (9 CFR 590.370). Under current 9 CFR

590.300 and proposed 9 CFR 590.310, official plants have the right to appeal inspection decisions.

6. Reinterpreting the Requirement for Continuous Inspection in 21 U.S.C. 1034(a)

The EPIA requires the continuous inspection of the processing of egg products whenever processing operations are being conducted in each plant processing egg products for commerce (21 U.S.C. 1034(a)). FSIS has interpreted this to require the presence of inspection program personnel at each egg products plant whenever the manufacturing of egg products is being conducted, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing, drying, or packaging egg products. This level of inspection coverage is similar to that required at meat and poultry slaughter establishments, where FSIS conducts inspection during all slaughter operations. In contrast, at meat and poultry processing establishments, FSIS conducts inspection at least once per shift.

Based on the Agency's experience inspecting egg products plants since 1995, the Agency believes that egg products operations are more similar to meat and poultry processing operations, and especially those that produce ready-to eat products, than they are to meat and poultry

slaughter operations, where inspection is required for each meat or poultry carcass. Like ready-to-eat meat and poultry processing operations, the typical egg products processing operation is a streamlined, automated process, with one or more lethality steps to destroy pathogens of concern in the finished product. As a result, FSIS is proposing to change the Agency's interpretation of "continuous inspection" in 21 U.S.C. 1034(a). Therefore, FSIS now intends to require inspection in egg products plants at least once per shift, instead of during all processing operations. FSIS welcomes comment on possible criteria the Agency might use in determining how inspection will be specifically adjusted in egg products plants.

Section 590.100 provides exemptions from continuous inspection under certain circumstances, provided that the conditions for exemption and the provisions of the regulations are met. Paragraph (b) of 9 CFR 590.100 provides an exemption from continuous inspection at any plant where the facilities, sanitation, and operating procedures are the same as required in part 590 for official plants and where the eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards for U.S. Consumer Grade B shell eggs, and the egg products processed

at such plant. Plants granted an exemption under 9 CFR 590.100(b) are called "exempted plants."

Instead of continuous inspection, exempted plants are subject to periodic inspections, provided they have met the facility, operating procedures and practices, and sanitation standards required for official egg products plants as contained in 9 CFR 590.500-590.580. They are also subject to other provisions applicable to official plants, which includes maintaining records which must be made available to duly authorized representatives of the Administrator for review. Product from exempted plants may not bear official identification (9 CFR 590.680(a)). Exempted product labels must bear the statement, "Exempted-E.P.I.A. Registration No. ____." The registration number is that assigned to the exempted plant as provided in 9 CFR 590.650.

The Agency's proposal to no longer require inspection coverage during all processing operations removes the need for this exemption. The circumstances provided by this exemption can be accommodated under FSIS's changed interpretation of "continuous inspection" in 21 U.S.C. 1034(a) and would allow such exempted plants to bear official identification. Therefore, FSIS is proposing to remove the specific exemption from continuous inspection

found in 9 CFR 590.100(b), as well as the regulations in 9 CFR 590.600-590.680 authorizing these types of exempted egg products plants. The other exemptions from inspection for certain types of egg products processing, provided at 9 CFR 590.100(e) and (g), would remain, but would be redesignated as paragraphs (b)(1) and (2). Paragraph (f), now reserved, would be removed.

III. Executive Orders 12866, 13563, and 13771 and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, or reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated a "significant" regulatory action under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget under Executive Order (E.O.) 12866.

A. Need for Regulatory Action

The proposed rule will enable official plants to increase efficiency from complying with less burdensome regulations. FSIS is proposing that the current "command and control" egg products inspection regulations be changed to more flexible regulatory requirements. Under this proposed rule, egg products plants would be required to develop and maintain HACCP systems. A HACCP system allows greater flexibility for producers to realize increased production efficiency. In addition, the proposed rule will allow plants to use different pasteurization methods. With 93 percent of egg products plants already under a HACCP system,¹⁸ many have incurred additional unnecessary costs from complying with FSIS requirements in terms of "command and control" regulations and by processing under their own HACCP systems. By operating under the HACCP system alone, egg products plants can use plant resources in a more efficient manner while controlling for hazards in innovative ways in their HACCP plans.

Furthermore, regulatory action is warranted by the non-negligible public health risks associated with pasteurized egg products. The FSIS 2005 risk assessment estimated 5,500 cases of *Salmonella* per year due to

¹⁸ RTI International. 2014. "Survey of Egg Packing and Egg Products Processing Plants." Revised Final Report. RTI Project no. 0211740.015.001. 3040 Cornwallis Rd., P.O. Box 12194 Research Triangle Park, NC 27709-2194. OMB No. 0583-0162.

pasteurized liquid egg products. This represents 0.5% of the approximately 1.03 million annual domestically acquired foodborne illnesses caused by *Salmonella* estimated by Scallan et al. (2011, *Emerging Infectious Diseases* 17(1):7-15). Gurtler et al. (2013, *Foodborne Pathogens and Disease*, 10(6):492-499) identifies four *Salmonella* outbreaks during 2007-2012 that were possibly caused by contaminated pasteurized egg products. Also, process control failures in the production of pasteurized egg products have the potential for especially serious health outcomes because the Food Code recommends pasteurized egg products for highly susceptible populations (FDA 2013 Food Code, Sec. 3-8).

Baseline of the Egg Products Industry

Currently, egg products are produced under FSIS jurisdiction by 77 egg products plants. Egg products include liquid, frozen, and dried whole eggs, whites, yolks, and various blends with or without non-egg ingredients. According to the FSIS Public Health Information System (PHIS) Database, we estimate that the egg products industry produced 1.8 billion pounds of dried, frozen, and liquid egg products for distribution in commerce and produced 4 billion pounds of liquid unpasteurized product for further processing in 2014.¹⁹ Liquid egg products are produced in 73 percent of plants and accounted for 19 percent of all egg products marketed as finished product in 2014²⁰. Liquid egg products represent the largest product type produced by egg products plants.

A survey by RTI International in 2014, Egg Products Industry Survey²¹, showed that 93 percent of egg products plants use a written HACCP plan to address at least one production step in their process²². The remaining 7 percent

¹⁹ In the Fiscal Year 2014, the monthly average production volume was used to calculate the annual estimate for 77 egg products plants in the PHIS database.

²⁰ In the Fiscal Year 2014, the monthly average production volume was used to calculate the percentage for 77 egg products plants in the PHIS database.

²¹ RTI International. 2014. "Survey of Egg Packing and Egg Products Processing Plants." Revised Final Report. RTI Project no. 0211740.015.001. 3040 Cornwallis Rd., P.O. Box 12194 Research Triangle Park, NC 27709-2194

²² RTI International. 2014. "Survey of Egg Packing and Egg Products Processing Plants." Revised Final Report. RTI Project no. 0211740.015.001. 3040 Cornwallis Rd., P.O. Box 12194 Research Triangle Park, NC 27709-2194

would need to create HACCP plans under this proposed rule, as well as any of the 93 percent of egg products plants that have HACCP plans for some egg products, but not for others.

This proposed rule would require that egg products plants maintain sanitation SOPs equivalent to the specifications of FSIS. Ninety-one percent of egg products plants already conduct sanitation procedures for food contact surfaces either daily or more frequently and document those procedures for sanitation standard operating procedures (Sanitation SOPs).²³

Egg products production is easily the least labor-intensive process of the industries and products that FSIS regulates. Egg products plants tend to be highly mechanized and staffed with relatively low numbers of employees. Based on the results of a 2014 industry survey,²⁴ no egg products plants employ enough employees to be categorized as HACCP size Large. Because of the high product volume output to low employee count that egg products plants enjoy, nearly all plants that have less than 10 employees have over \$2.5 million in annual sales,

²³ Ibid.

²⁴ Under the HACCP size definitions, large establishments have 500 or more employees and small establishments have fewer than 500 but more than 10 employees. Very small establishments have fewer than 10 employees or annual sales of less than \$2.5 million. These definitions are outlined in Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems (61 FR 38806 (July 25, 1996) available at: <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf>.

making them ineligible for the HACCP size Very Small category. Therefore, the large majority (98 percent) of egg products plants fall into the HACCP size Small category. In this section, FSIS discusses the size of individual plants. For a discussion of the size of egg products businesses under the Small Business Administration's (SBA) definition, see the initial Regulatory Flexibility Analysis section of this document.

Table 2 displays plants and processes.

Table 2. Egg Products Plants and Total Processes

Plants	Breaking	Liquid	Dried	Total Processes
77	56	52	17	125

FSIS inspection of egg products plants includes 95 inspection program personnel (IPP), who conduct daily pre-operational sanitation inspections and monitor sanitary conditions of the plant premises, facilities, and equipment continually during operations at every egg products plant in multiple shifts. FSIS IPP are responsible for observing the cleanliness, type, and wholesomeness of raw materials and finished products, the handling of ingredients, pasteurization, packaging, labeling, freezing, storing, and all other operations related to the processing and production of egg products. In the past, FSIS has determined through regulation that, under the EPIA, IPP are

required to conduct continuous inspection at egg products plants. This requirement means IPP must be on duty whenever eggs are broken; liquid eggs arrive at the receiving plant; egg products are blended, reconstituted, or reformulated; egg products are pasteurized or packaged; and non-denatured inedible egg products arrive at, or are shipped from, the plant.²⁵

Expected Cost of the Proposed Rule

Presented here are economic analyses for the breaking of shell eggs, the production of pasteurized liquid egg products (including frozen egg products), and the production of pasteurized dried egg products. Also provided are estimated government costs associated with this proposed regulation. All recurring and one-time cost estimates are in 2016 dollars, and discount rates of 3 percent and 7 percent are used to calculate annualized costs over a 10-year period. For the purposes of the cost estimate, FSIS did not consider plant HACCP size because of the regularity in size explained previously (98 percent small). FSIS does not anticipate costs experienced by Very Small plants to differ greatly from those experienced by Small plants, because this proposed rule does not require any major capital, structural, or machinery investment or

²⁵ U.S. Department of Agriculture, Egg Products Inspectors Handbook. AMS PY-Instruction No. 910. January, 1975

the hiring of additional employees, which can impose a large burden on Very Small plants.

Egg products plant personnel compensation (wages and benefits) that plants would need to provide to their employees because of the proposed regulation is derived using Bureau of Labor Statistics Occupational Employment Statistics wage rates and National Compensation Survey benefits percentages. The wage rate for a Quality Control (QC) manager is estimated to be \$51.47 per hour; for Supervisors or QC technicians, \$34.26 per hour; and for Production workers, \$13.00 per hour.²⁶ Plants may pay employees for benefits such as paid leave, health insurance, and retirement and savings, and FSIS applied a benefits factor²⁷ of two to the hourly wage rate to estimate a total compensation rate for a Quality Control (QC) manager at \$102.94 per hour; and for Supervisors or QC technicians at \$68.52 per hour; and for Production workers at \$26.00 per hour.

Hazard Analysis & Critical Control Points (HACCP) Systems:

The cost estimates for HACCP implementation include costs associated with plan development and reassessment,

²⁶ Estimates obtained from the Bureau of Labor Statistics May 2016 National Industry-Specific Occupational Employment and Wage Estimates, for Management Occupations (Occupational Code 11-0000), <https://www.bls.gov/oes/current/oes113051.htm#ind>, Food Scientists and Technologists (19-1012), <https://www.bls.gov/oes/current/oes191012.htm>, and Production Occupations (51-0000) <https://www.bls.gov/oes/current/oes513023.htm>.

²⁷ This analysis accounts for fringe benefits and overhead by multiplying wages by a factor of two.

training, and monitoring and recordkeeping costs. If egg products plants follow current time/temperature regulations, FSIS would accept their approach, and FSIS would not require that plants do a significant amount of analysis in their HACCP plan. Upon completion of the hazard analysis and development of the HACCP plans, plants are required to determine whether their HACCP plans are functioning as intended. During the initial validation period, plants are to test, repeatedly, the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions identified in the HACCP plan.²⁸ Plants are also required to perform an annual reassessment of their HACCP plans.

HACCP Plan Development and Reassessment: Egg products plants operate to produce a variety of products using a number of different processing techniques. Under this proposed rule, each plant would be required to evaluate its processes to determine the adequacy of existing written HACCP plans and the number of plans that would need to be created or modified to meet the requirements of the proposed rule. A large number of egg products plants already have HACCP plans for their processes. These plants will be required to validate and reassess their HACCP plans

²⁸ 9 CFR 417.4

annually, to ensure that their HACCP plans are consistent with the regulations that FSIS is proposing in this document. For plants that currently lack HACCP plans, FSIS estimated the cost of initial plan development and validation and annual reassessment and validation. Under this proposed rule, every egg products plant would be required to reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in raw materials, source of raw materials, or product formulation. For the purposes of estimating costs, FSIS simplified the production of egg products into three processes: the breaking of shell eggs, the production of pasteurized liquid egg products (including frozen egg products), and the production of pasteurized dried egg products.

Using these three process definitions and data from PHIS, FSIS categorized plants by process. For reference, Table 2 above displays plants and processes. Using results from the 2014 Egg Products Industry Survey, FSIS applied a distribution, by process, of plants responding affirmatively to having a written HACCP plan to the population of egg products plants.²⁹ Using this data, FSIS

²⁹ See Appendix A, Section 4.

estimated the number of processes in those plants that require a HACCP plan to be developed. This information is displayed in Table 3.³⁰

Table 3. Processes without Written HACCP Plans

Breaking	Liquid	Dried	Total Processes
9	12	3	24

For plan development and reassessment, FSIS used the Cost of Food Safety Investments³¹ final report, updated for inflation from 2014 to 2016 dollars using the Consumer Price Index (CPI) for Urban Consumers, and, with the assumed benefits factor of two. FSIS estimates the costs for plan development and reassessment using the low estimate, (plan developed internally - low estimate - \$17, 130), the high estimate (plan developed with consultant - high estimate - \$42,423), and the average of the mid-estimates of the plan developed with a consultant and internally (\$31,271).³² FSIS also incorporated an initial validation cost of \$27,408 (\$13,704 - \$41,112) and

³⁰ For the purposes of the table, the number of processes was rounded to the nearest whole number. For the purposes of cost calculations and to be more exact, the Agency kept the actual figures, including digits past the decimal point, for instance, the number of total processes is actually 24.2507 rather than 24. These figures are not exact whole numbers because the Agency used the survey participant responses for which processes they use, as percentages of the total survey responses. These percentages were used to derive the total number of establishments that use each process applying that to the total population of egg products plants in Agency data (please see appendix A).

³¹ RTI International. Cost of Food Safety Investments Final Report. Available at: <https://www.fsis.usda.gov/wps/wcm/connect/0cdc568e-f6b1-45dc-88f1-45f343ed0bcd/Food-Safety-Costs.pdf?MOD=AJPERES>. These cost figures were adjusted for inflation using the average CPI-U from 2014 to 2016.

³² For plan development costs, in order to mitigate outliers, the Agency selected the greater of the two lowest costs between developing the plan internally and the cost for developing with a consultant for the low estimate, and the lesser of the two highest costs between developing the plan internally or with a consultant for the high estimate.

an ongoing (yearly) reassessment cost of \$28,188 (\$14,094 - \$42,282) for all HACCP plans. FSIS applied these estimates to the number of processes needing HACCP plans to determine the cost of HACCP plan development, validation, and reassessment, displayed in Table 4.

Table 4. Estimated HACCP Plan Development, Validation, and Reassessment Costs (\$1,000s)

Cost Component	Initial Cost (Low Estimate - High Estimate)*	Recurring Cost (Low Estimate - High Estimate)*	Annualized Cost - 3% (Low Estimate - High Estimate) over 10	Annualized Cost - 7% (Low Estimate - High Estimate) over 10 years
Development	758.3 (415.4 – 1028.8)	0	86.3 (47.3 - 117.1)	100.9 (55.3 – 136.9)
Initial Validation* for 25 New Plans	667.4 (332.3 - 997.0)	0	75.6 (37.8 – 113.5)	88.4 (44.2 – 132.7)
Annual Reassessment**	2,839.9 (1420.2 – 4,259.9)	3,523.5 (1,761.8 – 5,285.3)	3,445.7 (1,722.8 – 5,168.5)	3,432.5 (1,716.3 – 5,148.8)

* These estimates are calculated using the actual number of unrounded processes or 24.2507 processes.

** Initially, plants with existing HACCP plans will begin reassessing in year 1. Plants without existing plans, after developing their plans in year 1, will begin reassessing their plans in the following years.

The above analysis does not include costs associated with taking a corrective action when routine monitoring of a CCP detects a deviation from an established critical limit. It is not possible to determine the costs of these corrective actions, but we expect that, for well-designed processes with HACCP, these costs would occur infrequently.

HACCP Training and Personnel: We assume that each egg products plant will employ a QC manager and a QC technician to ensure compliance with the proposed measures. Based on the 2014 Egg Products Industry Survey final report,

approximately 7 percent of plants do not employ any HACCP plans.³³ Thus, we assume 7 percent of plants (approximately five) will need to obtain training for a QC manager, assuming one per plant, and a QC technician and three production workers for each processing operation shift (an average of 1.7 shifts per plant based on the results of the Industry Survey).

Although the HACCP system is different than the current system, FSIS believes that in egg products plants, only a portion of production employees, or a minimum number per shift, would actually receive training, given that the duties for most of the production employees will remain very similar or even the same when the plant operates under HACCP. FSIS is seeking comment on its assumed staffing and training cost estimates.

FSIS used initial and recurring annual refresher training cost estimates (updated using the CPI for Urban Consumers from 2014 to 2016 dollars and the assumed benefit factor of two) and the number of hours of training from the Cost of Food Safety Interventions³⁴ final report updated with the assumed benefit factor of two. QC Managers would be trained initially at a cost of \$3,991.29 (ranging from

³³ See Appendix A, Section 5.

³⁴ RTI International. Cost of Food Safety Investments Final Report. Available at: <https://www.fsis.usda.gov/wps/wcm/connect/0cdc568e-f6b1-45dc-88f1-45f343ed0bcd/Food-Safety-Costs.pdf?MOD=AJPERES>. These cost figures were adjusted for inflation using the average CPI-U from 2014 to 2016.

\$1,995.65 to \$5,986.94), with an annual refresher at a cost of \$205.88 (\$102.94 to \$308.82). QC Technicians would be trained initially at a cost of \$3,165 (\$1,583 to \$4,748), with an annual refresher at a cost of \$137 (\$69 to \$206). An additional opportunity cost for training was added to account for the time lost when employees were in training at the per hour compensation rate (including wage and benefit factor) of the employees being trained for the length of the training and for replacement personnel to work covering the time of the training. Production employees would also need to be trained; however, FSIS assumed that this training would take place on the job, and therefore would only impose opportunity costs. We use an annual turnover rate of 27.9 percent³⁵ to estimate recurring costs due to employee separation and the need to train new employees. These estimates are displayed in Table 5.

Table 5. HACCP-related Training Costs (\$1000s)

Plants	Shifts	Initial Training Costs (Low Estimate - High Estimate)	Recurring Training Costs (Low Estimate - High Estimate)	Annualized Cost - 3% (Low Estimate - High Estimate) over 10 years	Annualized Cost - 7% (Low Estimate - High Estimate) over 10 years
5	9	78.9 (39.5 – 118.4)	27.9 (13.9 – 41.8)	33.7 (16.8 – 50.5)	34.7 (17.3 - 52)

HACCP Recordkeeping: The proposal requires facilities to record observations when monitoring CCPs and to document any deviations and corrective actions. The rule requires

³⁵ Ibid.

that an employee not involved in recording observations certify such records. Recordkeeping costs include the time it takes to make observations and to record the results of those observations, plus the cost of certifying and maintaining records. The level and extent of recordkeeping for the proposed rule should not change greatly for egg products plants already using HACCP plans. Plants with existing HACCP plans are already documenting CCPs, as well as documenting information for the current regulations. For these plants, there will be a cost savings and reduction in recordkeeping costs, because they are keeping records for both a HACCP system and the current regulations.

FSIS used data from the 2014 Egg Products Industry Survey to estimate how many plants do not have HACCP plans, and the number of plans needed at these plants. FSIS also estimated the number of shifts at those plants.³⁶ The cost of recordkeeping is dependent on several factors, each of which has to be documented in some manner, such as the number of HACCP plans developed by each plant, the number of shifts operated by each plant, the number of CCPs per HACCP plan, the number of pre-shipment reviews conducted,

³⁶ See Appendix A, Section 6.

and any decision-making for hazard analysis that may require documentation.

The numbers of CCPs in egg products plants likely vary considerably across the industry. An FSIS technical expert³⁷ suggested four to six CCPs per HACCP plan, as an average. Therefore, we assumed that the average number of CCPs is five per egg products plant, per plan. We assumed 3 minutes (+/- 1 minute) for monitoring recordkeeping and 1 minute (+/- 30 seconds) for certifying per CCP³⁸. FSIS is seeking comment on these time assumptions. From the above assumptions, we estimate (Table 6) the annual cost of HACCP recordkeeping and monitoring. The Agency seeks comment on the number of CCPs anticipated, taking into account the variables listed above.

Table 6. Annual HACCP Recordkeeping and Monitoring Costs (\$1000s)

Plans	Effective Annual Shifts	Annualized – 3% Recordkeeping Costs (Low Estimate - High Estimate) over 10 years	Annualized – 7% Recordkeeping Costs (Low Estimate - High Estimate) over 10 years	Annualized – 3% Monitoring Costs (Low Estimate - High Estimate) over 10 years	Annualized – 7% Monitoring Costs (Low Estimate - High Estimate) over 10 years
24	10,509	68.3 (45.5 – 91.9)	68.3 (45.5 – 91.1)	60.0 (30.0 – 90.0)	60.0 (30.0 -90.0)

³⁷ Curtis, P., North Carolina State University, Raleigh, NC. October 5, 2001. Personal communication with Catherine Viator, RTI. Reported in RTI International. 2002. "Pathogen Reduction and Other Technological Changes in the Meat, Poultry, and Egg Industries." RTI Project no. 07182.017. 3040 Cornwallis Rd., P.O. Box 12194 Research triangle park, NC 27709-2194

³⁸ FSIS estimated these approximate time estimates by first hand observation at egg products plants.

Table 7 presents a summary of the total HACCP-related costs as a result of the rule. These figures are annualized over 10 years at 3 percent and 7 percent discount rates.

Table 7. Total HACCP-related Industry Costs (\$1000s)*

Cost Component	Annualized Costs - 3% (Low Estimate - High Estimate) over 10 years	Annualized Costs - 7% (Low Estimate - High Estimate) over 10 years
Plan Development and Reassessment	3,607.7 (1808.0 – 5399.1)	3,621.9 (1,815.8 – 5,418.4)
Training	33.7 (16.8 – 50.5)	34.7 (17.3 – 52.0)
Recordkeeping & Monitoring	128.3 (75.5 – 181.1)	128.3 (75.5 – 181.1)
Total	3,769.7 (1,900.3 – 5,630.7)	3,784.9 (1,908.6 – 5,651.5)

*Numbers in table may not sum to totals due to rounding.

Sanitation Standard Operating Procedures (Sanitation SOPs)

Plan Development: For the most part, plants already have plans for sanitation insofar as FSIS already requires certain sanitation procedures. FSIS used responses from the 2014 Egg Products Industry Survey³⁹, which describes the number of plants where they train their employees on sanitation SOPs, to estimate the percentage of plants that have sanitation SOPs. This accounts for approximately 91 percent of all egg products plants. FSIS assumed that if a plant is training production employees, then it has a written plan in place that the training is based on and would likely meet the requirements of the proposed rule.

³⁹ See Appendix A, Section 1.

FSIS then applied this percentage to determine the number of plants that would need to develop written sanitation SOPs (approximately 7). The current Sanitation SOP requirements for egg products plants will not change greatly, because the basis and standards for the sanitation of the plants will remain consistent with the current guidelines. For the proposed rule, the Sanitation SOPs will be created by the plant to meet FSIS standards under the HACCP system.

FSIS used cost estimates from the Cost of Food Safety Interventions⁴⁰ final report, with labor costs updated for inflation from 2014 to 2016 dollars and for the benefit factor described previously. For plan development, FSIS estimated costs using the low estimate (plan developed internally - low estimate - \$17,130), the high estimate (plan developed with a consultant - high estimate, \$31,018), and the average of the mid-estimates of the plan developed internally and with a consultant (\$27,469).⁴¹ The costs of Sanitation SOP plan development are displayed in Table 8.

⁴⁰ RTI International. Cost of Food Safety Investments Final Report. Available at: <http://www.fsis.usda.gov/wps/wcm/connect/0cdc568e-f6b1-45dc-88f1-45f343ed0bcd/Food-Safety-Costs.pdf?MOD=AJPERES>

⁴¹ For plan development costs, in order to mitigate outliers, the Agency selected the greater of the two lowest costs between developing the plan internally and the cost for developing with a consultant, and the lesser of the two highest costs between developing the plan internally or with a consultant.

Table 8. Costs Associated with the Development of Sanitation SOPs (\$1000s)

Cost Component	Initial Cost (Low Estimate - High Estimate)	Recurring Cost (Low Estimate - High Estimate)	Annualized Cost - 3% (Low Estimate - High Estimate) over 10 years	Annualized Cost - 7% (Low Estimate - High Estimate) over 10 years
Development	185.5 (115.7 – 209.5)	0	21.1 (13.2 – 23.8)	24.7 (15.4 – 27.9)

Recordkeeping: Under the proposed rule, plants would be required to maintain daily records sufficient to document the implementation and monitoring of sanitation SOPs. FSIS used data from the 2014 Egg Products Industry Survey to estimate the proportion of plants keeping sanitation records that would meet the requirements of the proposed rule consisting of employee task performance and a log for deviations and corrective actions.⁴² FSIS then determined how many of those plants are completing recordkeeping tasks daily.⁴³ Those plants that are not conducting recordkeeping or are conducting inadequate recordkeeping based on the proposed sanitation SOPs requirements will incur costs to do so.

For plants that are not keeping adequate sanitation records, FSIS estimated costs of recordkeeping based on the frequency of reported recordkeeping tasks. FSIS assumed that each sanitation recordkeeping task would be performed by a production employee and would take approximately 15

⁴² See Appendix A, Section 2.

⁴³ At least 1 pre-operational sanitation inspection of product contact zones per 9 CFR 416.13 and 416.12(c).

minutes (+/- 5 minutes) to complete. A sanitation recordkeeping task would be performed daily, unless the plant reported performing a task more than daily, in which case FSIS assumed there would be one task per shift (an average of 1.7 shifts per plant based on the results of the Industry Survey). The average number of shifts was calculated using question 5.2 of the survey, which asks respondents their total number of production shifts per day⁴⁴. The responses by small and large plants to question 5.2 were combined along with the total responses to get percentages for average number of shifts. The calculation is $25\% \times 3 \text{ shifts} + 18\% \times 2 \text{ shifts} + 57\% \times 1 \text{ shift} = 1.7 \text{ shifts}$.

FSIS further assumed that a QC technician would review records for approximately 10 minutes (+/- 5 minutes) once per day. FSIS used the recordkeeping estimates and time assumptions to estimate the cost to industry for Sanitation SOP recordkeeping, displayed in Table 9.

⁴⁴ Please see Appendix A.

Table 9. Sanitation SOP Recordkeeping Costs (\$1000s)

Current Recordkeeping Practices	Recordkeeping Frequency	Number of Plants	Annualized – 3% Recordkeeping Cost (Low Estimate - High Estimate) over 10 years	Annualized – 7% Recordkeeping Cost (Low Estimate - High Estimate) over 10 years
In compliance with proposed rule	< Daily	7	11.4 (7.6 – 15.2)	11.4 (7.6 – 15.2)
	Daily	26	0	0
	> Daily	17*	0	0
Not in compliance with proposed rule	< Daily	3	4.6 (3.0 – 6.1)	4.6 (3.0 – 6.1)
	Daily	12	20.5 (13.7 -27.4)	20.5 (13.7 – 27.4)
	> Daily	12	34.2 (22.8 -45.7)	34.2 (22.8 -45.7)

*For number of plants, FSIS multiplies the percentages from the survey for each category by total number of plants (77). For the category >Daily, in compliance, the calculation of 77 X 22.8% yields 17.56. This count was rounded down to 17 plants to be consistent with the total number of plants in the analysis of 77.

Table 10. Sanitation SOP Monitoring Costs (\$1000s)

Current Recordkeeping Practices	Recordkeeping Frequency	Number of Plants	Annualized – 3% Monitoring Cost (Low Estimate - High Estimate) over 10 years	Annualized – 7% Monitoring Cost (Low Estimate - High Estimate) over 10 years
In compliance with proposed rule	< Daily	7	20.1 (10.0 – 30.1)	20.1 (10.0 – 30.1)
	Daily	26		
	> Daily	17*		
Not in compliance with proposed rule	< Daily	3	8.0 (4.0 - 12.0)	8.0 (4.0 – 12.0)
	Daily	12	36.1 (18.0 – 54.1)	36.1 (18.0 – 54.1)
	> Daily	12	36.1 (18.0 – 54.1)	36.1 (18.0 – 54.1)

*For number of plants, FSIS multiplies the percentages from the survey for each category by total number of plants (77). For the category >Daily, in compliance, the calculation of 77 X 22.8% yields 17.56. This count was rounded down to 17 plants to be consistent with the total number of plants in the analysis of 77.

Training Costs: Egg products plants that are implementing new sanitation SOPs and those not in compliance will also need to conduct initial training for

employees. Using data from the 2014 Egg Products Industry Survey, FSIS estimated the number of plants that will need to develop new sanitation SOPs (see Table 11) and the average number of shifts at those plants.⁴⁵ FSIS assumed that one QC Manager per plant, and one QC Technician and three production employees per shift would be trained.⁴⁶ FSIS is seeking comment on these assumptions. FSIS assumed the recurring training would occur for all 77 plants. FSIS used initial and recurring annual refresher training cost estimates from the Cost of Food Safety Interventions⁴⁷ final report updated for inflation from 2014 to 2016 dollars and with the assumed benefit factor of two. QC Managers would be trained initially at a cost of \$2,756 (\$1,378 to \$4,134) with an annual refresher at a cost of \$205.98 (\$102.94 to \$308.82). QC Technicians would be trained initially at a cost of \$2,342.97 (1,171.50 to 3,514.46) with an annual refresher at a cost of \$137 (\$68.52 to \$205.56). FSIS added an additional opportunity cost to account for the lost hours when employees are in training. Production employees would also need to be trained, however, FSIS assumed that this training would take place on the job and therefore would impose only opportunity costs.

⁴⁵ See Appendix A, Section 3.

⁴⁶ An FSIS expert has also agreed with the Industry Survey and provided the likely staff needing training at a typical egg products plant.

⁴⁷ See Footnote 33.

FSIS included recurring training costs to account for labor separation and the need to train new employees. To estimate these ongoing costs, FSIS used an annual labor turnover rate of 27.9 percent⁴⁸ and applied that percentage to the initial training costs. The Sanitation SOP-related training costs due to the rule are displayed in Table 11.

Table 11. One-time and Recurring Sanitation SOP Training Costs (\$1000s)

Plants	Shifts	Initial Training Costs (Low Estimate - High Estimate)	Recurring Training Costs (Low Estimate - High Estimate)	Annualized Cost - 3% (Low Estimate - High Estimate) over 10 years	Annualized Cost - 7% (Low Estimate - High Estimate) over 10 years
34	59	363.7 (214.7 – 545.6)	140.3 (79.3 – 225.2)	181.7 (103.8 – 287.3)	188.7 (107.9 – 297.8)

Table 12 presents a summary of the total sanitation SOPs-related costs due to the rule annualized over 10 years at 3 percent and 7 percent discount rates.

Table 12. Total Sanitation SOPs-related Industry Costs (\$1000s)*

Cost Component	Annualized Costs - 3% (Low Estimate - High Estimate) over 10 years	Annualized Costs - 7% (Low Estimate - High Estimate) over 10 years
Plan Development	21.1 (13.2 – 23.8)	24.7 (15.4 – 27.9)
Recordkeeping & Monitoring	171.0 (97.3 – 244.8)	171.0 (97.3 – 244.8)
Training	181.7 (103.8 – 287.3)	188.7 (107.9 – 297.8)
Total	373.9 (214.2 – 555.9)	384.5 (220.6-570.5)

*Numbers in table may not sum to totals due to rounding.

⁴⁸ Annual total separations rate for nondurable goods, Bureau of Labor Statistics Job Openings and Labor Turnover Survey, available at: <http://www.bls.gov/news.release/jolts.t16.htm>

Special Handling Statements on Labels:

The proposed egg products rule requires "Keep Refrigerated" or "Keep Frozen" statements for all egg products that require special handling to maintain their wholesome condition. Plants currently include this information on egg products labels; therefore, this new requirement for the industry should not create additional costs.

Costs from Requiring Egg Products Plants to Produce Egg Products That are Edible without Additional Preparation to Achieve Food Safety:

The proposed rule requires that egg products plants process egg products that are edible without additional preparation to achieve food safety. FSIS does not anticipate that these plants will need to change their pasteurization practices to meet this requirement and therefore will not incur additional costs, except as a part of their normal operations in regards to complying with HACCP plan verification and monitoring activities. These verification and monitoring activities are discussed above as part of the HACCP costs of this proposed rule for recordkeeping and monitoring. FSIS has developed a Compliance Guideline for Small and Very Small Plants that produce ready-to-eat egg products. This guidance document

is designed to help small and very small plants meet the proposed regulatory requirements by providing the best practice recommendations by FSIS, based on the best scientific and practical considerations. FSIS is seeking comment on this guidance document, which is posted on the Agency's Web page:

<<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index>>.

Below, the total industry costs are presented:

Table 13. Total Industry Costs (\$1,000) *

Cost Component	Annualized Costs - 3% (Low Estimate - High Estimate)	Annualized Costs - 7% (Low Estimate - High Estimate)
HACCP	3,769.7 (1,900.3 – 5,630.7)	3,784.9 (1908.6 – 5651.5)
Sanitation SOPs	373.9 (214.2 – 555.9)	384.5 (220.6 – 570.5)
Total	4,143.6 (2,114.5 – 6,186.6)	4,169.4 (2,129.2 – 6,220.0)

*Numbers in table may not sum to totals due to rounding.

Agency Costs

Training and Personnel: FSIS employs 95 egg products inspectors that exclusively inspect egg products plants. Some egg products plant inspectors already have HACCP training from past inspection experience in meat and poultry plants. For inspectors without prior experience, FSIS will need to train them in the HACCP system. The long-term objective of the Agency is to establish an inspection system where inspection program personnel would

be equally qualified to conduct inspection activities at meat or poultry establishments, and egg product plants.

The Agency anticipates that it will need to train 51 egg products inspection personnel⁴⁹ and 24 meat or poultry inspectors (non-egg products inspectors). Fifty one of these inspectors will require a 4-week training course on HACCP methods called Inspection Methods training, and 24 inspectors already trained in HACCP inspection will be trained in egg product inspection. The inspection methods training for egg products inspection personnel would be longer than for other plant personnel because it includes additional topics (e.g., processing and slaughter inspection in a HACCP environment, rules of practice, and fundamental food microbiology) that not all egg products plant personnel need to perform their job. The total costs (including travel, lodging, per diem, and training program) for the 4-week training program is approximately \$6,000⁵⁰ per inspector, and the one-week egg product inspection training is approximately \$1,200 per inspector. Therefore, the one-time Agency training costs total \$334,800 (51 x \$6,000)+(24 X \$1,200).

⁴⁹ FSIS Policy Development Staff (PDS) provided the number of personnel that will need training. PDS estimated this number by contacting each district manager in the field where egg products plants are located.

⁵⁰ This figure is a mean estimate of training costs from FSIS/OOEEET Center for Learning.

Replacement inspectors will be required during periods when egg products plant inspectors are being trained. The Agency's district offices estimate the cost of replacement inspectors to be \$2,800 per person⁵¹ for inspection methods training and \$700 per person for egg products inspection training. Consequently, the one-time cost of replacement inspectors is \$159,600 derived from (51 x \$2,800) and (24 X \$700). Thus, the total one-time cost of training inspectors at egg products plants is \$494,400. Table 14 provides the summary of the costs associated with inspector training.

Table 14. Inspection program training costs (\$1,000) at 3% and 7% discount rates annualized over 10 years.*

Cost Component	Number of IPP	Cost per IPP	One-time Cost	Annualized Cost - 3% over 10 years	Annualized Cost - 7% over 10 years
Inspection Methods Training	51	6	306	34.8	40.7
Egg Products Inspection Training	24	1.2	28.8	3.3	3.8
Replacement IPP	75		159.6	18.2	21.2
Total			494.4	56.3	65.8

*Numbers in table may not sum to totals due to rounding.

Total Costs: Table 15 provides a summary of the estimated total costs for the industry and Agency. The

⁵¹ This is the average GSA per diem for meals and hotel multiplied by the number of days replacement inspectors would be needed to fill positions.
<http://www.gsa.gov/portal/content/104877>

table includes annualized costs over 10 years at discount rates of 3 percent and 7 percent.

Table 15. Total Costs (\$1,000) *

Total Costs	Annualized Costs - 3% (Low Estimate - High Estimate) over 10 years	Annualized Costs - 7% (Low Estimate - High Estimate) over 10 years
Industry		
HACCP	3,769.7 (1,900.3 – 5,630.7)	3,784.9 (1,908.6 – 5,651.5)
Sanitation SOPs	373.9 (214.2 – 555.9)	384.5 (220.6 – 570.5)
Agency		
IPP Training	38.1	44.5
Replacement IPP	18.2	21.2
Total	4,199.9 (2,170.8 – 6,242.9)	4,235.2 (2,195.0 – 6,287.8)

*Numbers in table may not sum to totals due to rounding.

The total annualized cost to the egg products industry of the proposal is \$0.002 per pound of aggregate egg products (\$4,143,600 / 1.8 billion pounds) at the 3 percent discount rate. The cost of the proposed rule to the egg products industry is minimal, and we do not expect the costs from this rule to have impact on consumer prices.

Expected Benefits of the Proposed Rule

The proposed rule will provide firms in the egg products industry greater flexibility and incentives for innovation. Firms derive benefits from opportunities to innovate and employ more flexible production methods over time.⁵² Many egg products plants have already adopted the HACCP system for egg product processing. One reason for

⁵² Coglianese, Cary & David Lazer. 2003. "Management-Based Regulation: Prescribing Private Management to Achieve Public Goals". Law & Society Review 37.

this adoption is buyers of egg products (further egg processors or retailers) require the production of egg products to be done under the HACCP system. In addition, under a HACCP system, egg products plants can attain quality accreditations such as one by the Safe Quality Food Institute, which allows egg products plants to access different markets inaccessible to non-HACCP processors. Academic literature (please see next section) has also shown that an egg products plant's choice to process under a HACCP system as a management tool can also be internally driven by efficiency gains.⁵³

A number of studies in the last few decades have shown important efficiency gains for food production industries after moving into a HACCP system. In a study by Nganje and Mazzocco in 2003⁵⁴, individual plants in the red meat industry benefited from implementing HACCP by gaining efficiency in production. In a study by Henson et al. (2000)⁵⁵ on HACCP adoption in the UK dairy industry, the authors also report similar benefits such as "the reduction

⁵³ Kay Cao, Oswin Maurer, Frank Scrimgeour and Chris Drake. 2004. "The Economics of HACCP (Hazard Analysis & Critical Control Point): a Literature Review, Agribusiness Perspectives Papers", Paper 64, ISSN 1442-6951.

⁵⁴ Nganje W.E. and Mazzocco M.A.. 2003. "The Impact of HACCP on Factor Demand and Output Supply Elasticities of Red Meat". Journal of Agricultural and Resource Economics.

⁵⁵ Henson, S., Holt, G., and Northen, J. (2000). "Costs and benefits of implementing HACCP in the UK dairy processing sector". In L. J. Unnevehr (Ed.), The economics of HACCP: costs and benefits (pp.347-363).

in wastage, increases in product shelf life, and decreases in production costs.”⁵⁶

HACCP systems also enable firms that purchase egg products plant products to reduce costs of raw materials inspection, specification, and inventory.⁵⁷ Given the efficiency gains in different food production facilities under FSIS jurisdiction by implementing HACCP, FSIS reasonably expects that the egg products industry will gain some efficiency from HACCP implementation.

Benefits from removing current regulations:

A large benefit from moving away from the current regulatory framework is the lessening of administrative burdens on plants and plant personnel. With the movement to a HACCP-based system, IPP will change how they inspect egg products plants by ensuring that plants' HACCP systems are functioning as intended rather than inspecting for compliance with current specifications. This change in how inspection is done will allow for improved allocation of resources to more food- safety tasks and sanitary verifications both for the Agency and for egg products plants. It also allows egg product plants to employ

⁵⁶ Kay Cao, Oswin Maurer, Frank Scrimgeour, and Chris Drake, The Economics of HACCP (Hazard Analysis & Critical Control Point): a Literature Review, Agribusiness Perspectives Papers 2004, Paper 64, ISSN 1442-6951

⁵⁷ Kay Cao, Oswin Maurer, Frank Scrimgeour and Chris Drake, The Economics of HACCP (Hazard Analysis & Critical Control Point): a Literature Review, Agribusiness Perspectives Papers 2004, Paper 64, ISSN 1442-6951

resources in a manner that more efficiently produces safe product instead of allocating resources just to comply with FSIS regulations. For instance, instead of sampling product for time and temperature, a plant can design a system in which its HACCP plan specifies sampling products at a more convenient time in the process, allowing for better personnel resource management to improve production efficiency.

Another aspect of the reduced administrative burden is a reduced need for FSIS approval for changes to plant operations that deviate from current regulations. For example, official plants will no longer need to submit facility blueprints and specifications (plant changes) to the Agency when applying for a grant of inspection, nor will they need to obtain prior approval from FSIS for equipment and utensils proposed for use in preparing edible product or product ingredients. The approval process for a waiver to a regulation or for no objection to production changes will also be eliminated if this proposed rule is adopted. These changes provide cost savings to industry and the Agency and are quantified below. It takes industry on average 100 hours to make an industry submission as described above (waiver, plant blueprint, no objection, or equipment use), including additional correspondence with

FSIS. The Agency spends an average of 69 hours to review and approve each submission. FSIS is seeking comment on its estimates of the time it takes industry to develop a submission and to respond to FSIS requests in connection with the submission.

FSIS receives on average nine submissions per year from egg products plants. The submission process involves an egg products plant's QC technician providing the initial submission data and follow-up correspondence with Agency personnel. This follow-up correspondence includes responding to FSIS questions with supporting data. The QC technician is paid an hourly wage of \$68.52 per hour, which includes a benefit rate of two⁵⁸. An Agency reviewer would have a General Schedule 13 salary, step 3, at \$94.20 per hour, which includes a benefit factor of two⁵⁹. Eliminating these two submission processes will save industry approximately \$61,600 annually discounted over 10 years at the 7 percent rate. The Agency would save approximately \$58,498 annually discounted over 10 years at the 7 percent rate.

⁵⁸ Estimates obtained from the Bureau of Labor Statistics May 2016 National Industry-Specific Occupational Employment and Wage Estimates, for Management Occupations (Occupational Code 11-0000), <https://www.bls.gov/oes/current/oes113051.htm#ind>, Food Scientists and Technologists (19-1012), <https://www.bls.gov/oes/current/oes191012.htm>, and Production Occupations (51-0000) <https://www.bls.gov/oes/current/oes513023.htm>.

⁵⁹ Hourly rate, Washington DC, Office of Personnel Management https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB_h.pdf.

Table 16. Industry and Agency Savings from the Elimination of Agency Approval for plant and product processing changes (\$1,000s)*

Total Savings	Annualized Savings - 3% over 10 years	Annualized Savings- 7% over 10 years
Industry	61.6	61.6
Agency	58.5	58.5
Total	120.1	120.1

*Numbers in table may not sum to totals due to rounding.

The HACCP plan provision of the proposed rule will also give plants flexibility to design their pasteurization and sampling procedures. Ninety three percent of egg products plants have indicated that their plants conduct microbiological testing in addition to those required by regulation.⁶⁰ By giving plants the option to sample as determined in their HACCP plan, there may be a cost savings from sampling less. The proposed rule specifies that the final product must be produced to be edible without additional preparation to achieve food safety. This standard provides flexibility to an egg products plant by giving it the necessary end result of pathogen-free products without specifying direct instructions on the processing method. This allows plants to find the most efficient processing or sampling methods to best fit their own production process and resources to produce a pathogen-free product.

⁶⁰ RTI International. 2014. "Survey of Egg Packing and Egg Products Processing Plants." Revised Final Report. RTI Project no. 0211740.015.001. 3040 Cornwallis Rd., P.O. Box 12194 Research Triangle Park, NC 27709-2194

Additional Benefits from Generic Labeling: Additional benefits include cost reductions for the Agency and for the egg products plants that submit labels for changes to an existing label or for new label approvals. Currently, an egg products plant must submit a formal application along with a sketch of a product label to FSIS personnel for approval, regardless of the change (including a color or size change to a label). If the proposed rule is finalized, the approval process for certain labels will be streamlined, allowing egg products plants to use certain labels without submitting an application to FSIS because the labels will be generically approvable⁶¹. Labels that will not qualify for generic approval include temporary approvals, labels for export only that bear labeling deviations, or labels bearing special statements and claims. All other label types can be generically approved. Presently, many egg products plants use special claims on their labels (e.g., organic or free range) and so those labels would not qualify for generic approval. The Agency estimates that approximately 80 percent of labels have prior approval for these claims⁶². If these prior approved producers make other changes to the labels not involving

⁶¹ As required by 9 CFR 412, the Labeling and Program Delivery Staff (LPDS) evaluates certain sketch applications and all temporary applications for meat and poultry products. All other meat and poultry product label applications may be generically approved without evaluation by LPDS.

⁶² This was an approximation made by a label reviewer in the FSIS labeling group.

their pre-approved claims, they could qualify for generic labeling.

The number of egg products labels submitted in 2015 was approximately 520, and in 2016, the number rose to 708 labels. FSIS estimates that approximately 50 percent of these new labels would qualify for generic label approval each year. Generic approval would reduce the recordkeeping burden at the plant and Agency by about half the current levels. In order to estimate cost savings through the generic labeling process, the number of future label submissions was estimated based on the annual historic increase in submissions. Using the industry cost savings of \$25.00 per label from the prior label approval system: Generic Label Approval final rule⁶³, the proposed generic label approval process for egg products could save industry approximately \$16,000 annually, discounted over 10 years at the 7 percent rate, from not submitting labels. The Agency would save approximately \$61,000 annually, given that on average the review process takes approximately one hour, and a reviewer would have a General Schedule 13 salary, step 3 with a benefit factor of two,⁶⁴ having a total compensation of \$94.20.

⁶³ 78 FR 66826

⁶⁴ Estimates obtained from the Bureau of Labor Statistics May 2016 National Industry-Specific Occupational Employment and Wage Estimates, for Management Occupations (Occupational Code 11-0000), <https://www.bls.gov/oes/current/oes113051.htm#ind>, Food

Table 17. Savings from Generic Labeling (\$1000s) *

Total Savings	Annualized Savings- 3% over 10 years	Annualized Savings - 7% over 10 years
Industry	16	16
Agency	60.6	60.4
Total	76.7	76.4

*Numbers in table may not sum to totals due to rounding.

Better Agency Resource Coverage: Because all egg products plant inspectors will now be trained in HACCP and can staff FSIS-regulated establishments other than egg products plants, the Agency will experience an improvement in inspection coverage. In the egg products plants themselves, the Agency can also utilize HACCP trained inspectors as relief inspectors. Currently, egg products inspectors can only work in egg products plants.

Change in Inspector Coverage: Under the proposed rule, FSIS inspectors would no longer provide inspection during all processing operations at each egg products plant, but instead may be provided once per shift. Therefore, under the proposal, inspectors may inspect several plants within a reasonable commuting distance (i.e., patrol assignments similar to meat and poultry processing inspection). The Agency expects there to be salary savings associated with patrol assignments through a 3-year change in staffing. The Agency expects to reduce

Scientists and Technologists (19-1012), <https://www.bls.gov/oes/current/oes191012.htm>, and Production Occupations (51-0000) <https://www.bls.gov/oes/current/oes513023.htm>.

the number of egg products inspectors by 10 inspectors in year 1, 10 inspectors in year 2, and 10 inspectors in year 3, for a total reduction of 30 egg products inspectors through attrition and movement of inspectors to other positions in the Agency.

In addition to Agency savings, there would be cost savings to industry because there would be a reduction in egg products inspector overtime and holiday hours, which industry pays for, due to patrol assignments.

The Agency will incur costs for the additional travel inspectors will incur on patrol assignments, and the loss of overhead industry paid to the Agency for overtime and holiday hours worked. Agency travel costs include mileage increases for existing patrol assignments and GSA cars for new patrol assignments. Please see table 18 for a summary of total savings from the proposed changes in inspection coverage.

Table 18. Total Net Savings from Changes in Egg Products Inspection (\$1,000)*

Agency	Annualized Estimate- 3% over 10 years	Annualized Estimate- 7% over 10 years
<i>Costs</i>		
Changes in inspection coverage	1,421	1,421
<i>Savings</i>		
Reduction in salaries due to changes in inspection coverage	(2,046)	(2,005)
<i>Agency Net Budget Impact</i>	(625)	(548)
<i>Industry</i>		
<i>Savings</i>		
Elimination of inspection payments for overtime and holidays	(4,803)	(4,803)
<i>Grand Total Net Savings</i>	(5,428)	(5,388)

* Numbers in table may not sum to total due to rounding.

In summary, the benefits from this proposed rule include improvements in product quality, lower transaction costs, plant innovation, and generally lower operational costs. Additionally, the egg products plants will not have to comply with the current "command and control" regulations. By eliminating regulations, administrative burdens will be lessened, including those associated with submitting documentation to FSIS for changes to the plant and plant processes, waivers, and most egg products labels, resulting in cost savings. Industry will also benefit from the reduction in overtime and holiday pay paid for the

inspection of egg products plants. Table 19 summarizes the quantified costs and cost savings to industry and the Agency if the proposed rule is implemented. The rule provides a net cost savings of between \$1.3 million and \$1.4 million annualized over 10 years at the 7 percent and 3 percent rates.

Table 19. Total Costs and Net Benefits (\$1,000s) *

<i>Costs</i>	Annualized 3% Mid Estimate (Low Estimate - High Estimate) over 10 years	Annualized 7% Mid Estimate (Low Estimate - High Estimate) over 10 years
<i>Industry</i>		
HACCP	3,769.7 (1,900.3 – 5,630.7)	3,784.9 (1,908.6 – 5,651.5)
Sanitation SOPs	373.9 (214.2 - 555.9)	384.5 (220.6 - 570.5)
<i>Agency</i>		
IPP Training	38.1	44.5
Replacement IPP	18.2	21.2
Total Costs	4,199.9 (2,170.8 to 6,242.9)	4,235.2 (2,195.0 to 6,287.8)
<i>Savings</i>		
<i>Industry</i>		
Reduced Plant Approval Processes	-61.6	-61.6
Generic Labeling	-16	-16
Changes in inspection coverage	-4,803	-4,803
<i>Agency</i>		
Reduced Plant Approval Processes	-58.5	-58.5
Generic Labeling	-60.6	-60.4
Changes in inspection coverage	-625	-585
Total Savings	-5,625	-5,585
Grand Total Net Benefits Mid (low to high) savings minus costs	1,424.8(-618.2 to 3,453.9)	1,349.5(-703.1 to 3,389.7)

*Numbers in table may not sum to totals due to rounding.

Uncertainty Surrounding Public Health Impacts:

Currently, the regulations require specific times and temperatures for egg products pasteurization. If a plant wishes to employ an alternative time and temperature combination, the Agency reviews scientific research or data validating other methods of pasteurization (9 CFR 590.570(b)) and issues a "No Objection" letters (NOL) approving its use. The proposed rule will eliminate the codified time and temperature regulations and will require egg products plants to process egg products in a way that will ensure that the products are free of detectable pathogens. Due to a lack of data, FSIS is currently unable to compare food safety performance in egg products plants operating under the current regulations to those plants operating in a HACCP system under NOLs with differing pasteurization times and temperatures from those prescribed in the current regulations.

Under HACCP, an egg products plant would be required to conduct a hazard analysis to identify and list the biological, chemical, or physical food safety hazards that are reasonably likely to occur in its production process for a particular product and the measures to prevent, eliminate, or reduce the occurrence of those hazards to an acceptable level. The plant would also be required to

identify the points in each of its processes at which control is necessary to achieve this goal (9 CFR 417.2(c)(2)). These points are called "critical control points" (CCPs). The plant would have to establish critical limits for the preventive measures associated with each identified CCP. Plants would also be required to validate that their process works as intended (9 CFR 417.4). The HACCP and Sanitation SOP framework will make FSIS inspection more efficient and effective, because the egg products plant would be required to prevent food safety problems rather than react to problems without preventing recurrence.

FSIS has developed a Compliance Guideline for Small and Very Small Plants that produce ready-to-eat egg products. This document updates the current time and temperature regulations based on the best available scientific information.⁶⁵ It provides "safe harbors" for egg products plants that FSIS considers as recognized procedures that can be employed without any further validation studies. However, the plant would need to

⁶⁵ Gurtler, J.B., Marks, H.M., Bailey, R.B., Juneja, V. and Jones, D.R. 2013. Kinetics Model Comparison for the inactivation of *Salmonella* Enteritidis and Oranienburg in 10% salted liquid whole egg. *Foodborne Pathogens and Disease*. 10:492-499.
Gurtler, J.B., Marks, H.M., Jones, D.R., Bailey, R.B., and Bauer, N.E. 2011. Modeling the thermal inactivation kinetics of heat-resistant *Salmonella* Enteritidis and Oranienburg in 10 percent salted liquid egg yolk. *J. Food Prot.* 74:882-892.
Jordan, S.S., Gurtler, J.B., Marks, H.M., Jones, D.R. and Shaw, W.K. 2011. A mathematical model of inactivation kinetics for a four-strain composite of *Salmonella* Enteritidis and Oranienburg in commercial liquid egg yolk. *Food Micro.* 28:67-75.

validate that it is properly applying the FSIS time and temperature combinations provided in the guidance material and conduct monitoring and verification activities in the plant's operating environment.

FSIS will continue to test egg products for *Salmonella* and Lm. If FSIS detects pathogens in the product, plants that have identified the pathogen as reasonably likely to occur in the HACCP hazard analysis will be required to take corrective actions to ensure that they identify problems that led to production of contaminated product, ensure no adulterated product is in commerce, and take measures to prevent recurrence. Plants that have not identified the pathogen as reasonably likely to occur would need to take corrective actions and reassess their HACCP plans in accordance with 9 CFR 417.3(b). Currently, when FSIS detects positives in egg products plants, the Agency response is limited to preventing the product from which the sample was collected from entering commerce or requesting that the producer recall its products. FSIS inspectors currently repeatedly issue noncompliance reports at egg products plants with limited improvements in operations. Therefore, it is possible that the HACCP regulations will improve the operations of egg products plants.

Alternative Regulatory Approaches

The Agency considered two alternatives designed to achieve the regulatory objective outlined in the Need for the Rule section. However, this proposed rule was chosen as the least burdensome, technically acceptable regulatory approach.

Voluntary HACCP regulatory program: A voluntary HACCP system would be very close to the current system. In the current system, 93 percent of egg products plants already have implemented HACCP systems integrated into their processing. Because many plants have already changed to a HACCP system, the Agency does not foresee any non-HACCP operations voluntarily implementing HACCP that have not already done so. These plants would stay at status quo. Therefore, this regulatory option would not lead to a significant change in current egg products plants processing practices. However, there would be additional costs, such as inspector HACCP training and the costs of inspecting a dual system. Also, under the current regulations, continuous inspection prevents inspectors from working patrol assignments, which would save industry overtime costs and Agency resources. These savings would not be fully realized in a dual system. For the plants not operating under HACCP, there are possible consumer benefit

losses as some plants may fail to innovate and might continue to comply with current regulation, passing production costs on to consumers. Therefore, FSIS rejected this alternative.

HACCP for large volume egg products plants: In this alternative, only plants with a large production volume would be required to implement HACCP. This alternative would save Agency HACCP training costs for inspection personnel, who inspect small production plants. Small volume plants would be allowed to stay in a non-HACCP system, lowering industry costs. This alternative would need to have certain volume definitions to distinguish the type of plant considered in the alternative. A difficulty associated with the size definition process is that an egg products plant's volume may change depending on the season or from changes in its source eggs. These changes could affect the classification system, which is based on volume, and could create difficulties in identifying the plants most likely to be designated as large volume. Another drawback to this alternative is the possible costs to the small producer in the long run. Although the low-production egg products plants may save initially on costs by not implementing HACCP, this alternative may hurt the plants' long-run efficiencies and competitiveness because

they would not be gaining the flexibility to innovate that they would by producing under the HACCP system.

Table 20. Regulatory Alternatives Considered

Alternative	Costs	Benefits
1) Existing Voluntary Recordkeeping	Additional costs for the Agency.	No additional benefits.
2) HACCP only for large volume egg products plants	In the long run, small plants would incur more costs from the lack of efficiency gains associated with HACCP.	Small volume producers would save on costs from not having to change their production process and develop the requisite Sanitation SOP and HACCP plans. Large volume producers would acquire benefits from implementing HACCP.
3) The Proposed Rule	(\$1.34 million ⁶⁶) annual cost savings to industry and to the Agency.	Achievement of regulatory objective of regulations consistent with other FSIS regulations, clear responsibility of Agency vs. industry, and additional flexibility for industry.

Initial Regulatory Flexibility Analysis: The FSIS Administrator has made a preliminary determination that this proposed rule would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

There are 77 federally-inspected plants. We estimate that at least 12 are large businesses or companies with

⁶⁶ This cost is annualized at the 7 percent discount rate over 10 years.

multiple egg products plants⁶⁷. We estimate that approximately 46 plants are part of these larger companies, leaving 31 plants that could be considered small businesses. In the cost analysis above, FSIS estimated that the cost savings for the industry is approximately 733 thousand (7 percent, 10 years).

This results in an average cost savings to a plant of (\$9,200/plant) annualized (7 percent, 10 years). The average revenue for egg products plants is approximately \$104.4 million.⁶⁸ Therefore, FSIS believes that the total cost savings to revenue ratio per plant is .01 percent. FSIS is seeking public comment on its conclusion of no significant impact on small entities. FSIS has developed a Compliance Guideline for Small and Very Small Plants that produce ready-to-eat egg products. This guidance document is designed to help small and very small plants meet the proposed regulatory requirements by providing the best practice recommendations by FSIS, based on the best scientific and practical considerations. FSIS is seeking comment on this guidance document, which is posted on the

⁶⁷ These figures differ from the number of plants in HACCP size categories for small and large as mentioned earlier in the document, because the sizes are derived from the HACCP size rather than a business size. In this section, FSIS does not need HACCP sizes for egg products plants for the Regulatory Flexibility Analysis. Instead, FSIS must analyze egg products company or firm sizes instead of an egg products establishment sizes. The HACCP size of an establishment alone is not enough to verify whether it's part of a larger business. To determine whether a business is small, FSIS analyzed whether egg products establishments were part of larger companies.

⁶⁸ Derived from the RTI Industry Survey, Q.5.11, the weighted average of the midpoints of the respondents' answers to the level of annual revenue earned in the year prior to the survey. Q.5.11 What was the approximate value of egg product sales during the past year?

Agency's web page:

<<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index>>.

Appendix A to Executive Orders 12866 and 13563 and the Regulatory Flexibility Act Analysis⁶⁹

The 2014 Egg Products Industry Survey, conducted and published by RTI International, surveyed approximately 57 egg products plants with questions in regard to plants' use of HACCP plans, Sanitation SOPs, the number of plant personnel, hours of operation and the number of shifts, and current sampling practices. The survey design involved collaboration between FSIS personnel and RTI International. The full-scale data collection took place over a 16-week period from February 17, 2014, to June 9, 2014. The survey included 18 questions. The survey also provided information on production volume, types of product, and production processes. The survey was considered to be a census of the industry because all 77 egg products plants currently regulated by FSIS were contacted and asked to

⁶⁹ This Appendix describes how the Agency used the 2014 Egg Products Industry Survey conducted and published by RTI International to gather information on egg products plants relating to the cost section of this proposed rule. Specifically, this Appendix outlines how the survey questions were used to estimate the number of egg products plants that have Sanitation SOPs, HACCP plans, training, number of shifts, and record keeping.

Section 1) describes egg products plants' use of Sanitation SOPs. Section 2) outlines the estimates for egg product plants' recordkeeping for Sanitation SOPs. Section 3) describes egg products plants' training for Sanitation SOPs. Section 4) describes the type of product produced by egg products plants and their use of HACCP plans. Section 5) describes the number of egg products plants with HACCP plans. Section 6) estimates the average number of shifts for egg products plants without HACCP plans.

respond. The response rate to the survey was 72 percent. Fifty seven egg products plants completed the survey. Of these, 26 (46 percent) completed the survey via mail and 31 (54 percent) completed the Web survey. FSIS used the survey results to supplement the information that FSIS maintains in the Public Health Information System. The responses to the survey were masked so that individual plants could not be identified, so FSIS applied response distributions to the larger population of egg products plants to approximate baseline industry characteristics. In order to describe the egg products plants, which are under FSIS's jurisdiction, brief discussions of the major findings of the survey have been placed throughout this Executive Order 12866 and 13563 discussion and the regulatory flexibility analysis and footnoted accordingly. Please find the link to the survey here:

<http://www.fsis.usda.gov/wps/wcm/connect/df3e0400-aaa7-423f-bb11-ff080fc8ce2b/Survey-Egg-Products-09302014.pdf?MOD=AJPERES>.

Section 1 Sanitation SOPs

FSIS estimated the percentage of plants that train production employees for Sanitation SOPs using question 4.5: During the past year, what types of food safety training did permanent employees of this plant receive? A

plant was considered to train production employees if it responded affirmatively to choice b. Sanitation SOPs. 91.2 percent of respondents answered that employees receive Sanitation SOPs training.

Section 2 Recordkeeping for Sanitation SOPs

FSIS estimated the percentage of plants that currently meet the proposed recordkeeping requirements using survey question 2.2: "Which of the following records that are not required by FSIS does this plant maintain?" A plant was considered to meet both if it answered affirmatively to choices 1 - "Employee task performance log verification" and 2 - "Deviation and corrective action log."

FSIS then determined the frequency at which sanitation tasks are performed using question 2.6: "How frequently does this plant conduct sanitation inspections of product contact zones?" If a plant responded affirmatively to choice 1 - "More than once per shift," it was considered to be conducting sanitation tasks at a frequency greater than daily. If it responded affirmatively to choice 2 - "Once per shift before shift operations begin," and operates more than one shift daily (determined with question 5.2), then it was also considered to be conducting sanitation tasks at a frequency greater than daily. If it responded affirmatively to choice 2 and operates a single shift per

day, or if it responded affirmatively to choice 3 - "Once per day before daily operations begin," it was considered to be conducting sanitation tasks at a daily frequency. If it answered affirmatively to any other option, it was considered to conduct sanitation tasks less than daily.

Records in Compliance			Records Not in Compliance		
< Daily	Daily	> Daily	< Daily	Daily	> Daily
8.8%	33.3%	22.8%	3.5%	15.8%	15.8%

Section 3 Training for Sanitation SOPs

FSIS used the training estimates from Section 1 and assumed that any plant which did not provide training for Sanitation SOPs did not have a written plan. Then, FSIS estimated the number of shifts of employees needing training for Sanitation SOPs by averaging the reported number of shifts from question 5.2 - "How many production shifts are operated each day at this plant?" Only those plants that do not provide HACCP training were included in the average.

Plants	No Sanitation SOPs Training	Needed Sanitation SOPs	Average Shifts	Total Shifts
77	8.8%	7	1.7	8

Section 4 Use of HACCP plans

To determine the percentage of plants which have written HACCP plans in place for their respective

processes, FSIS used the survey to first determine which respondents produced products corresponding to the three main processes.

For breaking, FSIS considered all plants that responded to question 1.1: "Which statement below describes how this plant receives egg inputs?" and answered affirmatively to choice 1 -- "This plant receives shell eggs only" -- or to choice 2 -- "This plant receives both shell eggs and liquid or dried eggs."

For dried eggs, FSIS considered all plants that responded to question 1.11: "Does this plant produce this egg product form?" and answered affirmatively to choice e -- "Dried" -- or to choice f -- "Blended and dried."

For liquid eggs, FSIS considered all plants that which responded to question 1.11: "Does this plant produce this egg product form?" and answered affirmatively to choice a -- "Liquid"; to choice b -- "Blended and liquid"; to choice c -- "frozen"; to choice d -- "Blended and frozen"; or g -- "Extended shelf life liquid".

Next, for each process, FSIS determined if the respondent had a written HACCP plan using question 2.1: "What production steps are used by this plant, and if used, is the step addressed in a written plan?" Specifically, FSIS considered the plan acceptable if the plant responded

affirmatively to option 3 - "Used and Addressed in a Written HACCP Plan" for option j - "Breaking shell eggs"; option m - "Drying egg products"; or option n - "Pasteurizing dried egg whites", and option l - "Pasteurizing liquid eggs for breaking, dried, and liquid processes, respectively."

Breaking w/ HACCP	Dried w/ HACCP	Liquid w/ HACCP
84.6%	80.0%	76.5%

Finally, FSIS applied these percentages to PHIS egg products plants production data (see Table below) to estimate the number of processes currently operating without HACCP plans.

Plants	Breaking	Dried	Liquid	Total Processes
77	56	17	52	125

Breaking w/o HACCP	Dried w/o HACCP	Liquid w/o HACCP	Total Processes Operating w/o HACCP
9	3	12	24

Section 5 Plants with HACCP plans

FSIS used the results to question 2.1: "What production steps are used by this plant, and if used, is the step addressed in a written plan?" to determine the percentage of plants with no HACCP plans. Specifically, a plant was considered to have no HACCP plans if it did not respond with option 3 - "Used and Addressed in a Written

HACCP Plan for any of the following: j. Breaking shell eggs, l. Pasteurizing liquid eggs, m. Drying egg products, or n. Pasteurizing dried egg whites.”

Percent with No HACCP	Number of Plants (approximate) with No HACCP
7.%	5*

*The number of plants was rounded down

Section 6 Shifts for Plants without HACCP Plans

To estimate the number of shifts at plants without any HACCP systems in place, FSIS averaged the responses to question 5.2: “How many production shifts are operated each day at this plant?” for those respondents determined to not have HACCP plans as described in Section 5. This average (1.7 shifts) was then applied to the total number of plants estimated to be without HACCP systems.

Executive Order 13771

This proposed rule, if finalized as proposed, is expected to be an EO 13771 deregulatory action. We have estimated that this proposed rule would yield cost savings. Assuming a 7 percent discount rate and a perpetual time horizon and a starting year of 2018, the proposed rule would yield approximately \$1.29 million (2016\$) in annualized cost savings. Assessment of the specific costs

and cost savings may be found in the preceding economic analysis.

IV. Paperwork Reduction Act

FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*) and has determined that the paperwork requirements constitute new information collections.

Title: Egg Products Hazard Analysis and Critical Control Point (HACCP) Systems and Sanitation Standard Operating Procedures (SOPs).

Type of Collection: New.

Abstract: Under this proposed rule, FSIS is requiring official plants to develop and maintain HACCP and Sanitation SOP records and plans, as well as various transaction records. The egg products industry's documentation of its processes, first in a plan and thereafter in a continuous record of process performance, will be a more effective food safety approach than the sporadic generating of information by inspection program personnel. This documentation gives inspection program personnel a much broader picture of production than they can generate and provides them additional time to perform higher priority tasks. At the same time, it gives plant

managers a better view of their own process and more opportunity to adjust it to prevent safety defects.

Sanitation SOPs

To meet the proposed regulation's sanitation requirements, each processor will develop and maintain a Sanitation SOP. The Sanitation SOP would specify the cleaning and sanitizing procedures for all equipment and facilities involved in the production of every product. As part of the Sanitation SOP, a plant employee will record results of daily sanitation checks at the frequencies stated in the Sanitation SOP.

The burden of documenting the adherence to Sanitation SOPs is based on three factors: recording, reviewing, and storage. Recording encompasses conducting and inscribing the finding from an observation and filing of the document produced.

HACCP

Under this proposal, the requirements for the implementation of HACCP in official plants will be the same as those being met by meat and poultry products establishments operating under HACCP. The plant will maintain on file the name and a brief resume of the HACCP-trained individuals who participate in the hazard analysis and subsequent development of the HACCP plans. Plants will

develop written HACCP plans that include: Identification of hazards reasonably likely to occur in the production process; identification and description of the CCP for each identified hazard; specification of the critical limit which may not be exceeded at the CCP, and, if appropriate, a target limit; description of the monitoring procedure or device to be used; description of the corrective action to be taken if the limit is exceeded; description of the records which would be generated and maintained regarding this CCP; and description of the facility verification activities and the frequency at which they are to be conducted. Critical limits that are currently a part of FSIS regulations must be included. The adequacy of a plant's HACCP plan must be reassessed at least annually and whenever changes occur that could affect the hazard analysis or alter the HACCP plan.

The HACCP records should be reviewed by a plant employee other than the one whom produced the record, before the product is distributed in commerce. If a HACCP-trained individual is on-site, that person should be the reviewer. The reviewer would sign the records. Lastly, HACCP records generated by the processor would be retained on site for at least 1 year.

Labeling

Under this proposal, official plants will be authorized to use generically approved labels without specific evaluation by LPDS. In addition, frozen and refrigerated egg products will be required to bear labels that say, "Keep Frozen" or "Keep Refrigerated." Plants already use special handling statements, when appropriate, under general Agency policy governing special handling statements. Therefore, the Agency has already accounted for the labeling paperwork burden.

Estimate of Burden: FSIS estimates that each respondent will spend 927.58 hours per year on this information collection.

Respondents: Official egg products plants.

Estimated number of Respondents: 77

Estimated number of Responses per Respondent: 927.58

Estimated Total Annual Burden on Respondents: 71,424 hours

Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, Room 6065-S, South Agriculture Building, 1400 Independence Avenue, SW., Washington, DC 20250; (202) 720-5627.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both Gina Kouba, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

V. Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are

inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

VI. E-Government Act Compliance

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to government information and services, and for other purposes.

VII. Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Food Safety and Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

VIII. USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at <http://www.ocio.usda.gov/sites/default/files/docs/2012/Comp>

lain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail:

U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW
Washington, DC 20250-9410

Fax: (202) 690-7442

IX. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this *Federal Register* publication on-line through the FSIS Web page located at:

<http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, *Federal Register* notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information

to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects

9 CFR Part 416

Meat inspection, Poultry and poultry products, Sanitation.

9 CFR Part 417

Meat inspection, Poultry and poultry products, Record and recordkeeping requirements, Hazard Analysis and Critical Control Point (HACCP) Systems.

9 CFR Part 500

Administrative practice and procedure, Meat inspection, Poultry and poultry products, Rules of practice.

9 CFR Part 590

Eggs and egg products, Exports, Food grades and standards, Food labeling, Imports, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS proposes to amend 9 CFR chapter III as follows:

1. Revise the heading of subchapter E to read as follows:

SUBCHAPTER E-REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT, THE POULTRY PRODUCTS INSPECTION ACT, AND THE EGG PRODUCTS INSPECTION ACT

PART 416-SANITATION

2. Revise the authority citation for part 416 to read as follows:

Authority: 21 U.S.C. 451-470, 601-695, 1031-1056; 7 U.S.C. 450, 1901-1906; 7 CFR 2.18, 2.53.

PART 417-HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

3. Revise the authority citation for part 417 to read as follows:

Authority: 21 U.S.C. 451-470, 601-695, 1031-1056; 7 U.S.C. 450, 1901-1906; 7 CFR 2.18, 2.53.

4. In § 417.7, revise paragraph (b) to read as follows:

§ 417.7 Training.

* * * * *

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat, poultry, or egg products, including a segment on the development of a HACCP plan for a specific product and on record review.

PART 500-RULES OF PRACTICE

5. Revise the authority citation for part 500 to read as follows:

Authority: 21 U.S.C. 451-470, 601-695, 1031-1056; 7 U.S.C. 450, 1901-1906; (33 U.S.C. 1251 *et seq.*); 7 CFR 2.18, 2.53.

6. Amend §500.2 by revising paragraph (c) to read as follows:

§ 500.2 Regulatory control action.

* * * * *

(c) An establishment may appeal a regulatory control action, as provided in §§ 306.5, 381.35, and 590.310 of this chapter.

7. Amend § 500.3 by revising paragraphs (a) (1) and (a) (7) to read as follows:

§ 500.3 Withholding action or suspension without prior notification.

(a) * * *

(1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453, 21 U.S.C. 602, or 21 U.S.C. 1033;

* * * * *

(7) The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, or egg product, that has been found to be adulterated and that has not been reprocessed, in accordance with part 314 or part 381, subpart L, or part 590 of this chapter within three days of notification.

* * * * *

8. Amend § 500.5 by revising paragraphs (a) (5) and (c) to read as follows:

§ 500.5 Notification, appeals, and actions held in abeyance.

(a) * * *

(5) Advise the establishment that it may appeal the action as provided in §§ 306.5, 381.35, and 590.310 of this chapter.

* * * * *

(c) An establishment may appeal the withholding action or suspension, as provided in §§ 306.5, 381.35, and 590.310 of this chapter.

* * * * *

9. In § 500.6:

- a. Redesignate paragraphs (a) through (i) as paragraphs (a)(1) through (9).
- b. Designate the introductory text as paragraph (a).
- c. Revise newly redesignated paragraph (a)(9).
- d. Add reserved paragraph (b).

The revision and addition read as follows:

§ 500.6 Withdrawal of inspection.

(a) * * *

(9) A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA, section 18(a) of the PPIA, or section 18 of the EPIA.

(b) [Reserved]

10. In § 500.7, revise paragraphs (a)(3) and (5) to read as follows:

§ 500.7 Refusal to grant inspection.

(a) * * *

(3) Has not demonstrated that adequate sanitary conditions exist in the establishment as required by part 308, subpart H of part 381, part 416, or part 590 of this chapter;

* * * * *

(5) Is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA, section 18(a) of the PPIA, or section 18 of the EPIA.

* * * * *

11. In § 500.8, revise paragraphs (a) and (c) to read as follows:

§ 500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.

(a) FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat, poultry, or egg product, under section 7 of the FMIA, under section 8 of the PPIA, or under sections 7 or 14 of the EPIA.

* * * * *

(c) If FSIS rescinds or refuses approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat, poultry, or 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.

PART 590-INSPECTION OF EGGS AND EGG PRODUCTS (EGG PRODUCTS INSPECTION ACT)

12. The authority citation for part 590 is revised to read as follows:

Authority: 21 U.S.C. 1031-1056; 7 CFR 2.18, 2.53.

§§ 590.1 through 590.860 [Designated as Subpart A]

13. Designate §§ 590.1 through 590.860 as subpart A and add a heading for subpart A to read as follows:

Subpart A - GENERAL

14. Amend § 590.5 by:

- a. Revising the definition of *Administrator*.
- b. Removing the definition of *Chief of the Grading Branch* and *Dirty egg or Dirties*.
- c. Revising paragraph (c) of the definition of *Egg* and the definition of *Egg product*.
- d. Removing the definition of *Eggs of current production*, *Inspector/Grader*, and *National Supervisor*.
- e. Adding, in alphabetical order, the definition of *Official plant*.
- f. Removing the definition of *Official Standard*.
- g. Adding, in alphabetical order, the definition of *Official standards*.
- h. Revising the definition of *Pasteurize*.
- i. Removing the definition of *Plant*.
- j. Revising the definition of *Processing*.

k. Adding, in alphabetical order, the definition of *Program employee*.

l. Removing the definitions of *Regional Director*, *Sanitize*, and *Service*.

m. Revising the definition of *Shell egg packer*.

n. Adding, in alphabetical order, the definition of *Shipped for retail sale*.

The revisions and additions read as follows:

§ 590.5 Terms defined.

* * * * *

Administrator means the Administrator of the Food Safety and Inspection Service or any officer or employee of the Department of Agriculture to whom authority has been delegated or may be delegated to act in his or her stead.

* * * * *

Egg * * *

(c) *Dirty egg* or *Dirt* means an egg that has a shell that is unbroken and has adhering dirt or foreign material.

* * * * *

Egg product means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the

Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as the Secretary may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products. For the purposes of this part, the following products, among others, are exempted as not being egg products: Cooked egg products, imitation egg products, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, and sandwiches containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs. Balut and other similar ethnic delicacies are also exempted from inspection under this part.

* * * * *

Official plant means any plant in which the plant facilities, methods of operation, and sanitary procedures have been found suitable and adequate by the Administrator for the inspection of egg products pursuant to the regulations in this part and in which inspection service is carried on.

Official standards means the standards of quality, grades, and weight classes for eggs.

* * * * *

Pasteurize means the subjecting of each particle of egg products to heat or other treatments to destroy harmful viable microorganisms.

* * * * *

Processing means manufacturing of egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing or drying, or packaging or repackaging egg products at official plants.

* * * * *

Program employee means any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program.

* * * * *

Shell egg packer means any person engaged in the sorting of shell eggs from sources other than or in addition to the person's own production into their various qualities, either mechanically or by other means.

Shipped for retail sale means eggs that are forwarded from the processing facility for distribution to the ultimate consumer.

* * * * *

15. Amend § 590.10 by revising the third sentence to read as follows:

§ 590.10 Authority.

* * * The Food Safety and Inspection Service and its officers and employees will not be liable in damages through acts of commission or omission in the administration of this part.

§§ 590.17 and 590.22 [REMOVED]

16. Remove §§ 590.17 and 590.22.

17. Revise § 590.28 to read as follows:

§ 590.28 Other inspections.

Inspection program personnel will make periodic inspections of business premises, facilities, inventories, operations, transport vehicles, and records of egg handlers, and the records of all persons engaged in the business of transporting, shipping, or receiving any eggs or egg products.

* * * * *

18. Revise § 590.40 to read as follows:

§ 590.40 Egg products not intended for human food.

Periodic inspections will be made at any plant processing egg products which are not intended for use as human food of its operations and records to ensure compliance with the Act and the regulations in this part. Egg products not intended for use as human food shall be

denatured or decharacterized prior to being offered for sale or transportation unless shipped under seal as authorized in § 590.504(c) and identified as prescribed by the regulations in this part to prevent their use as human food.

19. Revise § 590.50 to read as follows:

§ 590.50 Egg temperature and labeling requirements.

(a) All shell eggs packed into containers destined for the ultimate consumer must be stored and transported under refrigeration at an ambient temperature of no greater than 45° F (7.2° C) and must bear a safe handling label in accordance with 21 CFR 101.17(h).

(b) Any producer-packer with an annual egg production from a flock of 3,000 or fewer hens is exempt from the temperature and labeling requirements of this section.

20. Revise § 590.100 to read as follows:

§ 590.100 Specific exemptions.

(a) [Reserved]

(b) The following are exempt, to the extent prescribed, from the continuous inspection of egg products processing operations in section 5(a) of the Act (21 U.S.C. 1034(a)), provided the conditions for exemption and the provisions of these regulations are met:

(1) The processing and sale of egg products by any poultry producer from eggs of his own flock's production when sold directly to a household consumer exclusively for use by the consumer and members of the household and its nonpaying guests and employees.

(2) The processing in 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, as well as the sale and possession of such products. Such products must be manufactured from inspected egg products processed in accordance with the regulations in this part and 9 CFR part 591 or from eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs.

§ 590.105 [REMOVED]

21. Remove § 590.105 and undesignated center heading "Performance of Service".

§§ 590.112, 590.114 and 590.116 [REMOVED]

22. Remove §§ 590.112, 590.114 and 590.116.

23. Add an undesignated center heading above § 590.118 and revise § 590.118 to read as follows:

Performance Of Service

§ 590.118 Identification.

Each program employee will be furnished with a numbered official badge that will be carried in a proper manner at all times while on duty. This badge will be sufficient identification to entitle the program employee entry at all regular entrances and to all parts of the official plant and premises to which the program employee is assigned.

§ 590.119 [REMOVED]

24. Remove § 590.119.

25. Revise § 590.120 to read as follows:

§ 590.120 Financial interest of inspectors.

(a) No program employee will inspect any product in which the employee, the employee's spouse, minor child, partner, organization in which the employee is serving as officer, director, trustee, partner, or employee, or any other person with whom the program employee is negotiating or has any arrangements concerning prospective employment, has a financial interest in the product.

(b) All program employees are subject to statutory restrictions with respect to political activities; e.g., 5 U.S.C. 7324 and 1502.

(c) Violation of the provisions of paragraph (a) of this section or the provisions of applicable statutes

referenced in paragraph (b) of this section will constitute grounds for dismissal.

(d) Program employees are subject to all applicable provisions of law and regulations and instructions of the Department and the Food Safety and Inspection Service concerning employee responsibilities and conduct. The setting forth of certain prohibitions in this part in no way limits the applicability of such general or other regulations or instructions.

26. Revise § 590.134(b) to read as follows:

§ 590.134 Accessibility of product and cooler rooms.

* * * * *

(b) The perimeter of each cooler room used to store eggs must be made accessible in order for the Secretary's representatives to determine the ambient temperature under which shell eggs packed into containers destined for the ultimate consumer are stored.

27. Revise § 590.136 to read as follows:

§ 590.136 Accommodations and equipment to be furnished by facilities for use of program employees in performing service.

(a) *Program employee's office.* Office space, including, but not limited to, furnishings, light, heat, and janitor service, will be provided without cost in the

official plant for the use of program employees for official purposes. The room or space set apart for this purpose must meet the approval of the Food Safety and Inspection Service and be conveniently located, properly ventilated, and provided with lockers or file cabinets suitable for the protection and storage of supplies and with accommodations suitable for program employees to change clothing. At the discretion of the Administrator, small official plants requiring the services of less than one full-time program employee need not furnish accommodations for program employees as prescribed in this section where adequate accommodations exist in a nearby convenient location.

(b) *Accommodations and equipment.* Such accommodations and equipment must include, but not be limited to, a room or area suitable for sampling product and a stationary or adequately secured storage box or cage (capable of being locked only by the program employee) for holding official samples.

28. Revise § 590.140 to read as follows:

§ 590.140 Application for grant of inspection.

The proprietor or operator of each official plant and official import inspection establishment must make application to the Administrator for inspection service

unless exempted by § 590.100. The application must be made in writing on forms furnished by the inspection service.

In cases of change of name or ownership or change of location, a new application must be made.

29. Revise § 590.142 to read as follows:

§ 590.142 Filing of application.

An application for inspection service will be regarded as filed only when it has been:

- (a) Filled in completely;
- (b) Signed by the applicant; and
- (c) Received in the appropriate District Office.

30. Revise § 590.146 to read as follows:

§ 590.146 Survey and grant of inspection.

(a) Before inspection is granted, FSIS will survey the official plant to determine if the construction and facilities of the plant are in accordance with the regulations in this part. FSIS will grant inspection, subject to 9 CFR 500.7, when these requirements are met and the requirements contained in § 590.149 are met.

(b) FSIS will give notice in writing to each applicant granted inspection and will specify in the notice the official plant, including the limits of the plant's premises, to which the grant pertains.

§ 590.148 [REMOVED]

31. Remove § 590.148.

32. Add § 590.149 to read as follows:

§ 590.149 Conditions for receiving inspection.

(a) Before receiving Federal inspection, a plant must have developed written sanitation Standard Operating Procedures, in accordance with part 416 and § 591.1(a)(1) of this chapter.

(b) Before receiving Federal inspection, a plant must conduct a hazard analysis, and develop and implement a HACCP plan, in accord with part 417 and § 591.1(a)(1) of this chapter. Conditional inspection may be provided for a period not to exceed 90 days, during which period the facility must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, a plant must conduct a hazard analysis and develop a HACCP plan applicable to that product, in accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the plant must validate its HACCP plan, in accordance with § 417.4 of this chapter.

33. Revise § 590.160 to read as follows:

§ 590.160 Clean Water Act; refusal, suspension, or withdrawal of service.

(a) Any applicant for inspection at a plant where the operations thereof may result in any discharge into the navigable waters in the United States is required by subsection 401(a)(1) (33 U.S.C. 1341) of the Clean Water Act as amended (86 Stat. 816, 91 Stat. 1566, 33 U.S.C. 1251 *et seq.*), to provide the Administrator with a certification, as prescribed in said subsection, that any such discharge will comply with the applicable provisions of sections 301, 302, 303, 306, and 307 of the Act (33 U.S.C. 1311, 1312, 1313, 1316, and 1317). No grant of inspection can be issued unless such certification has been obtained, or is waived, because failure of refusal of the State, interstate agency, or the Administrator of the Environmental Protection Agency to act on a request for certification within a reasonable period (which should not exceed 1 year after receipt of such a request). Further, upon receipt of an application for inspection and a certification as required by subsection 401(a)(1) of the Clean Water Act, the Administrator (as defined in § 590.5) is required by subparagraph (2) of said subsection to notify the Administrator of the Environmental Protection Agency for proceedings in accordance with that subsection. No grant of inspection can be made until the requirements of 401(a)(1) and (2) have been met.

(b) Inspection may be suspended or revoked and plant approval terminated as provided in subsection 401(a)(4) and (5) of the Clean Water Act, as amended (33 U.S.C. 1341(a)(4) and (5)).

34. Revise § 590.200 to read as follows:

§ 590.200 Records and related requirements.

(a) Persons engaged in the transporting, shipping, or receiving of any eggs or egg products in commerce, or holding such articles so received, and all egg handlers, except producer-packers with an annual egg production from a flock of 3,000 hens or fewer, must maintain records documenting, for a period of 2 years, the following, to the extent applicable:

(1) The date of lay, date and time of refrigeration, date of receipt, quantity and quality of eggs purchased or received, and from whom (including a complete address, unless a master list is maintained). Process records documenting that the temperature and labeling requirements in § 590.50(a) have been met must also be kept;

(2) The date of packaging, ambient air temperature surrounding product stored after processing, quantity and quality of eggs delivered or sold, and to whom (including a complete address, unless a master list is maintained);

(3) If a consecutive lot numbering system is not employed to identify individual eggs, containers of eggs, or egg products, record the alternative code system used, in accordance with § 590.411(c) (3);

(4) The date of disposal and quantity of restricted eggs, including inedible egg product or incubator reject product, sold or given away for animal food or other uses or otherwise disposed of, and to whom (including a complete address, unless a master list is maintained);

(5) The individual or composite (running tally) record of restricted egg sales to household consumers. Records should show number of dozens sold on a daily basis. The name and address of the consumer is not required;

(6) The date of production and quantity of egg products delivered or sold, and to whom (including a complete address, unless a master list is maintained);

(7) The date of receipt and quantity of egg products purchased or received, and from whom (including a complete address, unless a master list is maintained);

(8) The production records by categories of eggs such as graded eggs, nest-run eggs, dirties, checks, etc.; bills of sale, inventories, receipts, shipments, shippers, receivers, dates of shipment and receipt, carrier names, etc.

(b) All records required to be maintained by this section must be made available to an authorized representative of the Secretary for official review and copying.

(c) Records of all labeling, along with the product formulation and processing procedures as prescribed in §§ 590.410 through 590.412 of this chapter, must be kept by every person processing, except processors exempted under § 590.100 of this chapter.

35. Revise § 590.300 to read as follows:

§ 590.300 Appeal inspections.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector related to any inspection, file an appeal from such decision.

36. Revise § 590.310 to read as follows:

§ 590.310 Appeal inspections; how made.

Any appeal from the inspection decision of any program employee must be made to his or her immediate supervisor having jurisdiction over the subject matter of the appeal.

37. Revise § 590.320 to read as follows:

§ 590.320 How to file an appeal inspection or decision review.

The request for an appeal inspection or review of a program employee's decision may be made orally or in

writing. If made orally, written confirmation may be required. The applicant must clearly identify the product involved, the decision being appealed, and the reasons for requesting the appeal.

38. Revise § 590.340 to read as follows:

§ 590.340 Who must perform the appeal inspection or decision review.

An appeal inspection or review of a program employee's decision, as requested in § 590.310, must be performed by a program employee of FSIS other than the one who made the initial decision.

39. Revise § 590.350 to read as follows:

§ 590.350 Appeal samples.

An appeal sample will consist of product taken from the original sample containers plus an equal number of containers selected at random. A condition appeal cannot be made unless all originally sampled containers are available.

§§ 590.360 and 590.370 [REMOVED]

40. Remove §§ 590.360 and 590.370.

41. Revise § 590.410 to read as follows:

§ 590.410 Egg products required to be labeled.

(a) (1) Packaged egg products that require special handling to maintain their wholesome condition must have

the statement "Keep Refrigerated," "Keep Frozen," "Perishable Keep Under Refrigeration," or such similar statement prominently displayed on the principal display panel.

(2) Egg products that are distributed frozen and thawed prior to or during display for sale at retail must bear the statement "Keep Frozen" on the shipping container. Consumer-sized containers for such egg products must bear the statement "Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated."

(3) The labels of packages of egg products produced from shell eggs that have been treated with ionizing radiation must reflect that treatment in the ingredient statement on the finished product labeling.

(b) Containers, portable tanks, and bulk shipments of edible egg products produced in official plants must be labeled in accordance with §§ 590.411 through 590.415 and must bear the official identification shown in Figure 1 of § 590.413.

(c) 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, and printed and affixed on material that cannot be detached or effaced due to exposure to weather. Before the truck or tank is removed from the place where it is unloaded, the carrier must remove or obliterate the label. Such shipments must also bear the official identification shown in Figure 2 of § 590.415.

42. Revise § 590.411 to read as follows:

§ 590.411 Label approval.

(a) All official plants, including official plants certified under a foreign inspection system in accordance with § 590.910, must comply with the requirements contained in 9 CFR 412.1, except as otherwise provided in this part.

(b) For the purposes of 9 CFR 412.2, an official establishment or establishment certified under a foreign inspection system includes an official plant.

(c) Labels, containers, or packaging materials of egg products must show the following information, as applicable, on the principal display panel (except as otherwise permitted in this part), in accordance with the requirements of this part, or if applicable, 21 CFR 101.17(h):

(1) A statement showing by the common or usual names, if any, of the kinds of ingredients comprising the product. Formulas are to be expressed in terms of a liquid product

except for product that is dry-blended. Also, for product to be dried, the label may show the ingredients in order of descending proportions by weight in the dried form. However, the formula submitted must include the percentage of ingredients in both liquid and dried form. If the product is comprised of two or more ingredients, such ingredients must be listed in the order of descending proportions by weight in the form in which the product is to be marketed (sold), except that ingredients in dried product (other than dry blended) may be listed in either liquid or dried form. When water (excluding that used to reconstitute dehydrated ingredients back to their normal composition) is added to a liquid or frozen egg product or to an ingredient of such products (in excess of the normal water content of that ingredient), the total amount of water added, including the water content of any cellulose or vegetable gums used, must be expressed as a percentage of the total product weight in the ingredient statement on the label;

(2) The name, address and zip code of the distributor; qualified by such terms as "distributed by," or "distributors";

(3) The lot number or an alternative code indicating the date of production, in accordance with § 590.200(a);

(4) The net content;

(5) An official inspection symbol and the number of the official plant in which the product was processed under inspection as set forth in § 590.413;

(6) Egg products processed from edible eggs of the turkey, duck, goose, or guinea must be clearly and distinctly labeled as to the common or usual name of the product indicating the type of eggs or egg products used in the product, e.g., "Frozen whole turkey eggs," "Frozen whole chicken and turkey eggs." Egg products labeled without qualifying words as to the type of egg used in the product must be produced only from the edible egg of the domesticated chicken or the egg products produced from such eggs.

(d) Liquid or frozen egg products identified as whole eggs and processed in other than natural proportions as broken from the shell must have a total egg solids content of 24.20 percent or greater.

(e) Nutrition information may be included on labels used to identify egg products, providing such labeling complies with the provisions of 21 CFR part 101, promulgated under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. Since these regulations have different requirements for consumer

packaged products than for bulk packaged egg products not for sale or distribution to household consumers, label submission must be accompanied with information indicating whether the label covers consumer packaged or bulk packaged products. Nutrition labeling is required when nutrients, such as proteins, vitamins, and minerals are added to the product, or when a nutritional claim or information is presented on the labeling, except for the following, which are exempt from nutrition labeling requirements:

(1) Egg products shipped in bulk form for use solely in the manufacture of other food and not for distribution to household consumers in such bulk form or containers.

(2) Products containing an added vitamin, mineral, or protein, or for which a nutritional claim is made on the label, or in advertising, which is supplied for institutional food use only, provided that the manufacturer or distributor provides the required nutrition information directly to those institutions.

(3) Any nutrients included in the product solely for technological purposes may be declared solely in the ingredients statement, without complying with nutrition labeling, if the nutrient(s) is otherwise not referred to in labeling or in advertising. All labels showing nutrition information or claims are subject to review by

the Food and Drug Administration prior to approval by the Department.

(f) (1) No label, container, or packaging material may contain any statement that is false or misleading. If the Administrator has reason to believe that a statement or formulation shows that an egg product is adulterated or misbranded, or that any labeling, including the size or form of any container in use or proposed for use, with respect to eggs or egg products, is false or misleading in any way, the Administrator may direct that such use be withdrawn unless the labeling or container is modified in such a manner as the Administrator may prescribe so that it will not be false or misleading, or the formulation of the product is altered in such a manner as the Administrator may prescribe so that it is not adulterated or would not cause misbranding.

(2) If the Administrator directs that the use of any label, container, or packaging material be withdrawn because it contains any statement that is false or misleading, an opportunity for a hearing will be provided in accordance with § 500.8(c) of this chapter.

§ 590.412 [Redesignated as § 590.413]

43. Redesignate § 590.412 as § 590.413.

44. Add a new § 590.412 to read as follows:

§ 590.412 Approval of generic labels.

(a) All official plants, including official plants certified under a foreign inspection system in accordance with § 590.910, must comply with the requirements in 9 CFR 412.2, except as otherwise provided in this part.

(b) For the purposes of 9 CFR 412.2, an official establishment or establishment certified under a foreign inspection system includes an official plant.

45. Revise newly redesignated § 590.413 to read as follows:

§ 590.413 Form of official identification symbol and inspection mark.

(a) The shield set forth in Figure 1 of this section containing the letters "USDA" must be the official identification symbol used in connection with egg products to denote that the official plant receives official inspection service. The inspection mark used on containers of edible egg products is set forth in Figure 1 of this section, except that the plant number may be preceded by the letter "G" in lieu of the word plant. The plant number may also be omitted from the official mark if applied on the container's principal display panel or other prominent location and preceded by the letter "G."



Figure 1.

(b) [Reserved]

46. Revise § 590.415 to read as follows:

§ 590.415 Use of other official identification.

All unpasteurized egg products shipped from an official plant must be marked with the identification set forth in Figure 2 of this section. Such product must meet all requirements for egg products that are permitted to bear the official inspection mark shown in § 590.413, except for pasteurization, heat treatment, or other method of treatment sufficient to reduce *Salmonella*. Such product must not be released into consumer channels until it has been subjected to pasteurization, heat treatment, or other method of treatment sufficient to reduce *Salmonella*. After

pasteurization or treatment, the product may bear the official inspection mark as shown in § 590.413.



Figure 2.

§ 590.418 [Amended]

47. Amend § 590.418 by removing paragraphs (a) and (c) and redesignate paragraph (b) as an undesignated paragraph.

48. Revise § 590.420(a) and (b) to read as follows:

§ 590.420 Inspection.

(a) Inspection shall be made, pursuant to the regulations in this part, of the processing of egg products in each official plant processing egg products for commerce, unless exempted under § 590.100. Inspections, certifications, or specification-type gradings, and other inspections which may be requested by the official plant and are in addition to the normal inspection requirements and functions for the processing, production, or certification for a wholesome egg product under this part, shall be made pursuant to the voluntary egg products inspection regulations (part 592 of this chapter).

(b) Any food manufacturing establishment or institution which uses any eggs that do not meet the requirements of 21 U.S.C. 1044(a)(1) in the preparation of any articles for human food shall be deemed to be a plant processing egg products requiring inspection under the regulations in this part.

* * * * *

49. Amend § 590.422 by removing the last sentence of the section.

50. Amend § 590.430 by revising paragraph (b) to read as follows:

§ 590.430 Limitation on entry of material.

* * * * *

(b) Inedible egg products may be brought into an official plant for storage, processing, and reshipment provided it is handled in such a manner that adequate segregation and inventory controls are maintained at all times. The processing of inedible egg products must be done under conditions that will not affect the processing of edible products, such as processing in separate areas or at times when no edible products are being processed. If the same equipment or areas are used to process both inedible and edible eggs, then the equipment and processing areas used to process inedible eggs must be thoroughly

cleaned and sanitized prior to processing any edible egg products.

51. Revise § 590.435 to read as follows:

§ 590.435 Use of food ingredients and approval of materials.

(a) (1) No substance may be used in the processing of egg products, for any purpose, unless its use is authorized under 21 CFR as a direct food additive (part 172), a secondary direct food additive (part 173), an indirect food additive (parts 174-178), a source of radiation (part 179), an interim-listed direct food additive (part 180), a prior-sanctioned substance (part 181), a Generally Recognized As Safe (GRAS) substance (parts 182 or 184), or by 21 CFR 160.185, or by regulation in this chapter. Substances and ingredients used in the processing of egg products capable of use as human food must be clean, wholesome, and unadulterated.

(2) No substance which is intended to impart color in any egg product may be used unless such use is authorized under 21 CFR as a color additive (parts 73, 74, or 81) or by regulation in this chapter.

(b) Substances permitted for use in egg products under 21 CFR will be permitted for such use under this chapter, subject to declaration requirements in 9 CFR 424.22(c) and

9 CFR 590.411, unless precluded from such use or further restricted in this chapter. Such substances must be safe and effective under conditions of use and not result in the adulteration of product. The Administrator may require, in addition to listing the ingredients, a declaration of the additive and the purpose of its use.

(c) Chemical additives to be used in the processing of egg products must be safe under the conditions of their intended use and in amounts sufficient to accomplish their intended purpose. Chemical additives may not promote deception or cause the product to be otherwise adulterated or unwholesome. Scientific data showing the additive meets the above specified criteria must be maintained and made available to FSIS program employees.

52. Revise § 590.440(c) to read as follows:

§ 590.440 Processing ova.

* * * * *

(c) All products containing ova must be labeled in accordance with § 590.411.

§§ 590.500 and 590.502 [REMOVED]

53. Remove §§ 590.500 and 590.502.

54. Revise § 590.504 to read as follows:

§ 590.504 General operating procedures.

(a) Operations involving the processing, storing, and handling of eggs, ingredients, and egg products must be strictly in accordance with clean and sanitary methods and must be conducted as rapidly as practicable.

(b) (1) Egg products are subject to inspection in each official plant processing egg products for commerce.

(2) Any egg products not processed in accordance with the regulations in this part or part 591 or that are not otherwise fit for human food will be removed and segregated.

(c) (1) All loss and inedible eggs or inedible egg products must be placed in a container clearly labeled "inedible" and containing a sufficient amount of denaturant or decharacterant, such as an acceptable FD&C color additive, suspended in the product. Eggs must be crushed and the substance dispersed through the product in amounts sufficient to give the product a distinctive appearance or odor. Inedible product may be held in containers clearly labeled "inedible" which do not contain a denaturant as long as such inedible product is properly packaged, labeled and segregated, and inventory controls are maintained. Such inedible product must be denatured or decharacterized before being shipped from a facility.

(2) Denatured or decharacterized inedible egg products may be shipped from an official plant for industrial use or animal food, provided that it is properly packaged, labeled, and segregated, and inventory controls are maintained.

(d) (1) Egg products must be processed to meet the standard set out in § 590.570.

(2) Unpasteurized egg products may be shipped from an official plant to another official plant only when they are to be pasteurized, heat treated, or treated using other methods of treatment sufficient to reduce *Salmonella* in the second official plant. Shipments of unpasteurized egg products shipped from one official plant to another for pasteurization or treatment must be sealed in cars or trucks and labeled in accordance with § 590.410(c). Containers of unpasteurized egg product must be marked with the identification mark shown in Figure 2 of § 590.415.

(e) When inspection program personnel do not suspect noncompliance by an official plant with any provisions of this part, they may permit that plant to move egg products that have been sampled and analyzed for *Salmonella*, or any other reason, before receiving the test results so long as the plant maintains control of the products represented by the sample pending test results.

§ 590.506 [REMOVED]

55. Remove § 590.506.

56. Revise § 590.508 to read as follows:

§ 590.508 Candling and transfer-room operations.

Eggs must be handled in a manner that minimizes sweating prior to breaking or processing.

57. Amend § 590.510 by revising paragraphs (a) introductory text, (c) (1) and (3), and (d) introductory text to read as follows:

§ 590.510 Classifications of eggs used in the processing of egg products.

(a) The eggs must be sorted and classified into the following categories:

* * * * *

(c) (1) When presented for breaking, eggs must have an edible interior quality and the shell must be sound and free of adhering dirt and foreign material. However, checks and eggs with a portion of the shell missing may be used when the shell is free of adhering dirt and foreign material and the shell membranes are not ruptured.

* * * * *

(3) Eggs with meat or blood spots may be used if the spots are removed.

(d) All loss or inedible eggs must be placed in a designated container and handled as required in § 590.504(c). Eggs extensively damaged during breaking, whether not completely cracked open mechanically or in the movement of trays of eligible eggs for hand breaking, must be broken promptly. For the purpose of this section and § 590.522, inedible and loss eggs include crusted yolks, filthy and decomposed eggs, and the following:

* * * * *

58. Amend § 590.516 by revising the section heading and paragraph (a) to read as follows:

§ 590.516 Cleaning of eggs prior to packaging, breaking, or pasteurizing.

(a) All eggs, except as provided in § 590.801, must be clean prior to packaging, breaking, or pasteurizing. If a sanitizer is used, it must be used in accordance with FDA requirements for the intended use.

* * * * *

§ 590.520 [REMOVED]

59. Remove § 590.520.

60. Revise § 590.522 to read as follows:

§ 590.522 Egg products processing room operations.

Eggs used in processed egg products must be broken in a sanitary manner and examined to ensure that the contents are acceptable for human consumption.

§§ 590.530 and 590.532 [REMOVED]

61. Remove §§ 590.530 and 590.532.

62. Revise § 590.534 to read as follows:

§ 590.534 Freezing facilities.

Freezing rooms, either on or off the premises, must be capable of solidly freezing, or reducing to a temperature of 10° F or lower, all liquid egg products.

§§ 590.536, 590.538 through 590.540, 590.542, 590.544, 590.546 through 590.550, 590.552 and 590.560 [REMOVED]

63. Remove §§ 590.536, 590.538 through 590.540, 590.542, 590.544, 590.546 through 590.550, 590.552 and 590.560.

64. Revise § 590.570 to read as follows:

§ 590.570 Control of pathogens in egg products.

Egg products must be produced to be edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. Egg products are not required to bear a safe-handling instruction or other labeling that directs that the product must be cooked or otherwise treated for safety.

§ 590.575 [REMOVED]

65. Remove § 590.575.

66. Revise § 590.580 to read as follows:

§ 590.580 Pathogen reduction standards testing.

(a) Official plants must test to determine that the production of egg products is in compliance with the Act and the egg products inspection regulations.

(b) To ensure adequate pasteurization:

(1) Pasteurized liquid, frozen, and dried egg products, and heat treated dried egg whites must be sampled and analyzed for the presence of *Salmonella* spp. Such testing must be performed in a manner sufficient such that it is possible for the official plant to verify that the system is capable of eliminating *Salmonella* spp. at the time that the annual reassessment occurs, and as regularly as necessary between annual reassessments, to show that the system, when tested, is working.

(2) Samples must be analyzed for the presence of *Salmonella* spp. with such sequence, with such frequency, and using such laboratory methods as is sufficient to ensure that product is not adulterated.

(3) Samples must be drawn from the final packaged form.

(c) Results of all partial and completed analyses performed under paragraph (b) of this section must be

provided to inspection program personnel promptly upon receipt by the official plant. Positive test results must be provided to inspection program personnel immediately upon receipt by the official plant.

67. Add § 590.590 to read as follows:

§ 590.590 Use of irradiated shell eggs to produce egg products.

Irradiated shell eggs used to produce pasteurized egg products must be used in conjunction with heat or another lethality treatment to produce a ready-to-eat product. Unless otherwise approved by FDA, the irradiation treatment of the shell eggs must precede the heat or other lethality treatment applied to the egg products.

§§ 590.600 through 590.680 [Removed]

68. Remove the undesignated center heading "Exempted Egg Products Plants" and §§ 590.600 through 590.680.

69. Add an undesignated center heading and § 590.700 to read as follows:

Inspection and Disposition of Restricted Eggs

§ 590.700 Prohibition on disposition of restricted eggs.

(a) No person may buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation in any business in commerce any restricted eggs capable of use as human food, except as authorized in §§ 590.100 and 590.720.

(b) No egg handler may possess with the intent to use, or use, any restricted eggs in the preparation of human food, except as provided in §§ 590.100 and 590.720.

70. Add § 590.720 to read as follows:

§ 590.720 Disposition of restricted eggs.

(a) Except as exempted in § 590.100, eggs classified as checks, dirt, incubator rejects, inedibles, leakers, or loss must be disposed of by one of the following methods at the point and time of segregation:

(1) Checks and dirt must be labeled in accordance with § 590.800 and shipped to an official plant for segregation and processing. Inedible and loss eggs must not be intermingled in the same container with checks and dirt.

(2) By destruction in a manner that clearly identifies the products as being inedible and not for human consumption, such as crushing and denaturing or decharacterizing in accordance with § 590.504(c). The products must also be identified as "Inedible Egg Product-Not To Be Used As Human Food."

(3) Processing for industrial use or for animal food. Such products must be denatured or decharacterized in accordance with § 590.504(c) and identified as provided in §§ 590.840 and 590.860, or properly handled in a manner

that clearly identifies the products as being inedible and not for human consumption and does not adulterate egg product intended for human consumption. Notwithstanding the foregoing, product which was produced under official supervision and transported for industrial use or animal food need not be denatured or decharacterized if it is shipped under Government seal and received by a program employee as defined in this part.

(4) By coloring the shells of loss and inedible eggs with a sufficient amount of FD&C color to give a distinct appearance, or applying a substance that will penetrate the shell and decharacterize the contents of the egg. However, lots of eggs containing significant percentages of eggs having small to medium blood spots or meat spots, but no other types of loss or inedible eggs, may be shipped directly to official plants, provided they are conspicuously labeled with the name and address of the shipper and the wording "Spots—For Processing Only In Official Egg Products Plants."

(5) Incubator rejects must be broken or crushed and denatured or decharacterized in accordance with § 590.504(c) and labeled as required in §§ 590.840 and 590.860.

(b) Eggs that are packed for the ultimate consumer and have been found to exceed the tolerance for restricted eggs permitted in the official standards for U.S. Consumer Grade B but have not been shipped for retail sale must be identified as required in §§ 590.800 and 590.860 and must be shipped directly or indirectly:

(1) To an official plant for proper segregation and processing; or

(2) Be re-graded so that they comply with the official standards; or

(3) Used as other than human food.

(c) Records must be maintained as provided in § 590.200 to ensure proper disposition.

71. Add § 590.801 to read as follows:

§ 590.801 Nest-run or washed ungraded eggs.

Nest-run or washed ungraded eggs are exempt from the labeling provisions in § 590.800. However, when such eggs are sold to consumers, they may not exceed the tolerance for restricted eggs for U.S. Consumer Grade B shell eggs.

§§ 590.900 through 590.970 [Removed]

72. Remove undesignated center heading "Imports" and §§ 590.900 through 590.970.

73. Add subpart B, consisting of §§ 590.900 through 590.965, to read as follows:

Subpart B - Imports

Sec.

- 590.900 Definitions; requirements for importation into the United States.
- 590.901 Egg products offered for entry and entered to be handled and transported as domestic; entry into official plants; transportation.
- 590.905 Importation of restricted eggs.
- 590.910 Eligibility of foreign countries for importation of eggs and egg products into the United States.
- 590.915 Imported products; foreign inspection certificates required.
- 590.920 Import inspection application.
- 590.925 Inspection of eggs and egg products offered for entry.
- 590.930 Eggs and egg products offered for entry, retention in customs custody; delivery under bond; movement prior to inspection; handling; equipment and assistance.
- 590.935 Means of conveyance and equipment used in handling egg products offered for entry to be maintained in sanitary condition.
- 590.940 Identification of egg products offered for entry; official import inspection marks and devices.
- 590.945 Eggs and egg products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.
- 590.950 Labeling of immediate containers of egg products offered for entry.
- 590.955 Labeling of shipping containers of egg products offered for entry.
- 590.956 Relabeling of imported egg products.
- 590.960 Small importations for importer's personal use, display, or laboratory analysis.
- 590.965 Returned to the United States inspected and identified covered products; exemption.

Subpart B - Imports

§ 590.900 Definitions; requirements for importation into the United States.

(a) When used in this subpart, the following terms will be construed to mean:

(1) *Import (Imported)*. To bring within the territorial limits of the United States, whether that arrival is accomplished by land, air, or water.

(2) *Offer(ed) for entry*. The point at which the importer presents the imported product for reinspection.

(3) *Entry (entered)* means the point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection, as required by § 590.940.

(4) *Official Import Inspection Establishment*. This term means any establishment, other than an official establishment as defined in 9 CFR 301.2, where inspections are authorized to be conducted as prescribed in § 590.925 of this subchapter.

(b) No egg products may be imported into the United States unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient which renders them unhealthful, unwholesome, unadulterated, or unfit for human food. Such products must also comply with the regulations prescribed in this subpart to ensure that they adhere to the standards provided for in the Act. The provisions of this subpart

will apply to these products only if they are capable for use as human food.

(c) Approval for Federal import inspection must be in accordance with §§ 590.140 through 590.149.

(d) Egg products may be imported only if they are processed solely in the countries listed in § 590.910(b). § 590.901 Egg products offered for entry and entered to be handled and transported as domestic; entry into official plants; transportation.

(a) All egg products, after entry into the United States in compliance with this subpart, will be deemed and treated and, except as provided in §§ 590.935 and 590.960, will be handled and transported as domestic product, and will be subject to the applicable provisions of this part and to the provisions of the Egg Products Inspection Act and the Federal Food, Drug, and Cosmetic Act.

(b) Imported egg products entered in accordance with this subpart may, subject to the provisions of the regulations, be taken into official plants and be mixed with or added to egg products that are inspected and passed or exempted from inspection in such plants.

(c) Imported egg products that have been inspected and passed under this subpart may be transported in commerce only upon compliance with the applicable regulations.

§ 590.905 Importation of restricted eggs.

(a) No containers of restricted eggs other than checks or dirties will be imported into the United States. The shipping containers of such eggs shall be identified with the name, address, and country of origin of the exporter, and the date of pack and the quality of the eggs (e.g., checks or dirties) preceded by the word "Imported" or the statement "Imported Restricted Eggs-For Processing Only In An Official USDA Plant," or "Restricted Eggs-Not To Be Used As Human Food." Such identification shall be legible and conspicuous.

(b) For properly sealed and certified shipments of shell eggs for breaking at an official egg products plant, the containers need not be labeled, provided that the shipment is segregated and controlled upon arrival at the destination breaking plant.

§ 590.910 Eligibility of foreign countries for importation of eggs and egg products into the United States.

(a) (1) Whenever it is determined by the Administrator that the system of egg products inspection maintained by any foreign country, with respect to plants preparing products in such country for export to the United States, insures compliance of such plants and their products with requirements equivalent to all the inspection, building

construction standards, and all other provisions of the Act and the regulations in this part which are applied to official plants in the United States, and their products, and that reliance can be placed upon certificates required under this part from authorities of such foreign country, notice of that fact will be given by including the name of such foreign country in paragraph (b) of this section. Thereafter, products prepared in such plants which are certified and approved in accordance with paragraph (a) (3) of this section, will be eligible so far as this part is concerned for importation into the United States from such foreign country after applicable requirements of this part have been met.

(2) The determination of acceptability of a foreign egg products inspection system for purposes of this section must be based on an evaluation of the foreign program in accordance with the following requirements and procedures:

(i) The system must have a program organized and administered by the national government of the foreign country. The system as implemented must provide standards equivalent to those of the Federal system of egg products inspection in the United States with respect to:

(A) Organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and

regulations in all plants throughout the system at which products are prepared for export to the United States;

(B) Ultimate control and supervision by the national government over the official activities of all employees or licensees of the system;

(C) The assignment of competent, qualified inspectors;

(D) Authority and responsibility of national inspection officials to enforce the requisite laws and regulations governing egg products inspection and to certify or refuse to certify products intended for export;

(E) Adequate administrative and technical support;

(F) The inspection and residue standards applied to egg products produced in the United States.

(G) Other requirements of adequate inspection service as required by the regulations in this part.

(ii) The legal authority for the system and the regulations thereunder must impose requirements equivalent to those governing the system of egg products inspection organized and maintained in the United States with respect to:

(A) Official controls by the national government over plant construction, building and facilities, and equipment;

(B) Official supervision of the processing of egg products in plants by the assignment of inspectors to

plants certified under paragraph (a) (2) (iv) of this section to ensure that adulterated or misbranded product is not prepared for export to the United States;

(C) Any product that is prepared under inspection in a plant must be inspected in such a plant as often as the inspector deems necessary in order to ascertain if the product is unadulterated, wholesome, properly labeled, and fit for human food at the time it leaves the plant. Upon any such inspection, if any product or portion thereof is found to be adulterated, unwholesome, or otherwise unfit for human food, such product or portion thereof must be condemned and must receive such treatment as provided in § 590.504(c);

(D) Complete separation of plants certified under paragraph (a) (2) (iv) of this section from plants not certified, and the maintenance of a single standard of inspection and sanitation throughout all certified plants;

(E) Requirements for sanitation at certified plants and for sanitary handling of egg products;

(F) Official controls over condemned material until destroyed or removed and thereafter excluded from the plant;

(G) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter; and

(H) Other matters for which requirements are contained in the Act or regulations in this part.

(iii) Countries desiring to establish eligibility for the importation of egg products into the United States may request a determination of eligibility by presenting copies of the laws and regulations on which the foreign egg products inspection system is based and such other information as the Administrator may require with respect to matters enumerated in paragraphs (a) (2) (i) and (ii) of this section. Determination of eligibility is based on a study of the documents and other information presented and an initial review of the system in operation by a representative of the Department using the criteria listed in paragraphs (a) (2) (i) and (ii) of this section. Maintenance of eligibility of a country for importation of egg products into the United States depends on the results of periodic reviews of the foreign egg products inspection system in operation by a representative of the Department, and the timely submission of such documents and other information related to the conduct of the foreign inspection system, including information required by

paragraph (e) of section 20 of the Act, as the Administrator may find pertinent to and necessary for the determinations required by this section of the regulations.

(iv) The foreign inspection system must maintain a program to assure that the requirements referred to in this section, equivalent to those of the Federal system of egg products inspection in the United States, are being met. The program as implemented must provide for the following:

(A) Periodic supervisory visits by a representative of the foreign inspection system to each plant certified in accordance with paragraph (a) (3) of this section to ensure that requirements referred to in paragraphs (a) (2) (ii) (A) through (H) of this section are being met: Provided, that such visits are not required with respect to any plant during a period when the plant is not operating or is not engaged in producing products for exportation to the United States;

(B) Written reports prepared by the representative of the foreign inspection system who has conducted a supervisory visit, documenting his or her findings with respect to the requirements referred to in paragraphs (a) (2) (ii) (A) through (H) of this section, copies of which must be made available to the representative of the Department at the time of that representative's review upon

request by that representative to a responsible foreign meat inspection official: Provided, that such reports are not required with respect to any plant during a period when the plant is not operating or is not engaged in producing products for exportation to the United States; and

(C) Random sampling and testing at the point of production, for residues identified by the exporting country's inspection authorities or by this Agency as potential contaminants, in accordance with sampling and analytical techniques approved by the Administrator, provided that such testing is required only on samples taken of egg products intended for importation into the United States.

(3) Only those plants that are determined and certified to the Agency by a responsible official of the foreign egg products inspection system as fully meeting the requirements of paragraphs (a) (2) (i) and (ii) of this section are eligible to have their products imported into the United States. Plant eligibility is subject to review by the Agency (including observations of the plants by official program personnel representatives at times prearranged with the foreign egg products inspection system officials). Foreign plants certifications must be renewed annually. Notwithstanding certification by a foreign

official, the Administrator may terminate the eligibility of any foreign plant for the importation of its products into the United States if it does not comply with the requirements listed in paragraphs (a)(2)(i) and (ii) of this section, or if current plant information cannot be obtained. The Administrator will provide reasonable notice to the foreign government of the proposed termination of any foreign plant, unless a delay in terminating its eligibility could result in the importation of adulterated or misbranded product.

(i) For a new plant, or any plant for which information from last year's electronic certification or paper certificate has changed, the certification or certificate must contain: The date; the foreign country; the foreign plant's name, address, and foreign plant number; the foreign official's title and signature (for paper certificates only); the type of operations conducted at the plant (e.g., processing, storage, exporting warehouse); and the plant's eligibility status (e.g., new or relisted (if previously delisted)). Processing plant certifications must address the type of products produced at the plant (e.g., the process category).

(ii) If the plant information provided on the preceding year's electronic foreign plant certification or

paper certificate, as required in paragraph (a) (3) (i) of this section, has not changed, the certification or certificate must contain: The date, the foreign country, the foreign plant's name, and the foreign official's title and signature (for paper certificates only).

(4) Egg products from foreign countries not listed in paragraph (b) of this section are not eligible for importation into the United States, except as provided by §§ 590.960 and 590.965. The listing of any foreign country under this section may be withdrawn whenever it is determined by the Administrator that the system of egg products inspection maintained by such foreign country does not assure compliance with requirements equivalent to all the inspection, building construction standards, and other requirements of the Act and the regulations in this part as applied to official plants in the United States; or that reliance cannot be placed upon certificates required under this part from authorities of such foreign country; or that, for lack of current information concerning the system of egg products inspection being maintained by such foreign country, such foreign country should be required to reestablish its eligibility for listing.

(b) It has been determined that egg products from the following countries covered by foreign egg products

inspection certificates of the country of origin as required by § 590.915 are eligible under the regulations in this part for entry into the United States after inspection and marking as required by the applicable provisions of this part: **Canada, The Netherlands.**

§ 590.915 Imported products; foreign inspection certificates required.

(a) Except as provided in § 590.960, each consignment imported into the United States must have an electronic foreign inspection certification or a paper foreign inspection certificate issued by an official of the foreign government agency responsible for the inspection and certification of the product.

(b) An official of the foreign government agency must certify that any product described on any official certificate was produced in accordance with the regulatory requirements of § 590.910.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment; be submitted to import inspection personnel at the official import inspection establishment; be in English; and bear the official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue the inspection certificates for products imported into the United States.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

(1) The date;

(2) The foreign country of export and the producing foreign establishment number;

(3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;

(4) The product's description including the process category, the product category, and the product group;

(5) The name and address of the importer or consignee;

(6) The name and address of the exporter or consignor;

(7) The number of units (pieces or containers) and the shipping or identification mark on the units;

(8) The net weight of each lot; and

(9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

§ 590.920 Import inspection application.

(a) Applicants must submit an import inspection application to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application form.

(b) Import inspection applications for each consignment must be submitted (electronically or on paper) to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 590.960 and 590.965.

§ 590.925 Inspection of eggs and egg products offered for entry.

(a) (1) Except as provided in §§ 590.960 and 590.965 and paragraph (b) of this section, egg products offered for entry from any foreign country must be reinspected at an official import inspection establishment or official plant

by a program inspector before they may be allowed entry into the United States.

(2) Every lot of product must routinely be given visual reinspection by a program inspector for appearance and condition and be checked for certification and label compliance as provided in §§ 590.915, 590.950, and 590.955.

(3) Program inspectors must consult the electronic inspection system for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

(b) Official program personnel may take, without cost to the United States, from each consignment of egg product offered for entry, such samples of the products as are deemed necessary to determine the eligibility of the products for entry into the commerce of the United States. § 590.930 Eggs and egg products offered for entry, retention in customs custody; delivery under bond; movement prior to inspection; handling; equipment and assistance.

(a) No egg products required by this subpart to be inspected will be released from customs custody prior to required inspections, but such product may be delivered to the importer, or his agent, prior to inspection, if the importer furnishes a bond, in a form prescribed by the

Secretary of the Treasury, on the condition that the product must be returned, if demanded, to the collector of the port where the product was offered for clearance through customs.

(b) Notwithstanding paragraph (a) of this section, no product required by this subpart to be inspected will be moved prior to inspection from the port of arrival where first unloaded, and if arriving by water from the wharf where first unloaded at such port, to any place other than the place designated in accordance with this part as the place where the product must be inspected; and no product will be conveyed in any manner other than in compliance with this subpart.

(c) The importer, or his agent, must furnish such equipment and must provide such assistance for handling and inspecting, where applicable, egg products offered for entry as the program inspector may require.

(d) Official import inspection establishments must provide buildings and equipment that meet the sanitation requirements contained in 9 CFR part 416.

§ 590.935 Means of conveyance and equipment used in handling egg products offered for entry to be maintained in sanitary condition.

(a) Compartments of steamships, railroad cars, and other means of conveyance transporting any egg products to the United States, and all chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any egg products offered for entry into the United States, must be maintained in accordance with 9 CFR 416.4.

(b) All conveyances containing imported liquid egg products must be sealed by inspection authorities in the exporting country. Seals may be broken at U.S. port-of-entry for purposes of inspection by official program personnel or customs officers.

§ 590.940 Identification of egg products offered for entry; official import inspection marks and devices.

(a) Except for products offered for entry from Canada, egg products that upon reinspection are found to be acceptable for entry into the United States must be identified as "U.S. Inspected and Passed" product. The official inspection legend shown in paragraph (b) of this section will identify product only after completion of official import inspection and product acceptance.

(b) The official mark for identifying egg products offered for entry as "U.S. Inspected and Passed" must be in the following form, and any device approved by the

Administrator for applying such mark must be an official device.¹



Figure 3

(c) Owners or operators of plants, other than official plants, who want to have import inspections made at their plants, must apply to the Administrator for approval of their establishments for such purpose. Application must be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC, and must include all information called for by that form.

(d) No brand manufacturer or other person will cast or otherwise make, without an official certificate issued by official program personnel, a brand or other marking device containing an official inspection legend, or simulation thereof, as shown in § 590.940(b).

(e) The inspection legend may be placed on containers of product before completion of the official import

¹ The number "I-38" is given as an example only. The plant number of the official plant, facility, or official import inspection establishment where the product was inspected must be shown on each stamp impression.

inspection if the containers are being inspected by an import inspector who reports directly to a program supervisor, the product is not required to be held at the official import inspection establishment pending receipt of laboratory test results, and a written procedure for the controlled stamping, submitted by the official import inspection establishment and approved by the Food Safety and Inspection Service, is on file at the import inspection location where the inspection is to be performed.

(f) (1) The written procedure for the controlled release and identification of product should be in the form of a letter and must include the following:

(i) That stamping under this subpart is limited to those lots of product that can be inspected on the day that certificates for the product are examined;

(ii) That all products that have been pre-stamped will be stored in the facility where the import inspection will occur;

(iii) That inspection marks applied under this part will be removed from any lot of product subsequently refused entry on the day the product is rejected; and

(iv) That the establishment will maintain a daily stamping log containing the following information for each lot of product: the date of inspection, the country of

origin, the foreign establishment number, the product name, the number of units, the shipping container marks and foreign inspection certificate number covering the product to be inspected. The daily log must be retained by the establishment in accordance with § 590.200.

(2) An establishment's controlled program privilege may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that the establishment has failed to comply with the provisions of this subpart or any conditions imposed pursuant thereto. If the cancellation is oral, the decision and the reasons for it must be confirmed in writing, as promptly as circumstances allow. Any person whose controlled pre-stamping program privilege has been cancelled may appeal the decision to the Administrator, in writing, within ten (10) days after receiving written notification of the cancellation. The appeal must state all of the facts and reasons upon which the person relies to show that the controlled program was wrongfully cancelled. The Administrator will grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing must be held to resolve such conflict. Rules of practice concerning such a hearing

will be adopted by the Administrator. The cancellation of the controlled pre-stamping privilege will be in effect until there is a final determination of the preceding.

§ 590.945 Eggs and egg products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.

(a) (1) Official program personnel must report their findings as to any product that has been inspected in accordance with this subpart to the Director of Customs at the original port of entry where the same is offered for clearance through Customs inspection.

(2) When product is refused entry into the United States, the official mark to be applied to the product refused entry must be in the following form:

**UNITED STATES
REFUSED ENTRY**

Figure 4

(3) When product has been identified as "U.S. Refused Entry," official program personnel must request the Director of Customs to refuse admission of such product and to direct that it be exported by the owner or importer

within the time specified in this section, unless the owner or importer, within the specified time, causes it to be destroyed by disposing of it under the supervision of official program personnel so that the product can no longer be used as human food, or by converting it to animal food uses, if permitted by the Food and Drug Administration. The owner or importer of the refused entry product must not transfer legal title to such product, except to a foreign importer for direct and immediate exportation, or to an end user, e.g., an animal food manufacturer or a renderer, for destruction for human food purposes. "Refused entry" product must be delivered to and used by the manufacturer or renderer within the 45-day time limit provided in paragraph (a)(4) of this section. Even if such title is illegally transferred, the subsequent purchaser will still be required to export the product or have it destroyed under paragraph (a)(4) of this section.

(4) The owner or importer will have 45 days after notice is given by FSIS to the Director of Customs at the original port of entry to take the action required in paragraph (a)(3) of this section for "refused entry" product. An extension beyond the 45-day period may be granted by the Administrator when extreme circumstances

warrant it, e.g., a dock workers' strike or an unforeseeable vessel delay.

(5) If the owner or importer fails to take the required action within the time specified under paragraph (a) (4) of this section, the Department will take such actions as may be necessary to effectuate its order to have the product destroyed for human food purposes. The Department will seek court costs and fees, storage, and proper expenses in the appropriate forum.

(6) No egg product that has been refused entry and exported to another country pursuant to paragraph (a) (3) of this section may be returned to the United States under any circumstances. Any such product so returned to the United States will be subject to administrative detention in accordance with section 1048 of the Act and seizure and condemnation in accordance with section 1049 of the Act.

(7) Egg products that have been refused entry solely because of misbranding may be brought into compliance with the requirements of this chapter under the supervision of an authorized representative of the Administrator.

(b) Upon the request of the Director of Customs at the port where an egg product is offered for clearance through the customs, the importer of the product must, at the importer's own expense, immediately return to the Director

any product that has been delivered to the importer under this subpart and subsequently designated "U.S. Refused Entry" or found in any request not to comply with the requirements in this part.

(c) Except as provided in § 590.930(a) or (b), no person will remove or cause to be removed from any place designated as the place of inspection of egg products that the regulations in this part require to be identified in any way, unless the same has been clearly and legibly identified in compliance with this part.

(d) Any person receiving inspection services may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision. Any such appeal from a decision of an inspector must be made to the inspector's immediate supervisor having jurisdiction over the subject matter of the appeal, and such supervisor must determine whether the inspector's decision was correct. Review of such an appeal determination, when requested, must be made by the immediate supervisor of the Department employee making the appeal determination. The egg products involved in any appeal must be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

(e) All loss or inedible eggs, or inedible egg products must be disposed of in accordance with § 590.504(c) (1).

§ 590.950 Labeling of immediate containers of egg products offered for entry.

(a) Immediate containers of product offered for entry into the United States must bear a label, printed in English, showing:

(1) The name of the product;

(2) The name of the country of origin of the product, and for consumer packaged products, preceded by the words "Product of," which statement must appear immediately under the name of the product;

(3) [Reserved];

(4) The word "Ingredients" followed by a list of the ingredients in order of descending proportions by weight;

(5) The name and place of business of the manufacturer, packer, or distributor, qualified by a phrase which reveals the connection that such person has with the product;

(6) An accurate statement of the quantity;

(7) The inspection mark of the country of origin;

(8) Plant number of the plant at which the egg products were processed; and

(9) The date of production and plant number of the plant at which the egg products were processed or packed.

(b) For properly sealed and certified shipments of shell eggs for breaking at an official plant, the immediate containers need not be labeled, provided that the shipment is segregated and controlled upon arrival at the destination breaking plant.

(c) The labels must not be false or misleading in any respect.

§ 590.955 Labeling of shipping containers of egg products offered for entry.

Shipping containers of imported egg products are required to bear in a prominent and legible manner the name of the product, the name of the country of origin, the foreign inspection system plant number of the plant in which the product was processed, shipping or identification marks, production codes, and the inspection mark of the country or origin. Labeling on shipping containers must be examined at the time of inspection in the United States and if found to be false or misleading, the product must be refused entry.

§ 590.956 Relabeling of imported egg products.

(a) Egg products eligible for importation may be relabeled with an approved label under the supervision of

an inspector at an official plant or official import inspection establishment. The new label for such product must indicate the country of origin, except for egg products that are processed (repasteurized or, in the case of dried product, dry blended with product produced in the United States) in an official plant.

(b) Egg products that have been refused entry into the United States solely because of misbranding may be brought into compliance with the labeling requirements of this chapter.

(c) The label for relabeled products must state the name, address, and zip code of the distributor, qualified by an appropriate term such as "packed for", "distributed by", or "distributors".

§ 590.960 Small importations for importer's personal use, display, or laboratory analysis.

Egg products (other than those that are forbidden entry by other Federal law or regulation) from any country, that are exclusively for the importer's personal use, display, or laboratory analysis, and not for sale or distribution; that are sound, healthful, wholesome, and fit for human food; and that are not adulterated and do not contain any substance not permitted by the Act or regulations, may be admitted into the United States without

a foreign inspection certificate. Such products are not required to be inspected upon arrival in the United States and may be shipped to the importer without further restriction under this part, except as provided in 9 CFR 590.925(b), provided that the Department may, with respect to any specific importation, require that the importer certify that such product is exclusively for said importer's personal use, display, or laboratory analysis and not for sale or distribution. The amount of liquid, frozen, or dried egg products imported must not exceed 50 pounds.

§ 590.965 Returned to the United States inspected and identified covered products; exemption.

U.S. inspected and passed and so marked egg products exported to and returned from foreign countries will be admitted into the United States without compliance with this part upon notification to and approval of the Food Safety and Inspection Service, in specific cases.

SUBCHAPTER I-EGG PRODUCTS INSPECTION ACT

74. Add part 591 to read as follows:

PART 591 - SANITATION REQUIREMENTS AND HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS

Sec.

591.1 Basic requirements.

591.2 Hazard analysis and HACCP plan.

Authority: 21 U.S.C. 1031-1056; 7 CFR 2.18, 2.53.

§ 591.1 Basic requirements.

(a) All official plants must comply with the requirements contained in 9 CFR parts 416, Sanitation, and 417, Hazard Analysis and Critical Control Point (HACCP) Systems, except as otherwise provided in this chapter.

(b) For the purposes of 9 CFR parts 416, Sanitation, 417, Hazard Analysis and Critical Control Point (HACCP) Systems, and 500, Rules of Practice, an official establishment or establishment includes an official plant.

§ 591.2 Hazard analysis and HACCP plan.

Pursuant to 21 U.S.C. 1035 and 1043, the failure of an official plant to develop and implement a HACCP plan that complies with 9 CFR part 417, or to operate in accordance with the requirements in this part, may render the products produced under those conditions adulterated.

Done at Washington, DC, on: January 9, 2018.

Paul Kiecker

Acting Administrator.

[FR Doc. 2018-00425 Filed: 2/12/2018 8:45 am; Publication Date: 2/13/2018]