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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: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the egg products inspection regulations to require 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 FSIS's meat and poultry regulations. FSIS is eliminating the current, prescriptive regulations that are inconsistent with HACCP, Sanitation SOPs, and the proposed sanitation requirements. FSIS is also specifying in the regulations that official plants that produce pasteurized egg products are required to process them to be edible without additional preparation to achieve food safety.

In addition, FSIS is: providing for generic approval as part of the prior label approval system for egg products; making changes to labeling requirements for shell eggs consistent with those in the Food and Drug Administration (FDA) regulations; requiring special handling instructions on egg products that require special handling to maintain their wholesome condition; eliminating the requirements for prior approval by FSIS of egg products plant drawings, specifications, and equipment; and incorporating egg products plants into the coverage of the "rules of practice" that the Agency follows when initiating administrative enforcement actions. FSIS is also asserting jurisdiction over egg substitutes and freeze-dried egg products. Finally, FSIS is changing the Agency's interpretation of the requirement for continuous inspection and eliminating the unnecessary exemptions from continuous inspection. FSIS is not, however, eliminating the definition of "Eggs of current production," as proposed. It is retaining the current requirement that egg products produced from edible shell eggs of other than current production be clearly and distinctly labeled in close proximity to the common or usual name of the product to indicate that the product is produced from eggs that are in excess of sixty days old.

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*], except for the amendments to 9 CFR part 417, 590.149(b) and (c), 590.570(b), 590.580(b)(1), 591.1(b), and 591.2(a) and (c) which are effective [INSERT DATE 2 YEARS AFTER PUBLICATION IN THE *FEDERAL REGISTER*] and the amendments to 9 CFR part 416, 9 CFR 590.146, 590.149(a), 590.500, 590.502, 590.506, 590.508, 590.510(c)(1), (c)(3), and (d), 590.515, 590.516(a), 590.520, 590.522, 590.530, 590.532, 590.534, 590.536, 590.538, 590.539, 590.540, 590.542, 590.544 590.546, 590.550, 590.552, 590.560 590.570(a), and 591.1(a) and 591.2(b), which are effective [INSERT DATE 1 YEAR AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

Comment date: FSIS is seeking comments on the *Egg Products Hazards and Controls Guide*. Commenters may use the *Egg Products Hazards and Controls Guide* during the comment period. Comments must be received by [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website 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, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, 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, call (202) 720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Victoria Levine, Program Analyst, Office of Policy and Program Development by telephone at (202) 690-3184.

SUPPLEMENTARY INFORMATION:

Executive Summary:

On February 13, 2018, FSIS published a proposed rule to amend the egg products inspection regulations (9 CFR part 590 and other relevant parts) to require egg products plants to develop and implement Hazard Analysis and Critical Control Point (HACCP) Systems and Sanitation Standard Operating Procedures (Sanitation SOPs) and to comply with the Sanitation Performance Standards (SPS), in accordance with the regulations in 9 CFR parts 416 and 417 (83 FR 6314). Additionally, FSIS proposed:

- To replace prescriptive regulations, including those requiring prior approval by FSIS of egg products plant drawings, specifications, and equipment, and outdated pasteurization requirements, with a performance standard requiring that official plants process egg products to be edible without additional preparation to achieve food safety.
- To change the Agency's interpretation of "continuous inspection" to provide for the presence of inspectors at official plants at the same frequency that meat and poultry processing establishments are provided inspectors, i.e., at least once per shift.

- To require egg products plants to maintain control of egg products that have been sampled and tested for microbiological public health hazards until the test results become available.
- To apply the egg products regulations to egg substitutes and freeze-dried products and require inspection of these products.
- To eliminate the prohibition on the use of irradiated shell eggs in the production of egg products and food products containing them.
- To make egg products labeling requirements, including requirements for generically approved labeling and special handling labels, more consistent with the requirements for meat and poultry products.
- To align the import requirements for egg products more closely with the import requirements for meat and poultry products.
- To change organizational terms and job titles that appear in the regulations but are no longer used by FSIS.
- To replace the rules of practice governing enforcement procedures for egg product plants with those that apply to meat and poultry product establishments under 9 CFR

part 500. And,

- To add the undesignated paragraph defining the term *Program employee* and eliminate the undesignated paragraph defining the term *Eggs of current production*.

This final rule adopts all the proposed revisions to the egg products inspection regulations, except for the two proposed changes to the regulatory definitions. First, FSIS is not eliminating the definition for the term *Eggs of current production* from 9 CFR 590.5. Second, the Agency is not adding the undesignated paragraph that defines *Program Employee* to 9 CFR 590.5.

Cost and Benefits

Costs attributable to the final rule are those associated with the development and implementation of HACCP plans and Sanitation SOPs. The impact of the costs is 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.

The benefits of the final rule include providing greater flexibility and incentives for innovation through reductions in paperwork and eliminating unnecessary requirements. In addition, plants voluntarily meeting HACCP requirements and also complying with current prescriptive regulations are expected to reduce costs, because they will

be operating solely under HACCP requirements. Plants will also benefit from a reduction in overtime and holiday pay paid to FSIS due to changes in inspection coverage.

Table 1—Summary of Estimated Benefits and Costs	
Industry Benefits	• Elimination of requirements for requests of approval for waivers, blueprints, and labels.
	• A HACCP system allows for long-term efficiency gains resulting from removing barriers to innovation found in the existing command and control system.
	• Cost savings from the reduction of overtime and holiday pay paid to FSIS inspectors for inspection.
Agency Benefits	• 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, and label approval submissions to FSIS from industry.
Industry Costs	• Cost to the plant to create HACCP plans and Sanitation SOPs.
	• Costs to the plant for additional HACCP recordkeeping and monitoring.
	• Cost to the plant for training personnel in the HACCP system.
Agency Costs	• 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.		
Summary of Estimated Quantified Benefits and Costs			
	Low	**Mid**	**High**
Benefits ($1,000)	5,893	5,893	5,893
Costs ($1,000)	2,506.3	4,826.6	7,163.7
Net Benefits ($1,000)	-1,270.6	1,066.5	3,386.8
Figures were annualized over 10 years at the 7 percent discount rate. Numbers may not sum due to rounding.			

Table of Contents

I. Background

II. Comments and Responses

A. Continuous inspection

B. HACCP, Sanitation SOPs, and other sanitation requirements

C. Control of pathogens in egg products

D. Labeling

E. Blueprints

F. Freeze-dried egg products and egg substitutes

G. Exempted plant status

H. Eggs of current production

I. Implementation timeframe and training

J. Radioactive content of irradiated egg products

K. Temperature and labeling requirements

L. Dietary supplements

M. Hard-cooked eggs

N. Cooking as a lethality step

O. Egg breaking: proposed change to 9 CFR 590.522

P. Immersion-type shell egg washers

Q. Equivalency of foreign inspection systems

R. Draft *FSIS Compliance Guideline for Small and Very Small Plants that Produce Ready-To-Eat (RTE) Egg Products*

S. Shipment of unpasteurized egg products: proposed 9 CFR 590.410(c)

T. Proposed 9 CFR 590.504(d)(2)

U. Cooked, salted, and preserved eggs

V. Health and hygiene

W. Light

X. Ventilation

Y. Egg Handling: 21 U.S.C. 1034(d) and 1034(e)(1)

Z. Non-compliance reports

AA. Water supply and water, ice, and solution reuse

BB. Hold and test (9 CFR 590.504(e))

CC. Plant testing

DD. 9 CFR part 430

EE. Costs

FF. Food ingredients used during the production of egg products

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

IV. Paperwork Reduction Act

V. Executive Order 12988, Civil Justice Reform

VI. E-Government Act Compliance

VII. Executive Order 13175

VIII. USDA Nondiscrimination Statement

IX. Congressional Review Act

X. Additional Public Notification

I. Background

Miscellaneous information

The implementation of HACCP will eliminate many of the prescriptive regulations that lead to the issuance of waivers and no objection letters. Therefore, plants implementing HACCP earlier than two years after publication of this rule in the *Federal Register* will have their new technology waivers and no objection letters in effect at that time revoked on the date they implement HACCP. All other new technology waivers and no objection letters currently in effect will be revoked two years after this final rule is published in the *Federal Register*.

Egg substitutes and freeze-dried egg products will fall under FSIS's jurisdiction three years after this final rule is published in the *Federal Register*. Plants producing egg substitutes already under FSIS inspection because they also make inspected and passed egg products should have little difficulty meeting the Agency's regulatory requirements. For plants producing egg substitutes that are not currently under FSIS inspection, the Agency will provide additional information about how to meet the regulatory requirements prior to the effective date of this portion of this final rule.

Official plants may begin operating under HACCP and Sanitation SOP regulations at earlier dates, provided FSIS has verified that they are in compliance with the regulations. More information on implementation is provided below.

FSIS is discontinuing the PEPRLab Program 60 days after this final rule is published in the *Federal Register*.

Proposed Rule

On February 13, 2018, FSIS published a proposed rule to amend the egg products inspection regulations (9 CFR part 590 and other relevant parts) to require egg products plants to develop and implement Hazard Analysis and Critical Control Point (HACCP) Systems and Sanitation Standard

Operating Procedures (Sanitation SOPs) and to comply with the Sanitation Performance Standards (SPS), in accordance with the regulations in 9 CFR parts 416 and 417 (83 FR 6314). The proposed rule also required egg products to be produced to be edible without additional preparation to achieve food safety. In addition to these requirements, the proposed rule:

- Changed the Agency's interpretation of "continuous inspection" to provide for the presence of inspectors at official plants at the same frequency that meat and poultry processing establishments are provided inspectors, i.e., at least once per shift.
- Provided for generic approval for certain egg products labels.
- Made changes to labeling requirements for shell eggs consistent with those in FDA's regulations.
- Required special handling instructions on egg products.
- Eliminated the requirements for prior approval by FSIS of egg products plant drawings, specifications, and equipment. And
- Incorporated egg products plants into the coverage of the "Rules of Practice" that the Agency follows when initiating administrative enforcement actions.

The proposed rule's comment period closed on June 13, 2018, 120 days after its publication. After reviewing comments on the proposed rule, FSIS is finalizing, with two exceptions, the provisions in the February 2018 proposed rule.

In the proposed rule, FSIS proposed to eliminate the definition for the term *Eggs of current production* (83 FR 6332). As noted in the proposed rule, "*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. The term is an indicator of quality, not food safety, and, FSIS thought, might unduly restrict the availability of edible eggs. In response to comments opposed to removing the term, however, FSIS has decided to retain it in this final rule.

Second, FSIS is not adding the proposed undesignated paragraph that defines *Program Employee* to 9 CFR 590.5 (83 FR 6333). FSIS uses the phrase "inspection program personnel" rather than "program employee" to refer to inspectors and other field personnel. Therefore, instead of adding the undesignated paragraph *Program employee* to 590.5, FSIS is adding to 9 CFR 590.5 the undesignated paragraph "*Inspection program personnel*" because it is specific to FSIS field personnel. FSIS also is amending the following

regulations to replace the words "program employee," "import inspection personnel," "program inspector," "official program personnel," or "import inspector" with "inspection program personnel":

9 CFR 590.118

9 CFR 590.120

9 CFR 590.136

9 CFR 590.310

9 CFR 590.340

9 CFR 590.435

9 CFR 590.504

9 CFR 590.915

9 CFR 590.925

9 CFR 590.940

9 CFR 590.945

Technical Corrections

This final rule makes the following technical changes to the proposed to correct inadvertent errors in the proposed regulatory text:

- In paragraph (b) of 9 CFR 417.7, the word "processing" was inadvertently omitted from the existing regulatory text. The paragraph now reads, "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 processing, including a segment on the development of a HACCP plan for a specific product and on record review."

- A commenter noted that FSIS inadvertently omitted language in the definition of "egg product" in 9 CFR 590.5. The language has been restored and is discussed elsewhere in this document.
- The final language for 9 CFR 590.40 concerning egg products not intended for human food no longer contains a provision for shipping such product under seal, as authorized in 9 CFR 590.504(c), because in the final rule, 9 CFR 590.504(c)(1) no longer requires denatured or decharacterized egg products to move under Government seal and certificate.
- FSIS is correcting two typographical errors found in 9 CFR 590.149. Paragraph (a) references § 591.1(a)(1) of this chapter. The correct citation is § 591.1(a) of this chapter. Paragraph (b) references § 591.1(a)(1) of this chapter. The correct citation is § 591.1(a) of this chapter.
- FSIS is correcting a typographical error found in 9 CFR

590.411. Paragraph (b) references 9 CFR 412.2. The correct citation is 9 CFR 412.1.

- FSIS is correcting an error found in 9 CFR 590.412. Paragraph (a) states that official plants must comply with the requirements in 9 CFR 412.2, except as otherwise provided in this part. Section 412.2 permits the approval of generic labels. Official plants do not have to have generically approved labels. Therefore, the Agency is changing the word "must" in paragraph (a) to "may" and removing the phrase "except as otherwise provided in this part."
- FSIS is making the same technical correction to 9 CFR 590.415 and 590.504(d)(2). Both regulations refer to a performance standard that is different than the one that was proposed in 9 CFR 590.570. As proposed, they stated that the relevant standard is "sufficient to reduce *Salmonella*." The performance standard that will correctly reflect what was proposed in 9 CFR 590.570 is "sufficient to produce egg products that are edible without additional preparation to achieve food safety."
- FSIS is making a second technical correction to clarify the regulations at 9 CFR 590.504(d)(2). The paragraph states that shipments of unpasteurized egg products

shipped from one official plant to another official plant for pasteurization or treatment must be sealed in cars or trucks. FSIS is amending the paragraph to clarify that the official plant is responsible for sealing the car or truck. That the plant is responsible for sealing a shipment of unpasteurized egg products is consistent with the labeling requirements for such shipments, proposed (and made final) in 9 CFR 590.410(c).

- FSIS is making a change to 9 CFR 590.424(b) so that the egg products reinspection procedures are consistent with those in the meat regulations, are consistent with the new interpretation of the requirement for continuous inspection found in this final rule, and do not unduly restrict the formation of patrol assignments in egg products plants. Unlike the current egg products regulations, which require reinspection of egg products at the time they are brought into the official plant, the meat regulations permit products to be received in an official establishment during the absence of inspection program personnel. Such products are subject to reinspection by inspection program personnel at the official establishment in such manner and at such times as may be deemed necessary to assure

compliance with the regulations in Subchapter A of Chapter III, Title 9 of the Code of Federal Regulations. Paragraph (b) of 9 CFR 590.424 will permit the reinspection of egg products brought into an egg products plant under similar circumstances.

- FSIS is correcting a typographical error found in proposed 9 CFR 590.514(c)(2). The proposed paragraph stated that "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." It should instead read, "Undenatured egg products or inedible egg products that are not decharacterized may be shipped from an official plant for industrial use or animal food, provided that they are properly packaged, labeled, and segregated, and inventory controls are maintained." This will allow official plants to ship inedible egg products that look like wholesome egg products to entities desirous of such products, while at the same time ensuring that they are not diverted for human food use.
- In the preamble to the proposed rule, FSIS discussed in detail eliminating the regulations at 9 CFR 590.515,

regarding egg cleaning operations, as they are inconsistent with the proposed requirements for Sanitation Standard Operating Procedures (Sanitation SOPs). However, the Agency inadvertently failed to include an instruction in the regulatory text to do so. Nonetheless, FSIS received considerable support for its proposal to require official plants to develop and implement Sanitation SOPs and eliminate current regulatory provisions that are inconsistent with them. The Agency is therefore removing 9 CFR 590.515 from the egg products inspection regulations.

- FSIS is making a technical correction in the final version of paragraphs (b)(1) and (b)(2) of 9 CFR 590.504 so that they read the same as the current regulations. The proposed rule incorrectly removed the word "Eggs" from these regulations. In this final rule, the Agency is including the words "Eggs and" at the beginning of paragraph (b)(1) to read as follows: "Eggs and egg products are subject to inspection in each official plant processing egg products for commerce." It is also adding "eggs and" to paragraph (b)(2) so that it reads: "Any eggs and egg products not processed in accordance with the regulations in this part of part 591 or that are not otherwise fit for

human food will be removed and segregated."

- FSIS is making a technical correction to 9 CFR 590.570. Section 590.570, *Control of pathogens in egg products*, applies only to pasteurized egg products, not unpasteurized products. To clarify this, FSIS is changing the title and regulatory text of 9 CFR 590.570 by adding the word "pasteurized" to it to make clear that that regulation requires pasteurized product, not unpasteurized product, to be produced to be edible without additional preparation to achieve food safety. Unpasteurized egg products may continue to be sent to other official plants for further processing to achieve food safety; they may not, however, enter commerce (9 CFR 590.415). The title of 9 CFR 590.570 will read *Control of pathogens in pasteurized egg products*. FSIS is also adding the word "pasteurized" to the first and second sentences of 9 CFR 590.570 for the same reason.
- FSIS is making a technical correction to 9 CFR 590.590. The proposed regulation referred to a performance standard that is different than the one that was proposed in 9 CFR 590.570. As proposed, it stated that the relevant standard is "heat or another lethality treatment to produce a ready-to-eat product." The language that will correctly reflect what was proposed

in 9 CFR 590.570 is "Irradiated shell eggs used to produce pasteurized egg products must be used in conjunction with heat or another lethality treatment sufficient to produce egg products that are edible without additional preparation to achieve food safety."

- FSIS is making a technical correction to 9 CFR 590.910. On November 27, 2019, FSIS published a final rule amending its regulations to remove lists of foreign countries eligible to export meat, poultry, or egg products to the United States, and, instead, maintain such lists on its website (84 FR 65265). That final rule amended 9 CFR 590.910 and its title. FSIS is amending 9 CFR 590.510 and its title in this final rule to match the language newly amended by the *Publication Method for Lists of Foreign Countries Eligible To Export Meat, Poultry, or Egg Products to the United States* final rule (84 FR 65269). FSIS also made two technical corrections in the regulatory text. First, the Agency removed the word "continuous" before the phrase "Government inspection" in the first sentence of paragraph (a) to be consistent with the language used in this final rule. Second, FSIS removed the second to last sentence of paragraph (a) allowing the survey of the foreign inspection system to occur more expediently

by payment by the interested Government agency in the foreign country of the travel expenses incurred in making the survey.

- FSIS is making technical corrections to the titles of 9 CFR 590.925, 590.930, and 590.945. Each title refers to "eggs." The regulatory text, however, refers only to egg products. Removing the word "eggs" from these titles will eliminate any confusion that may exist regarding what product is being regulated.

Guidance for Small and Very Small Plants

FSIS is also announcing the availability of guidance to help small and very small plants producing egg products meet the pasteurization requirements proposed in this rulemaking. When FSIS published the proposed rule, FSIS posted a draft of the *FSIS Compliance Guideline for Small and Very Small Plants that Produce Ready-to-Eat (RTE) Egg Products* on its website and requested comments on it. FSIS has revised the draft guidance based on comments on the proposed rule, updated it regarding hazards related to *Listeria monocytogenes* (*Lm*) and residues, and improved readability.

Additionally, FSIS previously did not incorporate the pasteurization time and temperature requirements from 9 CFR 590.570 for liquid egg whites in the draft guidance. It had been intentionally excluded because the current scientific

literature indicates that the time and temperature for liquid egg whites in 9 CFR 590.570 does not achieve a 5-$\log_{10}$ reduction of *Salmonella*. FSIS reviewed the available data to determine the appropriateness of a 5-$\log_{10}$ reduction of *Salmonella* in egg whites as a safe harbor. As such, FSIS is incorporating a separate section with specific conditions under which the pasteurization time and temperature from 9 CFR 590.570 for liquid egg whites may be used as a safe harbor. Comments on the draft guidance are discussed in more detail below. FSIS has posted the final guidance, *FSIS Food Safety Guideline for Egg Products*, on its web page at *(http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index)*.

FSIS also is posting an *Egg Products Hazards and Controls Guide* on its web page at https://www.fsis.usda.gov/wps/wcm/connect/089c71f4-b634-44c8-a69c-389e289f50b2/egg-hazards-controls-guide.pdf?MOD=AJPERES. This guide will help egg products plants design and control safer food production systems, particularly small and very small plants that may need additional assistance as they develop their hazard analyses, support their hazard analyses decisions, and amend existing HACCP systems after reassessment. The guide identifies the process steps relevant to each process category, lists some

potential hazards in the process steps, and cites some of the controls frequently used by processors to address these hazards.

II. Comments and Responses

FSIS received 87 comments from consumers, individuals, a trade association representing the egg products industry, the egg products industry, a consumer group, a trade association representing egg farmers and egg further processing facilities, inspection program personnel (IPP), students and a college professor, an independent consultant, an engineer, an individual working in a field allied with the egg products industry, one foreign government, an FDA-regulated facility, and one U.S. government agency. Most commenters supported the proposed rule overall, with many stating that they thought that the proposed regulations would ensure food safety and protect public health. There was, however, disagreement among commenters about FSIS's suggested change to the Agency's interpretation of the requirement for continuous inspection and questions about the cost of the proposal.

FSIS also received some comments from consumers indicating confusion about the scope of the proposed rule. For example, one commenter asked whether the same standards that were proposed for egg products plants would be in place

for shell egg producers. The proposed rule did not include requirements for shell egg producers. FSIS regulates official egg products plants and their processing operations and does not generally regulate shell eggs outside of egg products plants, except when checking to ensure that shell eggs packed into containers destined for the ultimate consumer meet the packaging and labeling requirements of the EPIA and 9 CFR 590.50. Therefore, the comments received in response to this proposed rule dealing with shell egg producers and shell eggs located outside of official plants are outside the scope of this rulemaking. A second commenter expressed concern about animal welfare issues, while others requested aid, tax incentives, or rebates to offset the burden of changes required by this rulemaking. These comments were also all outside the scope of this rulemaking.

In addition, the Agency received comments about surplus broiler eggs/out-of-specification hatching eggs being thrown away and not used to produce egg products for consumption because they cannot meet the FDA's requirement that eggs sent for breaking be refrigerated at 45°F within 36 hours of lay (21 CFR 118.4(e)). These comments are outside the scope of this rulemaking

Below is a summary of comments received and FSIS's responses.

A. Continuous Inspection

Comments: FSIS received three comments from a trade association representing the egg products industry and from the egg products industry, generally in favor of FSIS's proposal to reinterpret "continuous inspection" to require the presence of inspectors in egg products plants at least once per shift, instead of during all processing operations. FSIS received 16 comments from individuals, students, a trade association representing egg farmers and egg further processing facilities, an individual working in a field allied with the egg products industry, and IPP opposing the change. FSIS received one comment asking for more details.

Comment: The college professor suggested that the decrease in the amount of onsite inspection would increase the burden on manufacturers to adhere to new standardized food safety and sanitation protocols.

Response: FSIS disagrees. Manufacturers must meet certain requirements under this final rule. The amount of onsite inspection provided does not change those requirements, and IPP do not help manufacturers meet these requirements by completing tasks for them. The burden remains the same, regardless of the amount of onsite inspection provided.

Comment: The comment from the consumer group stated that "continuous inspection" is defined in the EPIA. As such, according to this commenter, the proposed change would need to be done legislatively and not simply through a rulemaking as proposed by the Agency.

Response: FSIS disagrees. The EPIA does not contain a definition of "continuous inspection." Under 21 U.S.C. 1043, the Secretary of Agriculture has the authority to promulgate rules and regulations deemed necessary to carry out the provisions or purposes of the Act. Under this authority,[1] FSIS proposed a rule that would change its interpretation of "continuous inspection" because such change is necessary to effectively and efficiently administer the egg products inspection program.

As FSIS explained in the proposed rule, egg products operations are more like meat and poultry processing operations, and especially those that produce ready-to-eat (RTE) products, than they are meat and poultry slaughter operations, where inspection is required for each meat or poultry carcass. Like RTE meat and poultry processing operations, the typical egg products processing operation is a streamlined, automated process, with a lethality step to

[1] The Secretary of Agriculture's authority to exercise the functions contained in the EPIA is delegated to the Under Secretary of Food Safety and can be found in 7 CFR 2.18(a)(1)(ii)(C).

destroy pathogens of concern in the finished product (83 FR 6333). As a result, changing the Agency's interpretation of continuous inspection will allow FSIS to better use its inspection resources to conduct more efficient and effective inspections.

Comment: The trade association representing the egg products industry said that FSIS should move cautiously in forming a different approach to continuous inspection. This commenter pointed out that there are highly controlled processing steps, often requiring minimal human interaction, that may pose less risk than other processing steps, like breaking, blending, or pasteurizing, which are more like slaughter processes than not. For less risky processes, the commenter suggested that an inspector's unannounced presence for something less than the entire processing shift may be satisfactory.

Several commenters opposed to the proposed change in continuous inspection, including IPP and the engineer, argued that breaking eggs is more like meat and poultry slaughter than processing. Because inspection is required in slaughter plants for all slaughter operations, they stated that inspection should also be required during breaking operations.

Response: FSIS disagrees that breaking eggs is more like meat and poultry slaughter than processing. As discussed above, the Agency believes that egg products operations are more like meat and poultry processing operations than they are meat and poultry slaughter operations, because the typical egg products processing operation is a streamlined, automated process, with a lethality step to destroy pathogens of concern in the finished product. Further, the shift to processing inspection frequencies will give FSIS the flexibility to focus inspection coverage and tasks in consideration of public health risk, consistent with what the trade association comment recommended. FSIS's shift to processing inspection frequencies will take place in individual plants as they implement HACCP.

Comment: Three comments from the trade association representing the egg products industry and the two official plants supported the proposed change to the interpretation of continuous inspection, provided that the number of available inspectors is adequate to prevent interruptions in processing, in the movement of export shipments, or in the performance of certifications of customer specifications or requirements on a fee basis under the Agricultural Marketing Act. Similarly, one comment from an inspector stated that

monitoring the requirements for the Agricultural Marketing Service's Commodity Procurement Program would be difficult under patrol assignments, as would collecting samples and applying seals. In addition, this commenter said that patrol assignments would prevent the performance of final inspections. The trade association representing the egg products industry, an egg products plant, and the FDA-regulated facility asked about possible changes to inspection under the proposal.

Response: The Agency is required by the EPIA to adequately assign inspection resources to ensure that the requirements of the EPIA are being met. IPP in meat and poultry processing establishments are able to monitor the requirements for the Commodity Procurement Program, perform export certification, and provide fee-based inspection services, while on patrol assignments. They will be able to do so in egg products plants, as well.

When the proposed rule is finalized, egg products plants will continue to operate under inspection regulations during all hours of operation, but will most likely have an inspector present only once during each production shift. While at each plant, FSIS inspectors will monitor the plant's sanitary operating practices and the execution of its HACCP plan, such as the critical control point (CCP)

related to the heat treatment of egg products, conduct the Agency's food safety related Public Health Information System (PHIS) tasks, and perform other consumer protection tasks, such as conducting product labeling reviews. Under the final rule, however, plants will still be required to have approved operating schedules per 9 CFR 590.124.

Comment: One comment from the trade association representing the egg products industry stated that changing the Agency's interpretation of continuous inspection could result in inspection being inconsistently applied, that is, it would be provided as a matter of management efficiency rather than based on need. Under the new interpretation of continuous inspection, this commenter stated that inspection could significantly differ among two or more similar plants based on the location of each.

Response: As noted above, the EPIA requires the Secretary of Agriculture to adequately assign inspection resources, as he deems necessary, to ensure that the requirements of the Act are being met. Accordingly, the Agency will provide each plant the amount of inspection coverage that is appropriate for that plant and will provide an inspector at least once each operating shift. Additionally, FSIS inspectors in egg products plants will receive the same routine inspection tasks in PHIS, so

inspection activities that inspectors conduct will be consistent across all egg products plants. Moreover, FSIS has many years of experience with using patrol assignments to efficiently and effectively inspect the preparation of food products. Therefore, FSIS is confident that the use of patrol assignments, as necessary, will result in appropriate inspection assignments at all egg products plants.

Comment: The trade association representing the egg products industry, while commending the Agency's desire to reduce inspection costs to taxpayers and industry, questioned how much FSIS will save for government or industry. This commenter said that biosecurity concerns will impact the availability of IPP among plants and that egg products plants already have issues with the limited availability of IPP at certain times, usually during overtime periods. The commenter indicated that most overtime now required by the egg products industry is during times when nearby meat and poultry further processors, when they exist, are inactive or otherwise not required to have inspection.

Response: Through this final rule, the Agency will reduce the use of inspectors outside their normal work schedules and during overtime hours and holidays in plants by using patrol assignments. The use of patrol assignments

likely will reduce the costs for overtime and holiday hours because plants will not be required to operate under the previous interpretation of continuous inspection during overtime and holiday hours. As a result, industry should realize cost savings of approximately $4.8 million annualized at the 7 percent discount rate over ten years.

Comment: A comment from the trade association representing the egg products industry in favor of the proposed change pointed out that most firms already have very restrictive biosecurity systems in place and indicated that there are many restrictions on the movement of personnel within a single production or processing site for food safety and animal health reasons. While acknowledging that FSIS IPP already comply with industry biosecurity protocols, this commenter stated that IPP need to continue to honor all reasonable biosecurity requirements at inspected plants, including minimum times between entry to a plant and entry to another plant or farm. Another comment from an egg products plant said that FSIS needs to think about biosecurity when considering an inspector’s ability to visit more than one facility a day, as such restrictions may limit IPP travel among inspected plants, such as inline operations that house live chickens and off-line operations.

A comment from an inspector said that if continuous inspection is replaced with patrol assignments, only one facility in the assignment could have live birds, as other facilities having live birds would create biosecurity concerns. This commenter also stated that finding available replacements for IPP in cases of emergency would be difficult for FSIS, as a potential replacement could not have been in a facility with live birds within the time limit provided by the biosecurity policies of the other plants in the assignment. Another inspector said that by jeopardizing biosecurity measures, patrol assignments could result in other countries banning the export of egg products if there is an outbreak associated with eggs.

Response: Changing the interpretation of continuous inspection under the EPIA will allow for more flexibility to inspect egg products plants using patrol assignments, but FSIS will continue to assign inspectors to ensure both that the requirements of the EPIA are met and the biosecurity of plants is not compromised. IPP have successfully complied with the biosecurity measures put in place by official meat and poultry establishments and egg products plants since 2015, when FSIS issued FSIS Notice 17-15, *FSIS Program Personnel Hygiene and Biosecurity Practices*. Since that time, FSIS is unaware of any disease transmission caused by

the movement of IPP or issues regarding inspection coverage resulting from the implementation of industry biosecurity measures. When this final rule is issued, IPP will continue to follow biosecurity measures put in place by official establishments and plants in accordance with FSIS Directive 5060.1, *Hygiene and Biosecurity Practices*.

Comment: Two comments from IPP opposed to the proposed change in continuous inspection stated that the proposal would not protect public health or would be detrimental to the public. Two other inspectors said that continuous inspection is an integral part of the food safety aspect of egg products. Others said that without continuous inspection, plants will not follow HACCP and Sanitation SOP protocols, and as a result, will produce adulterated product. These commenters argued that plants will take short cuts because IPP will not be there to verify or monitor production, and they will break ineligible eggs. One inspector said that because plants will know when IPP arrive under a patrol assignment, there is no deterrent for them to not break ineligible eggs.

A comment by an inspector stated that without continuous inspection, IPP will not know what occurred before and after they are onsite. Another inspector said that with only one site visit a day in an egg products

drying plant operating 24 hours a day, seven days a week, equipment that is cleaned in place could potentially rarely be inspected. This commenter also said that IPP would not have the opportunity to observe or conduct many required tasks if the proposed change to continuous inspection is implemented.

Response: FSIS's paramount obligation is to protect the public health. This final rule does that by building the principle of prevention into production processes through HACCP and Sanitation SOP requirements. This final rule also protects public health by better delineating and clarifying the respective roles of industry and FSIS to ensure that egg products are produced in accordance with sanitation and safety standards and are not adulterated or misbranded within the meaning of the EPIA. FSIS and establishment data show that HACCP and the related sanitation requirements have been an effective system for reducing or eliminating food safety hazards in meat and poultry processing establishments, inspected under patrol assignments. IPP have had no difficulties verifying regulatory compliance. The application of HACCP to egg products processing should be no different and these changes should significantly enhance the effectiveness of the egg products inspection program. Under HACCP, FSIS will verify that plants have

conducted the hazard analysis to identify all hazards reasonably likely to occur and then will verify that plants follow their HACCP plans.[2] If plants do not follow their HACCP plans, FSIS will take regulatory enforcement actions in accordance with 9 CFR part 500.

Plants will not know when IPP are to arrive under a patrol assignment. Under patrol assignment inspection, FSIS will observe the breaking of shell eggs and will review plant records concerning incoming eggs to verify that plants are not breaking dirty eggs. Finally, FSIS will test product for pathogens and residues to verify that it is not adulterated.

HACCP is a flexible system tailored as a structured food safety program designed for a plant's specific processes and products. Once implemented, egg products plants will be required to develop and implement a HACCP system for food safety that is designed to prevent, eliminate, or reduce to an acceptable level the occurrence of biological, chemical, and physical hazards that are reasonably likely to occur in the plant's process. Plants will be responsible for developing and implementing HACCP plans that incorporate the controls that are necessary to

[2] Continuous inspection in egg products plants requires an inspector to be on the premises at least once per shift, not once per day. If a plant has multiple shifts, such inspector presence will be required for each shift.

produce safe egg products. Plants will also have to develop and maintain effective recordkeeping procedures that document the entire HACCP system and perform on-going verification procedures to ensure that the plant's HACCP system follows the regulatory requirements.

At the same time, proper sanitation is an important and integral part of every food process and a fundamental requirement under the law. Once the sanitation requirements under 9 CFR part 416 are implemented, all plants that process egg products will have to develop, implement, and maintain written Sanitation SOPs to prevent direct contamination or adulteration of product before and during operations (9 CFR 416.11). Plants will also be required to maintain daily records to document adherence to the SOPs (9 CFR 416.16).

The implementation of 9 CFR parts 416 and 417 for egg products plants modernizes inspection procedures consistent with inspection procedures in meat and poultry processing establishments, using the Agency's resources more efficiently and removing unnecessary regulatory obstacles to innovation by plants. This will ensure the same level of inspection oversight to achieve FSIS's public health mission and will not diminish the inspector's ability to conduct

verification procedures to ensure regulatory compliance by the egg products plants.

Comment: A comment from the college professor suggested that FSIS provide for video streaming feeds of several facilities simultaneously to one inspector to remotely monitor safety and sanitation operations, with another in-plant inspector supplementing the video stream with one in-person visit per shift. The commenter said that this would allow for more efficient use of manpower and be consistent with reducing the number of hours inspectors would be present in egg products plans.

Response: FSIS does not believe that it is necessary to constantly inspect operations via video to effectively inspect egg products plants. As mentioned above, FSIS has experience using patrol assignments to conduct food safety inspection. FSIS believes that by conducting patrol assignments, reviewing records, and sampling products, it obtains a complete view of establishment operations.

B. HACCP, Sanitation SOPs, and other sanitation requirements

Comment: Some commenters questioned whether the current regulations for egg products plants are equal to the requirements that the meat and poultry industry must meet and suggested the proposed requirements would "make egg products safer." Other commenters stated that egg products

would (and should) be regulated more strictly than meat and poultry products.

Response: The current and proposed egg products regulations are both effective, i.e., they prevent the adulteration and misbranding of egg products, and egg products produced under them are RTE and safe for consumption. However, the current regulations are overly prescriptive and not flexible. They do not, for example, allow official plants to tailor their control systems to the needs of their particular plants and processes. They do not allow official plants to innovate regarding facility design, construction, and operations, and they unnecessarily define the specific means needed to achieve sanitation requirements. The HACCP, Sanitation SOPs, and other sanitation requirements being finalized in this rulemaking are consistent with, and not stricter than, the meat and poultry regulations. They will ensure food safety protection while offering egg products plants flexibility in their operations and the ability to innovate.

Comment: FSIS received many comments in favor of requiring official plants to develop and implement HACCP Systems and Sanitation SOPs and to meet other sanitation requirements consistent with the meat and poultry regulations. Commenters, including individuals, academic

students, the trade association representing the egg products industry, and the trade association representing egg farmers and egg further processing facilities contended that these requirements would provide a more standardized approach for food safety across all products inspected by FSIS, serve to ensure uniformity among all egg products plants, and make the egg products inspection regulations more effective by eliminating numerous prescriptive command-and-control regulations. One comment from the individual working in a field allied with the egg products industry stated that a benefit of HACCP is its recordkeeping requirements, as records reviews by plant personnel and IPP would ensure the safety of product and that the system is functioning as required. The trade association representing egg farmers and egg further processing facilities supported the application of corrective actions to prevent the recurrence of detectable pathogens. Another comment from an individual supported the proposed HACCP and sanitation requirements because, according to the commenter, egg products present similar food safety risks as meat and poultry. The individual working in a field allied with the egg products industry stated that sanitation regulations for egg products should be consistent with those for meat and poultry, because dirt attached to eggs or equipment can

affect product integrity. Comments from the trade association representing the egg products industry and the egg products industry supported the proposed requirements for HACCP and Sanitation SOPs because, according to these commenters, many egg products plants have already voluntarily instituted these programs due to customers' requirements. These same commenters believed that the implementation of these programs will eliminate industry and IPP confusion due to the inconsistency of HACCP requirements in meat and poultry establishments and prescriptive command-and-control requirements in egg products plants.

Several commenters specifically expressed support for the proposed sanitation requirements. An individual stated that measures taken to improve the food supply are worthwhile, even if it means higher egg products prices for consumers. Other individuals felt that the provisions of the proposed rule could prevent future unsanitary conditions that may give way to spoiled or contaminated eggs.

One comment from a student stated that while shifting liability and responsibility for oversight onto manufacturers via HACCP and Sanitation SOPs would increase efficiency, such efficiency could not be measured until the proposal had been implemented. This commenter thought that FSIS should phase in the requirements of the proposed rule

for two to three years to measure the effectiveness of the new rule and make further changes to the regulations, if necessary.

Response: FSIS agrees with these comments supporting the proposed HACCP, Sanitation SOP, and other sanitation requirements. FSIS believes that the efficiency of HACCP and Sanitation SOPs, in general, has been shown. The meat and poultry industries have operated under these programs since the late 1990s; their efficiency in eliminating food safety hazards since that time has been clearly demonstrated. For example, by 2000-2001, cleaning and sanitation tasks and tasks required to implement HACCP had accounted for approximately a one-third reduction in the number of meat and poultry samples testing positive for *Salmonella* spp.[3] In addition, shortly after HACCP was introduced, *Salmonella* meat contamination levels were generally reduced, a finding consistent with improvement through HACCP implementation.[4] FSIS believes that the HACCP, Sanitation SOPs, and sanitation performance standards will similarly be effective in egg products plants. In any

[3] Economic Research Service, "The Interplay of Regulation and Marketing Incentives in Providing Food Safety," July 2009.
[4] Rose BE, Hill WE, Umholtz R, Ramnsom GM, James WO. 2002. "Testing for *Salmonella* in raw meat and poultry products collected at federally inspected establishments in the United States, 1998 through 2000." *J Food Prot* 65:937-947.

event, FSIS retains the authority to further amend its regulations as needed in the future.

Comment: A comment from an individual said that there needs to be a set, thorough way to fully examine and determine the cleanliness of equipment. This commenter also stated that cleaning and sanitizing solutions used on equipment in egg products plants should be identified and their use indicated on egg products labels.

Response: When the proposed rule becomes final, IPP will verify plants' compliance with the sanitation requirements in 9 CFR 416.3(a), which requires that equipment and utensils be maintained in sanitary conditions so as not to adulterate product. Cleaning and sanitizing solutions are not intended to be added to food and are not food ingredients. They do not need to be identified and their use indicated on egg products labels because they do not remain as a constituent of the finished egg product.

Comment: The engineer stated that FSIS needs to include a requirement for equipment standards, such as the E-3-A standards, or the 3-A standards used by the Agricultural Marketing Service in the dairy industry. This commenter stated that individual pieces of equipment can be quite complex and that the incorrect design, materials, manufacturing specifications, operation, and maintenance of

systems to process liquid and dried eggs can and will lead to product contamination.

Response: FSIS disagrees that the egg products inspection regulations need to include a requirement for equipment standards. When finalized, 9 CFR 416.3 will apply to egg products plants and clarify the requirements that plants select and maintain equipment to effectively prevent product contamination or adulteration. Plants will still need to ensure that product is not contaminated, adulterated, or misbranded during processing, handling, or storage. FSIS will verify that plant equipment and systems meet the sanitation performance standards through regular inspection tasks.

Comment: A consumer group questioned whether FSIS can determine if HACCP plans adopted by egg products plants are valid within the effective dates of the regulations.

Response: As with HACCP for meat and poultry processing, under this final rule, 9 CFR 417.4(a) requires plants to validate that their HACCP system works as intended within their plant. To validate their HACCP systems, plants need scientific support to show that their system can eliminate hazards and also need in-plant data showing that their system works as intended within the plant. FSIS will be able to verify compliance with these requirements. FSIS

has ample experience in reviewing and evaluating HACCP plans and their implementation in food processing environments. Given this, and FSIS's experience regulating the egg products industry specifically, FSIS anticipates no difficulties regulating the development and implementation of HACCP plans for egg products processing.

Section 9 CFR 590.149(b) will be effective two years after the publication date of this final rule. All existing plants will have 90 days starting on that effective date during which they must validate their HACCP plans. New plants will have 90 days from the date they receive their grant of inspection to validate their HACCP plans and plants producing new products will have 90 days from the date they start producing them during which to validate their HACCP plans. FSIS will verify whether plants have validated their HACCP systems after the effective date of the HACCP regulations and after any new plants have had time to validate their HACCP systems.

C. Control of pathogens in egg products

Comment: Three consumers supported the requirement that official plants be required to process egg products to be edible without additional preparation to achieve food safety. A comment from an inspector stated, however, that the new regulations would require unpasteurized egg products

to be tested and found negative before they could be shipped from the producing plant, without needing further cooking/pasteurization. As a result, the inspector stated that the egg product would no longer meet the definition of *Pasteurized* in 9 CFR 590.5.

Response: When finalized, the proposed rule will not allow unpasteurized egg products to enter commerce. This is consistent with the current regulations, which permit such product to move only to another official plant for further processing (9 CFR 590.415(a)). Proposed Section 590.570, *Control of pathogens in egg products*, applies only to pasteurized egg products, not unpasteurized products. To clarify any misunderstanding, FSIS changed the title and regulatory text of 9 CFR 590.570 by adding the word "pasteurized" to it to make clear that that regulation is requiring pasteurized product, not unpasteurized product, to be produced as edible without additional preparation to achieve food safety.[5] Unpasteurized egg products may continue to be sent to other official plants for further processing to achieve food safety; they may not, however, enter commerce (9 CFR 590.415).[6] The title of 9 CFR 590.570

[5] To verify whether egg products are edible without additional preparation to achieve food safety, FSIS samples and tests pasteurized egg products for *Salmonella* spp. and *Lm*.
[6] Unpasteurized egg products may also be exported from the U.S. to Canada for further processing to achieve food safety. See https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/requirements-for-processed-egg-products/canada-egg-products.

will read *Control of pathogens in pasteurized egg products*. FSIS is also adding the word "pasteurized" to the first and second sentences of 9 CFR 590.570 for the same reason.

Comment: One comment from an industry member stated that requiring egg products to be edible without additional preparation to achieve food safety would place a significant cost impact on plants that process unpasteurized egg products. In a similar vein, a comment from the engineer asked if egg breaking plants that do not have a kill step to eliminate pathogens and ship raw liquid egg products for further processing would be exempt from the regulations.

Response: Plants that process unpasteurized egg products do not have to treat egg products to be edible without additional preparation to achieve food safety. As noted above, unpasteurized egg products may continue to be sent to other official plants for further processing to achieve food safety; they may not, however, enter commerce (9 CFR 590.415). Therefore, there is no associated cost impact on plants that process unpasteurized egg products. Egg products in commerce currently cannot have any detectable pathogens. Therefore, requiring egg products to be edible without additional preparation to achieve food safety does not create any additional costs for producers of pasteurized egg products either. Plants that process

unpasteurized egg products, i.e., products that do not receive a kill step to eliminate pathogens, and ship raw liquid egg products for further processing are not generally exempt from the regulations, but they do not have to meet the requirements of 9 CFR 590.570, which applies only to pasteurized egg products.

D. Labeling

Comment: A comment from the trade association representing egg farmers and egg further processing facilities supported the Agency's proposal to make egg products labeling, including providing for generic labeling, more like labeling requirements for meat and poultry. An inspector noted that FDA-regulated egg substitutes may use food colorings not presently considered suitable by FSIS. This commenter stated that the generic labeling provisions would lead to unapproved ingredients being used in egg substitute products once they are under FSIS jurisdiction. An industry member sought assurances that existing label claims and product names on egg substitutes will continue to be allowed once the products are under FSIS jurisdiction.

Response: FSIS will actively review coloring and ingredient approvals for egg substitutes while those products transition from FDA's jurisdiction to FSIS's. FSIS

has a Memorandum of Understanding[7] with FDA that establishes the working relationship to be followed by FSIS and FDA when responding to requests (i.e., petitions or notifications) for the use of food additives, including sources of radiation and food contact substances, generally recognized as safe substances, prior-sanctioned substances, and color additives subject to FDA regulation and intended for use in the production of FSIS-regulated meat, poultry, and egg products. Under this agreement, FDA determines whether substances are safe for use in human food, and FSIS determines whether they are suitable for use in meat, poultry, or egg products. After the effective date of this final rule, the Agency will continue to work with FDA on assessing any food colorings or food ingredients used in egg substitutes.

FSIS is likely to approve label claims, product names on egg substitutes and similar products, and food colorings that have met FDA requirements. FSIS will conduct timely and transparent reviews of specific claims, products names, and food colorings, and will provide guidance on labeling claims and names for egg substitute and similar products.

[7] 225-00-2000 Amendment 1: Memorandum of Understanding Between the United States Department of Agriculture Food Safety Inspection Service and the United States Department of Health and Human Services Food and Drug Administration, (*http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm441552.htm*), 2000.

Comment: Another comment from the FDA-regulated facility asked if all liquid/frozen whole egg products must have 24.2 percent solids per 9 CFR 590.411(d) and if so, whether this requirement would eliminate from the marketplace the liquid/frozen product being sold now as whole egg but at 17 percent solids (products currently using gums and starches).

Response: As described, this egg product is prepared in other than natural proportions. Therefore, it would not comply with the requirement in 9 CFR 590.411(d) that liquid or frozen egg products identified as whole eggs and prepared in other than natural proportions, as broken from the shell, have a total egg solids content of 24.20 percent or greater. This rulemaking did not make substantive changes to 9 CFR 590.411(d). Under that regulation, as amended, "Liquid and 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." Such egg products may have a total egg solids content of less than 24.20 percent, but they may not be identified as "whole eggs." Such labeling would cause the products to be misbranded. They may, for example, be labeled as "Liquid Egg Product" with "Ingredients: egg whites, egg yolks."

E. Blueprints

Comments: The individual working in a field allied with the egg products industry said that the submission of drawings to USDA for prior approval before making structural changes should be kept and that plants should know what they can and cannot do prior to making changes.

Response: FSIS believes that the development and implementation of effective Sanitation SOPs and HACCP systems and compliance with the other sanitation requirements will meet the same objectives as prior approval of plant drawings and equipment specifications by FSIS. The prior approval process is inconsistent with FSIS's view of the appropriate division of responsibility between the Agency and official plants for the production of safe, unadulterated egg products. Plants develop and implement validated HACCP systems to produce safe egg products; FSIS verifies the efficacy of these processes through inspection activities, including product sampling and testing. Further, as discussed in the proposed rule, the prior approval requirement is an obstacle and too often a deterrent to innovation by official plants seeking to improve operations, and it contributes to the inefficient use of FSIS resources both in managing the approval system

and verifying official plants' compliance with approved facility and equipment specifications.

In addition, FSIS prior approvals are of limited value in ensuring good sanitation. They are limited in both (1) scope, in that they deal only with official plant facilities as presented in drawings and equipment presented as new, and (2) time, in that they are given once, on the condition that official plants will maintain a sanitary operating environment after their facilities and equipment are approved. The Sanitation SOP regulations and sanitation standards require plants to account for structural changes and maintenance over time.

The sanitation regulations set forth general principles for plant construction to ensure the maintenance of sanitary conditions and to prevent product adulteration. Paragraph (b) of 9 CFR 416.2 specifically addresses construction requirements in official establishments. Paragraph (b)(1) requires that establishment buildings meet certain sanitation requirements, while paragraphs (b)(2) and (3) provide requirements for interior construction and materials. Paragraph (b)(4) contains requirements for rooms and compartments in which edible product is processed, handled, or stored. The elimination of prior approval for drawings and equipment specifications will provide official

plants the flexibility to determine the specific steps to be taken to comply with these requirements.

Comment: The individual working in a field allied with the egg products industry thought that many egg products inspection regulations needed to be updated or removed due to gray areas, irrelevancy, or because inspection determinations are left to the discretion of each inspector. This commenter stated that consistency is not possible under the proposed regulations and that having more regulations that are firmly written with absolute requirements or circumstances would be extremely beneficial to plants.

Response: FSIS disagrees that such prescriptive regulations are needed in egg products plants. HACCP has been proven to be the best framework for building science-based process control into food production systems to prevent food safety hazards.[8,9] Furthermore, HACCP is a flexible system that will provide an establishment the ability to tailor its control systems to the needs of its particular processes.

The Agency is also removing some prescriptive sanitation requirements because they impede innovation and

[8] Neal D. Fortin, Food Regulation: Law, Science, Policy, and Practice, (Hoboken, NJ: John Wiley and Sons, 2017) 181

[9] Rose BE, Hill WE, Umholtz R, Ramnsom GM, James WO. 2002. "Testing for *Salmonella* in raw meat and poultry products collected at federally inspected establishments in the United States, 1998 through 2000." *J Food Prot* 65:937-947.

blur the distinction between plant and inspector responsibilities for maintaining sanitary conditions. The intent of the final regulation is to provide establishments with more flexibility to innovate regarding facility design, construction, and operations. Inspection program personnel are trained to evaluate an establishment's control system to ensure that the system as designed and implemented meets regulatory requirements.

F. Freeze-dried egg products and egg substitutes

Comment: The trade association representing the egg products industry and a member of industry were in favor of FSIS no longer exempting freeze-dried egg products from inspection, while these two commenters and a third member of industry were in favor of FSIS no longer exempting egg substitutes from inspection. One industry member asked that FSIS work with industry to implement inspection of egg substitutes in a manner to minimalize the costs to industry and to limit the potential disruption of supply to customers as these products are transitioned from FDA to FSIS jurisdiction.

Response: Producers of freeze-dried egg products and egg substitutes do not have to meet the requirements of this final rule until three years from the date of publication. Similarly, FSIS will not inspect production of these

products until that date. FSIS will be transparent concerning how it plans to inspect egg substitutes and freeze-dried egg products and will publish additional information concerning the transition as necessary.

Comment: The trade association representing the egg products industry noted that in the proposed rule FSIS removed egg products from the definition of an egg source for exempted products in 9 CFR 590.5 and stated that the change would lead to confusion on the part of food manufacturers and others.

Response: A portion of existing regulatory text was inadvertently omitted from the proposed term *Egg product* in 9 CFR 590.5. FSIS has reinserted that language so the definition now reads, "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 eggs or egg products, provided such products are prepared from inspected egg products or eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs."

G. Exempted plant status

Comment: The trade association representing the egg products industry and an industry member supported FSIS's decision to eliminate the exemption from continuous inspection available for any plant that meets the standards required for official plants in 9 CFR 590.500 through 590.580 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 found in 9 CFR 590.100(b). These same commenters also supported FSIS's decision to eliminate the corresponding regulations in 9 CFR 590.600-680 containing the requirements plants have to meet if they wish to be exempt from continuous inspection. Both commenters acknowledged that section 1044(a)(2) of the EPIA gives the Secretary of Agriculture discretion to exempt qualifying plants from specific provisions of the Act; however, both commenters stated that these regulatory provisions are inconsistent with the stated intent of the EPIA to protect the health and welfare of consumers.

Response: FSIS agrees with these comments. The exemption from continuous inspection found in 9 CFR 590.100(b) and the corresponding regulations in 9 CFR 590.600-680 would permit periodic inspection in egg products

plants. FSIS believes that such plants should be inspected at least once per shift. Therefore, the Agency is moving forward as proposed in the rule to eliminate the exemption from continuous inspection found in 9 CFR 59.100(b) for certain egg products plants and the exempted egg products plant regulations in 9 CFR 590.600-680.

H. Eggs of current production

A comment from a trade association representing the egg products industry agreed with FSIS that eggs over 60 days of age have lessened quality and will not meet most customers' expectations for functional properties. This commenter recommended that FSIS leave the "eggs of current production" definition in the regulations because, according to the commenter, the lessened value of product produced from eggs *not* of current production should be reflected on the label of that product. Other comments from IPP and the egg products industry opposed FSIS's proposal to remove the definition without explanation. Because FSIS agrees with the points raised by the first commenter, it is not eliminating the definition for the term "eggs of current production."

I. Implementation timeframe and training

Comment: A member of industry found the one-year implementation schedule for Sanitation SOPs and two-year

implementation schedule for HACCP acceptable. This commenter then asked that FSIS provide training for the industry when training is provided to FSIS inspectors at egg products plants to ensure that there is clear communication of FSIS's expectations for the programs between all parties. If the implementation timeframe listed does not provide sufficient time to provide training to both inspectors and industry, the commenter asked that the implementation be extended to complete both training and implementation steps.

Response: FSIS agrees that effective training of both FSIS and industry employees is critical to the success of Sanitation SOPs and HACCP. However, FSIS does not plan to allow industry to attend Agency training sessions because of complex logistical and cost considerations. The Agency also believes that responsible plant officials are in the best position to determine the training needs for each plant. As is discussed above, FSIS is providing guidance to the industry that the industry may decide to use to train industry employees. FSIS also believes that the current timeframe provides sufficient time for the industry to train its employees in Sanitation SOPs and HACCP and then implement each of the programs.

Comment: A comment from the college professor stated that because the effective implementation of HACCP and

Sanitation SOPs relies on well-trained and performing employees, user-centered training and instructional materials should be given added consideration to ensure a robust supportive framework is in place in the planned change. This commenter stated that FSIS should guide industry on how to adopt and implement HACCP and Sanitation SOPs, and training should be user-focused and modernized to maximize both agency and industry resources in the training and change implementation process. A comment from an individual said that promises for guidance about the proposed changes were mentioned in the proposal, but were not directly addressed.

Response: In the preamble to the proposed rule, FSIS said that it would provide additional guidance to plants on how to validate their HACCP systems (83 FR 6319). FSIS previously provided a *Compliance Guideline for Hazard Analysis Critical Control Point (HACCP) Systems Validation* in April 2015. While the examples in the compliance guideline reference meat and poultry products, the concepts contained in the document apply to egg products as well.

FSIS also is announcing the availability of a *Generic HACCP Models Guide for Egg Products* that will be published before the HACCP regulations are implemented. And, as discussed earlier, FSIS is making available its *FSIS Food*

Safety Guideline for Egg Products, which will help small and very small plants producing egg products meet the pasteurization requirements proposed in this rulemaking, and its *Egg Products Hazards and Controls Guide*, which will help egg products plants design and control safer food production systems. Both can be found on FSIS's web page.

J. Radioactive content of irradiated egg products

Comment: The foreign government asked FSIS whether it would test the radioactive content of irradiated egg products and if so, what test method or basis would the Agency use in the detection of radiation in egg products.

Response: FSIS is finalizing the proposed regulation 9 CFR 590.590, which will permit the use of irradiated shell eggs in the production of pasteurized egg products. As stated in the proposed rule, FDA amended its regulations in July 2000 to permit the use of ionizing radiation on shell eggs to reduce the level of *Salmonella* (July 21, 2000, 65 FR 45280). Ionizing radiation does not increase the normal radioactivity level of the food, regardless of how long the food is exposed to the radiation, or how much of an energy dose is absorbed. FSIS, therefore, does not intend to test for the radioactive content of egg products produced from irradiated shell eggs.

K. *Temperature and labeling requirements*

Comment: A federal agency asked FSIS to change proposed 9 CFR 590.50(b) by deleting the words "and labeling" from the paragraph because 21 CFR 101.17(h) does not exempt producer-packers with an annual egg production from a flock of 3,000 or fewer hens from its labeling requirements. The agency asked that FSIS do this so that it is clear that producer-packers with an annual egg production from a flock of 3,000 or fewer hens are exempt only from the temperature requirements of 9 CFR 590.50(a) and not the labeling requirements in 21 CFR 101.17(h).

Response: The EPIA exempts producer-packers with an annual egg production from a flock of 3,000 or fewer hens from the refrigeration and labeling requirements of that Act. Section 1034(e)(1)(A) and (B) of Title 21 of the U.S. Code requires the Secretary of Agriculture to make such inspections as the Secretary considers appropriate of a facility of an egg handler (including a transport vehicle) to determine if 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. However, 1034(e)(4) exempts any egg handler with a flock of not more than 3,000 layers from

an inspection by the Secretary and, therefore, exempts such egg handler from compliance with the refrigeration and labeling requirements of the EPIA. Nevertheless, producer-packers with an annual egg production from a flock of 3,000 or fewer hens are still required to comply with FDA's labeling requirement in 21 CFR 101.17(h) and 9 CFR 590.50(b) has been changed to reflect that requirement.

L. Dietary supplements

Comment: The FDA-regulated facility asked if "dietary supplements" are still exempt from labeling requirements.

Response: Dried, frozen, or liquid egg products that are dietary supplements, as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act), are exempt from FSIS labeling requirements because they are under FDA ,not FSIS, jurisdiction. However, dried, frozen, or liquid egg products that purport to be dietary supplements, but are represented for use as conventional foods or as the sole item of a meal or the diet do not, in fact, meet the definition of "dietary supplement" in 21 U.S.C. 321(ff)(2)(B)). Such products would be amenable to inspection under the EPIA and its conforming regulations and are therefore not exempt from FSIS's labeling requirements.

Comment: The FDA-regulated facility asked if dehydrated egg whites labeled as "dietary supplements" that

do not bear a USDA shield are still exempt from labeling requirements.

Response: These products are not exempt from labeling requirements. Dehydrated egg whites are amenable egg products under the EPIA. They must be processed in an official plant under FSIS inspection, contain labels that are not false or misleading, and bear the official mark of inspection.

M. Hard-cooked eggs

Comment: A comment from an inspector thought that it would make sense to move hard-cooked eggs from FDA's jurisdiction to FSIS's using the same logic as was used to transfer egg substitutes from FDA to FSIS jurisdiction.

Response: Egg substitutes are being transferred from FDA to FSIS because FSIS determined, and FDA agreed, that egg substitutes are in fact egg products, as defined in the EPIA. As such, they correctly belong under FSIS's oversight. Hard-cooked eggs, however, do not fit the definition of "egg product" under the EPIA, i.e., they are not dried, frozen, or liquid eggs. Therefore, they cannot be regulated by FSIS under that statute.

N. *Cooking as a lethality step*

Comment: The trade association representing the egg products industry and a member of industry asked FSIS to

clarify whether cooking under FSIS inspection is, and under the proposal will remain, an acceptable lethality step when properly validated. The industry member also asked that only finished (saleable) egg products be required to be RTE.

Response: Cooking unpasteurized egg products under *FSIS* inspection is an acceptable lethality step instead of pasteurization, if validated. Pasteurized or cooked egg products are required to be RTE.

O. Egg breaking: proposed change to 9 CFR 590.522

Comment: FSIS proposed to amend 9 CFR 590.522 by eliminating its numerous prescriptive sanitation provisions on breaking room operations and replacing them with a single provision requiring eggs used in processed egg products to be broken in a sanitary manner and examined to ensure that the contents are acceptable for human consumption. Comments from the trade association representing the egg products industry and the engineer stated that the language proposed for 9 CFR 590.522 would eliminate the requirement for individual examination of each egg after breaking and before commingling, and would therefore result in the production of unwholesome egg products because individual examination of eggs is still necessary to remove adulterated eggs from production.

Response: FSIS agrees with these comments and will amend proposed 9 CFR 590.522 to clarify that eggs must be broken individually and examined for wholesomeness. The Agency will insert the word "Each" at the beginning of the regulation so that it reads, "Each egg used in processed egg products must be broken in a sanitary manner and examined to ensure that the contents are acceptable for human consumption."

P. Immersion-type shell egg washers

Comment: As part of FSIS's proposal to eliminate 9 CFR 590.515, the explicit prohibition against the use of immersion-type washers is being eliminated (current 9 CFR 590.515(a)(7)). The trade association representing the egg products industry asked if the use of immersion-type washers will therefore be permitted, without the submission of a regulatory waiver, provided the egg products plant, working with an equipment manufacturer, validates the safety of the process.

Response: As discussed in the proposed rule, waivers of the type needed to permit the use of immersion-type washers will no longer be necessary (83 FR 6330). Under the final rule, the elimination of the prohibition on immersion-type washers will give plants the option to use such equipment, without applying for a regulatory waiver,

provided the equipment does not create insanitary conditions and does not adulterate product. The plant must also have documentation supporting its decision to use an immersion-type washer (417.4(a)(1) and 417.5(a)(1) and (a)(2)).

Because the implementation of HACCP will eliminate the need for most regulatory waivers, previous waivers and no objection letters (NOL) in effect will be revoked on the date the HACCP requirements become effective, unless a plant implements HACCP earlier than that date, as they will no longer be applicable. If a plant determines that it still needs a waiver or NOL, it will need to reapply for a new one.

Q. Equivalency of foreign inspection systems

Comment: A comment from the trade association representing the egg products industry questioned how FSIS verifies that imported egg products are as safe as products produced in the Unites States under FSIS inspection. This commenter also said that not all foreign HACCP programs ensure the same level of food safety as domestic HACCP systems and questioned how FSIS can verify that foreign countries require equivalent HACCP programs when FSIS audits those countries only infrequently. This commenter asked that FSIS increase transparency by identifying what is required of foreign governments, publicly sharing plans for

verifying that foreign governments have implemented the final rule changes before they manufacture egg products for the United States, and not permitting plants in foreign countries to self-designate that they are eligible to produce products for the United States. This commenter believes that the implementation date of the final rule should allow time for auditors trained in egg products and the new rules to first complete audits of the governments previously determined to be equivalent and that the approval of new countries should be delayed until those countries demonstrate to a qualified FSIS auditor full compliance with the requirements of the laws and regulations.

Response: Upon publication of the final rule, FSIS will notify countries either currently eligible to export egg products to the United States (Canada and the Netherlands), or that have requested eligibility to export egg products to the United States, of the new requirements. Before the effective dates of the HACCP, Sanitation SOP, and other sanitation requirements, these countries will be required to submit an updated Self-Reporting Tool and provide documentation that the country's laws, regulations, requirements, and procedures meet FSIS's new HACCP, Sanitation SOP, and other sanitation requirements. FSIS will determine on a case-by-case basis whether currently

eligible countries or countries that have requested eligibility have implemented requirements equivalent to this final rule. If countries currently shipping egg products do not meet these requirements, FSIS will require that they make necessary changes to be able to continue shipping product. For other countries, FSIS will not find their inspection systems equivalent and will not allow them to ship egg products to the United States until they meet necessary requirements. FSIS provides guidance on the equivalence process on its website at: *https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/Equivalence.* FSIS also publishes its on-site verification audit reports at: *https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports*. FSIS communicates initial equivalence decisions through the *Federal Register*.

Once FSIS determines a country's food safety inspection system to be equivalent, the foreign competent authority is responsible for certifying establishments that meet FSIS requirements. The foreign competent authority provides FSIS a list of certified establishments for review that is published on FSIS's website at:

https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/eligible-foreign-establishments.

R. Draft FSIS Compliance Guideline for Small and Very Small Plants that Produce Ready-To-Eat (RTE) Egg Products

Comment: FSIS received two comments supporting FSIS's draft *FSIS Compliance Guideline for Small and Very Small Plants that Produce Ready-to-Eat (RTE) Egg Products*. One commenter suggested that there would be some benefit to translating the guideline into Spanish and Chinese. This commenter also suggested that guidelines dealing with shell egg imports be translated into Dutch or French.

Response: FSIS will translate the final guidance, the *FSIS Food Safety Guideline for Egg Products,* into Spanish and will consider translating it into other languages. FSIS does not have guidance dealing with shell egg imports because it does not have jurisdiction over that product.

Comment: A comment from the trade association representing the egg products industry, noting that Table 1 on page 16 of the compliance guideline lists the current regulatory requirements for pasteurization treatments, asked why the times and temperatures for liquid egg whites were not included in the table. This commenter also asked for confirmation that FSIS is not suggesting two standards for

RTE egg products, i.e., one by regulation that requires the products to be edible without further preparation as verified by the absence of *Salmonella* and a second "administrative standard" that imposes a specific log reduction that may not be practical.

Response: The time and temperature pasteurization parameter for liquid egg whites was not included in Table 1 on page 16 of the draft guidance because the scientific literature indicates that it may no longer result in a minimum 5-$\log_{10}$ reduction of *Salmonella* in the product, which is the reduction consistent with other FSIS RTE safe harbors and the FDA's Shell Egg Rule (74 FR 33030, July 9, 2009).[10]

In response to the comments, FSIS reviewed the available data to determine the effectiveness of the previous time and temperature pasteurization parameter for achieving a 5-$\log_{10}$ reduction of *Salmonella* in egg whites as a safe harbor. The available research indicates that the natural antimicrobial properties of the albumen, the current vaccination and sanitation practices at the farm, and the

[10] In the 1998 Risk Assessment, FSIS stated, "[t]he pH of albumen has a significant effect on the reduction of SE, when liquid egg white is pasteurized. Pasteurization is more effective at higher pH levels. Egg albumen has a bicarbonate buffer system which allows the pH to rise very rapidly. The pH of a freshly laid egg is about pH 7.8 and rises to pH 8.7 or 8.8 over three days of storage. After that, the pH increases much more slowly over time to a maximum pH of 9.3 to 9.4. The time and temperature requirements of the pasteurization regulations were based on a pH of about 9 for egg white which was the case in 1969 when the regulations were written, and eggs did not arrive at the egg processing plant before three to five days. Since that time conditions have changed. Eggs reach the egg processing plant sooner now than in 1969, and the pH of the albumen is lower in eggs. For these reasons pasteurization today may be less effective than in 1969 because of the lower pH of eggs at the time of processing in 1998."

refrigeration requirement of eggs within 36 hours of lay all limit the growth of *Salmonella*.

Available studies examined *Salmonella* in eggs from chickens infected with *Salmonella*. Humphrey *et. al.*,[11,12] enumerated *Salmonella* from the egg, but also looked at *Salmonella* growth when inoculated into different parts of the egg (albumen versus yolk). Garibaldi *et. al.*,[13] enumerated *Salmonella* from whole egg and from the albumen while Gast and Beard[14] enumerated the *Salmonella* from the whole egg. Their studies demonstrated that most eggs had less than 1-$\log_{10}$ of *Salmonella* per egg while a few eggs had 2.1-$\log_{10}$ of *Salmonella*. Humphrey *et. al.,* (1991) determined that *Salmonella* inoculated into the outer edge of the albumen was less likely to grow than when inoculated next to the yolk membrane, fresh eggs were less likely to support *Salmonella* growth regardless of its position in the albumen, and that *Salmonella* positive eggs contained less than 1.3-$\log_{10}$ of *Salmonella* when stored at room temperature for less than three weeks. Gast and Beard (1992) studied the effect

[11] Humphrey, T.J., Baskerville, A., Mawer, S., Rowe, B., and Hopper, S. 1989. *Salmonella* Enteritidis phage type 4 from the contents of intact eggs: a study involving naturally infected hens. Epidemiology and Infection. 103:415-423.
[12] Humphrey, T.J., Whitehead, A, Gawler A.H.L, Henley, A., and Rowe, B. 1991. Numbers of *Salmonella* Enteritidis in the contents of naturally contaminated hens' eggs. Epidemiology and Infection. 106:489-496.
[13] Garibaldi, J.A., Lineweaver, H., and Ijichi, K. 1969. Number of Salmonellae in commercially broken eggs before pasteurization. Poultry Science. 48(3):1096-1101.
[14] Gast. R.K., and Beard, C.W. 1992. Detection and enumeration of *Salmonella* Enteritidis in fresh and stored eggs laid by experimentally infected hens. Journal of Food Protection. 55(3):152-156.

of storage temperature on frequency of isolation and concentration of *Salmonella* in eggs from experimentally infected hens and determined that eggs stored at 45°F for 7 days had 0.75-$\log_{10}$ of *Salmonella*. Since that time, the industry has continued to lower *Salmonella* levels in egg products. FSIS performed a *Salmonella* baseline survey from 2012 to 2013.[15] Results of that baseline indicate that raw liquid whole egg samples had -0.60-$\log_{10}$ to -0.31-$\log_{10}$ (95% confidence interval) *Salmonella*, meaning that there was 1 *Salmonella* organism per 2 to 4 mL. Raw liquid egg whites had -0.92-$\log_{10}$ to -0.24-$\log_{10}$ *Salmonella*, meaning that there was 1 *Salmonella* organism per 2 to 8 mL. In addition, FSIS sampling indicated that pasteurized egg whites had a *Salmonella* prevalence of 0.61% from 1995 to 1999. That prevalence decreased to 0.19% from 2013 to 2018.

Under ideal conditions (i.e., not from a farm that has *Salmonella* enteriditis (SE)-positive eggs), any *Salmonella* present in the eggs are not expected to reach more than 2.1-$\log_{10}$. As such, FSIS has incorporated a new, separate section into the *FSIS Food Safety Guideline for Egg Products* using the pasteurization time and temperature from 9 CFR 590.570. This section provides awareness that while the

[15] Food Safety and Inspection Service. 2013. Nationwide Raw Liquid Egg Products Baseline Survey. Retrieved from: https://www.fsis.usda.gov/wps/wcm/connect/f83a51b2-35b1-4451-a1cd-aac33e424ad7/Baseline-Raw-Liquid-Eggs.pdf?MOD=AJPERES

time and temperature does not always provide a 5-$\log_{10}$ reduction of *Salmonella* in egg whites, with the history in footnote 7 above, the compilation of the available scientific literature to support the safe use of the time and temperature, and the use of specific conditions under which the time and temperature may be used, the time and temperature can be used as a safe harbor.

Egg product plants sourcing from farms with SE-positive eggs may be unable to support the use of the egg white pasteurization time and temperature from 9 CFR 590.570, as these eggs need to be processed in a manner that achieves a 5-$\log_{10}$ reduction of *Salmonella* in accordance with the FDA 2009 Shell Egg Final Rule. For plants that are processing SE-positive eggs, FSIS included the tables in the appendix of the guideline to provide times and temperatures for egg whites to achieve the minimum 5-$\log_{10}$ reduction of *Salmonella*.

FSIS is not establishing two standards for RTE egg products. The standard that official plants must meet is found in proposed 9 CFR 590.570: egg products must be produced to be edible without additional preparation to achieve food safety. The tables in the appendix of the compliance guideline for pasteurization times and temperatures are not minimum lethalities, but rather safe

harbors for plants to follow and be reasonably certain that they will be meeting the requirement in 9 CFR 590.570, as well as meeting the supporting documentation requirement in 9 CFR 417.4(a) and 417.5(a). Consistent with other FSIS compliance guidelines, plants are not required to follow the safe harbors and may use alternate procedures, if they have adequate scientific support (9 CFR 417.4(a) and 417.5(a)) that the alternate procedure will meet the requirement in 9 CFR 590.570, as finalized.

S. Shipment of unpasteurized egg products: proposed 9 CFR 590.410(c)

Comment: Comments from IPP did not support the proposed change to eliminate the requirement that unpasteurized liquid egg products transported from one official plant to another be sealed and accompanied by an official certificate (9 CFR 590.410). One inspector stated that the proposal did not adequately allow for the monitoring of the movement of unpasteurized liquid egg product for further processing. A second inspector stated that he did not support the change to 9 CFR 590.410(c), which requires that bulk shipments must state that egg products are for further processing. This commenter stated that it would be unwise to advertise what a tanker may be loaded with due to the threat of agro-terrorism and bio-

terrorism in any liquid food industry. A third inspector sought clarification on what should happen when the load is shipped to a different location than originally intended.

Response: FSIS disagrees that the proposed change does not adequately allow for the monitoring of the movement of unpasteurized liquid egg product for further processing. The revised regulations provide adequate controls for the monitoring of shipments of unpasteurized products by plants and for adequate inspection by IPP. Egg products shipped for further processing must be in compliance with the revised regulation at 9 CFR 590.504(d)(2), which requires shipments of unpasteurized egg products shipped from one official plant to another for pasteurization or treatment be sealed by the official plant and labeled with the date of loading, per 9 CFR 590.410(c), and identified as intended for further processing, per 9 CFR 590.415.

The documentation and labeling requirements for shipments of unpasteurized egg products should raise no terrorism or tampering risks from terrorism. Significantly, the tanker identification for egg products shipped for further processing is already required at 9 CFR 590.415. Finally, clarification on IPP actions when the load is shipped to a different location than originally intended

will be provided to IPP through a directive after this rule is finalized.

Comment: The trade association representing the egg products industry asked if the exterior of bulk transport vessels carrying unpasteurized egg products must be labeled with the date of loading or if a bill of lading or other documentation accompanying the load is sufficient.

Response: The exterior of 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 (9 CFR 590.410(c)). Placing the date of loading on a bill of lading or other documentation accompanying the load is not sufficient.

Comment: A comment from an inspector stated that the movement of tankers without a *PY-200 Egg Products Inspection and Grading Certificate* (PY-200) would allow tankers carrying nondenatured inedible egg products to be washed and used for edible product with only plant examination and without FSIS visual inspection. One inspector did not support the revision of 9 CFR 590.504(d) as proposed. This commenter objected to the proposed paragraph because it eliminates the use of the PY-200, which is used to record

specific data associated with the shipment of unpasteurized egg products.

Response: The PY-200 serves as a label for bulk shipments of unpasteurized egg products. In proposed 9 CFR 590.410(c), FSIS changed how bulk shipments are labeled. When this rule is finalized, bulk shipments will no longer move under government seal and certificate; instead, they will move under company seal and 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. With the new labeling requirement for bulk shipments of unpasteurized products in place, there is no longer a need for the PY-200 to be used as a label. IPP will still verify that unpasteurized product is properly identified, moved to an official plant, and pasteurized.

It is not necessary for IPP to record the specific data associated with the shipment of unpasteurized egg products on a PY-200 cited by the commenter. When a tanker of unpasteurized egg products arrives at an official plant, IPP conduct an organoleptic reinspection of the product in accordance with 9 CFR 590.424(b). This can be done without marking down the tanker's date and time, temperature of the product (which is a data point that should specifically *not*

be taken), the seal numbers (which will no longer be a data point as this rule is eliminating the use of FSIS seals on tankers of unpasteurized products), and the transport vessel's license plate number.

Under this final rule, FSIS inspectors will also conduct sanitation verification activities, which will include tanker inspection, to verify that the plant is meeting its Sanitation SOP requirements. Official plants are responsible for storing inedible material in receptacles of such material and construction that their use will not result in the adulteration of any edible product or the creation of insanitary conditions (9 CFR 416.3(c)). In addition, a plant's Sanitation SOPs will have to address the cleaning of food contact surfaces of facilities, equipment, and utensils prior to the start of operations (9 CFR 416.12(c)). As such, egg products plants must ensure that tankers are cleaned before use and maintained in sanitary condition so as not to adulterate product. They must also verify that their Sanitation SOPs are current and effective. If they are not, the Sanitation SOPs must be revised. The issuance of the PY-200 certificate has no bearing on the sanitation of the tanker if the plant designates it as inedible and then decides to use it for edible purposes. The plant has to comply with the sanitation requirements and

FSIS IPP will have the opportunity to conduct sanitation tasks to verify the plant is meeting those requirements.

Comment: An inspector asked how plants would be required to maintain the cleanliness of equipment used for transporting liquid eggs under the proposed regulations.

Response: Under 9 CFR 416.3(a), equipment and utensils must be maintained in a sanitary manner so as not to adulterate product. Egg products plants are required under this regulation for ensuring that equipment used for transporting liquid eggs is sanitary before and after use.

T. Proposed 9 CFR 590.504(d)(2)

Comment: A comment from an inspector also proposed alternative language for 9 CFR 590.504(d)(2). This alternative language permits the shipment of nonpasteurized or salmonella positive egg products when they are to be pasteurized, repasteurized, or heat treated in another official plant and requires these shipments to be in cars or trucks with an accompanying certificate stating that the product is not pasteurized or is salmonella positive. It allows these shipments to be stored in other than the official plant facilities if the inspectors at the receiving and origin plants are aware of the disposition of the product until it is further processed. It requires

nonpasteurized or salmonella positive product to bear the identification mark shown in Figure 3 of § 590.415.

Response: FSIS agrees that the language in 9 CFR 590.504(d)(2) should allow for the shipment of *Salmonella*-positive egg products for further processing under appropriate controls. Therefore, FSIS is changing that paragraph to permit the movement of microbial pathogen-positive products, provided the products move under establishment controls, which include being sealed in a car or truck and labeled per 9 CFR 590.410(c). As a result of this change, FSIS also modified 9 CFR 590.410(c) to permit the movement of microbial pathogen-positive product. Containers of unpasteurized or microbial pathogen-positive egg product must be marked with the identification mark shown in Figure 2 of § 590.415.

The proposed language otherwise does not properly reflect FSIS's new regulations on the labeling of bulk shipments of unpasteurized or microbial pathogen-positive egg products that will become effective when this proposal is finalized (9 CFR 590.410(c)). The commenter's recommendation requires the shipment to move with an accompanying certificate stating that the product is not pasteurized or is microbial pathogen-positive and bears the identification mark shown in Figure 3 of § 590.415. Under

this final rule, shipments will not have to move with such an accompanying certificate. Instead, they will have to 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 in accordance with 9 CFR 410(c). They must also bear a label setting forth the identification found in Figure 2 in final 9 CFR 415.

U. Cooked, salted, and preserved eggs

Comment: A foreign government asked FSIS to exempt cooked, salted, and preserved eggs from the egg products inspection regulations related to refrigerated storage, transportation, and relevant labeling requirements.

Response: Cooked, salted and preserved eggs are not subject to the egg products inspection regulations because they are not egg products (i.e., they are not dried, frozen, or liquid eggs).

V. Health and hygiene

Comment: Paragraph (g) of 9 CFR 590.560 currently prohibits the use of perfume in any area where edible products are exposed. FSIS proposed to remove this provision in the proposed rule. One inspector noted that removing it could make it possible for employees to wear perfume. As a result, according to the commenter, Agency or

plant employees may not be able to smell spoiled eggs over the scent of the perfumes.

Response: Under this final rule, official plants must comply with the employee hygiene regulations in 9 CFR 416.5, which require that plant employees adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions. Therefore, to meet the regulations, plants are required to provide for an environment in which its employees can properly identify spoiled egg, which would include prohibiting employees from wearing perfumes that restrict employees' ability to smell spoiled eggs. FSIS will verify that the plant meets employee hygiene regulations and that no spoiled eggs adulterate the egg products.

W. Light

Comment: Current section 590.520(a) provides prescriptive requirements for lighting in egg products plant breaking rooms.[16] An inspector said that removing this regulation could potentially create inedible product since adequate lighting is necessary to identify loss or inedible eggs.

[16] The breaking room shall have at least 30 foot-candles of light on all working surfaces except that light intensity shall be at least 50 foot-candles at breaking and inspection stations.

Response: Section 416.2(c) requires establishments to provide lighting of good quality and sufficient intensity in areas where food is processed, handled, stored, or examined to ensure that sanitary conditions are maintained, and that product is not adulterated. Under the final rule, the plant is required to demonstrate that it has met this regulatory requirement. If an egg products plant were unable to identify loss or inedible eggs and prevent them from being broken because of inadequate lighting in the breaking room, IPP will find the plant noncompliant with the regulations and will take actions to prevent the adulteration of egg products.

X. Ventilation

Comment: A comment from an inspector noted that the current egg products inspection regulations addressing ventilation generally require that ventilation provide for a positive flow of outside filtered air through rooms and driers (e.g., 9 CFR 590.504(p), 506(c), 520(d), and 550(a)). This commenter stated that removing the positive air flow requirement could potentially produce an unwholesome product caused by unfiltered outside air.

Response: Under 9 CFR 416.2(d), establishments are required to provide ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent

the adulteration of product and the creation of insanitary conditions. Under this final rule, the egg products plant will be required to meet this regulation and ensure that unfiltered outside air does not adulterate product or create insanitary conditions. IPP will verify that the plant meets these requirements; if the plant does not, IPP will find the plant noncompliant with the regulations and will take actions to prevent the adulteration of egg products.

Y. Egg Handling: 21 U.S.C. 1034(d) and 1034(e)(1)

Comment: The trade association representing egg farmers and egg further processing facilities and an egg products industry member recommended that two provisions of the EPIA be maintained under current regulation: 21 U.S.C. 1034(d) and 21 U.S.C. 1034(e)(1).

Section 1034(d) of Title 21 of the U.S. Code authorizes the Secretary of Health and Human Services to inspect egg handlers (other than plants processing egg products) and their records, as well as the records and inventory of other persons required to keep records under section 1040 of the EPIA, to assure that only eggs fit for human food are used for such purpose and otherwise assure compliance by egg handlers and other persons with the requirements of section 1037 (Prohibited acts). The relevant regulatory provisions are 9 CFR 590.28 and 590.132.

Section 1034(e)(1) of Title 21 of the U.S. Code authorizes the Secretary of Agriculture to inspect the facility of an egg handler (including a transport vehicle) to determine if shell eggs destined for the ultimate consumer (A) are being held under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit after packing; and (B) contain labeling that indicates that refrigeration is required. The relevant regulatory provision is current 9 CFR 590.50(b).

Response: The EPIA was not amended by FSIS's proposed rule. Therefore, 21 U.S.C. 1034(d) and 1034(e)(1) remain unchanged. In addition, FSIS did not propose to eliminate either 9 CFR 590.28 or 9 CFR 590.132 in the proposed rule and thus will not be doing so in the final rule.

FSIS has combined into a new, single provision at 9 CFR 590.50(a), the requirement that shell eggs destined for the ultimate consumer be held under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit after packing and the requirement that such eggs contain labeling that indicates that refrigeration is required. Further, as proposed, FSIS's regulations for shell eggs packed into containers destined for the ultimate consumer will now require those products to bear safe handling instructions in

accordance with 21 CFR 101.17(h)(1),[17] instead of being labeled to specifically indicate that refrigeration is required. The safe handling instructions read "…keep eggs refrigerated…" FSIS's new requirement will take effect on the final rule's effective date.

Z. Non-compliance reports

Comment: The same egg products industry member also said that FSIS's enforcement through issuing noncompliance records (NRs) to plants needs to be further improved upon and that FSIS and plants need to follow up after the issuance of an NR so that future issues can be prevented.

Response: The NR serves as official notice to an official plant that some aspect of its operation is noncompliant. Certain regulations require that plants implement corrective actions or preventive measures to ensure future compliance (9 CFR 416.15 and 9 CFR 417.3). Depending on the NR, IPP may conduct additional inspection activities to verify that noncompliance documented on an NR has been corrected and that the plant has taken measures to prevent recurrence of the noncompliance (*see* FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*).

[17] 21 CFR 101.17(h)(1) says, "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly."

In addition, FSIS has numerous directives and notices that state that when noncompliance is found, IPP are to issue an NR to the establishment. The directives or notices typically state which regulation to cite on the NR. FSIS has also strengthened its approach to noncompliance and made it more data-driven. FSIS utilizes Early Warning Alerts through its Public Health Information System,[18] an additional tool for IPP, which are based on adverse trends in Public Health NRs[19] and give IPP the data to be able to determine trends and take appropriate actions. The Office of Field Operations typically has work unit meetings concerning new instructions to the field, including instructions on how to document noncompliance. FSIS training for the field includes training on new instructions issued to the field, again including instructions on how to document noncompliance.

AA. Water supply and water, ice, and solution reuse

Comment: Two comments from students requested clarification regarding the use of reconditioned water in 9 CFR 416.2(g)(4). One of them asked that FSIS define "raw product" and provide further clarification on the approved

[18] The Public Health Information System is a dynamic, comprehensive data analytic system that collects, consolidates and analyzes data in order to improve public health. https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/phis

[19] https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/fsis-data-analysis-and-reporting/data-reporting/public-health-regulations

uses of reconditioned water that is processed through advanced wastewater treatment facilities. The other saw the same conflict within the regulation and indicated that more specificity is needed for this part of the rule.

Response: Reconditioned water that is processed through advanced wastewater treatment facilities may be used in official plants. Any product, facilities, equipment, and utensils that come into contact with reconditioned water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in 416.2(g)(1). Therefore, once this rule is finalized, reconditioned water may be used in egg products plants on shell eggs prior to breaking and on facilities, equipment, and utensils within the plant. If reconditioned water is used on shell eggs, facilities, equipment, or utensils, they must be rinsed with non-reconditioned water prior to breaking or use (9 CFR 416.2(g)(4)).

BB. Hold and test (9 CFR 590.504(e))

Comment: FSIS received two comments regarding its hold and test policy for egg products in 9 CFR 590.504(d): one from the trade association representing egg farmers and egg further processing facilities supporting it and one from the individual working in a field allied with the egg products industry stating that it was not necessary.

Response: Requiring egg products plants to control product pending the receipt of pathogen test results has been a long-standing feature of the egg products inspection regulations (9 CFR 590.504(d)). In the rule, FSIS did not propose to change this policy, but revised its wording 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 (83 FR 6327).

An official plant's failure to maintain control of product pending FSIS or plant pathogen test results endangers public health. Not allowing product to move into commerce until the results of any testing for adulterants become available eliminates this concern. This is also consistent with the policy for other FSIS-regulated meat and poultry RTE products.

CC. Plant testing

Comment: A comment from the individual working in a field allied with the egg products industry stated that there is too much variability in egg product industry testing methods, and recommended that FSIS establish a *Salmonella* testing method that all egg products producers be required to use. This commenter also said

that standardizing test methods across the industry will allow for better analysis of results.

Response: To gain efficiencies and best protect public health, FSIS is moving towards a sampling program that is focused on production volume rather than the number of products produced. FSIS believes this approach will allow for a more risk-based allocation of samples. It will also align with our other sampling projects.

To ensure adequate pasteurization of egg products, egg products plants are required to sample and analyze pasteurized egg products and heat-treated dried egg whites for the presence of *Salmonella* (9 CFR 590.580(b)). Currently, laboratories that conduct such analyses for plants must participate in FSIS's Pasteurized Egg Product Recognized Laboratory (PEPRLab) Program. Under the PEPRLab Program, recognized laboratories must use a rapid screening method that is equivalent to conventional culture methods in their testing program. If they do not, they must use one of the following three cultural methods as their primary protocol for egg product analysis:

AMS – Laboratory Methods for Egg Products – Section I (1993 revision) and Section VII (1994 revision),

FSIS method – Microbiology Laboratory Guidebook (MLG) online, Chapter 4 – Isolation and Identification of *Salmonella* from Meat, Poultry, and Egg Products, or

FDA method – Bacteriological Analytical Method (BAM) online, Chapter 5 – *Salmonella*.

Sixty days after the publication of this final rule, FSIS will discontinue the PEPRLab Program. As a result, laboratories will no longer need to be accredited under it to perform microbiological testing for egg products plants. Egg products plants will be able to select commercial or private laboratories to analyze plant microbiological samples, such as the *Salmonella* spp. samples required by 9 CFR 590.580. To assist egg products plants with selecting such laboratories, FSIS has made available on its website its guide, *Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory*, which provides criteria for selecting a commercial or private microbiological testing laboratory to analyze establishment samples.

Under this final rule, egg products plants are required to ensure that microbiological testing meets their food safety needs. Egg products plants should clearly communicate their needs to the testing laboratory and direct them to any necessary testing protocols or any other

guidance, including the guide discussed above, on the FSIS website. The plant is required to take corrective actions in response to positive results (9 CFR 417.3). The plant should not assume that an unexpected result is incorrect. Re-sampling or retesting a sample is typically not an appropriate action. FSIS is not going to prescribe test methods because that would be inconsistent with HACCP regulations and inconsistent with other meat and poultry regulations.

DD. 9 CFR part 430

Comment: A comment from an inspector said that because egg products are RTE, egg products plants should have to comply with 9 CFR part 430, "Requirements for Specific Classes of Products," because after pasteurization, the product is exposed to the environment during cooling, adding of non-egg ingredients, and packaging. As such, the commenter said, the product should be sampled for *Lm*.

Response: Although eggs products are not currently subject to the requirements in 9 CFR part 430, Control of *Listeria monocytogenes* in Post-lethality exposed Ready-to-Eat Products (*Listeria* Rule), FSIS currently tests egg products for *Lm*. FSIS will continue to evaluate the data to

determine whether *Lm* contamination is a post-lethality hazard of concern for egg products.

EE. Costs

Comment: Several individuals and students expressed concern about the impact of the proposed rule on small businesses. Specifically, some of these commenters were concerned about the costs of transitioning to a HACCP system, including the range of HACCP development and validation costs, and whether establishments would need to hire more personnel and provide training. A few commenters noted that the proposed rule would improve food safety by preventing outbreaks, but also would be costly to small businesses. One individual was concerned that some small business operations would stop producing egg products because of the costs of implementing HACCP.

Comments from a trade association representing the egg products industry and egg products industry generally supported the proposed rule and stated that most egg products plants already have HACCP plans and Sanitation SOPs; therefore, according to these commenters, the costs of implementing HACCP and Sanitation SOPs should not be a burden to businesses. The trade association representing the egg products industry and the egg products industry also said that additional costs will only increase if the move to

mandatory HACCP is further delayed. These comments stated that most customers require that egg products plants have HACCP systems and that the current prescriptive command-and-control regulations cause confusion and limit innovation.

Response: The Agency agrees with the comments from the egg products industry that the cost of implementing HACCP and Sanitation SOPs should not be a burden to businesses. Comments from outside of the egg products industry mention three types of costs: HACCP development, validation, and labor costs. In response to these comments, FSIS used more recent data including updated wage rates for Agency personnel, industry production employees, quality control technicians, quality control managers, as well as employee turnover rates. In addition, FSIS has updated the following items for inflation:[20] travel and overtime costs for inspectors, the cost for HACCP development, Sanitation SOP development, HACCP training, Sanitation SOP training, and the cost for industry to review labels. This update to the Regulatory Impact Analysis leads to the conclusion that the rule has costs savings. The updated data did not change the Agency's estimates of the regulation's impacts on small businesses.

[20] Bureau of Economic Analysis: Table 1.1.9. Implicit Price Deflators for Gross Domestic Product.

Overall, this final rule is expected to be net beneficial, with quantified net benefits, because it provides greater flexibility and reduces burdensome regulations that limit innovation. For example, benefits include reductions in plant submissions to FSIS for waivers, labels, and blueprints, as well as reductions in costs from changes in inspection.

In the initial Regulatory Flexibility Act Assessment (RFA) in the proposed rule, FSIS estimated that approximately 31 plants could be considered small or very small businesses and will reap benefits, as will larger businesses. In this final rule, the Agency updated the final RFA to include an additional approach to estimating the number of small and very small businesses. In the final RFA, FSIS used the Agency-assigned HACCP small and very small plant sizes[21] to examine whether small and very small businesses will have cost savings from the rule. FSIS estimated that, based on a plant's HACCP size, approximately 72 of the 81 plants could be considered small or very small businesses and, similar to the approach used in the proposed rule, these businesses are estimated to have net quantified benefits/cost savings as a result of the final rule. The

[21] HACCP production size classes: large establishments, with 500 or more employees; small establishments, with 10-499 employees; and very small establishments, with fewer than 10 employees or annual sales of less than $2.5 million.

final RFA also includes a discussion comparing expected net cost savings to revenue and finds that the expected net cost savings are not significant compared to the revenue at the majority of small businesses. FSIS estimated that plants will experience an average annual cost savings of $5,500[22] per plant at the 7% discount rate and $5,800 per plant at the 3% discount rate for the mid-range estimates.

FSIS does not expect costs for developing a HACCP system to be overly burdensome for small plants. HACCP development costs and training are included in the range of the total costs and benefits shown in Table 1. Even with the inclusion of varying HACCP development costs, the final rule's mid-range estimates at the 3 and 7 percent rates show net benefits. In addition, most of the 81 egg products plants operate under a HACCP system. A 2014 survey by Research Triangle Institute (RTI) International, the "2014 Egg Products Industry Survey"[23], showed that 93 percent of egg products plants already use written HACCP plans. With 93 percent of egg products plants already under a HACCP system, many have incurred additional unnecessary costs from complying with FSIS requirements in terms of command-and-

[22] More information on the impact to small businesses can be found in the Regulatory Flexibility Act section of the proposed rule (83 FR 6344-6345).
[23] 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.

control regulations and by processing under their own HACCP systems. By operating under a 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.

Although this final rule includes compliance dates of two years for HACCP regulations and one year for Sanitation SOPs, plants may begin operating under HACCP and Sanitation SOP regulations at earlier dates, provided FSIS verifies their compliance with the regulations. FSIS provided these longer compliance periods to give plants which do not have HACCP plans in place additional time to meet FSIS requirements.

Comment: Several individuals and students stated that FSIS should provide some type of reimbursement program, tax rebates, subsidies, or other forms of reimbursement or aid to businesses for the changes described in the proposal.

Response: Forms of aid, tax rebates, or subsidies are beyond the authority of the Agency and the scope of the proposed rule. Notably, FSIS has developed the *FSIS Food Safety Guideline for Egg Products*. This guidance is designed to help small and very small plants meet the regulatory pasteurization requirements by providing the best practice recommendations by FSIS, based on the best

scientific and practical considerations. The Agency is also making available the *Egg Products Hazards and Controls Guide*, and the *Compliance Guideline for Hazard Analysis Critical Control Point (HACCP) Systems Validation*, both mentioned earlier in this document.

Comment: Several individuals stated that the proposed rule would increase the price of shell eggs and egg products. One individual stated that the proposed rule would be good for consumers, as long as the costs were low enough not to affect pricing. One individual said that an increase in the price of eggs or egg products would not be worth any resulting food safety benefit.

Response: While FSIS regulates official egg products plants and their processing operations, the Agency does not generally regulate shell eggs outside of egg products plants, except when checking to ensure that shell eggs packed into containers destined for the ultimate consumer meet the packaging and labeling requirements of the EPIA and 9 CFR 590.50. However, FSIS analyzed the final rule's impacts and found that it should not increase the price of liquid, frozen, dried egg products. Egg products plants would be unlikely to pass any benefits or costs onto purchasers because the marginal costs or cost savings of implementing a HACCP system are not enough to significantly

change the price for the product sold. In addition, price changes for egg products are unlikely because no one firm has enough market power to influence the price of egg products. Buyers and sellers are numerous and well informed so that all elements of monopoly are absent, and the market price of a commodity is beyond the control of individual buyers and sellers.

The price consumers face when purchasing a final product will likely not be affected from changes to the production of egg products, because egg products are often intermediary goods or one ingredient in a final product such as candy or baked goods. In addition, the fixed costs associated with the final rule are focused on the development of a HACCP system, and these firms operate for a long period of time. Fixed costs would not affect the average price of egg products.

Comment: An inspector said that the RTI Egg Products Industry Survey[24] was misleading because it stated that 93 percent of egg products plants use a written HACCP plan, but the overall response rate of the survey was only 72 percent. This individual questioned whether the 72 percent response rate meant that FSIS's estimates of HACCP reassessment costs

[24] 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.

was only 72 percent accurate. The egg products industry generally agreed with the survey that most plants already use HACCP. In addition, a trade association representing the egg products industry stated that its members are required to have HACCP.

Response: FSIS is satisfied with the design and response rate for the RTI Egg Products Industry Survey. RTI checked for nonresponse bias and concluded that the establishments that responded, adequately represented the industry. RTI also weighted the response data to account for non-responders. FSIS used the weighted RTI survey data throughout the Regulatory Impact Analysis.

The average paper-survey response rate for organizations is 35.7 percent, as shown in studies done in the U.S. from 2000 to 2005.[25] The response rate for the RTI Egg Products Industry Survey was 72 percent, far exceeding the average.

Comment: An independent consultant stated that it is reasonable to conclude that there will be no net deregulatory savings and that there will be possible net social costs from the rule because FSIS's cost savings estimate is so small. According to the comment, FSIS's cost

[25] Baruch, Yehuda and Holtom, Brooks. The Tavistock Institute, 2008. "Survey response rate levels and trends in organizational research." Human Relations, Volume 61(8): 1139-1160. SAGE Publications http://journals.sagepub.com/doi/pdf/10.1177/0018726708094863

estimates contain many uncertainties and do not contain variability and uncertainty analyses. According to an individual, FSIS did not include the long term and maintenance costs of HACCP development in the cost estimate, leading to an underestimation of costs.

The independent consultant also stated that the rule does not create benefits for egg products plants, such as improved efficiencies. However, the comment said that industry commenters would be better equipped to determine if FSIS's cost-benefit analysis is correct.

The independent consultant also argued that FSIS did not substantiate its claims that the rule will result in improvements to public health.

Response: The final rule's mid-estimates at the 3 and 7 percent rates show net benefits consistent with the proposed economic analysis (83 FR 6343). The estimate of net benefits does include both positive and negative numbers, but it is expected that the net benefits are more likely to be positive. The analysis accounts for uncertainty by including a range of costs. A more formalized uncertainty analysis is not justified by the small impact that this rule is likely to have. Please see Table 19 Total Costs and Net Benefits in this final rule. In addition, the quantitative components of the cost saving estimates are derived from the

elimination of waivers and blueprint submissions to FSIS, generic labeling savings, and savings from the reduction in overtime and holiday pay for inspection paid by industry. These submission processes and payments have less uncertainty and are based on Agency data. FSIS did include ranges of costs for items like HACCP development in the total cost estimates and low, mid, and high estimates of total costs, total benefits, and total net benefits (see Table 1) to show variability and uncertainty. FSIS also discounted and annualized costs and benefits at a 3 percent and 7 percent discount rate to show additional variability in the estimates.

FSIS did account for long-term maintenance costs in the form of reassessment costs and training for HACCP implementation. The total costs for HACCP development of $4.3 million as shown in Table 7 of the economic analysis of the final rule were based on costs that occur over a period of 10 years at a 7 percent discount rate. The costs for annual reassessment of HACCP plans, which occur on an annual basis beyond the first year of development, were included in the HACCP cost estimated. Long term employee training costs were also included in the cost estimated.

By requiring a HACCP system in egg products plants, benefits will increase in several ways. Currently, FSIS

estimates 93 percent of plants produce egg products with voluntary HACCP systems, as well as operating under the current required regulatory structure. As is noted above, FSIS expects that plants, with existing HACCP plans, will reduce their costs by operating in one system, rather than contributing resources into two different systems. The current regulations are overly prescriptive and not flexible. They do not, for example, allow plants to tailor their control systems to the needs of their plant and processes. They do not allow plants to innovate regarding facility design, construction, and operations, and they are unnecessary to define the specific measures to achieve sanitation requirements. By eliminating the command and control regulatory constraints and allowing plants to adopt a more flexible system, they should increase efficiency. Similarly, these same command and control requirements will continue to have the potential to interfere with innovation at egg production plants as they implement new production systems as well as more streamlined safety systems in the future. As a result, moving to a HACCP based system will allow plants to be more efficient over the long-term relative to the existing system. Also, as described in the foregoing, FSIS received comments from the egg products industry and a trade association representing the egg

product industry that supported requiring plants to develop and implement HACCP Systems and Sanitation SOPs.

FSIS is not claiming that this rule provides a significant improvement in public health outcomes relative to the current regulatory system. This rule is intended to remove regulatory barriers to innovation and remove unnecessary costs from the current system without reducing the public health protections provided by the current system.

Comment: An individual stated that unnecessary procedures might overcomplicate the system or increase the cost of egg products. Another individual said that if by implementing the proposed regulations FSIS can eliminate steps and decrease production and inspection costs, it should be done, as long as it does not jeopardize anyone's health or safety. This commenter also suggested that the money saved from not hiring IPP under the proposed changes to inspection be used towards lengthening and strengthening the new and more efficient process.

Response: FSIS believes that by implementing a HACCP-based system, it will be eliminating the unnecessary procedures that are currently overcomplicating the system. At the same time, the HACCP-based system will improve the effectiveness of egg products production and inspection. The

rule does change the way egg products plants are inspected by moving IPP into patrol assignments. Patrol assignments will allow FSIS to maintain the same level of food safety while allocating IPP more effectively across plants. The Agency will receive cost savings from attrition, because FSIS will not need to hire new IPP for continuous egg products plant inspection.

FF. Food ingredients used during the production of egg products

After the comment period ended, FDA suggested to FSIS alternative language for paragraphs (a)(1) and (2) of 9 CFR 590.435 that would more easily and accurately cover the use of food ingredients in egg products. Food ingredients (whether added directly or indirectly, including sources of radiation) used during the production of egg products are subject to regulation by FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Specifically, "food additives" as defined under 21 U.S.C. 321(s) and "color additives" as defined under 21 U.S.C. 321(t) must be authorized for that use (*see* 21 U.S.C. 348 and 379e). The definition of a "food additive" excepts certain uses, including uses that are generally recognized as safe among experts qualified by scientific training and experience to evaluate its safety

(*see* 21 CFR 170.30) and prior sanctioned uses (*see* 21 CFR part 181).

Paragraphs (a)(1) and (2) of 9 CFR 590.435 will continue to prohibit the use of food additives, sources of radiation, and color additives in egg products unless such use is authorized under the FD&C Act. FSIS is moving from paragraph (a)(1) to new paragraph (a)(3) the requirement that substances and ingredients used in the processing of egg products capable of use for human food be clean, wholesome, and unadulterated.

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

Executive Orders 12866, 13563, and 13771 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 (E.O.) 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated a "significant" regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has

been reviewed by the Office of Management and Budget under E.O. 12866.

FSIS has updated the costs and benefits from 2016 to 2019 dollars in this final regulatory impact analysis as compared to the Preliminary Regulatory Impact Analysis (PRIA) published in the proposed rule. These changes include: updated wage rates for Agency personnel, industry production employees, quality control technicians, quality control managers, and turnover rates for employees. In addition, FSIS has updated the following items for inflation:[26] travel and overtime costs for inspectors, the cost for HACCP development, Sanitation SOP development, HACCP training, Sanitation SOP training, and the cost for industry to review labels.

Need for Regulatory Action

The final rule will enable official plants to increase efficiency from complying with less burdensome regulations. The current "command and control" egg products inspection regulations will be changed to more flexible regulatory requirements. Under this final rule, egg products plants will be required to develop and maintain HACCP systems. A HACCP system allows greater flexibility for producers to

[26] Bureau of Economic Analysis: Table 1.1.9. Implicit Price Deflators for Gross Domestic Product.

realize increased production efficiency. In addition, the final rule will allow plants to use different pasteurization methods. With 93 percent of egg products plants already under a HACCP system,[27] 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 pasteurized liquid egg products. This represents 0.5% of the approximately 1.03 million annual domestically acquired foodborne illnesses caused by *Salmonella.*[28] In addition, there were four *Salmonella* outbreaks between 2007 and 2012 that were possibly caused by contaminated pasteurized egg products.[29] Also, because the Food Code recommends pasteurized egg products to highly susceptible populations (FDA 2013 Food

[27] 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.
[28] Scallan et a. 2011, Emerging Infectious Diseases 17(1): 7 - 15
[29] Gurtler et al., 2013, Foodborne Pathogens and Disease, 10(6):492-499

Code, Sec. 3-8), process control failures in the production of pasteurized egg products have the potential for especially serious health outcomes. By requiring egg products plants to operate in a HACCP system, the rule allows plants more flexibility to tailor their control systems to address any food safety requirements. HACCP has been proven to be the best framework for building science-based process control into food production systems to prevent food safety hazards.[30,31]

Baseline of the Egg Products Industry

As of May 26, 2020, egg products are produced under FSIS jurisdiction by 81 egg products plants. Egg products include liquid, frozen, and dried whole eggs, whites, yolks, and various blends with or without non-egg ingredients. For background, according to the FSIS Public Health Information System (PHIS) data, we estimated 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.[32] Liquid egg products are

[30] Neal D. Fortin, Food Regulation: Law, Science, Policy, and Practice, (Hoboken, NJ: John Wiley and Sons, 2017) 181

[31] Rose BE, Hill WE, Umholtz R, Ramnsom GM, James WO. 2002. "Testing for *Salmonella* in raw meat and poultry products collected at federally inspected establishments in the United States, 1998 through 2000." *J Food Prot* 65:937-947.

[32] 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.

produced in 73 percent of plants and accounted for 19 percent of all egg products marketed as finished product in 2014.[33] Liquid egg products represent the largest product type produced by egg products plants.

A survey by RTI International in 2014, Egg Products Industry Survey,[34] showed that 93 percent of egg products plants use a written HACCP plan to address at least one production step in their process.[35] The remaining 7 percent will need to develop HACCP plans under this final 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 final rule will 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 SOPs.[36]

Egg products production is easily the least labor-intensive process of the industries and products that FSIS

[33] In the Fiscal Year 2014, the monthly average production volume was used to calculate the percentage for 77 egg products plants in the PHIS data.
[34] 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
[35] 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
[36] 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

regulates. Egg products plants tend to be highly mechanized and staffed with relatively low numbers of employees. Therefore, the large majority (88 percent) of egg products plants fall into either the HACCP size small or very small size 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 final Regulatory Flexibility Analysis section of this document.

Table 2. Egg Products Plants and Total Processes

Plants	Breaking	Liquid	Dried	Total Processes
81	59	55	18	132

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.

Expected Cost of the Final 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 final regulation. All recurring and one-time cost estimates are in 2019 dollars, and discount rates of 3 percent and 7 percent are used to calculate annualized costs and savings over a 10-year period. For the purposes of the estimate, FSIS did not consider plant HACCP size because of the regularity in size explained previously (88 percent are small or very small plants). FSIS does not anticipate costs experienced by very small and small plants to differ greatly from those experienced by larger plants, because this final rule does not require any major capital, structural, or machinery investment or the hiring of additional employees, which can impose a large burden on very small or small plants.

Egg products plant personnel compensation (wages and benefits) that plants will need to provide to their employees because of the final 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 $55.34 per hour; for supervisors or QC technicians $36.63 per hour; and for production workers $14.23 per hour.[37] Plants may pay employees for benefits such as paid leave, health insurance, and retirement and savings, and FSIS applied a benefits and overhead factor[38] of two to the hourly wage rate to estimate a total compensation rate for a QC manager at $110.68 per hour; and for supervisors or QC technicians at $73.26 per hour; and for production workers at $28.46 per hour.

Hazard Analysis & Critical Control Points (HACCP) Systems:

The cost estimates for HACCP implementation include costs associated with plan development and reassessment, training, and monitoring and recordkeeping costs. If egg products plants follow current time/temperature regulations, FSIS will accept their approach, and FSIS will 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

[37] Estimates obtained from the Bureau of Labor Statistics May 2019 National Industry-Specific Occupational Employment and Wage Estimates, for Management Occupations (Occupational Code 11-3051), https://www.bls.gov/oes/current/oes113051.htm, Food Scientists and Technologists (19-1012), https://www.bls.gov/oes/current/oes191012.htm, and Production Occupations (51-3023) https://www.bls.gov/oes/current/oes513023.htm.

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

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.[39] 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 final rule, each plant will be required to evaluate its processes to determine the adequacy of existing written HACCP plans and the number of plans that will need to be created or modified to meet the requirements of the final rule. A large number of egg products plants already have HACCP plans for their processes. These plants will be required to reassess their HACCP plans annually, to ensure that their HACCP plans are consistent with the regulations in this final rule. For plants that currently lack HACCP plans, FSIS estimated the cost of initial plan development, annual reassessment, and validation. Under this final rule, every egg products plant will be required to reassess the adequacy of the HACCP plan at least annually and whenever

[39] 9 CFR 417.4

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.[40] Using this data, FSIS estimated the number of processes in those plants that require a HACCP plan to be developed. This information is displayed in Table 3.[41]

[40] *See* Appendix A, Section 4.

[41] 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 25.6181 rather than 26. 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).

Table 3. Processes without Written HACCP Plans

Breaking	Liquid	Dried	Total Processes
9	13	4	26

For plan development and reassessment, FSIS used the Cost of Food Safety Investments[42] final report, updated with the GDP Deflator and updated labor costs from 2014 to 2019 dollars, and, with the assumed benefits and overhead factor of two. FSIS estimated the costs in 2019 dollars for plan development and reassessment using the low estimate, (plan developed internally – low estimate – $18,315), the high estimate (plan developed with consultant - high estimate - $45,359), and the average of the mid-estimates of the plan developed with a consultant and internally ($33,435).[43] FSIS also incorporated an initial validation cost of $29,304 ($14,652 - $43,956) and an ongoing (yearly) reassessment cost of $854 ($427 - $1,281). 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.

[42] 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 GDP Deflator from 2014 to 2019.

[43] 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.

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

Cost Component	Cost Estimates (Low – High)			
	Initial Cost*	Recurring Cost	Annualized 3% over 10 years	Annualized 7% over 10 years
Development	856.0 (469.2 – 1,160.4)	0	97.4 (53.4 - 132.1)	113.9 (62.4 - 154.4)
Initial Validation* for 25 New Plans	750.7 (375.4 – 1,126.1)	0	85.4 (42.7 - 128.2)	99.9 (49.9 - 149.8)
Annual Reassessment**	3,208.2 (1,604.1 - 4,812.4)	3,980.8 (1,990.4 – 5,971.2)	3,892.9 (1,946.4 – 5,839.3)	3,878.0 (1,939.0 - 5817.0)

* These estimates are calculated using the actual number of unrounded processes or 25.6181 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 will 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 final measures. Based on the 2014 Egg Products Industry Survey final report, approximately 7 percent of plants do not employ any HACCP plans.[44] Thus, we assume 7 percent of

[44] *See* Appendix A, Section 5.

plants (approximately six) 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, will 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 used initial and recurring annual refresher training cost estimates (updated with the GDP Deflator and updated labor costs from 2014 to 2019 dollars and the assumed benefits and overhead factor of two) and the number of hours of training from the Cost of Food Safety Interventions[45] final report. QC managers will be trained initially at a cost of $4,282 ($2,141.17 - $6,423.51), with an annual refresher at a cost of $221.36 ($110.68 - $332.04). QC technicians will be trained initially at a

[45] 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 GDP Deflator from 2014 to 2019.

cost of $3,384 ($1,692 - $5,076), with an annual refresher at a cost of $147 ($73 - $220). 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 will also need to be trained; however, FSIS assumed that this training will take place on the job, and therefore will only impose opportunity costs. We use an annual turnover rate of 36.5 percent[46] 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	Cost Estimates (Low – High)			
		Initial Training	Recurring Training	Annualized 3% over 10 years	Annualized 7% over 10 years
6	9	87.3 (43.7 - 131.0)	38.3 (19.2 - 57.5)	43.9 (21.9 - 65.8)	44.8 (22.4 - 67.2)

HACCP Recordkeeping:

The rule requires facilities to record observations when monitoring CCPs and to document any deviations and corrective actions. The rule requires that an employee not

[46] Annual total separations rate for nondurable goods, Bureau of Labor Statistics Job Openings and Labor Turnover Survey, 2019, available at: http://www.bls.gov/news.release/jolts.t16.htm

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 final 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.[47] 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, and any

[47] *See* Appendix A, Section 6.

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 expert[48] 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 CCP.[49] From the above assumptions, we estimate (Table 6) the annual cost of HACCP recordkeeping and monitoring.

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

Plans	Effective Annual Shifts	Annualized Cost Estimates (Low – High)			
		Recordkeeping		Monitoring	
		3% over 10 years	7% over 10 years	3% over 10 years	7% over 10 years
26	11,101	79.0 (52.7 - 105.3)	79.0 (52.7 - 105.3)	67.8 (33.9 - 101.7)	67.8 (33.9 - 101.7)

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.

[48] 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

[49] FSIS estimated these approximate time estimates by first hand observation at egg products plants.

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

Cost Component	Annualized Cost Estimates (Low – High)	
	3% over 10 years	7% over 10 years
Plan Development and Reassessment	4,075.8 (2,042.6 – 6,099.6)	4,091.8 (2,051.4 – 6,121.3)
Training	43.9 (21.9 - 65.8)	44.8 (22.4 - 67.2)
Recordkeeping & Monitoring	146.8 (86.5 - 207.0)	146.8 (86.5 - 207.0)
Total	4,266.4 (2,151.1 – 6,372.4)	4,283.4 (2,160.3 – 6,395.5)

*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 Survey,[50] 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 will likely meet the requirements of the final rule. FSIS then applied this percentage to determine the number of plants that will need to develop written Sanitation SOPs (approximately 7). The

[50] *See* Appendix A, Section 1.

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 final 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 Interventions[51] final report, updated for inflation using the GDP Deflator and wage rates from 2014 to 2019 dollars and for the benefit factor described previously. For plan development, FSIS estimated costs using the low estimate (plan developed internally - low estimate - $18,315), the high estimate (plan developed with a consultant - high estimate, $33,164), and the average of the mid-estimates of the plan developed internally and with a consultant ($29,370).[52] The costs of Sanitation SOP plan development are displayed in Table 8. The recurring costs associated with Sanitation SOPs can be found in the recordkeeping, monitoring, and training sections found below.

[51] 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

[52] 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	Cost Estimates (Low – High)		
	Initial Cost	Annualized 3% over 10 years	Annualized 7% over 10 years
Development	208.6 (130.1 - 235.5)	23.7 (14.8 - 26.8)	27.8 (17.3 - 31.3)

Recordkeeping:

Under the final rule, plants will 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 will meet the requirements of the final rule consisting of employee task performance and a log for deviations and corrective actions.[53] FSIS then determined how many of those plants are completing recordkeeping tasks daily.[54] Those plants that are not conducting recordkeeping frequently enough (less than daily), or are not keeping the correct records during recordkeeping based on the final 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

[53] *See* Appendix A, Section 2.
[54] At least 1 pre-operational sanitation inspection of product contact zones per 9 CFR 416.13 and 416.12(c).

that each sanitation recordkeeping task will be performed by a production employee and will take approximately 15 minutes (+/- 5 minutes) to complete. A sanitation recordkeeping task will be performed daily, unless the plant reported performing a task more than daily, in which case FSIS assumed there will 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 day.[55] 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% X 3 shifts + 18% X 2 shifts + 57% X 1 shift = 1.7 shifts. Please see Table 9 for the estimated costs to industry for implementing Sanitation SOP recordkeeping.

FSIS further assumed that a QC technician will review or monitor records for approximately 10 minutes (+/- 5 minutes) once per day. FSIS used the adequacy and frequency of an egg product plant's current recordkeeping to estimate the cost to industry for additional monitoring of Sanitation SOP recordkeeping. These costs are displayed in Table 10.

[55] Please see Appendix A.

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

Current Recordkeeping	Recordkeeping Frequency	Number of Plants*	Annualized Recordkeeping Cost Estimates (Low – High)	
			3% over 10 years	7% over 10 years
Meets Requirements	< Daily	7	13.1 (8.8 - 17.5)	13.1 (8.8 - 17.5)
Does Not Meet Requirements	< Daily	3	5.3 (3.5 - 7.0)	5.3 (3.5 - 7.0)
	Daily	13	23.7 (15.8 - 31.5)	23.7 (15.8 - 31.5)
	> Daily	13	39.4 (26.3 - 52.6)	39.4 (26.3 - 52.6)

*For number of plants, FSIS multiplies the percentages from the survey for each category by total number of plants (81).

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

Current Recordkeeping	Recordkeeping Frequency	Number of Plants*	Annualized Monitoring Cost Estimates (Low – High)	
			3% over 10 years	7% over 10 years
Meets Requirements	< Daily	7	22.6 (11.3 - 33.8)	22.6 (11.3 - 33.8)
Does Not Meet Requirements	< Daily	3	9.0 (4.5 - 13.5)	9.0 (4.5 - 13.5)
	Daily	13	40.6 (20.3 - 60.9)	40.6 (20.3 - 60.9)
	> Daily	13	40.6 (20.3 - 60.9)	40.6 (20.3 - 60.9)

*For number of plants, FSIS multiplies the percentages from the survey for each category by total number of plants (81).

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.[56] FSIS assumed that one QC manager per plant, and one QC technician and three production employees per shift will be trained.[57] FSIS assumed the recurring training will occur for all 81 plants. FSIS used initial and recurring annual refresher training cost estimates from the Cost of Food Safety Interventions[58] final report, updated for inflation using the GDP Deflator and wage rates from 2014 to 2019 dollars and with the assumed benefits and overhead factor of two. QC managers will be trained initially at a cost of $2,954.18($1,477.09 to $4,431.27) with an annual refresher at a cost of $221.36($110.68 to $332.04). QC technicians will be trained initially at a cost of $2,505.14 (1,252.57 to 3,757.71) with an annual refresher at a cost of $146.52 ($73.26 to $219.78). FSIS added an additional opportunity cost to account for the lost hours when employees are in training. Production employees will also need to be trained, however, FSIS assumed that this training

[56] *See* Appendix A, Section 3.
[57] An FSIS expert has also agreed with the Industry Survey and provided the likely staff needing training at a typical egg products plant.
[58] 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.

would take place on the job and therefore will impose only opportunity costs.

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 36.5 percent[59] 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	Cost Estimates (Low – High)			
		Initial Training	Recurring Training	Annualized 3% over 10 years	Annualized 7% over 10 years
36	61	402.7 (238.3 - 604.1)	189.7 (108.3 - 300.7)	235.5 (135.4 - 369.5)	243.3 (140.0 - 381.1)

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.

[59] Annual total separations rate for nondurable goods, Bureau of Labor Statistics Job Openings and Labor Turnover Survey, 2019, available at: http://www.bls.gov/news.release/jolts.t16.htm

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

Cost Component	Annualized Costs (Low – High)	
	3% over 10 years	7% over 10 years
Plan Development	23.7 (14.8 - 26.8)	27.8 (17.3 - 31.3)
Recordkeeping & Monitoring	194.3 (110.7 - 277.8)	194.3 (110.7 - 277.8)
Training	235.5 (135.4 - 369.5)	243.3 (140.0 - 381.1)
Total	453.5 (261.0 - 674.1)	465.3 (268.1 - 690.3)

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

Special Handling Statements on Labels:

The final 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 final 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 final rule for recordkeeping and monitoring. Below, the total industry costs are presented:

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

Cost Component	Annualized Cost Estimates (Low – High)	
	3%	7%
HACCP	4,266.4 (2,151.1 – 6,372.4)	4,283.4 (2,160.3 – 6,395.5)
Sanitation SOPs	453.5 (261.0 - 674.1)	465.3 (268.1 - 690.3)
Total	4,719.9 (2,412.2 - 7,046.5)	4,748.7 (2,428.4 - 7,085.8)

*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 will 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 personnel[60] and twenty-four 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 will 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 $6,371.11[61] per inspector, and the one-week egg product inspection training is approximately $1,274.22 per inspector. Therefore, the one-time Agency training costs total approximately $355,500 (51 x $6,371.11) + (24 X $1,274.22).

Replacement inspectors will be required during periods when egg products plant inspectors are being trained. The

[60] 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.
[61] This figure is a mean estimate of training costs from FSIS/OOEET Center for Learning.

Agency's district offices estimate the cost of replacement inspectors to be $4,005.64 per person[62] for inspection methods training and $1,001.41 per person for egg products inspection training. Consequently, the one-time cost of replacement inspectors is approximately $228,300 derived from (51 x $4,005.64) and (24 X $1,001.41). Thus, the total one-time cost of training inspectors at egg products plants is $583,800. 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 Estimates	
				3% over 10 years	7% over 10 years
Inspection Methods Training	51	6.4	325.0	37.1	43.4
Egg Products Inspection Training	24	1.3	30.5	3.5	4.1
Replacement IPP	75		228.3	26.0	30.4
Total			584.0	66.6	77.8

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

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

Total Costs:

Table 15 provides a summary of the estimated total costs for the industry and Agency. The 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 Cost Estimates (Low – High)	
	3% over 10 years	7% over 10 years
Industry		
HACCP	4,266.4 (2,151.1 – 6,372.4)	4,283.4 (2,160.3 – 6,395.5)
Sanitation SOPs	453.5 (261.0 - 674.1)	465.3 (268.1 - 690.3)
Agency		
IPP Training	40.6	47.5
Replacement IPP	26.0	30.4
Total	4,786.5 (2,478.7 - 7,113.1)	4,826.6 (2,506.3 - 7,163.7)

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

Expected Benefits of the Final Rule

The final 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. Many egg products plants have already adopted the HACCP system for egg product processing. One reason for 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.

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 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. 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 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 $73.26 per hour, which includes a benefit and overhead rate of two. We assumed an Agency reviewer would have a General Schedule 13 salary, step 3, at $101.38 per hour, which includes a benefits and overhead factor of two.[63] Eliminating these submission processes will save industry approximately $65,900 annually discounted over 10 years at the 7 percent rate. The Agency will save approximately $63,000 annually discounted over 10 years at the 7 percent rate.

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

	Annualized Savings	
Total Savings	3% over 10 years	7% over 10 years
Industry	65.9	65.9
Agency	63	63
Total	128.9	128.9

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

The HACCP plan provision of the final 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

[63] Hourly rate, Washington DC, Office of Personnel Management https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2020/general-schedule/.

regulation.[64] By giving plants the option to sample as determined in their HACCP plan, there may be a cost savings from sampling less. The final 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.

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). 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

[64] 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

approvable.[65] Labels that will not qualify for generic approval include temporary approvals, labels for export only product 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 will not qualify for generic approval. However, the Agency estimates that approximately 80 percent of labels have prior approval for these claims.[66] If these prior approved producers make other changes to the labels not involving their pre-approved claims, they can also 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 will qualify for generic label approval each year. Generic approval will 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

[65] 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.

[66] This was an approximation made by a label reviewer in the FSIS labeling group.

increase in submissions. Using the industry cost savings of $26.55 per label from the Prior label Approval System: Generic Label Approval final rule[67] updated for inflation using the GDP Deflator to 2019 dollars, the final generic label approval process for egg products could save industry approximately $17,000 annually, discounted over 10 years at the 7 percent rate, from not submitting labels. The Agency will save approximately $66,000 annually, given that on average the review process takes approximately one hour, and the Agency assumed a reviewer would have a General Schedule 13 salary, step 3 at $101.38 per hour, which includes a benefits and overhead factor of two.[68]

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

	Annualized Savings	
Total Savings	3% over 10 years	7% over 10 years
Industry	17.1	17.1
Agency	65.2	65
Total	82.3	82.1

*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

[67] 78 FR 66826

[68] Hourly rate, Washington DC, Office of Personnel Management https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2020/general-schedule/.

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 final rule, FSIS inspectors will no longer provide inspection during all processing operations at each egg products plant, but instead may be provided once per shift. Therefore, under the rule, 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 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 over a 3 year period. The Agency estimates that the average salary for an egg products inspector is approximately $82,000[69] per year. Agency cost savings are reduced by an increase in travel expenses associated with patrol assignments, including mileage and additional General

[69] This salary was determined using the total savings figure provided by FSIS's Office of the Chief Financial Officer.

Services Administration (GSA) vehicles used for patrol. The Agency will also experience a loss of overhead industry paid to the Agency for overtime and holiday hours worked.

In addition to Agency savings, there will be cost savings to industry because there will be a reduction in egg products inspectors working overtime and holiday hours with the move to patrol assignments. Egg products plants will reduce the need for inspectors during hours of processing activities, including during overtime and holiday hours. FSIS estimates that egg products plants will have reduced costs for reimbursing the Agency for approximately 65,000 overtime hours and approximately 2,800 holiday hours per year[70] for the industry as a whole. The reimbursable rates to the Agency for overtime and holidays are $74.76 to $89.56 per hour, respectively.[71] The industry savings will go into effect within the first year and continue annually. Please see table 18 for a summary of total savings from the final changes in inspection coverage.

[70] The industry hours saved was derived from FSIS's Office of the Chief Financial Officer.
[71] Although 2020 rates are currently available, FSIS used the 2019 rates to estimate cost savings to be consistent with the other costs in the analysis and to not over estimate total cost savings. The 2019 dollar rates can be found here: https://www.federalregister.gov/documents/2018/12/20/2018-27521/2019-rate-changes-for-the-basetime-overtime-holiday-and-laboratory-services-rates

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

	Annualized Estimates	
Agency	3% over 10 years	7% over 10 years
Costs		
Changes in inspection coverage	1,557	1,557
Savings		
Reduction in salaries due to changes in inspection coverage	(2,172)	(2,129)
Agency Net Budget Impact	(615)	(572)
Industry		
Savings		
Elimination of inspection payments for overtime and holidays	(5,110)	(5,110)
Grand Total Net Savings	*(5,725)*	*(5,682)*

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

In summary, the benefits from this final 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. The rule provides a net cost savings of between $1.1 million and $1.2 million annualized over 10 years at the 7 percent and 3 percent rates.

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

	Annualized Costs and Net Benefits (Low – High)	
Costs	3% over 10 years	7% over 10 years
Industry		
HACCP	4,266.4 (2,151.1 – 6,372.4)	4,283.4 (2,160.3 – 6,395.5)
Sanitation SOPs	453.5 (261.0 - 674.1)	465.3 (268.1 - 690.3)
Agency		
IPP Training	40.6	47.5
Replacement IPP	26.0	30.4
Total Costs	4,786.5 (2,478.7 - 7,113.1)	4,826.6 (2,506.3 - 7,163.7)
Savings		
Industry		
Reduced Plant Approval Processes	-65.9	-65.9
Generic Labeling	-17.1	-17.1
Changes in inspection coverage	-5,110	-5,110
Agency		
Reduced Plant Approval Processes	-63.0	-63.0
Generic Labeling	-65.2	-65.0
Changes in inspection coverage	-615	-572

Total Savings	-5,936	-5,893
Grand Total Net Benefits	1,149.6 (-1,177.0 to 3,457.4)	1,066.5 (-1,270.6 to 3,386.8)

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

Alternative Regulatory Approaches

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

Voluntary HACCP regulatory program: A voluntary HACCP system will 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 will stay at status quo. Therefore, this regulatory option will not lead to a significant change in current egg products plants processing practices. However, there will 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. These patrol assignments will save industry overtime costs and Agency resources. These savings will 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 will be required to implement HACCP. This alternative will save Agency HACCP training costs for inspection personnel, who inspect small production plants. Small volume plants will be allowed to stay in a non-HACCP system, lowering industry costs. This alternative will 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 will not be gaining the flexibility to innovate that they will 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 will incur more costs from the lack of efficiency gains associated with HACCP.	Small volume producers will save on costs from not having to change their production process and develop the requisite Sanitation SOP and HACCP plans. Large volume producers will acquire benefits from implementing HACCP.
3) The Final Rule	($1.1 million[72]) 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.

Regulatory Flexibility Act (RFA)—Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), this

[72] This cost savings is annualized at the 7 percent discount rate over 10 years.

final rule will not have a significant economic impact on a substantial number of small entities in the United States.

The Agency received comments regarding the impact on small businesses, and FSIS provided responses to these comments earlier in the preamble to this final rule. Please see the "Comment and Response" section. FSIS also updated this final Regulatory Flexibility Act (RFA) assessment from the preliminary RFA assessment that was published in the proposed rule to provide additional analysis in response to comments. However, the results of the analysis are the same. While this final rule is estimated to result in cost savings for small and very small businesses, these savings are not estimated to have a significant economic impact.

In the initial RFA assessment in the proposed rule, the Agency found that at least 12 of the 77 egg products plants were larger businesses or companies with multiple egg products plants. FSIS estimates that approximately 46 plants are part of these larger companies, leaving 31 plants that could be considered small businesses.[73]

Alternatively, in response to comments, FSIS also looked at plants' HACCP sizes to assess the impact on small businesses. A plant's HACCP size can be used to categorize

[73] The Agency considered businesses that were part of a larger corporation or business network to be a large business for the purpose of this RFA.

its business size. HACCP sizes are assigned based on the number of employees and revenue: small plants have 10-499 employees and very small establishments have fewer than 10 employees or annual revenue of less than $2.5 million. Currently, FSIS inspects 81 egg products plants, 57 are HACCP size small and 15 are HACCP size very small. Regardless of how plants are categorized, the average per plant cost savings using the 3 percent mid-range estimate is approximately $5,800 per plant and at the 7 percent mid-range estimate is approximately $5,500 per plant.

Given that the final rule is expected to result in cost savings, FSIS expects small plants to benefit from the final rule. However, this benefit is not expected to be significant. The Research Triangle Institute's "2014 Egg Products Industry Survey"[74] identifies small plants as those with annual product volume of 50,000,000 pounds or less. In the survey, 83 percent of small businesses report more than $2.5 million in revenue, with nearly 22 percent reporting at least $50 million in revenue. As such, cost savings of $5,800 is less than 1 percent of revenue and is considered to have an insignificant economic impact.

[74] 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

Executive Order 13771

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), FSIS has estimated that this final rule will yield cost savings. FSIS estimates that the per plant industry cost savings using the 3 percent mid-range estimate is approximately $5,800 per plant and at the 7 percent mid-range estimate is approximately $5,500 per plant. Assuming a 7 percent discount rate, a perpetual time horizon, and a starting year of 2020, the final rule will yield approximately $1.1 million (2019$) in annualized cost savings. However, due to the potential for unquantified costs, OMB has designated this rule as an E.O. 13771 regulatory action.

Appendix A to Executive Orders 12866 and 13563 and the Regulatory Flexibility Act Analysis[75]

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

[75] 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 final 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.

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 regulated by FSIS were contacted and asked to 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: https://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 final 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
81	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
81	59	18	55	132

Breaking w/o HACCP	Dried w/o HACCP	Liquid w/o HACCP	Total Processes Operating w/o HACCP
9	4	13	26

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%	6*

*The number of plants was rounded up

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.

IV. Paperwork Reduction Act

FSIS sought, but did not receive, comments on its proposed information collection in the proposed rule (83 FR 6347). In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or record keeping requirements included in this final rule have been submitted for approval to the Office of Management and Budget (OMB). This information collection request is at OMB awaiting approval. FSIS will collect no information associated with this rule until the information collection is approved by OMB.

Copies of the information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250-3700; (202) 720-5627.

V. Executive Order 12988, Civil Justice Reform

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/Complain_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

E-*mail*: program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

IX. Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this final rule is not a "major rule," as defined by 5 U.S.C. 804(2).

X. 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 *Constituent 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.

9 CFR Part 591

Eggs and egg products, Reporting and recordkeeping requirements, Administrative practice and procedures.

For the reasons set forth in the preamble, FSIS is amending 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 processing, 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. Adding, in alphabetical order, the definition of *Inspection program personnel*.

e. Removing the definition of *Inspector/Grader* and *National Supervisor*.

f. Adding, in alphabetical order, the definition of *Official plant*.

g. Removing the definition of *Official Standard*.

h. Adding, in alphabetical order, the definition of *Official standards*.

i. Revising the definition of *Pasteurize.*

j. Removing the definition of *Plant*.

k. Revising the definition of *Processing.*

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 eggs or egg products, provided such products are prepared from inspected egg products or eggs 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.

* * * * *

Inspection program personnel 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.

* * * * *

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.

* * * * *

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 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 safe handling instructions 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 layers is exempt from the temperature and labeling requirements of this section. Such

producer-packer is still required to comply with the labeling requirements in 21 CFR 101.17(h).

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 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.

§§ 590.112, 590.114 and 590.116 [REMOVED]

22. Remove §§ 590.112, 590.114 and 590.116.

23. Revise § 590.118 to read as follows:

Performance Of Service

§ 590.118 Identification.

Inspection program personnel 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 inspection program personnel entry at all regular entrances and to all parts of the official plant and premises to which inspection program personnel are assigned.

§ 590.119 [REMOVED]

24. Remove § 590.119.

25. Revise § 590.120 to read as follows:

§ 590.120 Financial interest of inspectors.

(a) Inspection program personnel will not inspect any product in which he or she has a financial interest; or that is produced by a plant at 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 that is produced by any other person with whom inspection program personnel are negotiating or have any arrangements concerning prospective employment.

(b) All inspection program personnel 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) Inspection program personnel 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:

<u>§ 590.134 Accessibility of product and cooler rooms.</u>

* * * * *

(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 inspection program personnel in performing service.

(a) *Inspection program personnel 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 inspection program personnel 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 inspection program personnel to change clothing. At the discretion of the Administrator, small official plants requiring the services of less than one full-time inspector need not furnish accommodations for inspection program personnel 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 inspection program personnel) 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) of this chapter.

(b) Before receiving Federal inspection, a plant must conduct a hazard analysis, and develop and implement a HACCP plan, in accordance with part 417 and § 591.1(a) of this chapter. A conditional grant of 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:

<u>§ 590.160 Clean Water Act; refusal, suspension, or withdrawal of service.</u>

(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:

<u>§ 590.200 Records and related requirements.</u>

(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 layers 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:

<u>§ 590.300 Appeal inspections.</u>

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:

<u>§ 590.310 Appeal inspections; how made.</u>

Any appeal from the inspection decision by inspection program personnel must be made to the 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 inspection program personnel'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 inspection program personnel's decisions, as requested in § 590.310, must be performed by inspection program personnel of FSIS other than the one who made the initial decision.

39. Revise § 590.350 to read as follows:

§ 590.350 Appeal samples.

A condition 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 and microbial pathogen-positive 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:

<u>§ 590.411 Label approval.</u>

(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 412.1, 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 contents;

(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 turkeys, ducks, geese, or guineas must be clearly and distinctly labeled with the common or usual name of the product and 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.

(7) Egg products which are produced in an official plant from edible shell eggs of other than current production or from other egg products of shell eggs of other than current product must be clearly and distinctly labeled

in close proximity to the common or usual name of the product, e.g., Manufactured from eggs of other than current production."

(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:

<u>§ 590.412 Approval of generic labels.</u>

(a) All official plants, including official plants certified under a foreign inspection system in accordance with § 590.910, may comply with the requirements in 9 CFR 412.2.

(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:

<u>§ 590.413 Form of official identification symbol and inspection mark.</u>

(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."[76]

Figure 1.

[76] The number "42" is given as an example only. The plant number of the official plant where the product was inspected must be shown on each label.

(b) [Reserved]

46. Revise § 590.415 to read as follows:

§ 590.415 Use of other official identification.

All unpasteurized or microbial pathogen-positive egg products shipped from an official plant must be marked with the identification set forth in Figure 1 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 produce egg products that are edible without additional preparation to achieve food safety. 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 produce egg products that are edible without additional preparation to achieve food safety. After pasteurization or treatment, the product may bear the official inspection mark as shown in § 590.413.[77]

[77] The number "42" is given as an example only. The plant number of the official plant where the product was inspected must be shown on each label.

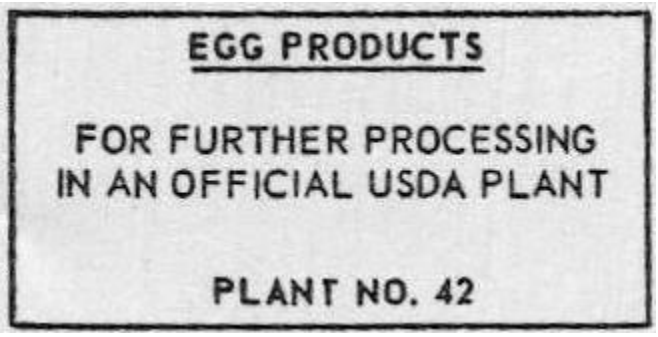

Figure 1.

§ 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 § 590.424 by revising paragraph (b) to read as follows:

§ 590.424 Reinspection.

* * * * *

(b) All egg products brought into any official plant shall be identified by the operator of the official plant at the time of receipt at the official plant and shall be subject to reinspection by inspection program personnel at the official plant in such manner and at such times as may be deemed necessary to ensure compliance with the regulations in this part. Upon reinspection, if any such product or portion of it is found to be unsound, unwholesome, adulterated, or otherwise unfit for human food, such product or portion shall be condemned and shall receive such treatment as provided in § 590.422, and shall, in the case of other products, be disposed of according to applicable law.

51. 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 they are 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.

52. Revise § 590.435 to read as follows:

§ 590.435 Use of food ingredients and approval of materials.

(a)(1) No substance which is a "food additive" as defined under 21 U.S.C. 321(s), including sources of radiation, may be used in the processing of egg products unless this use is authorized under the Federal Food, Drug, and Cosmetic Act.

(2) No substance which is intended to impart color in any egg product may be used unless such use is authorized under the Federal Food, Drug, and Cosmetic Act.

(3) Substances and ingredients used in the processing of egg products capable of use as human food must be clean, wholesome, and unadulterated.

(b) Substances permitted for use in egg products in subsection(a) 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) Substances 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. Such substances 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 inspection program personnel.

53. 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]

54. Remove §§ 590.500 and 590.502.

55. 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 done in a sanitary manner.

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

(2) Any eggs and egg products not processed in accordance with the regulations in this part or part 591 or that are not otherwise fit for human food must 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 FDA-approved 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) Undenatured egg products or inedible egg products that are not decharacterized 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 or microbial pathogen-positive 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 produce egg products that are edible without additional preparation to achieve food safety in the second official plant. Official plants must maintain control of shipments of unpasteurized or microbial pathogen-positive egg products shipped from one official plant to another official plant for pasteurization or treatment. Shipping plants must seal such shipments in cars or trucks and label

them in accordance with § 590.410(c). Containers of unpasteurized or microbial pathogen-positive egg product must be marked with the identification mark shown in Figure 2 of § 590.415.

(e) Inspection program personnel may allow an official plant to move egg products that have been sampled and analyzed for *Salmonella*, or for any other reason, before receiving the test results, if they do not suspect noncompliance by the plant with any provisions of this part. The official plant must maintain control of the products represented by the sample pending the results.

§ 590.506 [REMOVED]

56. Remove § 590.506.

57. 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.

58. 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:

* * * * *

<u>§ 590.515 [REMOVED]</u>

59. Remove § 590.515.

60. 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]

61. Remove § 590.520.

62. Revise § 590.522 to read as follows:

§ 590.522 Egg products processing room operations.

Each egg 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]

63. Remove §§ 590.530 and 590.532.

64. 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]

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

66. Revise § 590.570 to read as follows:

§ 590.570 Control of pathogens in pasteurized egg products.

Pasteurized 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. Pasteurized 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]

67. Remove § 590.575.

68. 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 by the official plant 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 frequency and using such laboratory methods as is sufficient to ensure that product is not adulterated. For each category of product, sampling should be conducted on a rotating basis.

(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.

69. Add § 590.590 to read as follows:

<u>§ 590.590 Use of irradiated shell eggs to produce egg products.</u>

Irradiated shell eggs used to produce pasteurized egg products must be used in conjunction with heat or another lethality treatment sufficient to produce egg products that are edible without additional preparation to achieve food

safety. 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]

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

71. 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 or 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 or 590.720.

72. Add § 590.720 to read as follows:

§ 590.720 Disposition of restricted eggs.

(a) Except as exempted in § 590.100, eggs classified as checks, dirts, 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 dirts 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 dirts.

(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)(1). 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 handled 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.

(4) By coloring the shells of loss and inedible eggs with a sufficient amount of an FDA-approved color additive 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)(1) 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.

73. Add § 590.801 to read as follows:

<u>§ 590.801 Nest-run or washed ungraded eggs.</u>

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]

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

75. 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 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 egg 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).

<u>§ 590.901 Egg products offered for entry and entered to be handled and transported as domestic; entry into official plants; transportation.</u>

(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 egg products into the United States.

(a) Whenever it is determined by the Administrator that the system of egg products inspection maintained by any foreign country is such that the egg products produced in such country are processed, labeled, and packaged in accordance with, and otherwise comply with, the standards of the Act and these regulations including, but not limited to the same sanitary, processing, facility requirements, and Government inspection as required in §§ 590.500 through 590.580 applicable to inspected articles produced within the United States, notice of that fact will be given according to paragraph (b) of this section. Thereafter, egg products from such countries shall be eligible for importation into the United States subject to the provisions of this part and other applicable laws and regulations. Such product must meet, to the extent applicable, the same standards and requirements that apply to comparable domestic product as set forth in these regulations. Egg products from foreign countries not deemed eligible in accordance with paragraph (b) of this section are not eligible for importation into the United States, except as provided by § 590.960. In

determining if the inspection system of a foreign country is the equivalent of the system maintained in the United States, the Administrator shall review the inspection regulations of the foreign country and make a survey to determine the manner in which the inspection systems are administered within the foreign country. After approval of the inspection system of a foreign country, the Administrator may, as often and to the extent deemed necessary, authorize representatives of the Department to review the system to determine that it is maintained in such a manner as to be the equivalent of the system maintained by the United States.

(b) A list of countries eligible to export egg products to the United States is maintained at *http://www.fsis.usda.gov/importlibrary*.

§ 590.915 Imported products; foreign inspection certificates required.

(a) Except as provided in §§ 590.960 and 965, 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 inspection program personnel.

(d) The paper foreign inspection certificate must accompany each consignment; be submitted to inspection program 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 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 inspection program personnel before they may be allowed entry into the United States.

(2) Every lot of product must routinely be given visual reinspection by inspection program personnel for appearance and condition and be checked for certification and label compliance as provided in §§ 590.915, 590.950, and 590.955.

(3) Inspection program personnel 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) Inspection 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 commerce of the United States.

§ 590.930 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 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 program inspectors 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.

[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.

(d) No brand manufacturer or other person will cast or otherwise make, without an official certificate issued by inspection 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 inspection if the containers are being inspected by inspection program personnel who report 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.

<u>§ 590.945 Egg products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.</u>

(a)(1) Inspection 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," inspection 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 program inspectors 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 a program inspector relating to any inspection, file an appeal from such decision. Any such appeal from a decision of a program

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).

<u>§ 590.950 Labeling of immediate containers of egg products offered for entry.</u>

(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, if applicable,;

(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) The date of production and the 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.

<u>§ 590.955 Labeling of shipping containers of egg products offered for entry.</u>

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) 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 marked egg 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

76. Add part 591 to read as follows:

PART 591 - SANITATION REQUIREMENTS AND HAZARD ANALYSIS AND CRITICIAL 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 part 416, Sanitation, except as otherwise provided in this chapter.

(b) All official plants must comply with the requirements contained in 9 CFR part 417, Hazard Analysis and Critical Control Point (HACCP) Systems, except as otherwise provided in this chapter.

(c) 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.

(a) 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 may render the products produced under those conditions adulterated.

(b) Pursuant to 21 U.S.C. 1035 and 1043, the failure of an official plant to operate in accordance with the

requirements in 9 CFR part 416, Sanitation, may render the products produced under those conditions adulterated.

(c) Pursuant to 21 U.S.C. 1035 and 1043, the failure of an official plant to operate in accordance with the requirements in 9 CFR part 417, Hazard Analysis and Critical Control Point (HACCP) Systems, may render the product produced under those conditions adulterated.

(d) Pursuant to 21 U.S.C. 1035 and 1043, the failure of an official plant to operate in accordance with the requirements in 9 CFR part 500, Rules of Practice, and 590, Inspection of Eggs and Egg Products (Egg Products Inspection Act) may render the products produced under those conditions adulterated.

Done at Washington, DC, on:

Paul Kiecker,
Administrator.