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

FSIS NOTICE

63-22

10/26/22

REVISED - PROFILE AND REGULATORY UPDATES IN DOMESTIC EGG PRODUCTS PLANTS IMPLEMENTING THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM REQUIREMENTS

I. PURPOSE

This notice cancels FSIS Notice 47-21, *Profile Updates in Domestic Egg Products Plants Implementing Sanitation Standard Operating Procedures or That Opt-In Early to Implement the Hazard Analysis and Critical Control Point System Requirements* and provides updated instructions for District Office (DO) personnel and inspection program personnel (IPP) to update plant information in the Public Health Information System (PHIS) for egg products plants for implementation of the Hazard Analysis and Critical Control Point (HACCP) requirements (<u>9 CFR part 417</u>). This notice also provides instructions to update the Establishment Profile product groups for egg product plants to ensure that accurate product groups are selected in the Establishment Profile and provides instructions for IPP to verify the revised regulatory requirements as instructed in <u>FSIS Directive</u> 5000.1, *Verifying an Establishment's Food Safety System*. IPP are to note that in PHIS they will see the term "establishment" used for egg product plants.

II. BACKGROUND

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

B. On October 31, 2022, all egg products plants are required to meet the requirements of 9 CFR 417 (HACCP). The PHIS changes made through the instructions below will prompt PHIS to assign the appropriate inspection tasks to those plants, so IPP can document verification of HACCP requirements.

NOTE: IPP assigned to egg products plants that were approved to opt-in early to implement the HACCP requirements will only need to verify the HACCP processing categories for accuracy. IPP are to follow the instructions under Section IV, V, and VI below, to update PHIS if the establishment profile has not been updated so that the applicable HACCP processing categories are accurate.

DISTRIBUTION: Electronic	NOTICE EXPIRES: 11/1/23	OPI: OPPD

III. RESPONSIBILITIES FOR VERIFYING THE GRANT OF INSPECTION PAGE

IPP are to review the plant grant information in PHIS with the appropriate HACCP processing categories, to verify the products produced are identified correctly. When a product is not identified correctly, IPP are to update the product groups. When a HACCP processing category is not identified correctly, IPP are to contact the DO through the Frontline Supervisor (FLS). The DO personnel are to follow the procedures from the PHIS Establishment Profile User Guide for Headquarters and District Office Personnel included as Attachment 1 to enter the HACCP processing categories information into the applicable field on the grant of inspection page. DO personnel are to enter all of the information on the grant page because it is necessary for PHIS to generate the appropriate tasks.

IV. IPP RESPONSIBILITIES FOR VERIFYING THE ESTABLISHMENT'S FOOD SAFETY SYSTEM

A. IPP are to follow the instructions in <u>FSIS Directive 5000.1</u>, to verify an egg products plant's compliance with the Sanitation SOP and other sanitation requirements of <u>9 CFR 416</u> and the HACCP requirements of <u>9 CFR 417</u>.

B. IPP are to verify the revised and new regulatory requirements listed in <u>Attachment 3</u> using the HACCP methodology from <u>FSIS Directive 5000.1</u>. Instructions for how to verify each specific <u>9 CFR part 590</u> regulation listed in <u>Attachment 3</u> are not included in <u>FSIS Directive 5000.1</u> because these regulations are not routinely verified by IPP. However, similar to meat and poultry (e.g., <u>9 CFR part 304</u>, or <u>381.22</u>) these regulations are foundational requirements that relate to the establishment's HACCP system and when IPP determine the establishment is in compliance with 9 CFR part 416 and 417, the establishment is generally also in compliance with the listed 9 CFR part 590 regulations.

EXAMPLE: IPP verify the establishment's HACCP system is designed and implemented in a manner to effectively consider biological hazards including *Salmonella* in the pasteurized egg products produced at the establishment. IPP gather information, assess the significance of their observations, and determine the establishment is operating in compliance with 9 CFR part 417. In this example scenario, the establishment is also in compliance with 9 CFR 590.570 because the establishment has incorporated the performance standard that the pasteurized egg product must be edible without additional preparation to achieve food safety into the HACCP system.

V. IPP RESPONSIBILITIES FOR ENTERING HACCP SYSTEM INFORMATION TO UPDATE PROFILE INFORMATION

A. IPP are to access the USDA FSIS PHIS Establishment Profile User Guide, by clicking on IPP Help and selecting the PHIS Help icon, for instructions to record HACCP information and product information for all products produced by the plant as referenced below in Table 1.

B. IPP are to verify and enter the plant's HACCP plan information in the PHIS establishment profile. IPP are to navigate to the PHIS establishment profile, HACCP menu, HACCP plans page. The HACCP Plans page has two tabs: Summary and HACCP Plans. IPP are to review the plans listed on the Summary tab and verify the information is accurate when plans are already listed on this tab. IPP are to click on 'Add a HACCP Plan' on the HACCP Plan tab of the page to enter new HACCP plan details. IPP are to complete the following information in PHIS for the plant's HACCP plan:

- 1. Name the HACCP plan in the Plan Name text box. If the plant does not title their HACCP plan, identify it using a name that other FSIS personnel can use to identify the plan easily (e.g., Heat Treated Shelf-Stable Dried Whole Egg HACCP Plan);
- 2. In the Signature Date field, enter the most recent date of the HACCP plan;

- In the Processing Category field, select the appropriate HACCP processing categories for each HACCP plan. FSIS defines HACCP processing categories (<u>9 CFR 417.2</u>) based on food science principles. <u>Attachment 2</u> of this notice describes the HACCP processing categories applicable for egg products plants; and
- 4. Enter a brief description of the lot definition by selecting +Add Comments to access the Comments text box.

NOTE: FSIS does not require plants to identify any of their HACCP systems information or other documentation using the list of PHIS categories.

C. IPP are to refer to <u>Attachment 1</u> for more detailed instructions on how to add HACCP information to the Establishment Profile.

VI. IPP RESPONSIBILITIES FOR UPDATING PROFILE INFORMATION ON PRODUCT INFORMATION

A. IPP are to click on the "Products" menu of the Establishment Profile and verify the products listed in PHIS during the Update Establishment Profile tasks assigned before October 21, 2022. IPP are to add or edit the products to complete *Finished Product Type*, *Finished Product Category*, *Product Group*, and *Product Group Details* (average daily volume information and number of days of production) for each of the plant's product types. Table 1 below contains a list of product groups available in PHIS for egg products plants as they relate to the HACCP processing category and finished product categories. IPP are to enter all product groups that apply to a specific plant's operations by checking the appropriate boxes. IPP are to verify the HACCP information before attempting to enter products. The HACCP Plan Name is a required field for a new product. Additional information on processing categories is found in Attachment 2.

TABLE 1: PHIS Product Category List (Egg Products Plants)			
HACCP Processing Category	Finished Product Category	Finished Product Type	Product Group
Raw Non- Intact	Raw non- intact egg products	Raw (Unpasteurized bulk or packaged)	 Whole eggs or Yolks (<2% added ingredients) Egg Yolk (with or without ingredients) Whole eggs with added yolks (with >2% salt or sugar) Egg whites (w/wo added ingredients) Egg products (blends of whole egg, egg whites, and/or yolks w/wo added ingredients) Spray-dried egg whites (w/wo added ingredients) Pan-dried egg whites

	RTE fully cooked egg products		 Whole eggs or yolks (<2% added ingredients) Egg Yolk (with or without added ingredients) Egg products (blends of whole egg, egg whites, and/or yolks) Whole eggs with added yolks (w >2% added salt or sugar) Whole egg or yolks (w/ >2% salt or sugar) Egg whites (w/wo added ingredients)
Fully Cooked – Not Shelf Stable	RTE egg product fully cooked w/o subsequent exposure to environment	RTE (Pasteurized bulk or packaged)	
Heat Treated – Shelf Stable	RTE dried egg products	RTE (Pasteurized Dried Egg Products)	 Egg yolk (with or without added ingredients) Egg products (blends of whole egg, egg whites, and/or yolks Whole eggs w/ added Yolks (w >2% salt or sugar) Spray-Dried Egg Whites (w/wo added ingredients) Whole Eggs or Yolks (<2% added ingredients) Pan Dried Egg Whites

- B. IPP are to ensure that any production data in the obsolete product groups filter field listed under the Eggs/Egg Products category is accurately entered as the appropriate product group, associated with the applicable HACCP Processing category, listed in Table 1 above before October 31, 2022. IPP are to select the product group entry in the profile that corresponds to a HACCP processing category in Attachment 2. IPP are to then select the appropriate volume category based on the average daily volume for the product group and the number of production days per month.
- C. IPP are to select the trashcan icon to delete obsolete product groups under the Eggs/Egg Products category during the next Update Establishment Profile Task after October 31, 2022.
- D. IPP are to enter or update each product group that corresponds to a product the plant produces for shipment.
- E. IPP are to also select the average daily volume (in pounds) from the drop down on the "HACCP Volumes" tab of the Products page.

VII. IPP RESPONSIBILITIES FOR SELECTING NEW PHIS TASKS

- A. Approximately 24 hours after the profile changes described above have been made, IPP are to review the Establishment Profile Inspection Tasks menu to verify that one or more of the following inspection tasks appear in the Inspection Tasks page which corresponds to the HACCP information recorded in the profile:
 - 1. Raw Non-Intact HACCP task;
 - 2. Fully Cooked-Not Shelf Stable HACCP task;

- 3. Heat Treated-Shelf Stable HACCP task; and
- 4. Hazard Analysis Verification (HAV) task.
- B. IPP are to verify that the inspection tasks identified under A above are selected on the Inspection Task page of the profile for all egg products plants prior to October 31, 2022. IPP are to verify the Grant information, HACCP plans, and products listed in the establishment profile if the inspection tasks are not listed 48 hours after the fields are updated and contact their supervisor if the information in the profile is accurate, but the tasks are not listed.
- C. IPP are to refer to <u>FSIS Directive 13,000.1</u>, *Scheduling In-Plant Inspection Tasks in PHIS* for additional information about managing inspection tasks in PHIS.

VII. QUESTIONS

Refer questions regarding this notice to your supervisor or as needed to the Office of Policy and Program Development through <u>askFSIS</u> or by telephone at 1-800-233-3935. When submitting a question, complete the <u>web form</u> and select General Inspection Policy for the inquiry type.

NOTE: Refer to <u>FSIS Directive 5620.1</u>, Using askFSIS, for additional information on submitting questions.

Assistant Administrator

Office of Policy and Program Development

Kachel a. Edelstein

Users

In order to completely set up an establishment and its profile, different users will be required to enter the relevant information according to the table below. Table 1 lists the role and the process that role can complete.

Table 1: Roles and Processes

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Role	Process
Grant Curator (Domestic &	Add Establishment, Update/Edit Application for
Import)	Federal Inspection
Consumer Safety Inspector Frontline Supervisor Public Health Veterinarian District Manager (DM)/Deputy District Manager (DDM)	Enter Establishment Profile
Resource Management Assistant (Domestic-OFO) or RMPS (HQ) DM/DDM	Create and Edit Assignments

Access PHIS

PHIS is a Web-based application that you access through a Web browser, such as Microsoft Edge. Your computer must be connected to the FSIS network, via VPN or direct connection for this task.

To access PHIS (using LincPass):

- 1. Open a Web browser and navigate to https://phis.fsis.usda.gov, or click Start > FSIS Applications > USDA FSIS PHIS Online.
- 2. The PHIS Dashboard opens.

To access PHIS (using eAuthentication):

- Open a Web browser and navigate to https://phis.fsis.usda.gov, or click Start > FSIS Applications > USDA FSIS PHIS Online
- 2. Enter your eAuthentication user name or password.
- 3. Click Login. The PHIS Dashboard opens.

Update/Edit Application for Federal Inspection

A user with the Grant Curator (Domestic & Import) user role to update/edit grant of inspection information can follow these steps:

- 1. Log in as a Grant Curator.
- 2. Click Establishment Profile to open Establishment page, in the Establishment Search box, enter the establishment number or all or part of the establishment name. Select Search. PHIS displays matching records on the All Establishment tab.

- 3. Click on the 'Open' icon for the applicable establishment selected to display the Profile Summary page.
- 4. From the menu select 'Grants' to open Grants and Voluntary Reimbursable Services page
- Select the 'Egg' tab and scroll down on page to 'Types of Product' (HACCP Processing Categories) and click the box on the applicable HACCP Processing Categories: Fully Cooked – Not Shelf Stable, Heat Treated – Shelf Stable, Raw – Non-Intact
- 6. Select Save Profile.

NOTE: For plants that produce 'Raw Non-Intact products', the 'Egg Breaking' box needs to be selected also, under the 'Types of Products' (HACCP Processing Category), as this directly impacts residue sampling algorithm.

Access Establishment Profile

A user with one of the following roles can access the Establishment Profile page: Consumer Safety Inspector, Public Health Veterinarian or Frontline Supervisor.

- 1. Log in using the appropriate role (e.g., Consumer Safety Inspector).
- 2. Click on Establishment Profile > Select Establishment.
- 3. Enter the establishment number in the Search by Est.Number field and click the red colored magnifying glass icon 'Search'. PHIS displays matching records on the tab. IPP can enter G followed by the establishment number in the search box if necessary to refine the search. Identify the plant and click the 'open' icon. This will take you to the Profile Summary page.

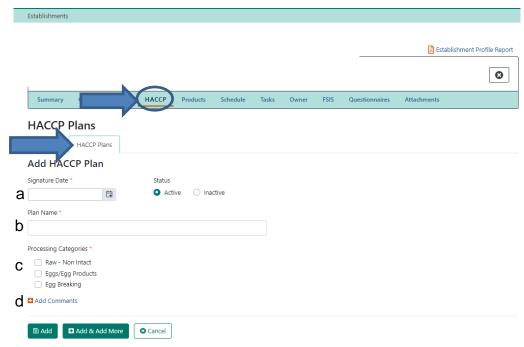
Add HACCP Plans

In order for you to be able to add Product Groups, which are necessary for certain tasks to be distributed, you must first enter the applicable HACCP plans. When you add a HACCP Plan, you identify the HACCP Processing Categories necessary for Product Groups.

There are two sections on the HACCP Plans page: Summary and HACCP Plans. Summary, which lists the HACCP Processing Categories, number of HACCP plans, Average daily volumes and Grant(s) specific to the establishment. The Summary section is updated whenever you add a new HACCP Plan. You must enter HACCP Plan data in order to add product groups.

To add a HACCP Plan:

- 1. Log on to PHIS.
- 2. Click Establishment Profile > Select Establishment.
- 3. Search for and select the establishment.
- 4. Click HACCP.
- 5. Click HACCP Plans tab.
- 6. Click +Add HACCP Plan



- 7. Enter the required information as shown in above screenshot.
 - a. Signature Date *
 - b. Plan Name *
 - c. Processing Category* (choose from Fully Cooked Not Shelf Stable, Heat-Treated – Shelf Stable, or Raw – Non-Intact)
 - d. Click +Add Comments to include Lot Definitions (e.g., clean up to clean up, day's production)

NOTE: *(asterisk) indicates mandatory field

- Click Add. PHIS adds the record to the grid.
 A message appears that the plan has been added successfully.
- 9. To enter additional HACCP plan(s) IPP are to select the Add & Add More. Repeat steps 1-7 for each hazard analysis you want to add.

Enter Products

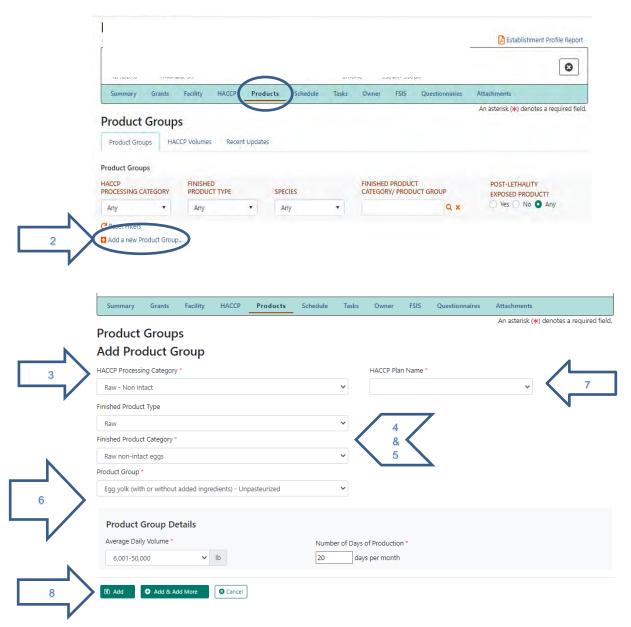
Product Groups must be added in PHIS before tasks can be distributed. Data on the HACCP Processing page is needed in order to add a new product group. For consistency in entering products and product volume review the information in FSIS Directive 5300.1.

To enter products (follow these steps as illustrated in the screenshots below):

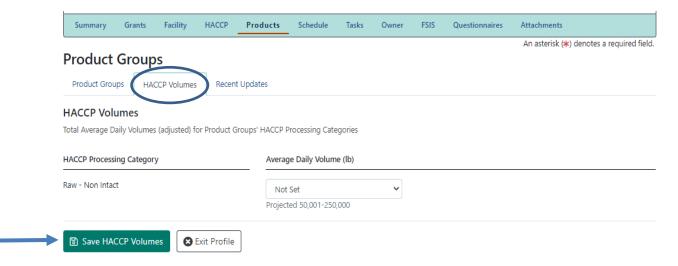
- 1. Click Establishment Profile > Select Establishment > Products.
- 2. Click Add a new Product Group.
- 3. Complete the required field for the HACCP Processing Category* and select the appropriate category.
- 4. After selecting the HACCP Processing category, the Finished Product type* and Finished Product Category* will appear.
- 5. From the drop down menu select the Finished Product Type and Finished Product Category, once completed the Product Group* box will appear.

- 6. Select each Product Group that applies and then choose a volume from the Average Daily Volume* (pounds per day) fields and enter the Number of Days of Production*.
- 7. Choose the appropriate HACCP Plan Name*.
- 8. Click Add. To enter additional Product Groups IPP are to select the Add & Add More and repeat steps above for each product group.

NOTE: IPP are to review the plant's records that are available and have a bearing on the plant's production volume. IPP may need to consult with plant management for this information, if few or no records exists. If unsuccessful and the volume data is not known, IPP are to select the highest volume range.



^{*}Screenshot example for Raw – Non-Intact egg products



- 9. Click on HACCP Volumes tab and select the value for each HACCP Processing Category for the Average Daily Volume from the drop down menu.
- 10. Click Save HACCP Volumes.

HACCP PROCESSING CATEGORIES FOR EGG PRODUCTS

- A. **Raw Non-Intact**: This HACCP processing category applies to plants that break shell eggs and manufacture unpasteurized raw egg products. These products may include finished products, such as unpasteurized liquid eggs with no ingredients added.
- B. **Fully Cooked Not Shelf Stable**: This HACCP processing category applies to establishments that further process unpasteurized or pasteurized liquid egg products by using primarily a lethality heat process step (e.g., pasteurization) to achieve food safety. The finished products (pasteurized liquid with or without ingredients) that establishments produce under this HACCP processing category are not shelf stable. FSIS requires the products to be frozen or refrigerated for food safety purposes.
- C. **Heat Treated Shelf Stable**: This HACCP processing category applies to establishments that further process unpasteurized or pasteurized liquid egg products by using a heat treatment processing step to achieve food safety. The finished products (dried egg products and some liquid egg products) produced under this HACCP processing category are considered pasteurized, as well as shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes.

Old Regulation	Type of	New Regulation	Regulatory Change
	Change		, , ,
9 CFR 417.7(b)	Revised	9 CFR 417.7(b)	Under the final rule, individuals performing the functions listed in paragraph (a) of 9 CFR 417.7 shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat, poultry, or egg products processing, including training on the development of a HACCP plan for a specific product and on record review.
	Added	9 CFR 590.149(b) and (c)	The final rule added 9 CFR 590.149(b) and (c) to the egg products inspection regulations and requires egg products plants to conduct a hazard analysis, and develop and implement a HACCP plan per part 417 and 9 CFR 591.1(a) before they may receive Federal inspection. A 90-day conditional grant of inspection during which the facility must validate its HACCP plan may be provided. Before producing a new product for distribution in commerce, egg products plants must also conduct a hazard analysis and develop a HACCP plan applicable to that product in accordance with 9 CFR 417.2. The HACCP plan must be validated during a period not to exceed 90 days after the new product is produced for distribution in commerce.
	Added	9 CFR 590.504(d)(1)	The final rule added paragraph (d)(1) to 9 CFR 590.504, which requires egg products to be processed to meet the performance standard set out in 9 CFR 590.570.
9 CFR 590.504(g)	Removed	9 CFR 590.504(a)	The final rule eliminated the egg products requirement that products or materials that create an objectionable condition not be processed, stored, or handled in any place where eggs or egg products are processed, stored, and replaced it with the egg products requirement that egg products operations be done in a sanitary manner.

9 CFR 590.504(j) 9 CFR 590.504(l)	Removed	9 CFR 590.435(b) 9 CFR 590.420(a)	The final rule eliminated the egg products requirement that substances and ingredients used in the processing of egg products capable of human food to be clean, wholesome, and unadulterated from 9 CFR 590.504(j) and replaced it with the same text in 9 CFR 590.435(a)(3). The final rule eliminated the egg
		9 CFR 590.504(b)(1)	products requirement that egg products be inspected to determine the wholesomeness of the finished product from 9 CFR 590.504(I) and replaced it with text in 9 CFR 590.420(a) and 9 CFR 590.504(b)(1) requiring inspection in plants processing egg products or making such plants subject to inspection.
9 CFR 590.504(o)	Revised	9 CFR 590.504(d)(1)	The final rule revised 9 CFR 590.504(o) and redesignated it as 9 CFR 590.504(d)(1), which requires egg products to be processed to meet the performance standard set out in 9 CFR 590.570.
9 CFR 590.504(o)(1)	Revised	9 CFR 590.580(b)(2)	The final rule revised 9 CFR 590.504(o)(1) and redesignated it as 9 CFR 590.580(b)(2), which requires the analysis of samples for Salmonella spp. with such frequency and using such laboratory methods as is sufficient to ensure that product is not adulterated. For each product, sampling should be conducted on a rotating basis.
9 CFR 590.504(o)(2)	Revised	9 CFR 590.504(d)(2)	The final rule revised 9 CFR 590.504(o)(2) and redesignated it as 9 CFR 590.504(d)(2), which permits the shipment of unpasteurized or microbial pathogen-positive products 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 plant, provided control of such shipments is maintained between official plants. Shipments must be labeled

			in accordance with 9 CFR 590.510(c) and containers must be marked with the identification mark shown in Figure 2 of 9 CFR 590.415.
9 CFR 590.504(o)(3)	Removed	9 CFR 590.504(c)(2) 9 CFR 590.504(d)(2)	The final rule eliminated 9 CFR 590.504(o)(3), which permitted unpasteurized salted egg products containing 10 percent or more salt added to be shipped from an official plant directly to a manufacturer of acidic dressings. Such product 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 may also move from one official plant to a second official plant for further processing.
9 CFR 590.530(a) and (e)	Removed	9 CFR 416.2(b) 9 CFR 416.4(a) 9 CFR 416.4(b) 9 CFR 416.12–416.16 9 CFR 417.2(a) 9 CFR 417.5(a)(1)	The final rule eliminated the egg products liquid egg cooling requirements and replaced them with SPS construction requirements, food-contact surface requirements, and non-food contact surface requirements. It also replaced the egg products requirements with the Sanitation SOPs requirements prohibiting direct contamination and requiring that product be protected from adulteration during processing.
9 CFR 590.530(b)	Removed	9 CFR 416.4(d) 9 CFR 416.12–416.16 9 CFR 417.2(a) 9 CFR 417.5(a)(1)	The final rule eliminated the egg products requirement that compliance with temperature requirements for cooling liquid eggs is satisfactory only if the entire mass of the liquid meets the requirements.
9 CFR 590.530(c) and (d)	Removed	9 CFR 416.4(d) 9 CFR 416.12–416.16 9 CFR 417.2(a) 9 CFR 417.5(a)(1)	The final rule eliminated specific egg products liquid egg cooling and temperature requirements and the requirement that agitators be operated such that foaming will be minimized. It replaced these with the sanitation standard performance requirements that product be protected from adulteration during processing. It also replaced the egg products requirements with the Sanitation SOPs requirements prohibiting direct contamination and requiring that product be protected from

9 CFR 590.570(b)	Removed	9 CFR 590.570	adulteration during processing. It also eliminated the egg products provision allowing liquid cooling and holding temperatures not otherwise provided for to be used and replaced it with the SPS requirement that product be protected from adulteration during processing. The final rule eliminated the time/temperature pasteurization requirements for egg products found in 9 CFR 590.570(b) and
			replaced them with a performance standard.
9 CFR 590.575	Removed	9 CFR 590.570	The final rule eliminated the heat treatment requirements for dried egg whites found in 9 CFR 590.575 and replaced them with the performance standard found in 9 CFR 590.570.
9 CFR 590.580(d)	Revised	9 CFR 590.580(b)(1)	The final rule eliminated 9 CFR 590.580(d) and replaced it with 9 CFR 590.580(b)(1) to require the sampling and analysis of pasteurized liquid, frozen, and dried egg products for the presence of Salmonella spp. to ensure adequate pasteurization. This testing must be performed in such a way that it is possible for the official plant to verify that the system is capable of eliminating Salmonella spp.
	Added	9 CFR 591.1(b)	The final rule added 9 CFR 591.1(b) to the egg products inspection regulations requiring all official plants to comply with the HACCP Systems requirements contained in part 417, except as otherwise provided.
	Added	9 CFR 591.2(a)	The final rule added 9 CFR 591.2(a) to the egg products inspection regulations stating that the failure of an official plant to develop and implement a HACCP plan that complies with part 417 may render the products produced under those conditions adulterated.
	Added	9 CFR 591.2(c)	The final rule added 9 CFR 591.2(c) to the egg products inspection regulations stating that the failure of an official plant to operate in accordance with the

HACCP Systems requirements in
part 417 may render the products
produced under those conditions
adulterated.