UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC

FSIS DIRECTIVE

5030.2

4/17/14

MANAGING THE ESTABLISHMENT PROFILE IN THE PUBLIC HEALTH INFORMATION SYSTEM (PHIS) FOR EGG PRODUCTS INSPECTION

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL MAY 4, 2014

CHAPTER I - GENERAL

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) responsible for maintaining information in PHIS at egg products plants, which are governed by the regulatory requirements of 9 CFR 590 and 592. IPP are to note that in PHIS they will see the term "establishment" used for egg product plants.

KEY POINTS:

- Inspection procedures have changed because of the implementation of PHIS, which has replaced the Performance Based Inspection System (PBIS);
- The directive provides instructions to IPP on how to access PHIS;
- The directive provides instructions on Establishment Profile information recorded in PHIS; and
- The directive provides instructions on the Plants Operational Schedules, Facilities and Equipment, Plant Task List, Production Volume, FSIS Sampling results, and other PHIS profile features.

II. BACKGROUND

PHIS is a web-based Information Technology (IT) system used by IPP for reporting detailed information regarding inspection activities, noncompliance reports, and other inspection-related matters, such as microbiological sampling requests and results. PHIS replaced the functions of the Performance-Based Inspection System (PBIS), which was used extensively by IPP located in meat and poultry establishments. IPP in official egg products plants also used PBIS but for limited functions related to inspection activities (i.e., food defense). Agency personnel that were responsible for maintaining information in PBIS will remain responsible for maintaining the same information in PHIS. Existing and future IT programs will integrate seamlessly with PHIS to allow authorized users to analyze inspection data in conjunction with other electronic data sources available to the Agency.

III. HOW TO ACCESS PHIS

A. PHIS is accessible from the following link on the FSIS website: <u>https://phis.fsis.usda.gov</u>. All PHIS

DISTRIBUTION: Electronic

users are to provide a level 2 eAuthentication User ID and password in order to access PHIS. IPP can also access PHIS on any FSIS standard-loaded computer by selecting PHIS from the "Start" menu under FSIS applications.

B. PHIS is a role-based system where IPP access roles are dependent upon their work assignments and duties. The access roles assigned to IPP, serve to permit or restrict IPP access to PHIS data and functionality. For example, an import inspector can only edit profile information for the official import inspection establishments in his or her assignment based on his or her prescribed user role. It is possible for IPP to have more than one PHIS user access role. For example, a PHV may also conduct tasks assigned to a CSI. PHIS user roles are created by the PHIS Administrator and are assigned by the District Office (DO).

IV. INSPECTOR HOMEPAGE

A. The inspector homepage is the first screen that PHIS displays to IPP users after they have successfully accessed the system. The homepage contains the following three tabs: *My Dashboard, My Establishments, and My Inspections and Samples.* Each tab displays information pertinent to the user's inspection assignments and user roles.

B. PHIS does not present information on the inspector homepage to users who are not field personnel.

V. ESTABLISHMENT PROFILE

A. The "Establishment Profile" is a left navigation menu option that appears after logging into PHIS. The establishment profile is a series of webpages that IPP use to enter data about official plants, official import inspection establishments, and other facilities where FSIS provides inspection services. The profile includes information on the egg products produced, the processes performed, the equipment employed, the food safety system the egg products plant has put in place, and other general information. FSIS uses the establishment profile information to assign routine or directed inspection tasks, to create tailored inspection tasks, to generate FSIS sample requests, and to manage inspection assignments.

B. IPP are to select a specific plant (e.g., the house icon) or facility for PHIS to display an establishment's profile information. IPP can view particular plants or facilities in their assignment by clicking on the "My Establishments" tab from the inspector homepage after logging into PHIS.

C. Alternatively, IPP can search for a plant or facility by selecting "Establishment Profile" in the Navigation menu and then selecting "Select Establishment" in the submenu. IPP are to refer to the PHIS User guide for additional information regarding use of the left navigation menu options.

VI. HOW TO CREATE AN ESTABLISHMENT PROFILE FOR EGG PRODUCTS PLANTS

For official egg products plants or other facilities (e.g., approved off premise freezers) the Resource Management Analyst (RMA) will assign a plant number and enter information into PHIS regarding the application for a grant of inspection or for inspection services. During the application process, an FLS, EIAO, or other designated personnel will visit the applicant's plant and collect information needed to determine whether the plant should receive a conditional grant of inspection. This information is to be provided to the appropriate DO (see <u>FSIS Directive 5220.1</u>, *Granting, Refusing, Voluntary Suspension or Voluntary Withdrawal of Federal Inspection Service*). Some of the information that is entered into PHIS during the grant application process will be used to populate the

plant profile.

VII. IPP RESPONSIBILITIES IN PERFORMING THE ESTABLISHMENT PROFILE INSPECTION TASK

A. The assigned IIC is responsible for keeping the information in the establishment profile up-to-date and accurate. The plant profile information is essential to the Agency's goal of protecting public health. FSIS uses the data for generating inspection tasks, for automated reporting, and for ad-hoc data analysis. FSIS has also migrated relevant profile information from PBIS into the PHIS establishment profile for all existing domestic and import establishments, including egg products plants.

B. IPP are to perform the establishment profile inspection task by reviewing and updating the information in the establishment profile. IPP are to click on "Establishment Profile" on the left navigation menu to view the sub-links needed to access the establishment profile pages. IPP have user role permissions to edit profile information for plants that are in their inspection assignments only.

C. IPP are to review the establishment profile task monthly to ensure the information is correct. IPP are also to perform the task when information recorded in the profile is out-of-date, and when IPP learn of changes while performing other inspection tasks.

D. IPP are to provide a copy of the establishment profile to a management official during the weekly meeting. The management official will have an opportunity to affirm or to correct any of the profile information in PHIS. When management responds with a correction, IPP are to update the plant profile data only after verifying plant records or other data that is needed to support the basis for the correction. IPP are to resolve any issues or discrepancies regarding profile information before they are to document the task as completed in PHIS.

NOTE: IPP are to refer to the PHIS User Guide for step-by-step information on updating the establishment profile.

CHAPTER II – THE PROFILE

I. PROFILE INFORMATION FOR OFFICIAL EGG PRODUCTS PLANTS

IICs are to complete establishment profile information for egg products plants when performing the PHIS establishment profile task. IPP are to gather information pertaining to the official plant and edit the establishment profile by selecting options from the drop down lists whenever possible. IPP are to follow the guidance in the following sections in this chapter of this directive:

II. ESTABLISHMENT CONTACTS

A. The *Contacts* submenu contains two tabs - "Establishment" and "FSIS Personnel." IPP are to click on "add new Contact" to enter plant contacts on the establishment tab. IPP can enter contact information according to a specific shift or one contact for the facility, if necessary.

B. Contact types are used in PHIS to designate a specific plant person that will receive system generated notifications or official Agency correspondence. This contact information will be available in other parts of PHIS, such as when IPP are selecting a contact to receive notification of noncompliance reports.

C. IPP are to select one or more of the following contact types and enter the designated plant personnel's name:

- 1. Select "Recall Contact" if the contact serves as a contact person during a recall situation.
- 2. Select "Emergency Contact" if the Agency is to contact this person during an emergency, such as a natural disaster or sudden closure at the plant.
- 3. Select "Lab Sample Results Contact" if the Agency is to send laboratory sample results to this person electronically.

III. GENERAL

A. The *General* submenu option contains five data entry tabs that contain plant addresses and general information regarding the plant. PHIS displays information on the "Establishment" and "Ownership" tabs as read-only to IPP users. The DO is responsible for editing this information while managing the grant application process.

B. IPP are to update and maintain information under the "Jurisdiction," "Inspection Exemptions," and "Other" tabs. The "Other" tab contains the following information:

- 1. Recall plan information
- 2. Food Defense Plan
- 3. Establishment size
- 4. AMS/FNS school lunch program, including the date of last contract award for the egg product plant
- 5. Geographic location
- 6. Names under which the plant is Doing Business As (DBA)
- 7. Address Information. FSIS considers this address the primary address where IPP perform inspection. IPP are to maintain and update plant addresses other than the "physical address." The physical address will display in PHIS to IPP users as a pre-populated address in the "List of Addresses" table. The DO has permission to edit the physical address while managing the grant application process. If IPP note changes to the physical address, IPP are to inform the management official to contact the DO with the change of address.

C. IPP are to click on "add new address" to enter additional plant addresses and select the following address types from a list of options for each address entered:

- 1. Select "Mailing Address" if the Agency is to use the address to mail official constituent information or other general correspondence regarding FSIS inspection.
- 2. Select "Overnight Mailing Address" if the Agency is to use the address for its contracted overnight carrier service to deliver express mail for Agency correspondence. The Agency-contracted overnight carrier service will not deliver packages to certain addresses, such as a PO Box.

- 3. Select "FSIS Inspection Office Mailing Address" if the Agency is to use the address to mail information to IPP assigned at the plant or facility.
- 4. Select "Laboratory Sample Supplies Address" if the Agency is to use the address to deliver laboratory sample supplies to IPP via the Agency-contracted overnight carrier service. In many cases, this address will be the same as the Overnight Mailing Address.

D. IPP are to complete the optional comment field for plant addresses to provide directions or leave comments to assist visiting FSIS personnel for entry, especially if the plant is difficult to find. IPP can also access directions using electronic maps within PHIS.

IV. FACILITY AND EQUIPMENT

A. IPP are to click on "Facility" from the plant profile menu to access the data entry screens for entering information on the inspection area and any purposed plant construction projects. The inspection area is the plant designated inspected premises that are subject to FSIS inspection.

B. IPP are to click on "Equipment" from the establishment profile menu to access the data entry screens for entering information on methods used for a special process and types of special equipment used.

V. PLANT OPERATIONAL SCHEDULES

A. IPP are to click on "Operational Schedules" from the PHIS establishment profile menu to access the data entry screens for completing information on the plant's operational schedules. The "Operational Schedules" submenu contains the following four tabs: "Approved Hours of Inspection," "Pre-OP inspection," "Break Time," and "Seasonal."

B. PHIS will display the approved hours of inspection information as read-only to IPP users. The DO has permission to edit this information during the grant application process. IPP are to review the information to ensure that the information that they record is consistent with the plant's approved hours of inspection.

C. IPP are to enter scheduling information on when the plant is ready for FSIS personnel to perform pre-operational inspection and when the plant takes routine work breaks. IPP also are to enter information on when the plant will not be operating using the seasonal tab. Periods of inactivity are days within the approved operating hours that the plant does not operate, such as holidays or during extended periods such as for seasonal production. IPP can also record inactive days using the plant calendar.

VI. INSPECTION TASKS

IPP also are to review the inspection activities listed in the "Inspection Tasks" sub-menu of the establishment profile. The task list contains tasks that are applicable to a particular plant and a particular shift and is generated by PHIS based on information entered in the establishment profile. IPP are responsible for ensuring that the correct FSIS inspection tasks are listed in the task list. IPP can also remove tasks that are not applicable by providing a justification for removing the system-generated task.

VII. PRODUCT VOLUME INFORMATION

A. IPP are to click on "Products" and complete finished product class information for each of the establishment's operations. Product groups are those egg products produced under a specific process or plant operation. Therefore, "finished" products are the packaged products that are intended to be shipped. Table 1 below contains a list of the egg products finished product groups. IPP are to select all product groups that apply to the specific plant's operations by checking the appropriate boxes. Additional information on processing categories is found in Attachment 1.

TABLE 1: PHIS Product Category List (Egg Products Plants)					
Finished	Product Group Category		Production Volumes Categories (by Product Groups)		
Category					
Egg Products	Unpasteurized	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) *Whole Egg blends (w/wo added ingredients) 		
	Pasteurized – Not Shelf Stable	Pasteurized (bulk or packaged)	 Whole eggs or yolks (<2% added ingredients other than salt or sugar) Whole eggs with added yolks or *whole egg blends (w >2% added ingredients other than salt or sugar) Egg whites (w/wo added ingredients) Imitation/Substitutes 		
	Pasteurized – Shelf Stable	Pasteurized (bulk or packaged	 Whole eggs with added yolks (w/ >2% salt or sugar) Whole egg or yolks (w/ >2% salt or sugar) 		
		Pasteurized Dried Egg Products	 Whole eggs or yolks (w/wo added ingredients) *Whole egg blends (w/wo added ingredients) Whole eggs with added yolks (w/ >2% salt or sugar) Spray-Dried Egg Whites (w/wo added ingredients) Pan Dried Egg Whites 		

NOTE: In PHIS for egg products, the Finished Product Category for all the product groups listed for a particular plant will always be "Egg Products," and the HACCP Category will always be "Eggs/Egg Products".

*Whole egg blends - consists of whole egg, egg whites, and/or egg yolks

B. Next, IPP are to complete the average daily product volume information under the PHIS Products tabs. IPP are to select a volume range that represents the average daily production for each product group selected. Table 1 contains the product groups that IPP should use for selecting a volume range (See Table 2). IPP are to enter production volume information for the products produced during the production days since the profile task was last completed.

Table 2: PHIS Volume Ranges
Average Daily Volume (lbs. per day)
1 – 1,000
1001 – 3,000
3,001 - 6,000
6,001 - 50,000
50,001 - 250,000
250,001 - 600,000
> 600,000

- To compute the average daily volume, IPP are to take the monthly volume of finished product divided by the number of production days. (e.g., Spray Dried Egg Whites: 250,000 lbs. ÷ 25 production days = 10,000 lbs. daily average, IPP would select the 6001 to 50,000 volume range.)
- 2. IPP are to also enter the number of days production in the **No. of days of production** box by typing the actual number of days in a month the plant produces the specific finished product.

C. IPP are to review the establishment's shipping records, receipts, production records, or any other records that are available and that bear on establishment production volume. If few or no records exist, IPP are to select the highest reasonable volume range for a particular product group based on the production capacity at the establishment.

D. The **Volumes** tab provides the total HACCP volume produced on an average day for each HACCP category. In PHIS for egg products what is displayed in the Volume tab for HACCP Category is "Eggs/Egg Products." To determine the average daily HACCP Volume, the IPP are to add all the average daily volume for the product groups produced by the plant.

VIII. PROFILE QUESTIONS

A. The "Profile Questions" sub-link contains questions that are to be completed and reviewed monthly

as part of the profile inspection task. The questions may contain information regarding the plant microbiological testing programs or other information regarding plant practices that can be used to provide information on inspection procedures.

NOTE: FSIS will activate this function in a future enhancement to PHIS and will provide further guidance at a later date.

IX. NEW TECHNOLOGIES INFORMATION

This section contains information on "No Objection letters" or "Waivers" issued by FSIS New Technology personnel. IPP are to click on "innovations" and review the information on the No Objection letters associated with the plant.

NOTE: FSIS will activate this function in a future enhancement to PHIS and will provide further guidance at a later date.

CHAPTER III – OTHER PROFILE INFORMATION

I. ESTABLISHMENT SUMMARY HOMEPAGE

A. All establishments where FSIS provides inspection services will have a PHIS homepage that contains relevant inspection information. The homepage contains information about the establishment from every available source within the Agency.

B. In some cases, Agency personnel at headquarters and in the field offices are the primary source of information that is available on the establishment homepage in PHIS. IPP are to use the information on the establishment homepage to assist them in performing verification tasks.

II. GRANTS AND APPROVALS INFORMATION

A. IPP can view the grant of inspection entered by the DO. The DO must complete the grant application and grant of inspection information in PHIS for PHIS to display the information.

B. IPP cannot edit the information associated with the grant of inspection or grant application. If any of the information is not correct, IPP are to contact their DO.

III. FSIS STAFFING INFORMATION

The government office phone number and the names and positions of Agency personnel assigned to a particular plant or facility are viewable from the homepage. The homepage will also indicate which establishments are part of a rotational assignment.

IV. SPECIAL PROJECT PARTICIPATION

Headquarters personnel post information on the establishment homepage to inform users that a particular establishment is participating in a special project, such as a special baseline sampling study.

NOTE: FSIS will activate this function in a future enhancement to PHIS and will provide further guidance at a later date.

V. FSIS SAMPLING RESULTS AND ELIGIBILITY

IPP can view information about every FSIS sampling verification program, as well as sampling programs that apply to a specific establishment. IPP can also access the FSIS sampling history and see pending sample requests for a specific establishment.

VII. FSIS TRAINING INFORMATION

IPP can view the type of training required to perform inspection verification at a particular establishment.

VIII. FSIS APPEALS INFORMATION

IPP are to follow the instructions in <u>FSIS Directive 13,000.3</u>, Responding in PHIS to Industry Appeal of a Noncompliance Record (NR) when an establishment appeals an NR.

IX. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through <u>askFSIS</u> or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter Directive 5030.2
Question Field:	Enter question with as much detail as possible.
Product Field:	Select (General Inspection Policy) from the drop-down menu.
Category Field:	Select (Egg Products) from the drop-down menu.
Policy Arena:	Select (Domestic U.S. Only) from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question.**

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FOOD SAFETY PROCESSING CATEGORIES

A. **Egg Products – Unpasteurized:** This food safety processing category applies to establishments that break shell eggs and receive unpasteurized raw egg products. Establishments in the unpasteurized egg products processing category may produce finished products such as unpasteurized liquid eggs with no ingredients added.

B. **Egg Products – Pasteurized-Not Shelf Stable:** This food safety processing category applies to establishments that further process 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 food safety processing category are not shelf stable. FSIS requires the products to be frozen or refrigerated for food safety purposes.

C. **Egg Products – Pasteurized-Shelf Stable:** This food safety 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 food safety 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.