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

# **FSIS PHIS DIRECTIVE**

5220.1 Revision 1

1/30/13

# GRANTING OR REFUSING INSPECTION; VOLUNTARY SUSPENDING OR WITHDRAWING INSPECTION; AND REINSTATING INSPECTION UNDER PHIS

#### I. PURPOSE

This directive provides instructions to Front Line Supervisors (FLSs), District Managers (DMs), Regional Import Field Supervisors (RIFSs), and Deputy Directors of Operations (DDOs) for granting an establishment's request to receive inspection services, to have inspection services voluntarily suspended or withdrawn, and to reinstate inspection after voluntary suspension or voluntary withdrawal. This directive also provides instructions for entering data related to these activities into the Public Health Information System (PHIS).

## **KEY POINTS:**

- Clarifies FSIS employees' responsibilities for gathering and recording information related to the application of inspection into PHIS;
- Clarifies routing of all new application to the Evaluation and Enforcement Division (EED) for review, prior to processing;
- Provides instructions for recording a conditional grant of inspection; and
- Clarifies the circumstances in which conditional grants are to be terminated and inspection not granted

#### **II. CANCELLATION**

FSIS PHIS Directive 5220.1, Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS, dated 4/11/11

FSIS Directive 5220.1, Revision 1, Granting, Refusing, Voluntary Suspension or Voluntary Withdrawal of Federal Inspection Service, dated 9/24/92

#### **III. REASON FOR REISSUANCE**

FSIS is reissuing this directive to provide updated instruction related to the PHIS and the instructions related to the Office of Program Evaluation, Enforcement, and Review (OPEER), EED, review of the application and to clarity how establishment numbers are assigned in PHIS. Also, the revision includes instructions related to the new recall plan requirements. Lastly, Attachment 1 to this directive includes instructions from the PHIS Users Guide regarding inputting establishment information into PHIS.

#### **IV. REFERENCES**

9 CFR Parts 304, 305, 327, Part 381, subparts D, E, and 416, 417, and 418

**DISTRIBUTION:** Electronic

OPI: OPPD

AR0002836

#### V. GRANTING INSPECTION AT OFFICIAL MEAT AND POULTRY ESTABLISHMENTS

A. When an applicant requests a grant of inspection, the District Office (DO) is to provide the following link which contains the necessary instructions and forms to be completed:

## http://www.fsis.usda.gov/Regulations & Policies/Grant of Inspection Guideline/index.asp

- B. The DO also is to provide copies of the following:
  - 1. The application for inspection, FSIS Form 5200-2, Application for Federal Inspection, and FSIS Form 5200-15, Hours of Operations Request/Approval;
  - 2. The application guidelines;
  - 3. The Sanitation Standard Operating Procedures Guidelines for Meat & Poultry Establishments; and
  - 4. <u>FSIS Directive 8080.1</u>, Recall of Meat and Poultry Products, including Attachment 1, Product Recall Guidelines for Firms.

C. Upon receipt of an application, the DM or designee is to:

- 1. Review the application for completeness and check appropriate boxes for the applicable Acts under which the establishment will operate; and
- 2. Return to the applicant any application that is not complete and specify the areas of the form that need attention.

D. The revised FSIS Form 5220-1 does not require Social Security Numbers; however, the DM is to request that applicants supply their Federal Employer Identification numbers and Dunn and Bradstreet numbers.

E. After the DM reviews the application and determines that it is complete, the DM or designee is to forward an electronic copy of the application to the OPEER, EED, at <u>AEBCorrespondence</u> and request a compliance background inquiry of the applicant's business and responsibly connected persons identified on the application. Processing of the application may proceed only after completion of the EED evaluation and notification of the findings.

F. Upon receipt of the request for a compliance background inquiry on an applicant, EED is, within its resources, to conduct applicable database and other inquiries related to any criminal or compliance background of the individuals or firms listed on the application. EED will respond in writing (via e-mail) to the DM or designee with its findings regarding moving forward with processing all applications that DOs forward to it.

G. In cases where the application (including a revised or updated application for an existing grant of inspection) lists convictions, or if the DM is aware that one of the responsibly connected persons has a criminal history, the DM is to send a letter to the applicant to inform him or her that EED will further evaluate the application.

H. If EED determines that inspection should not be granted, it will initiate action to refuse to grant inspection in accordance with 9 CFR 500.7. EED will keep the DM informed and updated about the evaluation process and any applicable enforcement activities. EED is also to establish communication with the applicant as FSIS' primary point of contact during the case evaluation and enforcement process.

I. If EED finds and notifies the DO that there is no basis for not continuing to process the application, the DM is to:

- 1. Complete the top portion of the recommendation for granting inspection (FSIS Form 5200-4) and forward it to the FLS;
- 2. Assign the FLS or designee to visit and review the applicant's facility; and
- 3. Initiate a record in PHIS to reserve an establishment number. (See Attachment 1 for inputting establishment information into PHIS.)
  - a. For a new applicant, PHIS will automatically assign an establishment number, and all corresponding types of operation will be reserved for the establishment under the same number for future use.
  - b. For existing establishments that are applying for additional inspection services, DO personnel are to add the requested inspection service to the establishment's grant page in the PHIS profile. One official establishment will have one establishment number with different inspection type indicators (e.g., 38 M or 38 P) to differentiate the types of service that FSIS provides. In certain limited circumstances, an establishment can request a specific establishment number, such as when a new application is submitted because of a change of location or ownership of an establishment, as set out in 9 CFR 304.1(c).
- J. In processing the application, the FLS is to:
  - 1. Visit the prospective establishment to review the physical plant and equipment and determine whether they comply with 9 CFR 416.1 through 416.5;
  - 2. Determine whether the prospective establishment has developed written Sanitation Standard Operating Procedures (Sanitation SOPs) as set out in 9 CFR 416.11 through 416.16;
  - Determine whether the prospective establishment has conducted a hazard analysis, or had one conducted, for all processes and has developed a Hazard Analysis and Critical Control Point (HACCP) plan for the processes that it plans to perform where one or more hazards are reasonably likely to occur, as described in 9 CFR 417;
  - 4. Determine whether the prospective establishment has developed written recall plans in accordance with 9 CFR 418;
  - 5. Complete the portion of FSIS Form 5200-4 entitled, "Recommendation on Application for Inspection" with recommendations for correcting any noncompliance observed or issuing a conditional grant of inspection; and
  - 6. Return the completed FSIS Form 5200-4 to the DM.

K. The DM is to review the returned FSIS Form 5200-4 and other pertinent information provided by the FLS to determine whether the establishment should be granted a conditional grant of inspection services. The DM is to determine based on the information provided whether the applicant:

- 1. Has a HACCP plan as required by 9 CFR 417;
- 2. Has prepared Sanitation SOPs as required by 9 CFR 416.11 through 416.16;

- 3. Has demonstrated that sanitary conditions exist at the prospective establishment as set out in 9 CFR 416.1 through 416.5; and
- 4. Has demonstrated, if it is a slaughter establishment, that it can handle and slaughter livestock humanely.

L. If the DM decides there may be a basis to refuse to provide inspection and not to grant conditional inspection, he or she is to write to the applicant informing him or her that the matter has been referred to OPEER EED. The DM will provide pertinent information to EED in accordance with <u>FSIS Directive</u> 8010.5.

M. If the DM decides that inspection service should be provided to the establishment, he/she is to issue a conditional grant of inspection. The DM is to issue FSIS Form 5200-1, checking the box indicating "conditional," which provides conditional inspection. The DM is also to return a signed copy of FSIS Form 5200-15 to the establishment, stating the approved operating hours and agreeing with establishment management on a date to inaugurate conditional inspection. The DM is then to ensure that his/her staff updates PHIS to reflect the conditional status of the grant and the establishment's approved operating hours (see PHIS Users Guide).

N. During the 90 days following the issuance of the conditional grant of inspection, in accordance with 9 CFR 304.3(b) and 381.22(b), the DM is to gather information upon which to decide whether the establishment meets the terms of the conditional grant of inspection as set out in Section V, F., above. In addition to drawing on information in PHIS and gathered by the FLS and the Inspector-in-Charge (IIC), the DM is to direct IPP to verify that the establishment has validated its HACCP plans as instructed by <u>FSIS PHIS Directive 5000.1</u>, Verifying an Establishments Food Safety System, Section VIII.

O. For livestock slaughter facilities, before the end of the 90-day period, the DVMS is to determine, based on an assessment of Human Handling Activities Tracking System (HATS) data and NRs, whether livestock are being handled and slaughtered humanely. The DVMS is to issue a Memorandum of Interview (MOI) that sets out his or her findings to the DM. If the DM determines that the establishment has handled or slaughtered livestock inhumanely, he or she is to suspend inspection at the establishment as set out in 9 CFR 500.3(b) and document the reason for the suspension in a letter to establishment management. (Access <u>FSIS Directive 6910.1</u>, District Veterinary Medical Specialist (DVMS) – Work Methods.)

P. Within 90 days of issuing the conditional grant, if the DM determines that the establishment has validated its HACCP system as required by 9 CFR 417.4(a) and has met all other terms as set out in V, I. above of the conditional grant of inspection, he or she is to sign and issue a Grant of Inspection, FSIS Form 5200-1, and update PHIS to reflect the establishment's status.

Q. If at the end of the 90-day conditional grant period, the DM determines that the establishment has not validated the HACCP system, has handled livestock inhumanely, or has not met any other terms of the conditional grant, he or she is to terminate the assignment of inspectors at the establishment and inform the establishment management in writing of the specific provision of 9 CFR 500.7(a) that necessitates the refusal of inspection. The DM is to also inform establishment management of the opportunity for a hearing in accord with the Uniform Rules of Practice, 7 CFR Subtitle A., Part 1, Subpart H, and initiate a file in the Administrative Enforcement Report (AER) system as set out in <u>FSIS Directive 5100.3</u>, Administrative Enforcement reporting (AER) System. The DM is to then contact EED in accordance with <u>FSIS Directive 8010.5</u>, Case Referral and Disposition, and provide it with the reason the grant of inspection should be refused so that EED can start the formal process of refusing inspection (9 CFR 500.7(b).

R. For most meat and poultry establishments, an initial 90-day validation period corresponds to approximately 60 working days of records for review. Some small and very small establishments may

operate less than 5 days per week. However, at least 13 available production days of records for review need to be available for FSIS to determine whether an establishment operating less than 5 days per week has validated its system. To allow such small and very small establishments the time necessary to gather data to validate their HACCP plans, the DM may allow an additional 30 days of operations under the conditional grant of inspection before an establishment needs to have completed validation of its HACCP plans.

S. When the DM grants inspection services, he or she is to send the Grant of Inspection and application to the following persons:

- 1. Original to the applicant;
- 2. Copy to the official establishment if the establishment and the applicant have different mailing addresses;
- 3. Inspector-In-Charge:
- 4. DO staff for entry into PHIS; and
- 5. For Talmadge-Aiken establishments only, appropriate State meat or poultry inspection program personnel.

T. The DO is to maintain official file copies of the application, recommendation, grant, and related documents. In addition, the DM is to ensure that PHIS is updated to accurately reflect the status of the establishment.

U. When the DM becomes aware of any significant changes in an establishment or its operations (i.e., new ownership, changed corporate structure, new location, type of operation, or change in operating hours), the DM is to request that the establishment submit an updated application or FSIS Form 5220-15, and then have DO staff enter the changes into PHIS.

V. The DM is to maintain the updated application on file and verify that the updates are reflected in the PHIS Establishment Profile.

**NOTE**: An establishment that wishes to alter its approved hours of operation will submit a revised FSIS Form 5200-15 to the DO. The DM is to consider the request for change in hours as set out in 9 CFR 307.4 and 381.37.

#### **VI. NOT GRANTING INSPECTION AT AN ID WAREHOUSE**

A. An ID Warehouse is a facility at which FSIS provides voluntary identification service for meat or poultry products as described in 9 CFR 350.3(a) and 362.2(c). 9 CFR 350.3(a)(2) and 362.2 (c) (2) prohibit FSIS from providing identification service at an official meat or poultry establishment.

B. Therefore, it is important for the District Manager NOT to approve voluntary identification service at an establishment that has a meat or poultry grant. If an ID warehouse applies for a grant of inspection, the DM is to rescind the approval for voluntary ID service when he or she gives the establishment a conditional grant of inspection.

C. If an official meat or poultry establishment (with a grant of inspection) does not actually perform slaughter or processing activities that require inspection, but only performs repackaging or relabeling activity, the DM is to consider whether to withdraw the grant of inspection and offer the facility voluntary ID service instead.

#### **VII. GRANTING INSPECTION AT OFFICIAL IMPORT INSPECTION ESTABLISHMENTS**

A. When an applicant requests an import grant of inspection, the Regional Import Field Supervisor (RIFS) is to provide the following link which contains the necessary instructions and forms to be completed:

#### http://www.fsis.usda.gov/Regulations & Policies/Grant of Inspection Guideline/index.asp

B. The Import Inspection Division (IID) headquarters is to also provide copies of the following to the applicant:

- 1. Application for import inspection, Form 5200-2 and FSIS Form 5200-15, Hours of Operations Request/Approval;
- 2. Application guidelines;
- 3. Chapter 1 of FSIS PHIS Directive 5000.1; and
- 4. Contact information for the Regional Import Field Office (RIFO) that will be reviewing the establishment
- C. Upon receipt of an application, the IID Director or designee is to:
  - 1. Review the application for accuracy and completeness and check the appropriate boxes for applicable Acts under which the establishment will operate; or
  - 2. Return to the applicant any application that is not complete, and specify the area of the form that needs attention.

D. After the IID Director reviews the application and determines that it is complete, the IID Director or designee is to forward an electronic copy of the application to the OPEER, EED, to <u>AEBCorrespondence@fsis.usda.gov</u> and request a compliance background inquiry of the applicant's business and responsibly connected persons identified on the application. Processing of the application may proceed only after completion of the EED evaluation and notification of the findings.

**NOTE**: If the application lists convictions, or the IDD Director is aware that one of the responsibly connected persons has, a criminal history (including a revised or updated application for an existing grant of inspection), the IDD Director is to send a letter to the applicant informing him or her that the application has been forwarded to EED for further evaluation.

E. Upon receipt of the request for a compliance background inquiry on an applicant, EED is, within its resources, to conduct applicable database and other inquiries related to any criminal or compliance background of the individuals or firms listed on the application. EED will respond in writing (via e-mail) to the IDD Director or designee with its findings of all applications that are received from the IDD.

F. If EED determines that inspection should not be granted, it will initiate action to refuse to grant inspection in accordance with 9 CFR 500.7. EED will keep the DM informed and updated about the evaluation process and any applicable enforcement activities. EED is also to establish communication with the applicant as FSIS' primary point of contact during the case evaluation and enforcement process.

G. If EED finds that there is no basis for not continuing to process the application, EED notifies the IDD. The IID Director is to:

- 1. Complete the top portion of FSIS Form 5200-4 and forward it to the RIFS with a copy going to the DDO; and
- 2. Assign the RIFS to conduct an initial visit and review of the applicant's facility.
  - a. For a new applicant, PHIS will automatically assign an establishment number, and all corresponding types of operation (meat, poultry, and reimbursable service) will be reserved for the establishment under the same number for future use.
  - b. For applicants that are applying for additional inspection services, IID personnel are to add the requested inspection service to the applicant's grant page in the PHIS profile. One official import establishment will have one establishment number with different type indicators (e.g. 38 M, 38 P, 38 G, 38 I) to differentiate the types of service FSIS provides. In certain limited circumstances, a specific establishment number can be requested, such as when a new application is submitted because of a change of location or ownership of an establishment as set out in 9 CFR 304.1(c).

H. When the prospective import establishment notifies the RIFS that it is ready to start operations, the RIFS is to:

- 1. Visit the prospective import establishment to review the physical plant and equipment and determine whether they comply with 9 CFR Part 416 and make a recommendation on the granting of import inspection services.
- 2. Determine whether the prospective import establishment has the equipment necessary to complete the import inspections identified on the application. This includes refrigerated space to hold an entire shipment of refrigerated or frozen products, scales, and office space.
- Determine whether the establishment will be inspecting products from Animal and Plant Health Inspection Service (APHIS) restricted countries, and if it is, whether it has the appropriate space and equipment to safely do so;
- 4. Complete FSIS Form 5200-4 entitled "Recommendation on Application for Inspection." Provide recommendations for correcting any noncompliance observed to the DDO and IID Director along with actions taken by the establishment; and
- 5. Revisit the facility when the establishment notifies the RIFS that all noncompliant observations are corrected and forward the approved completed FSIS Form 5200-4 to the IID Director.

I. The IID Director is to:

- 1. Review the completed recommendation form;
- 2. Determine whether to grant the establishment import inspection services;
- 3. Issue the Grant of Import Inspection (FSIS Form 5200-1) and FSIS Form 5200-15, Hours of Operation Request/Approval as appropriate;
- 4. Send the original of the Grant of Inspection document to the applicant, along with a copy of the application. The Director of IID is to also send the official import establishment copies of the grant and application if the establishment and applicant have different mailing addresses;
- 5. Send copies of the grant and application to the RIFO and the IID staff for entry into PHIS;

- 6. Maintain official copies of the application, recommendation, grant, and related documents; and
- 7. Notify APHIS if the import establishment has been granted inspection and is eligible to inspect APHIS restricted shipments of products.

J. When the RIFO becomes aware of any significant changes in an official import establishment or its operations, he or she is to request that the establishment submit an updated application or FSIS Form 5220-15 (i.e., new ownership, changed corporate structure, new location, or change in operating hours), and forward the updated application or Form 5220-15 to the IID Director.

K. The IID Director is to maintain the updated application on file and verify that the updates are maintained in the PHIS by OIA Headquarters.

#### VIII. OFFICIAL ESTABLISHMENT OR OFFICIAL IMPORT INSPECTION ESTABLISHMENT VOLUNTARY SUSPENSION OR WITHDRAWAL OF INSPECTION

A. When an FLS, in the case of an official establishment, or RIFS, in the case of an official import inspection establishment, receives a written request for a voluntary suspension or voluntary withdrawal of inspection services, he or she is to explain to the establishment the differences between the two.

- 1. A voluntary withdrawal of inspection is permanent, and establishments wishing to reinstate inspection must reapply for inspection services.
- 2. A voluntary suspension of inspection services is temporary and normally will not exceed 120 calendar days. An establishment may request such suspensions for purposes of sale, major structural changes, or remodeling. An establishment on voluntary suspension may have a situation arise that is beyond its control (such as inability to obtain equipment on schedule, inability to complete major structural changes because of weather conditions, or other valid reasons). In such a case, the DM or the IID Director, as appropriate to the type of establishment, may extend the 120-day period, if the Assistant Administrator, OFO or OIA, as appropriate, concurs. The DM or IID Director may grant establishments that operate on a seasonal basis a suspension of more than 120 days but not for more than a year.

B. The FLS or RIFS is to accept written requests from establishments for a voluntary suspension or voluntary withdrawal of inspection services.

C. The FLS or RIFS is to forward the establishment's request letter, including the effective date of the requested voluntary action, to the DM or the IID Director for processing.

D. The DM or IID Director is to issue the voluntary suspension or voluntary withdrawal of inspection form (FSIS Form 5200-3) and forward the original to establishment management. The DM and the Director of IID are to maintain a copy of the form and any related documents.

E. The DM or the IID Director is to verify that the suspension or withdrawal is properly recorded and documented in PHIS.

F. After being contacted by the establishment during the voluntary suspension, the FLS or RIFS is to notify the DM or the IID Director that the establishment has requested that inspection be reinstated.

- 1. Before inspection is reinstated, the FLS or RIFS is to visit the establishment to determine whether its facilities and equipment warrant the reinstatement.
- 2. In cases where the establishment warrants reinstatement of inspection, the FLS or RIFS is to recommend reinstatement of inspection service to the DM or IID Director. In cases in which the

establishment does not warrant reinstatement of inspection, the FLS or RIFS is to not recommend reinstatement of inspection services to the DM or IID Director.

G. The DO or the IID Director is to ensure that the data in PHIS is updated to reflect the establishment's status.

# IX. REFUSAL OR WITHDRAWAL OF INSPECTION SERVICE

A. The DM or the IID Director is to notify the Director of EED when there is reason to believe inspection services should be refused or withdrawn (other than voluntary withdrawal) from an applicant or recipient of inspection service.

B. The DM or the IID Director is responsible for initiating inquiries, assembling documentation, and maintaining contact with EED, regarding the refusal or withdrawal of inspection services. In those instances when the DM or the IID Director has a basis, under the FSIS Rules of Practice, to refuse to provide, or to initiate action for the withdrawal of inspection services, the DM or the IID Director is to refer the matter to EED for review and appropriate action in accordance with <u>FSIS Directive 8010.5</u>.

Refer questions through supervisory channels.

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Assistant Administrator Office of Policy and Program Development

# Attachment 1: PHIS Data Entry Instructions for Existing and New Establishments

# A. Overview

The following flow chart describes the basic process for setting up an establishment and assignment in PHIS so inspectors can begin scheduling tasks and entering inspection results.



#### B. Users

In order to completely set up an establishment and its profile, several user roles are required. Table 1 lists the role and the process that role can complete.

Table 1: Roles a	and Processes
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Role	Process
Grant Curator (Domestic & Import)	Add Establishment
Consumer Safety Inspector Frontline Supervisor Public Health Veterinarian DM/DDM	Enter Establishment Profile
RMA (Domestic-OFO) or RMPS (HQ) DM/DDM	Create and Edit Assignments

# C. Before You Begin

Before you start entering data for existing establishments into PHIS, you should gather as much information as possible about the establishment.

Where applicable, the source of the information is noted in parentheses after the step. In some cases, specific block numbers are given, such as (Source: Block #3 Application for Inspection (AFI)). Note that

those numbers are derived from the most recent version of the form. If you are working with older forms, please be aware the numbering may have changed.

#### 1. What You Need

The following information is necessary:

- Original/Copy if the application for federal inspection
- Original/Copy of the grant of inspection
- Assignment list with personnel
- Access to the PBIS detailed profile
- Contact information for the following:
  - All contacts in PBIS
  - The FSIS Inspection Office Mailing Address
  - The Lab Sample Supplies Address
- Access to in-plant personnel who can relay information about the establishment's HACCP Plans, Hazard Analyses, Products, and Slaughter Lines

#### 2. Access PHIS

PHIS is a Web-based application that you access through a Web browser, such as Internet Explorer. Your computer must be connected to the FSIS network for this task.

#### a. To access PHIS:

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

#### D. Add Establishment

To add a new establishment to PHIS, you will need the information contained in the Application for Federal Inspection (AFI). A user with the Grant Curator (Domestic & Import) user role starts the process of adding an establishment to PHIS. Also, please confirm with the SRMA that the appropriate circuit has been created in PHIS before you get started.

Tip: Be sure to save your work periodically so you do not lose any data you have entered.

#### a. To add an establishment:

These instructions explain how to add a meat or poultry grant. For voluntary reimbursable services agreements, see the next section titled "To add a voluntary reimbursable service agreement."

- 1. Log in as a Grant Curator.
- 2. Click Establishment Profile > Add Establishment.
- 3. Click Add new Grant. The Application for Federal Inspection (AFI) page opens.
- 4. For the Date field, enter today's date.
- 5. For the PBIS Establishment ID field, enter the establishment ID from PBIS Reader or other legacy system.

**NOTE:** Once you save this record, **you can no longer edit the PBIS Establishment ID field. Please verify the number is correct before clicking Save**. This number typically contains no more than 4 digits and does not contain any letters. (Source: PBIS Profile)

Application f	or Federal Inspection (AFI)
Application	
Date*:	6/12/2011
PBIS Establishment ID:	3458 (This is listed as EstID in PBIS reader – NOT the Est number.)
Type*:	New  O Change of Ownership
	○ Change of Location ○ Application Extension
Type of Inspection Required	Meat Poultry Egg Import

NOTE: Egg and Import establishments are not in PHIS as of summer 2011.

6. Select the Type of Inspection Required: Meat or Poultry. (Source: Block #3 AFI)

**NOTE:** The page refreshes after each time you select a Type of Inspection. Please allow time for the page to refresh after each check; otherwise, you may have to redo some data entry. It is OK to select both check boxes, you just need to pause between each selection. If you do have both types selected, a separate meat section and a separate poultry section are made available for data entry further down on the page.

Select the Form of Organization. (Source: Block #5 AFI)
 NOTE: By default, Individual is selected. If you select a different option, the page refreshes and additional fields may become available. For example, if you select Corporation, the page refreshes and fields for Corporate Information appear on the page.

8. Complete the required fields in the Applicant (Owner) section. (Source: Blocks #8 and #9 AFI)

- a. Name
- b. Telephone
- c. Mailing Address
- 9. Complete the required fields in the Plant section. (Source: Blocks #10a and #11 AFI)
  - a. Name
  - b. Telephone
  - c. Physical Location
  - d. Mailing Address

**NOTE:** If the Phone Number, Physical Location, or Mailing Address is the same as the applicant's, you can select the appropriate check boxes to copy the information.

Phone Number Same as Applicant's Phone Number

Physical Location Same as Applicant's Mailing Address

Mailing Address Same as Applicant's

- e. Enter information in the Co-located Official Establishments block if you have co-located establishment information. (Source: Block #17 AFI)
- f. Enter information in the Doing Business As block if you have doing-business-as information. (Source: Block #13 AFI)
- g. The Ready to Operate date is not required for existing establishments, but if you have the historical information, you can enter it.
- 10. Select the Animals to be Slaughtered and/or Types of Products in the Meat Inspection and/or Poultry Inspection sections. Be sure to select all applicable check boxes. This information is critical

12

to the proper assignment of tasks to this establishment. (Source: Blocks #18 and #19 AFI) **NOTE:** For slaughter establishments, you must select at least one of the check boxes in the Animals to be Slaughtered section.

- 11. In the Ownership and Management Information section, enter the required fields.
  - a. Person Signing Application (This is the non-FSIS person who signed application) (Source: Block #27 AFI)
- 12. In the FSIS Information section, enter the required fields:
  - a. Establishment Number
    - i. Click Add new Establishment Number. (Source: Block #2 Grant of Inspection (GOI)).
    - ii. Select the Type of Inspection. The available values are based on what you chose in step 5. (Source: Block #7 GOI)

For Ownership Number, PHIS defaults to the next available number. As you are entering a grant for an existing establishment, delete the default value and type the already assigned establishment number. Enter numerals only.

- **NOTE:** There is a change in the format of establishment numbers in PHIS. Where in PBIS a number could be 00038A M, in PHIS it would be M38A. The M is the "type" (meat); the 38 is the "ownership number;" and the A is the "suffix."
- iii. Enter a suffix in the Suffix field if applicable. After you click the Suffix field, a preview of what the establishment number will look like appears below the suffix data-entry field.

FSIS Information					<b>1</b> 4	
	·		•			
Establishment Number*	annan ann a gur (ASA 1973). Sas a-sann a-san-	anna 1997 ann an Anna a	ARABANYA ANA TI POWER LAANYA TI PI			an a
🗈 Add new Establishmen	t Number					
<u>Type of Inspection</u>		Establishme	nt Number			
Add New Establishment	Number				The Ar	
Type of Inspection*:	Meat	*				
Ownership Number*:	38					
Suffix:	A					
Establishment Number:	M38A	·				
				1	Save] [C:	ancel

- iv. Click Save.
- v. Repeat this process for each Type of Inspection.
- b. Approver's Name, typically the District Manager or the approver on the application (Source: Block #35 AFI)
- c. Date Approved (Source: Block #36 AFI)
- 13. In the Circuit section, select the Area from the drop-down list. (For example, "65 Albany, NY" and "35 Syracuse" as the Circuit.)
- 14. Click Finish. The grants are listed on the Grant/Voluntary Reimbursable Service page with a Status of "Reserved."
- 15. Click Reserved to change the status of each grant.
- 16. From the New Status field, select "Recommended" for each grant.

- 17. Click Recommended. You can continue to update the grant until you reach the "Granted" status, or you can begin entering the establishment profile information, which is covered in the next section titled "Enter Establishment Profile."
- 18. From the New Status field, select "Conditional."
- 19. Enter the required fields:
  - a. Inauguration Date (Source: Block #8 GOI)
    NOTE: Once you save this record, you can no longer edit the Inauguration Date field.
    - Please verify the date is correct before clicking Save.
  - b. Approved Hours of Operation (Sources: PBIS Profile or Hours of Operation form) **NOTE:** Use the PBIS profile for the most up-to-date hours of operation.
    - i. Click Add new Inspection Hour
    - ii. Select the Shift.
    - iii. Select the days the establishment operates.
    - iv. Enter the Start time and End time.
    - v. Click Save.
    - vi. Repeat this process for each shift.
  - c. Select Yes for "Applicant qualified by OPEER?"
  - d. Click Save.
  - e. Repeat steps a-d for each type of inspection.
- 20. Click "Conditional."
- 21. From the New Status field, select "Granted."
- 22. Select Yes for "Has the establishment validated its HACCP Plans?"
- 23. Click Save.
- 24. Repeat steps 20 23 for each grant.

#### b. To add a voluntary reimbursable services agreement:

These instructions explain how to add voluntary reimbursable services agreements. If you have already entered a meat or poultry grant, much of the information in the voluntary reimbursable services agreement will be pre-populated.

- 1. Log in to PHIS as a Grant Curator.
- 2. For new establishments, click Establishment Profile > Add Establishment. For existing establishments, click Select Establishment, search for the establishment, and select it.
- 3. Click Grants and Approvals.
- 4. On the Grants/Voluntary Reimbursable Service page, click Add New Voluntary Reimbursable Agreement.
- 5. In the Date field on the Application for Voluntary Services (AVS) page, type today's date. (MM/DD/YYYY)
- 6. For the Type of Inspection Required, select New.
- 7. Select the Form of Organization.

**NOTE:** By default, Individual is selected. If you select a different option, the page refreshes and additional fields may become available. For example, if you select Corporation, the page refreshes and fields for Corporate Information appear on the page.

- 8. Complete the required fields in the Applicant (Owner) section. (Source: Blocks #4 through #8 AVS)
  - a. Name
  - b. Telephone
  - c. Mailing Address
- 9. Complete the required fields in the Plant section. (Source: Block #9 AVS)
  - a. Name
  - b. Telephone
  - c. Physical Location
  - d. Mailing Address

**NOTE:** If the Phone Number, Physical Location, or Mailing Address is the same as the applicant's, you can select the appropriate check boxes to copy the information.

- 10. In the Services Requested block, select the appropriate services or voluntary slaughter information. (Source: Block #15 AVS)
- 11. Enter the required fields in the Ownership and Management Information section. (Source: Blocks #18 through #20 AVS)
- a. Person Signing Application (This is the non-FSIS person who signed application)
- 12. In the FSIS Information section, enter the required fields:
  - a. Establishment Number
    - i. Click Add new Establishment Number.
    - ii. For Ownership Number, if a meat or poultry grant already exists, PHIS defaults to already assigned number; otherwise, PHIS displays the next available number. If you are entering information for an existing plant that has a meat or poultry grant, accept the already assigned number. If you are entering information for an existing plant that does not have a meat or poultry grant, but already has an establishment number, overwrite the next available number value so that it matches the current establishment number.
    - i. Enter a suffix in the Suffix field if applicable. After you click the Suffix field, a preview of what the establishment number will look like appears below the suffix data-entry field.
    - iii. Click Save.
  - b. Approver's Name, typically the District Manager or the approver on the application (Source: Block #25 AVS)
  - c. Date Approved (Source: Block #26 AVS)
- 13. In the Circuit section, select the Area and Circuit from the drop-down lists. (For example, "65 Albany, NY" and "35 Syracuse" as the Circuit.)
- 14. Click Finish. The voluntary approval is listed on the Grant/Voluntary Reimbursable Service page with a Status of "Reserved."
- 15. Repeat steps 3-15 for each additional voluntary approval you need to enter.
- 16. Click Reserved to change the status of the voluntary approval.
- 17. For the New Status field, select "Recommended" for the voluntary approval.
- 18. Click Save.
- 19. On the Grant/Voluntary Reimbursable Service page, click Recommended.

- 20. For the New Status field, select "Granted" for the voluntary approval.
- 21. Click Save.
- 22. On the Grant/Voluntary Reimbursable Service page, select the operating status from the dropdown list.
- 23. Verify that the status is Active.
- 24. Click Save.
- 25. Repeat steps 16-24 to modify the status for each voluntary approval.

#### E. Enter Establishment Profile

This section explains how to enter information for Contacts, Slaughter, HACCP, and Products. Review the information provided in FSIS Directive 5300.1 on Managing the Establishment Profile in the PHIS. A user with one of the following roles is required for Establishment Profile data entry: Consumer Safety Inspector or Frontline Supervisor.

- 1. Log in as a Consumer Safety Inspector.
- 2. Click Establishment Profile > Select Establishment.
- Enter the establishment number in the Number field and click Search.
  NOTE: The Number field only accepts numerals. Do not enter M, P, or any suffixes.
- 4. Click the house icon to select the establishment.

Name	<u>Number</u>	<u>Circuit</u>	<u>City</u>	<u>State</u>
Dudley Poultry Co. Inc	M1392 + P1392	35 -	Middlesex	New York

- 5. Click Contacts.
- 6. Click Add New Contacts.
- Select the Position first, and then click the applicable types: NOTE: If the establishment receives lab sample results via email, be sure to enter the FSIS Lab Sample Result Contact and include an email address.
- 8. Click Save.
- 9. Repeat Steps 6 8 for each position.
- 10. Click General.
- 11. On the Establishment tab, click Add New Address.
- 12. Enter the address information:
  - i. At a minimum, enter the following address types: FSIS Inspection Office Mailing Address, Overnight Mailing Address (in PBIS this is the "Overnight FedEx Address"), and the Laboratory Sample Supplies Address.

**Tip:** You can select more than one type by holding down the Ctrl key and selecting the Address Type. This will create multiple records with the same address.

- ii. Address Line 1 and Address Line 2 (if applicable)
- iii. City
- iv. State
- v. Postal Code
- 13. Click Save.
- 14. Click the Jurisdictions tab.
- 15. Select the appropriate jurisdiction.

NOTE:

Do not select State, as this option is not currently supported in PHIS. For Cross Utilization plants, select FSIS Inspection Only.

16. Click Save.

- 17. Click the Other tab.
- 18. Select the HACCP Establishment Size.
- 19. Enter the Latitude and Longitude for the establishment if you have the information.
- 20. Click Save.

#### 1. Add Hazard Analyses and 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 Hazard Analyses and HACCP plans. When you add a Hazard Analysis, you identify the HACCP Processing Categories necessary for Product Groups. For more information review FSIS Directive 5300.1.

There are two sections on the HACCP Processing page: Summary, which lists the HACCP Processing Categories specific to the establishment and the Hazard Analyses. The Summary section is updated whenever you add a new Hazard Analysis. You must enter a Hazard Analysis before entering a HACCP Plan.

HACCP Plans are associated with a specific Hazard Analysis. You may need to contact IPP in order to complete this information.

#### a. To add a Hazard Analysis:

- 1. Log on to PHIS.
- 2. Click Establishment Profile > Select Establishment.
- 3. Search for and select the establishment.
- 4. Click HACCP.
- 5. Click Add New Hazard Analysis.
- 6. Enter the required information.
  - a. Document Name
    - b. Date
    - c. HACCP Processing Category
  - d. Lot Definitions
- 7. Click Save.

A message appears that the analysis has been added successfully.

8. Repeat steps 1 – 7 for each hazard analysis you want to add.

# b. To add a HACCP Plan to a Hazard Analysis:

After adding a hazard analysis, you can create HACCP plans. You may need to contact IPP in order to complete this information.

- 1. Log on to PHIS.
- 2. Click Establishment Profile > Select Establishment.
- 3. Search for and select the establishment.

4. Click the triangle to the left of the Hazard Analysis that you are adding a HACCP plan to.

Hazard Analyses	Date	Edit	Delete
RAW PRODUCT - GROUND	6/7/2011	Ø	đ
HACCP Plan	Date	Edit	Delete
Add HACCP Plan			

5. Click Add HACCP Plan.

- 6. Enter the required information:
  - a. Plan Name
  - b. Signature Date

- c. HACCP Processing Category
  - **NOTE:** The Hazard Analysis field is pre-filled for you.
- 7. Click Save.
- 8. Repeat steps 5 7 to add additional HACCP Plans to the selected analysis.

#### 2. 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 FSIS Directive 5300.1.

#### a. To enter products:

- 1. Click Establishment Profile > Products.
- 2. Click Add new Product Group.

Depending on the HACCP Processing Categories identified previously, you will see one or more tabs on the Add new Product Group page.

3. For each tab, complete the required fields. After selecting the Finished Product Category, select each Product Group that applies and then choose a volume from the Average Daily Volume pounds per day fields.

NOTE: If the volume data is not known, select the highest volume range.

Product Group*:	Average Daily Volume pounds per day
Further processed poultry parts (Boneless and/or Skinless Parts)	3,001 - 6,000 💌
Poultry parts (including necks/feet & giblets)	3,001 - 6,000 🗸
🗹 Whole Bird	3,001 - 6,000 🔹

- 4. Select the species.
- 5. Enter the Intended Use

**NOTE:** If you select Other, enter the other Intended Use in the space provided.

- 6. Click Save.
- 7. Repeat this process for each product.
- 8. Click the Volumes tab and select a value for each HACCP Processing Category.

Products Volumes	
HAUCP Volumes	
Raw - Intact	Select 🔹
Raw - Non Intact	1 - 1,000 🔻
Slaughter	Select 🔹
	Save Cancel

9. Click Save.

#### 3. Add Slaughter Lines

If the establishment is a slaughter establishment, click Slaughter to enter slaughter lines. Slaughter lines should be entered after you have entered HACCP and Product information. A slaughter line

should be entered for each shift that slaughters; you cannot create one slaughter line that covers multiple shifts. Shifts can, however, have multiple slaughter lines. For additional Slaughter information review FSIS Directive 5300.1.

- 1. Click Add new Line.
- 2. Enter the required fields:
  - a. Shift
  - b. Inspection Type
  - c. Line Name

If a slaughter line has not already been entered the drop-down list will be empty. In this case, click the circle to the left of the second box and enter a slaughter line name. In the image below "Emu" appears in the second box as an example.

	Line Name*:	O Select	 
٤.			
- 34			

- d. Class
- e. Slaughter System
- f. Inspection System

After entering data for items a through f, the page refreshes and subclass options are available.

# 3. Subclass

After selecting a subclass, the page refreshes and you can select the number of heads/hours for each subclass.

Subclass*:	Contrick		
	🗹 Emu	Select	
	Rhea	Select	
Comments:		1 to 133 heads/hours	·
		134 to 272 heads/hours	
		273 to 419 heads/hours	
		420 to 560 heads/hours	
		· ·	

- 4. Click Save.
- 5. Repeat steps 1-4 for each slaughter line.

#### F. Create Assignments

Now that the establishment has been updated with core data, it must be placed into an inspection assignment. This task must be completed by a user with the RMA or RMPS user role. To perform this task, you will need the RIS Assignment Sheet and RIS Position Listing.

Assignments should be created by supervisory order. For example, create a Supervisory Consumer Inspector assignment prior to creating any subordinate in-plant assignments, such as a GS-7.

**NOTE:** If you search for a person and cannot find him or her in the resulting list, it is possible that the record is not flagged appropriately. To flag a personnel record: Login as an RMA and click Resource Management > Personnel. On the Personnel page use the Filter Personnel Resources block to search for the record. Select the record and verify that the IsField check box is selected. Click Save.

#### a. To create assignments:

- 1. Log in as an RMA.
- 2. Click Resource Management > Circuit.
- 3. Select your circuit from the list.
- 4. On the IPS tab, click Add new Circuit IPS.
- 5. Enter the required information:
  - a. Number
  - b. Type
- 6. Click Save.
- 7. Click Return to Previous Page.
- 8. From the left menu, click Assignments.
- 9. To select the IPS you just created, complete the District, Circuit, and IPS fields.
- 10. Click Add New Assignment.
- 11. At this point, you cannot select the Headquarter Plant, so leave the HQ Point and the HQ Point Shift fields blank.
- 12. Verify or enter the required information:
  - a. Number
  - b. Number of Positions
  - c. Slaughter On Line
  - d. Role
  - e. Frequency
  - f. Coverage
  - g. Standard Job
  - h. External Travel % (This can be found on the Position Listing)
  - i. Supervising Asgn

13. Click Save.

14. Click Assign Personnel Resources and Establishments (the green arrow).

🖹 Ac	ld new Assignme	nt					
	Assignment	<u>Grade</u>	Duty Station	No of Positions	Export	Edit	Remove
<b>%</b>	6535-04-01	4		9	Ŷ	ø	đ
U							

- 15. On the Assign Establishment tab, click the Search Establishments bar to expose the establishment search fields. By default, you will see a list of all the establishments in that circuit (separated by shift).
- 16. Click Assign next to each establishment you want to add to the assignment.
- 17. On the Staffing Requirements tab, enter the External Travel amount, if necessary, and click Update.
- 18. If you have another establishment, repeat steps 14-17; otherwise, go to the next step.
- 19. Click the Assign Personnel Resources tab.
- 20. Click the Search Personnel Resources bar to expose the personnel search fields.
- 21. Search for personnel to assign. NOTE: If the person is not showing up here, go to the personnel section and verify that the box "Is field" is checked on his/her profile.
- 22. Click Assign if the user is permanently in this assignment. Click Coverage if the user does temporary coverage.

**NOTE:** Users can only be in one permanent assignment.

- 23. If this is a permanent assignment and if the user is the IIC, go to the next step; otherwise, go to Step 27.
- 24. Click the edit pencil under Assign as IIC. Additional fields appear.
- 25. Select the Is IIC check box and the establishment for which the user is the IIC.
- 26. Click Save.
- 27. Click Return to Previous Page.
- 28. On the Assignment page, click the edit pencil for the new assignment record.
- 29. In the General Information block, to the right of the HQ Point field, click Search.
- 30. On the Search Establishments window, a list of all the establishments associated with the new assignment appears. Select the appropriate check box for the Headquarter Plant.
- 31. Click Select.
- 32. On the Assignment page, click Save.

#### G. Verify Completeness

After you have completed the data entry for an establishment, verify that the record contains all of the following information:

- One or more grants with inspection activities for each grant (requires grant curator to check the appropriate boxes under "animals to be slaughtered" or "types of products" on Grant page)
- Establishment Jurisdiction
- Days and Hours of Operation

Depending on the type of establishment verify that the record contains some or all of the following information:

- Hazard Analyses (including name, date, and HACCP category)
- HACCP Plan (including the name, date, HACCP category, and associated hazard analysis)
- Product Volumes
- HACCP Category Production Volumes



United States Department of Agriculture

Food Safety and Inspection Service

FSIS Directive 2610.1

**Revision 6** 

# FSIS Issuance System

# FSIS ISSUANCE SYSTEM

# TABLE OF CONTENTS

# PART ONE-BASIC PROVISIONS

# Title

Page No.

Ι.	PURPOSE												- 1
II.	CANCELLATION									· .			1
III.	REASON FOR REISSUANCE .							•.		•			1
IV.	REFERENCES												1
V.	ABBREVIATIONS AND FORMS.		• .						•	•			1
VI.	POLICY.								•				2
VII.	DELEGATIONS OF AUTHORITY				•		•						2
	A. Signature Authorities				· .						•		2
	B. Cancellation Authorities .												2
VIII.	CLEARANCE REQUIREMENTS									·.		•	2
IX.	TYPES OF ISSUANCES												3
Х.	EFFECTIVE DATES.												3
XI.	NUMBERING SCHEMES		•										3
XII.	FILING AND AVAILABILITY									•.			4
	A. Filing		•				•			•			4
	B. Availability									•			4
	ATTACHMENT 1-1, Subject Matte	er C	las	sifi	cat	ion	Sy	vste	m				5
							-						

#### PART TWO-PREPARING FSIS ISSUANCES

RESF	PONSIB	ILITIE	S.					•									•	•	13
Α.	OPI.		·					•	•	• .						•			13
В.	IMAB.				•.														13
C.	PID.						•					•							14
D.	Clearan	ice Re	view	Offi	cial	s	•				• .								15
E.	LERD								•			•							15
F.	EMD .									•									15
G	Employ	ees.				•	•								•				15
H.	Manage	ers and	d Sup	pervi	isor	s													15
REVI	SIONS /	AND A	MEN	IDM	EN	TS					÷				•				16
Α.	Revisio	ns			• .		•	•			•			•		•	•		16
В.	Amendr	ments									•		-						16
ADDI	TIONAL	INFO	RMA	TIO	Ν		•					•			•		•		16

i

II.

111.

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