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

FSIS DIRECTIVE

5300.1 Revision 1 10/19/16

MANAGING THE ESTABLISHMENT PROFILE IN THE PUBLIC HEALTH INFORMATION SYSTEM

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL MONDAY, NOVEMBER 21, 2016.

CHAPTER I - GENERAL

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) in meat and poultry establishments, import establishments, identification (ID) warehouses and other facilities where FSIS provides reimbursable inspection services (hereafter referred to as "PHIS establishments") on how to maintain the establishment profile in the Public Health Information System (PHIS). It is important that IPP maintain an accurate and up-to-date establishment profile to ensure the correct tasks are assigned to each establishment. FSIS uses the establishment profile information to assign both routine and directed inspection tasks, manage inspection assignments, determine eligibility for sampling, and generate FSIS sample requests, automated reporting, and ad-hoc data analysis. As such, IPP are to dedicate time each month to verifying the accuracy of the establishment profile.

II. CANCELLATION

FSIS PHIS Directive 5300.1, Managing the Establishment Profile in the Public Health Information System, 4/11/14

III. SIGNIFICANT CHANGES

- A IPP are to focus on a specific area of the establishment profile each month according to a rotating schedule.
- B. Chapter II, Section VIII has been expanded with additional directions to IPP on entering product group information, instructions for calculating the average daily product volume, an option for entering zero for product volume, and additional guidance on responding to PHIS questionnaires.
- C. Product groups were updated in the PHIS Product Category List in Attachment 2, including a change to the name of the "RTE Product with NRTE (no separation)" product category to "NRTE Product with RTE Component" product category.
- D. The product group "Lard/Oils" has been added for oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats.

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E. An intended use option has been added for selecting "Receives additional lethality treatment at a federally inspected establishment" for post-lethality exposed ready-to-eat (RTE) product.

IV. BACKGROUND

PHIS is a web-based IT system used by IPP for reporting detailed information regarding inspection verification, reinspection of foreign products, export certification, noncompliance records, and other inspection activities.

V. HOW TO ACCESS PHIS

- A. PHIS is accessible from the following link on the FSIS website, https://phis.fsis.usda.gov. All PHIS users must provide a level 2 eAuthentication User ID and password or a valid LincPass and PIN 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. IPP are prescribed user access roles to permit or restrict access to PHIS data and functionality. IPP user access roles are dependent upon their work assignment and duties. For example, an import inspector can only edit profile information for the import establishments in his or her assignment based on their prescribed user roles. Some IPP may also have more than one PHIS user access role. PHIS user roles are created by the PHIS Administrator and are assigned by the District Office (DO).

VI. INSPECTOR HOMEPAGE

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, My Inspections and Samples**. Each tab displays information pertinent to the IPP's inspection assignments and user roles. PHIS does not present information on the inspector homepage to users who are not field personnel.

VII. ESTABLISHMENT PROFILE

- A. The **Establishment Profile** is a left navigation menu option that appears after logging in to PHIS and includes a series of sub-links that IPP use to enter data about official establishments, approved import establishments, and other facilities where FSIS provides inspection services. The profile includes information on the products produced, the processes performed, the equipment employed, the Hazard Analysis Critical Control Point (HACCP) systems utilized, and other general information. IPP are to click on **Establishment Profile** on the left navigation menu in order to view the sub-links needed to access the establishment profile pages.
- B. IPP are to select a particular establishment or facility in order for PHIS to display an establishment's profile information. IPP can view particular establishments 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 an establishment or facility by clicking **Establishment Profile** and then clicking on the **Select Establishment** sub-link from the left navigation menu. The **Select Establishment** sub-link allows IPP to search for a particular establishment.

NOTE: IPP are to refer to the PHIS Help Button or the <u>PHIS Quick Reference Guide</u> for additional information on left navigation menu options.

VIII. HOW TO CREATE AN ESTABLISHMENT PROFILE

For PHIS establishments, the Grant Curator (GC) assigns an establishment number and enters information regarding the application for grant of inspection or inspection services. During the application process, a Front Line Supervisor (FLS), Enforcement, Investigations and Analysis Officer (EIAO), or other designated personnel will visit the applicant's establishment and report the information gathered at the establishment (see FSIS PHIS Directive 5220.1, Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS). Some of the information entered into PHIS during the grant application process will be used to populate the establishment profile.

IX. IPP RESPONSIBLITIES FOR PERFORMING THE ESTABLISHMENT PROFILE INSPECTION TASK

A. The assigned inspector in charge (IIC) is responsible for keeping the information in the establishment profile up-to-date and accurate. The establishment profile information is essential to the Agency's goal of protecting public health because FSIS uses the data for generating inspection tasks, determining eligibility for sampling programs, for automated reporting and for ad-hoc data analysis. When an establishment begins production of a new product, there is a significant change in product volume, an establishment address changes or there is a jurisdiction change, IPP are to update the establishment profile as soon as the change occurs to ensure the appropriate inspection tasks are being generated. Other changes, not directly related to task scheduling and sampling eligibility, can be completed during the routine monthly **Update Establishment Profile** task.

The following profile features aid in the determination of task scheduling and sampling eligibility and are critical to keep updated and accurate:

- 1. HACCP Processing Category
- 2. Product Volume Information
- 3. Jurisdiction
- 4. Sampling Supplies Address

B. IPP are to perform the routine **Update Establishment Profile** inspection task monthly by updating the information in the establishment profile with any new information and reviewing the establishment task list. IPP are also to focus on verifying the accuracy of a specific area of the establishment profile each month according to the following schedule:

Table: Establishment Profile Update Schedule		
Month	Profile Information Focus Area	
January	Establishment Contacts	
February	HACCP Systems Information for Raw-Intact product categories	
March	HACCP Systems Information for Raw-Non-Intact product categories	
April	HACCP Systems Information for Thermally Processed-Commercially Sterile, Not Heat Treated–Shelf Stable, and Heat Treated–Shelf Stable product categories	
May	HACCP Systems Information for Fully Cooked–Not Shelf Stable, Product with Secondary Inhibitors–Not Shelf Stable, and Heat Treated but Not Fully Cooked–Not Shelf Stable product categories	
June	General Profile Information	
July	Product Information for Raw-Intact product categories	
August	Product Information for Raw-Non-Intact product categories	
September	Product Information for Thermally Processed-Commercially Sterile, Not Heat Treated–Shelf Stable, and Heat Treated–Shelf Stable product categories	
October	Product Information for Fully Cooked–Not Shelf Stable, Product with Secondary Inhibitors–Not Shelf Stable, and Heat Treated but Not Fully Cooked–Not Shelf Stable product categories	
November	Slaughter Information	
December	General Profile Information	

- C. IPP are to also perform the **Update Establishment Profile** task if they become aware while performing other inspection tasks, or through communication with a management official, that the establishment is producing a new product. IPP can only edit profile information for establishments within their inspection assignments.
- D. Upon entering a new assignment, or when changes occur to an existing assignment, IPP are to provide a copy of the Establishment Profile Report to a management official at the establishment during a weekly meeting. The management official will have an opportunity to affirm or correct any of the profile information in PHIS.
- E. To generate the Establishment Profile Report, IPP are to:
 - 1. Select the establishment under the **Establishment Profile** tab on the left navigation menu;

- 2. Scroll down to the bottom of the page and find the **Reports** tab; and
- 3. Click on **Reports** and then select **Establishment Profile Report**. This will generate the report that can then be saved or printed.
- F. If management responds with a correction, IPP are to update the establishment profile only after verifying establishment records or other data needed to support the basis for the correction. IPP are to resolve any issues or discrepancies regarding profile information before they document the task as completed in PHIS.

CHAPTER II – THE PROFILE

I. PROFILE INFORMATION FOR PHIS ESTABLISHMENTS

When performing the **Update Establishment Profile task**, IPP are to gather information from a management official at the establishment or facility, in conjunction with the guidance in the following parts of this chapter, to complete the establishment profile in PHIS:

Part II: Establishment Contacts

Part III: General

Part IV: Establishment Task List

Part V: HACCP Systems Information (meat and poultry establishments only)

Part VI: Slaughter Information (meat and poultry establishments only)
Part VII: Product Information (meat and poultry establishments only)

Part VIII: Production Volume Information (meat and poultry establishments only)

Part IX: Profile Questionnaires

II. ESTABLISHMENT CONTACTS

- A. The **Contacts** page contains two tabs: **Establishment** and **FSIS Personnel**. IPP are to click on **Add New Contact** to enter establishment contacts on the establishment tab. IPP are to use the "edit" or "delete" icons to modify contact information for the establishment when changes occur. IPP can enter contact information according to operating shift if necessary.
- B. For each establishment contact entered, IPP are to enter the following information, at a minimum:
 - 1. Position;
 - 2. First name;
 - 3. Last name;
 - 4. Phone number and e-mail address: and
 - 5. A contact type if applicable.

NOTE: If none of the listed choices of position exactly match the contact's actual position title, IPP are to select the choice that seems closest to the position title.

- C. Contact types are used in PHIS to designate a specific establishment person that will receive system generated notifications or official Agency correspondence.
- D. IPP are able to select from one or more of the following contact types:

- 1. Select **Emergency Contact** if the Agency is to contact this person during an emergency such as a natural disaster or sudden closure at the establishment;
- 2. Select **Export Coordinator** if the Agency is to contact this person regarding issues pertaining to exported products;
- 3. Select **Lab Sample Result Contact** if the Agency is to send electronic lab results to this person;
- 4. Select **Recall Contact** if the Agency is to contact this person in the event of a recall; or
- 5. Select Establishment Administrator when the establishment provides the name of the individual who will serve as the first Establishment Administrator. In order for an establishment to access PHIS there must be an individual designated to serve as Establishment Administrator entered into the profile. IPP only need enter the initial Establishment Administrator in PHIS for enrollment validation.
- E. FSIS intends to use several contact types for electronic communications to establishments. If available, IPP are to include an email address for at least one of these contact types: Lab Results, Plant Manager, Supervisor, President/GM, or Owner.

III. GENERAL

- A. The General page includes five tabs that contain establishment addresses and general information regarding the establishment. PHIS displays most information on the **Establishment** and **Ownership** tabs as read only to IPP users. The GC is responsible for editing this information while managing the grant application process. The five tabs are:
 - Establishment tab, the pre-populated physical address listed in the List of Addresses table is
 considered by FSIS to be the primary address where IPP perform inspection. If IPP note changes
 to the physical address, IPP are to inform the management official to contact the GC with the
 change of address information.
 - a. IPP are to click on "Add New Address" to enter additional establishment addresses and select the following address types from a list of options for each address entered:
 - Select Company Mailing Address if the Agency is to use this address to mail official constituent information and other general correspondence regarding FSIS inspection;
 - ii. Select **Overnight Mailing Address** if Agency is to use this 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;
 - iii. Select **FSIS Inspection Office Mailing Address** if the Agency is to use this address to mail information to IPP assigned at the establishment or facility; or
 - iv. Select **Laboratory Sample Supplies Address** if the Agency is to use this 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.

NOTE: IPP are to enter a complete **Laboratory Sample Supplies Address** for every establishment. The labs are unable to send sampling supplies to establishments with missing or invalid addresses.

2. **Ownership** tab, the pre-populated owner's name, phone number, mailing address, and organization information is displayed;

NOTE: IPP are to update and maintain information under the **Jurisdiction**, **Exemptions**, and **Other** tabs.

- 3. **Jurisdiction** tab lists the following information:
 - a. Whether the establishment is under FSIS inspection only, State inspection only or Talmadge-Aiken only. Establishments under Talmadge-Aiken jurisdiction utilize state inspectors to conduct federal inspection activities and these establishments are considered federally inspected establishments;
 - b. (Import Facilities Only) If the facility is either:
 - i. FSIS Inspection only;
 - ii. Customs Bonded Warehouse Some import establishments are also a Customs Bonded Warehouse; or
 - iii. APHIS-Approved Defrost Facilities- When cooked beef is imported from an Animal and Plant Health Inspection Services (APHIS) Restricted country (Foot and Mouth Disease, Rinderpest), the product must move to an approved APHIS defrost facility (import establishment) for FSIS to perform a pink juices exam for APHIS under a Memorandum of Understanding (MOU) between APHIS/FSIS;
 - c. Whether the establishment is a dual jurisdiction establishment and provides dual inspection with the Food and Drug Administration (FDA.) IPP are to review the establishment's approved grant of inspection to verify that the establishment is an approved dual jurisdiction establishment before making changes; and
 - d. Whether the establishment employs an Agricultural Marketing Service (AMS) Grading/Quality Control program, such as to provide products for the National School Lunch Program;
- 4. **Exemptions** tab displays any exemptions the establishment may be considered under, such as, custom processing, custom slaughter, retail, or religious exemptions of poultry; and

NOTE: IPP are to verify that establishments are properly performing under a religious exemption for the slaughter and handling of poultry before making changes to this section (Please refer to <u>FSIS Directive</u> <u>6030.1</u>, *Religious Exemption for the Slaughter and Processing of Poultry*, and <u>9 CFR 381.11</u>).

- 5. **Other** tab contains the following information:
 - a. Recall Plan Information;
 - b. Food Defense Plan;

- c. Establishment Size;
 - i. Large Establishments are defined as establishments with 500 or more employees;
 - ii. Small Establishments are defined as establishments with 10 or more employees but fewer than 500 employees; and
 - iii. Very Small Establishments are defined as establishments with fewer than 10 employees or annual sales of less than \$2.5 million;
- d. Geographic Location;
- e. Names under which the establishment is Doing Business As (DBA); and
- f. FSIS IPP office telephone number and fax number.

NOTE: IPP are to review and verify the profile information is accurate for recall plan information, food defense plan, and establishment size. IPP are to enter a size for every establishment in PHIS, including egg products plants and facilities under voluntary inspection.

IV. ESTABLISHMENT TASK LIST

- A. IPP are also to review the inspection activities listed in the **Inspection Tasks** sub-menu of the Establishment Profile. The establishment task list contains tasks that are applicable to a particular establishment, and a particular shift, and is generated by PHIS based on information entered in other parts of the establishment profile. IPP are responsible for ensuring the correct FSIS inspection tasks are listed in the establishment task list.
- B. Some verification tasks that appear on the establishment task list may not apply to the establishment's operations. IPP are to review the establishment task list when they review the establishment profile and de-select those tasks that do not apply to the establishment's current operations. Likewise, IPP are also to review the tasks that have previously been de-selected to ensure that those tasks still do not apply to the establishment's current operations. To de-select a task, IPP are to click on **Inspection Tasks** and then click the applicable edit icon. When IPP make a change on the establishment task list, PHIS will require them to record a justification for that change. Please refer to <u>FSIS Directive 13,000.1</u>, *Scheduling In-Plant Inspection Tasks in PHIS*, for more information on when to de-select tasks.

V. HACCP SYSTEMS INFORMATION

- A. IPP are responsible for verifying complete and accurate profile information regarding the establishments' hazard analysis and HACCP plan. When entering HACCP Systems information into PHIS, IPP are to adhere to the following steps:
 - 1. IPP are to gather information from the establishment on its HACCP system including the hazard analysis and HACCP plan (if applicable);
 - 2. IPP are to select generic options from a drop down list to assist in the collection of HACCP system information. FSIS does not require establishments to identify any of their HACCP systems information or other documentation using the list of PHIS product categories;
 - 3. <u>Hazard analysis and HACCP Plan Information:</u> Select **Add New Hazard Analysis** to access the hazard analysis information. IPP must enter the hazard analysis information before PHIS allows

users to enter the HACCP plan and product information. IPP are to complete only the following information in PHIS for the establishment's hazard analysis and HACCP plan:

- a. Name the HACCP plan or hazard analysis. If the establishment does not title their hazard analysis and associated HACCP plan, identify it using a name that other FSIS personnel can use to identify the plan easily (i.e. Raw Intact Steak HACCP Plan);
- b. In the **Date** section, enter the most recent date of the HACCP plan or hazard analysis;
- c. IPP are to select one or more HACCP processing categories for each HACCP plan or hazard analysis based on the processing steps performed at the establishment. FSIS defines HACCP processing categories (<u>9 CFR 417.2</u>) based on food science principles. <u>Attachment 1</u> of this directive describes the HACCP processing categories; and
- d. Enter a brief description of the lot definition in the text box.

VI. SLAUGHTER INFORMATION

- A. IPP are to complete the following information on the establishment's slaughter operation for each shift:
 - 1. Slaughter line information: Each line and line name;
 - 2. Slaughter Class: Select a slaughter class for each line;
 - 3. Slaughter system information for each line;
 - 4. Inspection system for each line;
 - 5. Number of physical slaughter lines;
 - 6. Number of slaughter lines operating simultaneously; and
 - 7. Comments.

EXAMPLE 1: At a large poultry slaughter establishment operating two evisceration lines at the same time on two shifts, IPP would enter 2 for the "Number of Physical Slaughter Lines" and enter 2 for "Number of Slaughter Lines Operating Simultaneously Per Shift."

EXAMPLE 2: At a large beef slaughter establishment operating one line on two shifts, IPP would enter 1 for the "Number of Physical Slaughter Lines" and enter 1 for "Number of Slaughter Lines Operating Simultaneously Per Shift."

EXAMPLE 3: At a very small sheep and goat slaughter establishment that operates a stationary rail with gambrels, each species would be a separate slaughter line, but IPP would enter 1 for the "Number of Physical Slaughter Lines" and enter 1 for "Number of Slaughter Lines Operating Simultaneously Per Shift."

VII. PRODUCT INFORMATION

A. IPP are to click on **Products** and complete finished product category information for each of the establishment's HACCP plans. Finished product information represents the end products of the establishment's processing steps. <u>Attachment 2</u> contains a list of finished products, as they are associated with the HACCP processing categories. <u>FSIS Directive 10,240.4</u>, *Verification Activities of the*

Listeria monocytogenes (Lm) Regulation and the Ready To Eat (RTE) Sampling Program contains additional guidance regarding RTE finished product categories.

NOTE: If the product is box-in box-out (i.e., just being stored at the establishment) it should not be included in the finished product category information.

- B. IPP are to enter or update one product group entry in the profile at a time. If IPP enter or update multiple product groups at the same time, PHIS will not apply the intended use field correctly, which will affect sampling assignments.
- C. To delete a product group entry, select the trashcan icon to delete the entry.
- D. IPP are to enter or update each product group separately by intended use. If more than one intended use is listed for a finished product group, IPP are to enter the product group separately (one time under each intended use). Do not select both and do not leave it blank.
 - 1. IPP are to select the "For RTE Cooking Only" option only if the product is intended for use in ready-to-eat (RTE) products at another federally inspected establishment, and only if the establishment records and controls support the intended use. IPP are to follow the instructions in <u>FSIS Directive 10,250.1</u>, Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products, to determine whether the intended use of the product is for processing into RTE product, and whether the establishment has controls to ensure that the product is processed into RTE product.
 - 2. IPP are to select "Other" for the intended use if product is intended for consumer cooking (the product is ready-to-cook), goes to other official establishments for further processing (but not RTE treatment), is exported, goes to hotels/restaurants/institutions, or goes to a facility other than an official domestic establishment.
 - 3. IPP are to select the "Receives additional lethality treatment at a federally inspected establishment" for RTE product that will be shipped to another official establishment where it will receive an additional full lethality treatment.

E. IPP are to click on **Add New Product Group** and then select the appropriate tab - Raw, NRTE, RTE or Thermally processed - and complete the required fields under the corresponding tab. Table 1 contains the HACCP process categories associated with Raw products, Not ready-to-Eat (NRTE) Products, RTE Products and thermally processed products.

NOTE: All finished products produced under the Fully Cooked – Not Shelf Stable HACCP processing category are considered RTE. FSIS defines RTE products in 9 CFR 430.1.

Table 1: PHIS Product Tabs by HACCP Category				
	Finished Products			
HACCP Processing Categories	Raw Product	NRTE Product	RTE Products	*Thermally Processed Product
Slaughter	•			
Raw – Intact (Raw Not Ground)	•			
Raw –Non Intact (Raw Ground)	•			
Thermally Processed – Commercially Sterile				•
Not Heat-Treated - Shelf Stable		•	•	
Heat Treated – Shelf Stable		•	•	
Fully Cooked – Not Shelf Stable			•	
Product with Secondary Inhibitors – Not Shelf Stable		•	•	
Heat Treated but Not Fully Cooked – Not Shelf Stable		•		

^{*} Products in the Thermally Processed-Commercially Sterile HACCP Category must be RTE

VIII. PRODUCTION VOLUME INFORMATION

A. IPP are to complete product volume information on the **Products** page. IPP can edit product volume information for an existing product group entry by clicking the edit icon, or add a new product group.

NOTE: IPP will need to determine the average daily production volume, or pounds per day, prior to completing the PHIS products information page. To calculate the average daily volume, IPP are to follow three steps:

1. Estimate the total volume produced for all products produced in each **Product Group** entry in the previous calendar month. 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 for products produced within each product group over the previous month. The product groups represent the most refined finished product information selected in PHIS and, for example, include such product groups as Ground Beef Product, Beef Manufacturing Trimmings, Mechanically Separated Product, Poultry Parts (legs, breasts, wings ONLY), and NRTE Processed Meat. Finished product information should represent the end products the establishment ships and are selected based on intended use of products in each product group;

NOTE: Only finished product information, the product as it is shipped from the establishment, should be entered under products. Box-in box-out product should not be included. Products are only entered once under one category. For example, a carcass that is entered under the Raw Product-Intact Processing Category would not also be entered under the Slaughter HACCP Processing Category.

- 2. Determine the number of days the product group was produced in the previous calendar month and divide the total volume produced for each product group by that number. IPP are also to enter the number of days of production in the field at the bottom of the page; and
- 3. Select one of the volume ranges listed in Table 2 that best represents the average daily production for that particular product group. If there was no production for that product group in the previous month but the establishment plans to produce the product in the future (i.e. seasonal product) IPP can enter "0" for the production volume. If little or no records exist, IPP will need to make a best estimate based on their direct knowledge of the operation and select the highest volume range for a particular product group based on the production capacity at the establishment. If the establishment does not agree with the volume range chosen, they should provide evidence to support the volume estimate.

NOTE: After making changes concerning products and volume, IPP are to present an updated establishment profile report to establishment management officials at a weekly meeting.

Table 2: PHIS Volume Ranges
Average Daily Volume (lbs. per day)
0
1 - 100
101 – 1,000
1,001 – 3,000
3,001 – 6,000
6,001 - 50,000
50,001 – 250,000
250,001 – 600,000
600,001 - 1,000,000
> 1,000,000

B. If an establishment produces two or more types of product that are **within the same product group** and that have the same intended use, IPP are to enter the total volume for all products within that product group in a single entry.

EXAMPLE: If an establishment produces raw chicken patties (average daily production of 3,000 pounds) and raw chicken sausage (average daily production of 5,000 pounds) that are not intended for a lethality treatment at another federally-inspected establishment, IPP would enter both types of poultry products as a single entry under "Other Comminuted," with the average daily volume representative of the total volume of both products (8,000 pounds).

IX. PROFILE QUESTIONS

A. The **Profile Questionnaire** page contains periodic questionnaires with "begin" and "end" dates. IPP are to review this section monthly as part of the **Update Establishment Profile** inspection task. The questions may contain information regarding the establishments' HACCP system reassessments, pathogen control programs, chemical interventions, microbiological testing programs or other information regarding establishment practices that can be used to inform Agency activities.

- B. When a profile questionnaire appears in PHIS, IPP are to complete and submit the questionnaire during their next scheduled **Update Establishment Profile** inspection task unless otherwise instructed. If IPP completed the monthly **Update Establishment Profile** inspection task before receiving the profile questionnaire, they are to create a directed **Update Establishment Profile** task in order to complete the profile questionnaire.
- C. After clicking on the **Profile Questionnaire** page, IPP are to locate the applicable questionnaire in the box and click the "open" icon. After completing all questions in the questionnaire, IPP are to submit the profile questionnaire and then mark the **Update Establishment Profile** task as completed.
- D. IPP may view or print the questions before completing the questionnaire. To view or print the questions, IPP are to click the "open" arrow to access the questionnaire, select "Reports", then select "Full Questionnaire Report" to generate a PDF file for viewing or printing. Next, IPP are to select "Go Back to Questionnaire" and then select "Save & Close."
- E. IPP are not to issue noncompliance records (NRs) or take enforcement actions based on the responses to questionnaires. If IPP determine that there is noncompliance with regulatory requirements while reviewing establishment information for completing the questionnaire, they are to initiate a directed instance of the relevant verification task, following the instructions in <u>FSIS Directive 13.000.1</u>. Within the task, IPP are to record the findings and document the noncompliance, following the instructions in <u>FSIS Directive 5000.1</u>, *Verifying an Establishment's Food Safety System*.

NOTE: For more information on questionnaires please refer to the <u>PHIS Quick Reference Guide on</u> Questionnaires

CHAPTER III – OTHER PROFILE INFORMATION

I. PROFILE SUMMARY HOMEPAGE

- A. All establishments where FSIS provides inspection services will have a PHIS homepage that contains relevant inspection information. The following information can be viewed on the profile summary homepage:
 - 1. **Basic-** This page displays a brief overview of establishment profile information;
 - 2. **Products** This page displays finished product category, product group name, product volume, and number of days of production;
 - 3. **Reports-** This page contains a link to the Establishment Profile Report;
 - 4. **Personnel** This page provides information on FSIS coverage assignments, FSIS assignment rotation information, and approved hours of operation;
 - 5. **NR**-This page displays a list of NR's, including, the NR number, status, and date of issuance;
 - 6. **Food Safety Assessments (FSA)** IPP can view FSA information including the date of the last FSA, as well as any FSAs completed in PHIS for that establishment;
 - 7. Laboratory Sampling- This page displays sample history; and
 - 8. **Types of Inspection-** This page displays mandatory inspection services, as well as voluntary reimbursable services, and grant history information.

II. GRANTS AND APPROVALS INFORMATION

IPP can view the grant of inspection information entered by the GC. IPP cannot edit the information associated with the grant of inspection or grant application. If any of the information is incorrect, IPP are to contact the GC. The GC must complete the grant application and grant of inspection information in order for PHIS to display the information. This section also contains a list of Voluntary Reimbursable Overtime services approved by the DO.

III. FSIS TRAINING INFORMATION

Based on the operations at the establishment, this section lists the types of training IPP would be expected to have in order to perform verification tasks for an assignment.

IV. 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 5300.1**

Question Field: Enter question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select Public Health Information System (PHIS) from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, select Continue and then select Finish Submitting Question.

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

Assistant Administrator

Office of Policy and Program Development

ATTACHMENT 1: HACCP PROCESSING CATEGORIES

A. Slaughter: This HACCP processing category applies to establishments that slaughter livestock or poultry. Slaughter establishments typically produce raw intact finished products.

NOTE: If the establishment produces raw intact products that could be listed under either the Slaughter or Raw Product-Intact category, IPP are to list the product under only one of the categories to prevent duplicate entries. IPP are to use the Raw Product-Intact category for these products whenever possible.

- B. Raw Product—Intact: This HACCP processing category applies to establishments that further process directly following the slaughter processing steps or after receiving raw products. The processing steps at the establishment include the meat fabrication or poultry cut-up. If the establishment also slaughters, these steps are typically applied after the chilling requirements (9 CFR 381.66) are met for poultry carcasses, or after meat carcasses are cooled. Establishments in the Raw Product-Intact HACCP processing category may produce finished products such as raw poultry (in whole or in part) or raw meat products such as primal or subprimals. Beef manufacturing trimmings (e.g., pieces of meat remaining after steaks, roasts, and other intact cuts) is also an example of intact raw beef product. Product that has been marinated intact or non-vacuum tumbled is considered raw intact product. FSIS considers raw products to be intact unless they have undergone any of the processes associated with the non-intact HACCP processing category.
- C. Raw Product—Non-intact: This HACCP processing category applies to establishments that further process by using processing steps such as grinding, comminuting, injecting product with solutions or other liquids, marinating non-intact, vacuum tumbling, or mechanical tenderization by needling, cubing, pounding devices or other means of creating non-intact product. Examples of finished products in this category include raw products reconstructed into formed entrees, comminuted products and advanced meat recovery product. If the establishment produces bench trim or pieces of meat produced from non-intact meat, then the bench trim or pieces are also considered non-intact.
- D. Thermally Processed-Commercially Sterile: This HACCP processing category applies to establishments that use a thermal processing step. Thermally processed, commercially sterile finished products are products in cans or flexible containers such as pouches, or semi-rigid, as in lunch bowls. Thermally processed, commercially sterile products are addressed in Subpart G, 318.300 311 for meat food products, and Subpart X, 381.300 to 311, for poultry products.
- E. Not Heat Treated Shelf Stable: This HACCP processing category applies to establishments that further process by curing, drying, or fermenting processing step as the sole means by which product achieves food safety. Establishments in this HACCP processing category may apply a low-level heat treatment as long as the heat treatment is not used as means to achieve food safety. The finished products produced under this HACCP processing category are shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes.
- F. Heat Treated-Shelf Stable: This HACCP processing category applies to establishments that further process by using a heat treatment processing step to achieve food safety in combination with curing, drying, or fermenting processing step to achieve food safety. The finished products produced under this HACCP processing category are shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes. If the establishment produces product using the processing steps applicable under this processing category and the product is not shelf stable, the establishment is producing product under the HACCP processing category, Fully Cooked Not Shelf Stable.
- G. Fully Cooked-Not Shelf Stable: This HACCP processing category applies to establishments that further process products by using primarily a full lethality heat process step (i.e. cooking) to achieve food safety. The finished products 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. These products also meet the definition of Ready to Eat (RTE) as defined in 9 CFR 430.1.

- H. Heat Treated but Not Fully Cooked Not Shelf Stable: This HACCP processing category applies to an establishment that further processes products that are (1) not ready-to-eat products (NRTE) or (2) raw otherwise processed products that are refrigerated or frozen throughout the product's shelf life. Meat and poultry products are produced using a heat process that meet one of the following criteria:
- The heat-processing step is not adequate to achieve food safety. Products may be partially cooked or heated to set batter on a raw product.
- The heat processing step applied to meat or poultry component was adequate to achieve food safety, however product is further processed, assembled, or packaged so that cooked meat or poultry products contacts non-ready to-eat product ingredients. In this case, the final product is in a form that is not edible without additional preparing to achieve food safety. An example of this product is potpie product that contains cooked chicken and raw dough.
- I. Product with Secondary Inhibitors-Not Shelf Stable: This HACCP processing category applies to establishments that further process by using a curing processing step or a processing step using other ingredients that inhibit bacterial growth. These products are generally refrigerated or frozen throughout the product's shelf life. This would be products that received treatment or whose formulations contain ingredients that change the product characteristics (e.g., lower water activity, change the pH, etc.) to the point that product characteristics are altered, promoting microbial inhibiting qualities associated with the treatments or additives. An example of this type of product would be dry cured ham. Depending on the process and ingredients, these products may or may not meet the definition of RTE as defined in 9 CFR 430.1.

PHIS Product Category List (Meat & Poultry Establishments)			
HACCP Processing Categories	Finished Product Category	Production Volume Categories (by Product Groups)	
Slaughter Or Raw Product - Intact	Raw intact beef	 Carcass (including carcass halves or quarters) Primals and Subprimals¹ Beef Manufacturing Trimmings Cheek Meat Cuts² (including Bone-in and Boneless Meats) Head Meat Weasand Meat Heart Meat Edible Offal³ Bench Trim (trimmings from animals not slaughter at the est.) Trim produced by sister processing establishment Other Intact⁴ 	
	Raw intact pork	 Carcass (including carcass halves or quarters) Primals and Subprimals¹ Cheek Meat Cuts² (including Bone-In and Boneless Meats) Head Meat Edible Offal³ Trimmings from Intact Pork Other Intact⁴ 	
	Raw intact meat – other (sheep, goat)	 Carcass (including carcass halves or quarters) Primals and Subprimals¹ Cuts² (including Bone-In and Boneless Meats) Edible Offal³ Other Intact⁴ 	
	Raw intact chicken ⁵	 Whole bird Poultry Parts (legs, breasts, wings ONLY)⁶ Other Poultry Parts (including feet, necks, and giblets) Raw Stuffed Poultry Products Other Intact Poultry Products 	

Raw intact turkey ⁵	 Whole bird Poultry Parts (legs, breasts, wings ONLY) Other Poultry Parts (including feet, neck, and giblets) Raw Stuffed Poultry Products Other Intact Poultry Products
Raw intact poultry – other (ducks, geese, squab)	 Whole bird Poultry Parts (including necks, feet, and giblets) Boneless and/or Skinless Parts

Ground Beef Product from in-house source Slaughter materials Hamburger/Beef Patty Product - Advanced Meat Recovery (AMR) Or - Formed Steaks Raw - Ammoniated Beef Beef trimming from non-intact beef Product -Non-Intact Bench Trim (derived from non-intact beef not slaughtered at the establishment) - Low Temperature Rendered Product- Finely Textured Beef (FTB) Low Temperature Rendered Product- Partially Defatted Beef Fatty Tissue (PDBFT) - Low Temperature Rendered Product-Partially Defatted Chopped Beef (PDCB) Non-Intact Cuts² (including Bone-In and Boneless Meats) Other Non-Intact Product (fresh sausage, meatloaf, gyros, meatballs, etc.) Raw ground, Ground Beef Product from purchased source comminuted, or materials otherwise non-Ground Beef combined with other species intact beef from in-house source materials Ground Beef combined with other species from purchased source materials Fabricated Steaks and other Non-Intact **Subprimals** Hamburger/Beef Patty combined with other species from in-house source materials Hamburger/Beef Patty combined with other species from purchased source materials Mechanically tenderized products from inhouse source materials Mechanically tenderized products from purchased source materials - Portioned raw ground beef product Raw ground beef product produced from source materials accompanied by a COA, no bench trim Raw ground beef product from non-intact source materials, no bench trim

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Raw ground, comminuted, or otherwise non-intact pork	 Cuts² (Tenderized, Injected, Pumped, or Vacuum-Tumbled- including Bone-In and Boneless) Primals and Subprimals¹ (Tenderized, Injected, Pumped, or Vacuum-Tumbled) Trimmings from non-intact pork Ground Product Advanced Meat Recovery (AMR) Mechanically Separated (Species) Sausage, Patties, or other formed products Other Comminuted Other Non-Intact
Raw ground, comminuted, or otherwise non- intact meat – other (sheep, goat, combination species)	 Ground Product Advanced Meat Recovery (AMR) Other Non-Intact Mechanically Separated (Species)
Raw ground, comminuted, or otherwise non- intact chicken ⁷	 Ground Product Mechanically Separated (Species) Other Comminuted Injected, Tenderized, or Vacuum Tumbled Parts (legs, breasts, wings ONLY) Injected, Tenderized, or Vacuum tumbled Other Parts (including feet, neck, and giblets) Injected, Tenderized, or Vacuum Tumbled Whole Bird Raw Stuffed Poultry Products Other Non-Intact but not Comminuted Poultry Products
Raw ground, comminuted, or otherwise non- intact turkey ⁷	 Ground Product Mechanically Separated (Species)⁸ Other Comminuted Injected, Tenderized, or Vacuum Tumbled Parts (legs, breasts, wings ONLY) Injected, Tenderized, or Vacuum Tumbled Other Parts (including feet, neck, and giblets) Injected, Tenderized, or Vacuum Tumbled Whole Bird Raw Stuffed Poultry Products Other Non-Intact but not Comminuted Poultry Products

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	Raw ground, comminuted, or otherwise non- intact poultry – other (ducks, geese, squab)	Ground ProductMechanically Separated (Species)Other Non-Intact
Not Heat	Raw (NRTE) otherwise processed meat	 Not-Stuffed NRTE Product with RTE Component¹² Stuffed
Treated – Shelf Stable Heat Treated	Raw (NRTE) otherwise processed poultry	 Not-Stuffed NRTE Product with RTE Component¹² Stuffed
– Shelf Stable	RTE ⁹ acidified/fermente d meat (without cooking)	 RTE fermented meat (sliced and not-sliced) according to Lm Alternative¹¹-post-lethality exposed RTE fermented meat (sliced and not-sliced) not post-lethality exposed
	RTE ⁹ acidified/fermente d poultry (without cooking)	 RTE fermented poultry (sliced and not-sliced) according to Lm Alternative¹¹ –post-lethality exposed RTE fermented poultry (sliced and not-sliced) not post-lethality exposed
	RTE ⁹ dried meat	 RTE dried meat (sliced and not-sliced) according to Lm Alternative¹¹-post-lethality exposed RTE dried meat (sliced and not-sliced) not post-lethality exposed Lard/oils¹³
	RTE ⁹ dried poultry	 RTE dried poultry (sliced and not-sliced) according to Lm Alternative¹¹-post-lethality exposed RTE dried poultry (sliced and not-sliced) not post-lethality exposed
	RTE ⁹ salt-cured meat	 RTE salt cured meat (sliced and not-sliced) according to Lm Alternative¹¹ –post-lethality exposed RTE salt cured meat (sliced and not-sliced) not post-lethality exposed
	RTE ⁹ salt-cured poultry	 RTE salt cured poultry (sliced and not-sliced) according to Lm Alternative¹¹ –post-lethality exposed RTE salt cured poultry (sliced and not-sliced) not post-lethality exposed

Heat Treated but Not Fully Cooked – Not Shelf Stable	Raw (NRTE) otherwise processed meat	 Not-Stuffed NRTE Product with RTE Component¹² Stuffed
	Raw (NRTE) otherwise processed poultry	 Not-Stuffed NRTE Product with RTE Component¹² NRTE Stuffed Chicken Products that appear RTE¹⁰
Product with Secondary Inhibitors – Not Shelf Stable	RTE ⁹ salt-cured meat (PLE)	 RTE salt cured meat (sliced and not-sliced) according to Lm Alternative¹¹ –post-lethality exposed RTE salt cured meat (sliced and not-sliced) not post-lethality exposed
	RTE ⁹ salt-cured poultry (PLE)	 RTE salt cured poultry (sliced and not-sliced) according to Lm Alternative¹¹ –post-lethality exposed RTE salt cured poultry (sliced and not-sliced) not post-lethality exposed
	NRTE otherwise processed meat	 Not-Stuffed NRTE Product with RTE Component¹² Stuffed
	Raw (NRTE) otherwise processed poultry	 Not-Stuffed NRTE Product with RTE Component¹² Stuffed
Fully Cooked – Not Shelf Stable	RTE ⁹ fully-cooked meat (PLE)	 Hot Dog Products according to Lm Alternative⁷ Salad/Spread/Pate according to Lm Alternative¹¹ Meat + Nonmeat Components according to Lm Alternative¹¹ Sausage Products Diced/Shredded according to Lm Alternative¹¹ Patties/Nuggets according to Lm Alternative¹¹ Other Fully cooked sliced product according to Lm Alternative¹¹ Other Fully cooked not sliced product according to Lm Alternative¹¹ Poultry Parts or Meat Cuts according to Lm Alternative¹¹

	RTE ⁹ fully- cooked poultry (PLE)	 Hot Dog Products according to Lm Alternative⁷ Salad/Spread/Pate according to Lm Alternative¹¹ Poultry + Nonpoultry Components according to Lm Alternative¹¹ Sausage Products Diced/Shredded according to Lm Alternative¹¹ Patties/Nuggets according to Lm Alternative¹¹ Other Fully cooked sliced product according to Lm Alternative¹¹ Other Fully cooked not sliced product according to Lm Alternative¹¹ Poultry Parts or Poultry Cuts according to Lm Alternative¹¹
	RTE ⁹ fully-cooked meat without subsequent exposure to the environment	 Hot Dog Products not post-lethality exposed Salad/Spread/Pate not post-lethality exposed Meat + Nonmeat Components not post-lethality exposed Sausage Products not post-lethality exposed Diced/Shredded not post-lethality exposed Patties/Nuggets not post-lethality exposed Other Fully cooked sliced product not post-lethality exposed Other Fully cooked not sliced product not post-lethality exposed Poultry Parts or Meat Cuts
	RTE ⁹ fully-cooked poultry without subsequent exposure to the environment	 Hot Dog Products not post-lethality exposed Salad/Spread/Pate not post-lethality exposed Poultry + Nonpoultry Components Poultry Parts or Poultry Cuts Sausage Products not post-lethality exposed Diced/Shredded not post-lethality exposed Patties/Nuggets not post-lethality exposed Other Fully cooked sliced product not post-lethality exposed Other Fully cooked not sliced product not post-lethality exposed
Thermally Processed - Commerciall y Sterile	Thermally processed, commercially sterile	Thermally Processed Products (includes products in Cans/Pails, Flexible Pouches, Trays, Jars and Bag-n-Box)

¹ 9 CFR 316.9(b) defines primal parts as wholesale cuts of carcasses customarily distributed to retailers. Primals are further cut down into subprimals.

² A "cut" is a consumer size portion from primals, portion cuts, or a tray ready products. ³ Edible Offal includes tails, feet, etc.

⁴Other Intact includes fat.

⁵ The product groups "Poultry Parts ("including necks/feet and giblets", "Further processed poultry parts (Boneless and/or Skinless Parts)" and "Boneless and/or Skinless Parts") are obsolete and are not be used.

⁶ As defined in 9 CFR 381.170(b), Standards for kinds and classes and for cuts of raw poultry.

The Product Group "Other Non-Intact" is obsolete and is not to be used.

⁸As defined in 9 CFR 381.173.

⁹ RTE is defined in 9 CFR 430.

¹⁰ NRTE stuffed chicken products that appear RTE contain raw, comminuted chicken breast meat or whole chicken breast meat, but the finished product is heat-treated only to set the batter or breading and impart an RTE appearance. The product typically is stuffed with ingredients such as a raw vegetable, butter, cheese or meat such as ham. ¹¹Listeria monocytogenes (Lm) alternatives are Alt 1; Alt 2, Choice 1; Alt 2, Choice 2; Lm Alt 3

¹² Product that contains both a cooked meat or poultry RTE component and a Not-ready-to-eat component, such as a Pot Pie with an RTE filling and raw dough.

¹³ Oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats.