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

FSIS PHIS DIRECTIVE

5300.1

4/11/11

MANAGING THE ESTABLISHMENT PROFILE IN THE PUBLIC HEALTH INFORMATION SYSTEM (PHIS)

I. PURPOSE

This directive provides instructions to Inspection Program Personnel (IPP), including Import Inspection Personnel, responsible for maintaining information in Public Health Information System (PHIS) at meat and poultry establishments, import establishments, identification (ID) warehouses and other facilities where FSIS provides reimbursable inspection services

NOTE: IPP not trained in PHIS functions will continue using Performance-based Inspection System (PBIS) until provided with further instructions (i.e., IPP at egg product plants or certain export facilities).

- II. [RESERVED]
- III. [RESERVED]
- IV. REFERENCES
- 9 CFR 300 to end

The PHIS User Guide is available via the FSIS Intranet on the PHIS page under Resources.

V. BACKGROUND

A. PHIS is a web-based IT system used by IPP for reporting detailed information regarding inspection verification, reinspection of foreign products, export certification, noncompliance reports, and other inspection activities. PHIS replaces the functions of the PBIS, Supplier Tracking *E. coli* O157:H7 Positives (STEPS), Automated Import Inspection System (AIIS) and Food Safety Assessment (FSA) reporting instrument and other IT systems that are transiting

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To PHIS. Agency personnel responsible for maintaining information in the replaced systems will maintain the same information in PHIS. Existing and future IT programs will integrate seamlessly with PHIS to allow authorized users to analyze inspection data in conjunction with other electronic data sources available to the Agency.

VI. 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 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 dependant 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).

VII. INSPECTOR HOMEPAGE

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

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

VIII. ESTABLISHMENT PROFILE

A. The "Establishment Profile" is a left navigation menu option that appears after logging in to PHIS. The establishment profile is a series of webpages 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 HACCP systems that the establishment has put in place, and other general information. FSIS uses the establishment profile information to assign routine inspection tasks, to create tailored inspection tasks, to generate FSIS sample requests, and to manage inspection assignments.

- B. IPP must 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" submenu item from the left navigation menu. The select establishment page allows IPP to search for a particular establishment. IPP are to refer to the PHIS User guide for additional information on left navigation menu options for the establishment profile.

IX. HOW TO CREATE AN ESTABLISHMENT PROFILE

- A. For meat and poultry establishments or other facilities where FSIS provides inspection, the Resource Management Analyst (RMA) is to assign an establishment number and enter information regarding the application for grant of inspection or inspection services. During the application process, a FLS, 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). Some of the information that is entered in PHIS during the grant application process will be used to populate the establishment profile.
- B. For import establishments, Import Inspection Division Headquarters (IID-HQ) are to process the grant application and maintain the grant of inspection information in PHIS. During the application process, IID-HQ may consult the Regional Field Supervisor, Import Surveillance Liaison Officer, or other designated personnel for assistance to complete the import establishment profile.

X. IPP RESPONSIBLITIES FOR PERFORMING THE ESTABLISHMENT PROFILE INSPECTION TASK

- A. IPP are 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, for automated reporting and for ad-hoc data analysis. FSIS has migrated relevant profile information from PBIS into the PHIS establishment profile for all existing domestic and import establishments.
- B. IPP are to perform the establishment profile inspection task by reviewing and updating the information in the establishment profile. IPP are to click on "establishment profile" on the left navigation menu in order to view the sub-links needed to access the establishment profile pages. IPP have user role permissions to edit profile information for establishments that are in their inspection assignments only.

C. PHIS will display the establishment profile task monthly. IPP are also to perform the task when information recorded in the profile is out-of-date, and when IPP learn of changes while performing other inspection tasks or when communicating with a management official at the establishment or facility.

NOTE: During the PHIS transition period, IPP are to perform the profile task at an alternative frequency. IPP are to follow the supplemental instruction on completing the establishment profile task in FSIS Notice 17-11, Public Health Information System (PHIS) Transition. See link:

http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/17-11.pdf

D. IPP are to provide a copy of the establishment profile 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. When management responds with a correction, IPP are to change their response only after seeing establishment records or other data that is needed to support the basis for the correction. IPP are to resolve any issues or discrepancies regarding profile information before they are to document the task as completed in PHIS.

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

CHAPTER II – THE PROFILE

I. PROFILE INFORMATION FOR MEAT AND POULTRY ESTABLISHMENTS

A. IPP located in the Office of Field Operations (OFO) are to complete establishment profile information for meat and poultry establishments when performing the PHIS establishment profile task. IPP are to follow the guidance in the following parts in this chapter of the directive:

Part II: Establishment Contacts

Part III: General

Part IV: Facility and Equipment

Part V: Establishment Operational Schedules

Part VI: Establishment Task List

Part VII: HACCP Systems Information

Part VIII: Slaughter Information
Part IX: Product Information

Part X: Production Volume Information

Part XI: Profile Questions

Part: New Technologies Information

B. Import inspection personnel are to complete establishment profile information in PHIS for import establishments. IPP are to follow the guidance in the following parts of this chapter of the directive:

Part II: Establishment Contacts

Part III: General

Part IV: Facility and Equipment

Part V: Establishment Operational Schedules

Part VI: Establishment Task List

Part XI: Profile Questions

Part XII: New Technologies Information

NOTE: Import Inspection Division Headquarters (IID HQ) personnel are to enter pre-stamp information into the import establishment's profile in PHIS and update as necessary (see Part IV: Facility and Equipment).

C. IPP located in OFO are to complete establishment profile information in PHIS for ID warehouses and other facilities. IPP are to follow the guidance in the following parts in this chapter of the directive:

Part II: Establishment Contacts

Part III: General

Part IV: Facility and Equipment

Part V: Establishment Operational Schedules

Part VI: Establishment Task List

Part XI: Profile Questions

D. The following section describes the information that IPP are to review and update when performing the establishment profile task. IPP are to gather information from a management official at the establishment or facility to perform the task. IPP are to edit establishment profile information by selecting options from drop down lists wherever possible. Headquarters personnel are responsible for editing the drop down lists in PHIS.

II. ESTABLISHMENT CONTACTS

- A. The *Contacts* submenu contains two tabs "Establishment" and "FSIS Personnel." IPP are to click on "add new Contact" to enter establishment contacts on the establishment tab. IPP can enter contacts information according to operating shift if necessary.
- B. Contact types are used in PHIS to designate a person that will receive system generated notifications or official Agency correspondence. Their contact information will be available in other parts of PHIS such as when IPP are selecting a contact to receive notification of noncompliance reports.
- C. IPP are to select one or more of the following contact types for each contact person:
 - 1. Select "Recall Contact" if the contact serves as a contact person during a recall situation.
 - Select "Emergency Contact" if the Agency is to contact this person during an emergency such as a natural disaster or sudden closure at establishment.
 - 3. Select "Lab Sample Results Contact" if the Agency is to send laboratory sample results to this person electronically.
 - 4. Select "E. coli O157:H7 Positive Supplier Contact" if the Agency is to contact this person electronically when the establishment is identified as a supplier of raw beef that tests positive E. coli O157:H7.

III. GENERAL

A. The *General* submenu option contains five data entry tabs that contain establishment addresses and general information regarding the establishment. PHIS displays information on the "Establishment" and "Ownership" tabs as read only to IPP users. The DO has responsibility to edit this information while managing the grant application process.

- B. IPP are to update and maintain information on "Jurisdiction", "Inspection Exemptions" and "Other" tab. The other tab contains the following information:
 - 1. Recall plan information
 - 2. Food Defense Plan
 - Establishment HACCP size
 - 4. AMS/FNS school lunch program including the date of last contract award for beef processing establishments and egg product plants.
 - 5. Geographic location
 - 6. Names under which the establishment is Doing Business As (DBA)
- 7. Address Information. IPP are to maintain and update establishment address other than the "physical address". The physical address is the address where IPP perform inspection. FSIS also considers this address the primary address. The physical address will display in PHIS to IPP users as a prepopulated address in the "List of Addresses" table. The DO has permissions to edit the physical address while managing the grant application process. If IPP note changes to the physical address, IPP are to inform the management official to contact the DO with the change of address.
- C. IPP are to click on "add new address" to enter additional establishment addresses and select the following address types from a list of options for each address entered:
 - Select "Mailing Address" if the Agency is to use the address to mail official constituent information and other general correspondence regarding FSIS inspection.
 - 2. Select "Overnight Mailing Address" if Agency is to use the address for its contract service, FedEx, to deliver express mail for agency correspondence. FedEx will not deliver packages to certain addresses such as a PO Box.
 - Select "FSIS Inspection Office Mailing Address" if the Agency is to use the address to mail information to IPP assigned at the establishment or facility.
 - 4. Select "Laboratory Sample Supplies Address" if the Agency is to use the address to deliver laboratory sample supplies to IPP via Fed Ex. In many cases, this address will be the same as the Overnight Mailing Address.
- D. IPP are to complete the optional comment field for establishment addresses to provide directions, or leave comments to assist visiting FSIS personnel for

entry, especially if the establishment is difficult to find. IPP can also access directions using electronic maps within PHIS.

IV. FACILITY AND EQUIPMENT

- A. IPP are to click on "Facility" from the establishment profile menu to access the data entry screens for entering information on the inspection area and the establishment construction projects. The inspection area is the size of the area at the establishment that is subject to FSIS inspection.
- B. IPP are to click on "Equipment" from the establishment profile menu to access the data entry screens for entering information on methods used to thermally process hermetically sealed containers for establishments in the thermal processing HACCP category. For import establishments, IPP will enter Pre-Stamp program information and equipment information. The Import Equipment tab is inactivated for IPP users assigned to domestic establishments.

V. ESTABLISHMENT OPERATIONAL SCHEDULES

- A. IPP are to click on "Operational Schedules" from the PHIS establishment profile menu to access the data entry screens for completing information on the establishment's operational schedules. The "Operational Schedules" submenu contains the following four tabs: Approved Hours of Inspection, Pre-OP inspection, Break Time, Seasonal.
- B. PHIS will display the approved hours of inspection information as read only to IPP users. The District or Regional office has permissions to edit this information during the grant application process. IPP are to review the information to ensure that the information that they record is consistent with the establishment's approved hours of inspection.
- C. IPP are to enter scheduling information on when the establishment is ready for FSIS personnel to perform pre-operational inspection and when the establishment takes routine work breaks. IPP are also to enter information on when the establishments is not operating using the seasonal tab. Periods of inactivity are days within the approved operating hours that the plant does not operate such as during holiday periods or during extended periods such as for seasonal production. IPP can also record inactive days using the establishment calendar.

VI. ESTABLISHMENT TASK LIST

A. IPP are also to review inspection activities lists in the "establishment task list" profile sub-menu. The establishment task list contains tasks that are applicable to a particular establishment that PHIS generates 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. IPP can add tasks that are applicable to the establishment if necessary based on their knowledge of the establishment's production practices. These new tasks will be added to the establishment task last. IPP can also remove tasks that are not applicable by providing a justification for removing the system-generated task.

VII. HACCP SYSTEMS INFORMATION

A. The HACCP system information was not collected previously under PBIS for establishments operating under the HACCP regulations in 9 CFR 417. The HACCP system information must be complete in order for PHIS to generate inspection tasks, IPP are responsible for completing profile information regarding the establishments' Hazard Analysis and HACCP plan in PHIS.

NOTE: During the PHIS transition period, IPP are to complete the HACCP section of the establishment profile after they have completed the Hazard Analysis Verification (HAV) task. IPP are to follow the supplemental instruction in FSIS Notice 17-11, Public Health Information System (PHIS) Transition. See link:

http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/17-11.pdf

- B. IPP are to gather information from the establishment on its HACCP system including the Hazard Analysis, HACCP plan (if applicable), and written prerequisite programs that are referenced in the hazard analysis. IPP are to be familiar with the establishment's processing steps and corresponding hazards addressed in the establishment's food safety programs.
- C. 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 options in PHIS.
- D. <u>HACCP Processing Categories:</u> IPP are to click on "Add new hazard analysis" to access HACCP Processing Category information in PHIS. IPP are to complete the HACCP Processing Category information as part of completing information required for the Hazard Analysis and HACCP plan information in PHIS.
 - 1. 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 establishments; and

- FSIS defines HACCP processing categories (9 CFR 417.2) based on food science principles. <u>Attachment 1</u> of this directive describes the HACCP processing categories to listed in the drop down options.
- E. <u>Hazard Analysis and HACCP Plan Information</u>: IPP are to select "add new hazard analysis" to access the hazard analysis information. IPP must enter the hazard analysis information before PHIS allows users to enter HACCP plan and product information. IPP are to complete the following information in PHIS for the establishment's hazard analysis and HACCP plan:
 - 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).
 - 2. In the "Date" section, enter the date of the HACCP plan or Hazard analysis.
 - Enter information on lot definition and the product's intended use. For
 establishments with HACCP plans under the Slaughter, Raw-Intact, and
 Raw-Non-Intact processing categories, IPP are to select the intended use
 (e.g. for cooking only, for non-intact use) of the establishment's product
 after it leaves the establishment.
- F. <u>Processing Steps:</u> IPP are to select the generic processing step that best represents the process steps contained in the establishment's hazard analysis and HACCP plan based on their knowledge of the establishment's process. HACCP plans are unique to each establishment's process and products. Consequently, the establishment's processing steps may not exactly match the generic list in PHIS. The processing steps options are generic and represent well-known processing steps where establishments typically apply its controls and interventions based on industry practices.

If the establishment's hazard analysis refers to processing steps that are more broad or specific than the options in the drop down lists, IPP are to observe the process and inquire with the establishments in order to select the processing steps that best represent the establishment's process.

G. <u>Hazards:</u> IPP are to select from a list of options the chemical, physical, and biological hazards that corresponds to each processing step. If the establishment's hazard analysis refers to generic terms such as "pathogens," IPP are to inquire about the specific pathogens to which the establishment is referring. <u>Table 1</u> contains the list of hazards available in PHIS.

TABLE 1: Drop-Down List of Hazards			
Biological – Other			
Biological – <i>E.coli</i> O157:H7			
Biological - Listeria monocytogenes (Lm)			
Biological – Salmonella			
Biological - Spore Forming Pathogens			
Biological – Campylobacter			
Biological – Other Pathogens			
Specified Risk Material (SRM/BSE)			
Physical – Metal			
Physical – Bone			
Physical – Other			
Chemicals – Allergens			
Chemicals – Residues			
Chemicals – Other			
Biological - E. coli O157:H7 and Lm;			
Biological - E. coli O157:H7 and Salmonella			
Biological - <i>E. coli</i> O157:H7, <i>Salmonella</i> and Lm.			

- 1. IPP are to complete information on whether the establishment considers the hazards as reasonably likely to occur.
- 2. If any of the hazards are reasonably likely to occur, IPP are to complete information on the CCP designed to control the food safety hazard. IPP are to select a type of CCP that most closely matches a CCP in the establishments HACCP plan from a drop down list of options in PHIS. <u>Table 2</u> contains the list of options for CCP types.
- 3. If the establishment identifies the hazards as not reasonably likely to occur based on its supporting documentation, IPP are to select an option that indicates that the establishment has supporting documentation on file.
- 4. If the establishment identifies the hazards as not reasonably likely to occur because of measures such as pre-requisite programs, IPP are complete the information on the pre-requisite program by selecting a type of prerequisite from a drop down list of options that most closely matches the prerequisite program referenced in the establishment's hazard analysis. Table 2 also contains the list of drop down options for pre-requisite programs.

TABLE 2: Drop Down List of CCP & Prerequisites:
Temperature Control - (freezing, refrigerating, cooking, chilling, hot-packing, etc.)
Purchase Specifications (Includes Letter of Guarantee or Certificate of Analysis)
Microbiological Testing (Routine)
Allergen Program
BSE Program
Lm Program: Sanitation
Lm Program: Sanitation/Testing
Lm Program: Intervention: Antimicrobial Process or Agent Applied
Ingredient Control and Labeling
Intervention: Antimicrobial Process or Agent Applied
Metal Detector
Sanitary Dressing Program
Product Examination
Equipment Examination
Other – (limited text field)

VIII. SLAUGHTER INFORMATION

A. IPP are to enter slaughter information for establishments in the slaughter HACCP processing category (See HACCP section). The DO must complete voluntary slaughter information in PHIS in order for PHIS to display voluntary slaughter options. IPP to update the voluntary slaughter classes based on the operations at the establishment. The DO is notified automatically of any changes to the voluntary slaughter classes when IPP update the information in the profile.

- B. IPP are to complete the following information on the establishment's slaughter operation in PHIS 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. Comments

IX. PRODUCT INFROMATION

A. IPP are click on "products" and complete finish product class information for each of the establishment's HACCP plan. Finished product information are the end products of the establishment's processing steps that are shipped.

Attachment 2 contains a list of finished products, as they are associated with the HACCP processing categories.

B. IPP are to click on the appropriate tab in PHIS, "Raw", "NRTE", "RTE" or "Thermally processed" and complete product information in PHIS. <u>Table 3</u> contains the HACCP process categories associated with Raw products, Not ready to Eat Products (NRTE), Ready to Eat Products (RTE) and thermally processed products. FSIS defines RTE products in the 9 CFR 430.1 regulatory requirements.

NOTE: All finished products produced under the Fully Cooked – Not Shelf Stable HACCP processing category is considered RTE. If the establishment does not consider the products RTE, IPP are to enter the establishment's HACCP information under the heat treated but not fully cooked – not shelf stable HACCP processing category.

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Table 3: 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		•		

X. PRODUCTION VOLUME INFORMATION

A. IPP are to complete product volume information on the PHIS products tabs. IPP are to select a volume range in <u>Table 5</u> that represents the average daily production for particular product groups. <u>Attachment 2</u> contains the product groups that IPP should use for selecting a volume range. IPP are to enter

production volume information for the products produced during the production days since the profile task was last completed.

Table 5: PHIS Volume Ranges
Average Daily Volume (lbs per day)
1 – 1,000
1,001 – 3,000
3,001 – 6,000
6,001 – 50,000
50,001 – 250,000
250,001 - 600,000
> 600,000

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

XI. PROFILE QUESTIONS

A. The Profile Questions sub-link contains questions that are to be completed and reviewed monthly as part of the profile inspection task. The questions may contain information regarding the establishment microbiological testing programs or other information regarding establishment practices that can be used to information inspection procedures.

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

XII. NEW TECHNOLOGIES INFORMATION

A. This section contains information on No Objection and Salmonella Initiative Project (SIP) Letters issued by FSIS Headquarters personnel. IPP are click on "innovations" and review the information on the SIP or No Objection letters associated with the establishment. IPP are to review the SIP or No Objection letter, the submitted protocol and verification sheet.

B. If IPP the establishment provides a copy of a No Objection letter that is not listed in establishment's profile, IPP are to search for the particular no objection letter in PHIS and associate it with the establishment.

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

CHAPTER III – OTHER PROFILE INFORMATION

I. ESTABLISHMENT SUMMARY HOMEPAGE

A. All domestic and import establishments, ID warehouses or other facilities where FSIS provides inspection services will have a PHIS homepage that contains relevant inspection information. The homepage contains information about the establishment from every available source within the Agency.

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

II. GRANTS AND APPROVALS INFORMATION FOR DOMESTIC AND IMPORT ESTABLISHMENTS

A. IPP can view the grant of inspection information that the DO or regional office input. DO must complete the grant application and grant information in PHIS in order for PHIS to display the information.

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

III. FSIS STAFFING INFORMATION

The names and position of Agency personnel assigned to a particular establishment or facility are viewable from the homepage. The homepage will also indicate which establishments are part of a rotational assignment.

IV. SPECIAL PROJECT PARTICIPATION

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

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

V. FSIS SAMPLING RESULTS AND ELIGIBILITY

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

VI. FSA INFORMATION

IPP can view FSA information including the date of the last FSA as well as any FSA's completed within PHIS. FSA completed previously in other electronic formats will not be transferred into PHIS.

VII. FSIS TRAINING INFORMATION

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

VIII. FSIS APPEALS INFORMATION

When an establishment appeals an inspection decision, IPP are to record the appeal by using the FSIS appeals application located on the establishment homepage.

NOTE: FSIS will activate this function in a future enhancement to PHIS. FSIS will notify IPP when to use this PHIS functionality and provide additional information in a future FSIS policy issuance.

Refer questions regarding this directive to the Policy Development Division through *askFSIS* at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator

Office of Policy and Program Development

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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.
- 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. 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 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, mechanically separated species 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 Categories 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 Categories are shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes. If the establishment produces using the processing steps applicable under this processing category and the product is not shelf stable, then 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 (e.g. cooking) to achieve food safety. The finished products that establishments produce under this HACCP Processing Categories 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, poultry and egg 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 pot pie 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. Depending on the process and ingredients, these products may or may not meet the definition of RTE as defined in 9 CFR 430.1.

ATTACHMENT 2: PRODUCTS

PHIS Prod	PHIS Product Category List (Meat & Poultry Establishments)		
HACCP Processing Categories	Finished Product Category	Production Volume Categories (by Product Groups)	
Slaughter Raw Product - Intact	Raw intact beef	 Carcass (including carcass halves or quarters) Other primals and subprimals¹ (including Bone in and Boneless Meat Cuts) Beef Manufacturing Trimmings Beef Components (including Head Meat, Cheek Meat & Weasand Meat) Edible Offal³ Bench Trim (trimmings from animals not slaughter at the est.) Other Intact⁴ 	
	Raw intact pork	 Carcass (including carcass halves or quarters) Other primals and subprimals¹ (including Bone in and Boneless Meat Cuts) Edible Offal³ Other Intact⁴ 	
	Raw intact meat – other (sheep, goat)	 Carcass (including carcass halves or quarters) Other primals and subprimals¹ (including Bone in and Boneless Meat Cuts) Edible Offal³ Other Intact⁴ 	
	Raw intact chicken	Whole birdPoultry parts (including necks/feet & Giblets)Boneless and/or Skinless Parts	
	Raw intact turkey	Whole birdPoultry parts (including necks/feet & Giblets)Boneless and/or Skinless Parts	
	Raw intact poultry – other (ducks, geese, squab)	 Whole bird Poultry parts (including necks/feet & Giblets) Boneless and/or Skinless Parts 	
Slaughter Raw Product – Non-Intact	Raw ground, comminuted, or otherwise non- intact beef	 Ground Beef Product (beef only and beef with other species) Hamburger/Beef Patty Product (beef only and beef with other species) Fabricated Steaks and other Non-Intact Subprimals¹ (including Bone in and Boneless Meats that are fabricated, restructured, mechanically tenderized or injected) Advanced Meat Recovery (AMR) Ammoniated Beef Mechanically Separated Product Beef trim (derived from non-intact beef) Bench Trim (derived from non-intact beef) Low Temperature Rendered Product (includes Finely Textured Beef (FTB), Partially Defatted Chopped Beef (PDCB), or Partially Defatted Beef Fatty Tissue (PDBFT) 	

	Raw ground, comminuted, or otherwise non- intact pork	 Ground Product Advanced Meat Recovery (AMR) Mechanically Separated Product 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 Product
	Raw ground, comminuted, or otherwise non-intact chicken	- Ground Product - Mechanically Separated Product - Other Non-Intact
	Raw ground, comminuted, or otherwise non-intact turkey	- Ground Product - Mechanically Separated Product - Other Non-Intact
	Raw ground, comminuted, or otherwise non-intact poultry – other (ducks, geese, squab)	- Ground Product - Mechanically Separated Product - Other Non-Intact
Not Heat	Raw (NRTE) otherwise processed meat	- NRTE Processed Meat (Stuff and Unstuffed)
Treated – Shelf Stable	Raw (NRTE) otherwise processed poultry	- NRTE Processed Poultry (Stuff and Unstuffed)
Heat Treated – Shelf Stable	RTE ² acidified/fermented meat (without cooking) - PLE	 RTE fermented meat (sliced and not-sliced) according to Lm Alternative⁵ RTE fermented meat (sliced and not-sliced) not post-lethality exposed
	RTE ² acidified/fermented poultry (without cooking) - PLE	 RTE fermented poultry (sliced and not-sliced) according to Lm Alternative⁵ RTE fermented poultry (sliced and not-sliced) not post-lethality exposed
	RTE ² dried meat (PLE)	 RTE dried meat (sliced and not-sliced) according to Lm Alternative⁵ RTE dried meat (sliced and not-sliced) not post-lethality exposed
	RTE ² dried poultry (PLE)	 RTE dried poultry (sliced and not-sliced) according to Lm Alternative⁵ RTE dried poultry (sliced and not-sliced) not post-lethality exposed
	RTE ² salt-cured meat (PLE)	 RTE salt cured meat (sliced and not-sliced) according to Lm Alternative⁵ RTE salt cured meat (sliced and not-sliced) not post-lethality exposed

	RTE ² salt-cured poultry (PLE)	 RTE salt cured poultry (sliced and not-sliced) according to Lm Alternative⁵ 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	- NRTE meat products (stuffed and unstuffed)
	Raw (NRTE) otherwise processed poultry	- NRTE poultry products (stuffed and unstuffed)
Product with Secondary Inhibitors – Not Shelf Stable	RTE ² salt-cured meat (PLE)	 RTE salt cured meat (sliced and not-sliced) according to Lm Alternative⁵ RTE salt cured meat (sliced and not-sliced) not post-lethality exposed
	RTE ² salt-cured poultry (PLE)	 RTE salt cured poultry (sliced and not-sliced) according to Lm Alternative⁵ RTE salt cured poultry (sliced and not-sliced) not post-lethality exposed
	Raw (NRTE) otherwise processed meat	- NRTE meat products (stuffed and unstuffed)
	Raw (NRTE) otherwise processed poultry	- NRTE poultry products (stuffed and unstuffed)
Fully Cooked – Not Shelf Stable	RTE ² fully-cooked meat (PLE)	 Hot Dog Products according to Lm Alternative⁵ Salad/Spread/Pate according to Lm Alternative⁵ Meat + Nonmeat Multicomponent according to Lm Alternative⁵ Sausage Products Diced/Shredded according to Lm Alternative⁵ Patties/Nuggets according to Lm Alternative⁵ Other Fully cooked sliced product according to Lm Alternative⁵ Other Fully cooked not sliced product according to Lm Alternative⁵
	RTE ² fully- cooked poultry (PLE)	 Hot Dog Products according to Lm Alternative⁵ Salad/Spread/Pate according to Lm Alternative⁵ Meat + Nonmeat Multicomponent according to Lm Alternative⁵ Sausage Products Diced/Shredded according to Lm Alternative⁵ Patties/Nuggets according to Lm Alternative⁵ Other Fully cooked sliced product according to Lm Alternative⁵ Other Fully cooked not sliced product according to Lm Alternative⁵
	RTE ² 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 Multicomponent 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
	RTE ² fully-cooked poultry without subsequent exposure to the environment	 Hot Dog Products not post-lethality exposed Salad/Spread/Pate not post-lethality exposed Meat + Nonmeat Multicomponent 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
Thermally Processed - Commercially Sterile	Thermally processed, commercially sterile	Thermally Processed Products (includes products in Cans/Pails, Flexible Pouches, Trays, Jars and Bag-n-Box)

¹ Subprimals includes retail cuts of beef commonly used in the beef industry.
² RTE is defined in 9 CFR 430.
³ Edible Offal includes tails, feet, etc.

Note: By definition, RTE cured, dried or fermented product meet at least Alt 2 Lm requirements. Note: Lm Alternative questions and log reductions from FSIS From 10,240-1 apply to each RTE product group

⁴Other Intact includes fat.

⁵Listeria monocytogenes (Lm) alternatives are Alt 1; Alt 2, Choice 1; Alt 2, Choice 2; Lm Alt 3