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

FSIS PHIS DIRECTIVE

13,000.2

4/11/11

PERFORMING SAMPLING TASKS IN OFFICIAL ESTABLISHMENTS USING THE PUBLIC HEALTH INFORMATION SYSTEM

I. PURPOSE

This directive provides instructions to Inspection Program Personnel (IPP) and Enforcement Investigation and Analysis Officers (EIAOs) on performing sampling tasks in official establishments for FSIS domestic sampling programs using the Public Health Information System (PHIS).

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

Federal Meat Inspection Act Poultry Products Inspection Act Egg Products Inspection Act 9 CFR Parts 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 software application that streamlines all scheduling, assigning, tracking and documentation for FSIS's sampling tasks. PHIS provides the ability to create and manage FSIS sampling tasks. Types of sampling tasks include the following:

- 1. Directed sampling, such as MT43 sampling of raw ground beef or routine *Listeria monocytogenes* (RLm) sampling performed in conjunction with a FSA; and
- 2. Unscheduled, collector generated sampling, such as in-plant FAST and KIS™; product sampling for residue testing in response to a positive in-plant FAST test; or product sampling in response to a foodborne illness outbreak investigation.

B. The PHIS User Guide provides step-by-step instructions for sampling in domestic establishments based on different PHIS user roles. IPP, including Consumer Safety Inspectors (CSIs) and Public Health Veterinarians (PHVs), and EIAOs, including PHVs trained in EIAO methodology, will schedule and complete directed and collector generated sampling tasks using PHIS.

VI. GENERAL INSTRUCTIONS FOR PERFORMING SAMPLING USING PHIS

A. IPP and EIAOs are to review the relevant FSIS Directives and Notices for instructions on accessing sample collection procedures specific to the sampling program. Links to FSIS Directives and Notices are available through the PHIS Homepage, under the "My Dashboard" tab in the "Smart Links" menu box.

B. IPP and EIAOs are to refer to FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications, for instructions on packaging and sealing sample boxes to ensure the integrity of samples submitted to laboratories for analysis.

C. IPP and EIAOs are to continue to order sample supplies using the Outlook Sampling Mailboxes. The ability to request sample supplies at the time of sample scheduling will be included in a future PHIS enhancement. IPP and EIAOs will receive official notification when this enhancement is initiated.

D. IPP and EIAOs are to refer to the PHIS User Guide for detailed instructions on documenting FSIS sampling tasks using PHIS, scheduling the sampling task, entering sampling data into PHIS for the sample collected, and printing sampling forms. PHIS sampling functions are performed in a connected mode and are not available in the disconnected state. Some sampling functions will be available in the disconnected state in a future PHIS enhancement. IPP and EIAOs will receive official notification when this enhancement is initiated.

E. With the implementation of PHIS, IPP and EIAOs will no longer receive printed copies of FSIS laboratory sample request forms by mail. As a result, IPP and EIAOs must print a laboratory sample form upon completion of the sample collection task, sign the form, and place it in the sample box with the collected sample.

VII. IPP SAMPLING TASKS

A. The PHIS task calendar function was designed to provide flexibility to IPP in determining when to perform their assigned inspection task, including sampling tasks. Using PHIS, IPP are to respond to requests for FSIS sample scheduling and collection.

B. IPP are to refer to FSIS Directive 13,000.1, Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS), for general instructions on how to use the PHIS Task Calendar to schedule inspection tasks, including FSIS verification sampling. IPP are also to review the relevant FSIS Directives and Notices for instruction on sample collection procedures specific to the sampling program. IPP are to refer to the

PHIS User Guide for step-by-step instructions on how to document laboratory sampling tasks within PHIS. When scheduling a sampling task, IPP are to:

- 1. Refer to the collection date range indicated in PHIS for the requested sample;
- Use their knowledge of establishment operations to schedule laboratory sampling tasks at a time when the establishment is producing the requested product type to be sampled and is provided the opportunity to hold all product represented by the sample;
- Consider the priority of sampling tasks relative to the tasks already on their calendars and ensure that the most important tasks are completed by the end of the month; and
- 4. Ensure that sampling tasks are scheduled so that they can be completed within the time allowed for sample collection, as shown in PHIS.

C. Directed Sampling Task: PHIS displays sampling tasks on the Task List based on the sampling programs for which the establishment is eligible or as follow-up samples in response to positive test results. IPP are to add the sampling tasks to their Task Calendars and schedule the sampling task.

D. Collector Generated Samples: Under some circumstances, IPP may initiate sample collection tasks that do not exist on their Task List. For example, IPP assigned to livestock slaughter establishments may perform in-plant residue screening tests, such as the Kidney Inhibition Swab (KIS[™]) or Fast Antimicrobial Screen Test (FAST) and may also collect and submit product samples for residue analysis in response to positive FSIS in-plant residue screening tests.

- 1. KIS[™] and FAST Sampling: IPP assigned to livestock slaughter establishments are to record the results of in-plant residue screening tests (KIS[™] or FAST) for each tested carcass in the Daily Disposition Record page of PHIS. IPP are to refer to the PHIS Users Guide for instructions on recording in-plant residue testing information in PHIS. When IPP record a positive or indeterminate result for an in-plant residue screening test, PHIS will automatically prompt them to enter information about the resulting laboratory sample submission for confirmatory residue testing. IPP are to enter the required information, print the sample form, sign the form, and ship the sample, using the instruction provided in Sections VI and VII of this directive.
- 2. In situations where IPP need to collect other types of sampling, they are to contact their Frontline Supervisor (FLS) through their supervisory chain of command and request sample collection. IPP are to provide information to the FLS on the type of sample to be collected and a justification for the sample collection request. Upon approval of the sample collection, the IPP will add the sampling task to their Task Calendar and follow the instructions provided in Sections VI and VII of this directive to complete the sampling task.

E. Scheduling a Sampling Task: To schedule a directed sampling task, IPP are to access their Task List, select the sampling task, and click the "Add" link adjacent to the Task Name to access the Assign Task pop-up window. In the pop-up window, IPP are to enter a sample collection date. The parcel pickup date (the date of sample pickup by the carrier, such as FedEx) is generated when the sample collection date is entered and will default to the sample collection date. IPP are to change the parcel pickup date, if necessary, based on the availability of the carrier for sample pickup. IPP are to verify that there is laboratory capacity available for receipt of the sample at the FSIS laboratory for the parcel pickup date indicated and then click the "Save" button to schedule the sample and close the pop-up window. The sampling task will appear on the Task Calendar on the date scheduled.

NOTE: The requested collection date will be checked against the laboratory capacity and reservation module of PHIS, and confirmation will be provided indicating that there is available laboratory capacity on the requested collection date for the type of sample being collected. If capacity is not available, IPP are to select an alternate date. Once sample scheduling is completed, PHIS will display the address of the FSIS Laboratory that is scheduled to receive and analyze the sample.

F. IPP are to submit requests for sampling supplies through the appropriate Sampling Supplies Outlook Mailbox. IPP are to include in their request the establishment name and number, IPP contact information, the project code for the scheduled sample, the scheduled date for sample collection and any special requests for supplies, if needed.

G. Completing a Sampling Task: IPP are to refer to the PHIS User Guide for detailed instructions on entering sample collection data. To assist them in their sampling task, IPP may choose to print a draft copy of the sampling form from PHIS for use as a reference during sample collection and to document product information to be recorded in PHIS. IPP are to enter the data requested in the data fields provided. When sample collection data entry is completed, IPP are to click the "Submit to Lab" button, print a finalized form, sign the form, and place it in the sample box. PHIS will display a message stating that the sample collection information has been successfully submitted.

VIII. EIAO SAMPLING TASKS

A. EIAOs may be required to collect samples as directed samples or collector generated samples. For directed samples, the EIAO begins by accepting an assigned sampling task. For collector generated samples, the EIAO must create the sampling task request and submit it to the District Case Specialist (DCS) or Supervisory EIAO (SEIAO) for approval before the sample can be scheduled.

B. EIAOs are to refer to the PHIS User Guide for instructions on how to accept, schedule, and complete sampling tasks within PHIS. The Sample Collection Web page provides access to data input screens for laboratory sample collection.

C. Directed Sampling Tasks: To accept and schedule directed sampling tasks, EIAOs are to:

- Select "Worklists" from the left navigation menu on their Homepage, locate the sampling project in the FSA number column, and click on the "Assignment Disposition" link;
- Click on the appropriate button to accept or decline the assignment in the Sampling Assignment Disposition page. If the assignment is declined, give a justification in the textbox provided. If the assignment is accepted, enter the estimated start and completion dates for the assignment, indicate the number of samples or sample units to be collected for the sampling task, fill in all required data fields and click on the edit icon to access the Sample Collection-Sample Management page;
- 3. Click on the Schedule Sample link to access the sample scheduling pop-up window in the Sample Collection-Sample Management page. In the pop-up window, enter the requested sample collection date. The parcel pickup date (the date of sample pickup by the carrier, such as FedEx) will default to the sample collection date. EIAOs are to change the date, if necessary, based on the availability of the carrier for sample pickup. Verify that there is laboratory capacity available for receipt of the sample at the FSIS laboratory for the parcel pickup date indicated; and
- 4. Review the information entered, verify its accuracy, make any corrections, if needed, and click the "Save" button to schedule the sample.

D. Collector Generated Sampling Tasks: EIAOs must initiate collector generated sampling tasks and these tasks must be approved by the DCS or SEIAO before the samples are scheduled and collected. EIAOs are to refer to PHIS Users Guide for instruction on creating a collector generated sampling task. To schedule collector generated FSA sampling tasks, EIAOs are to select "Create Collector Generated FSA Sample Task" from the left navigation menu on their Homepage, enter the requested data in the data fields provided and click "Submit Directed Task" to complete the request. If the collector generated sampling task is approved, the sampling task will be added to the EIAO's Worklist.

E. Scheduling a Sampling Task: To schedule a directed sampling task, EIAOs are to access their Worklist, select the sampling task, and click the edit icon in the sample project data field row to open the Sample Collection-Sample Management page. EIAOs are to then click on the Schedule Sample link to access the sample scheduling pop-up window. In the pop-up window, EIAOs are to enter a sample collection date. The parcel pickup date (the date of sample pickup by the carrier, such as FedEx) is generated when the sample collection date is entered and will default to the sample collection date. EIAOs are to change the parcel pickup date, if necessary, based on the availability of the carrier for sample pickup. They are to verify that there is laboratory capacity available for receipt of the sample at the FSIS laboratory for the parcel pickup date indicated and then click the "Save" button to schedule the sample and close the pop-up window. PHIS will display the address of the FSIS Laboratory that is scheduled to receive and analyze the sample.

F. Completing a Sampling Task: EIAOs are to refer to the PHIS User Guide for detailed instructions on entering sample collection data. To assist them in their sampling task, EIAOs may choose to print a draft copy of the sampling form from PHIS for use as a reference during sample collection and to document product information to be recorded in PHIS. EIAOs are to enter the data requested in the data fields provided. When sample collection data entries are completed, the EIAOs are to click the "Submit to Lab" button, print a finalized form, sign the form and place it in the sample box.

IX. REPORTING SAMPLE RESULTS

IPP will receive FSIS positive sample results through alerts on their Inspector Homepage. FSIS negative sample results and additional sample results information are accessible through the Establishment Profile Summary page. IPP and EIAOs can continue to access LEARN for information on FSIS sample results. EIAOs will continue to receive FSIS positive sample results through the Biological Information Transfer and Email System (BITES).

X. SAMPLES NOT COLLECTED

In situations where a sampling task cannot be completed within the designated time frame, (e.g., product not being produced during the sampling window for a directed sampling task) or when IPP or EIAOs fail to collect samples or must reschedule a sampling task that had been scheduled for collection through the laboratory capacity function, IPP and EIAOs are to follow the instructions provided in the PHIS User Guide to reject or cancel a sampling task. IPP and EIAOs are to provide a justification for rejecting or cancelling the sample and click "Save" to cancel the sampling task and remove the sample from the reserved laboratory capacity.

XI. DATA ANALYSIS

On at least an annual basis, the Data Analysis and Integration Group (DAIG), within the Office of Data Integration and Food Protection (ODIFP), will analyze completion rates and results of sampling tasks in conjunction with other FSIS data sources and outside public health information. The DAIG will also perform analyses on an ad hoc basis, as necessary. Additionally, based on these analyses, DAIG will make recommendations regarding the relative priorities and frequencies of sampling tasks to address identified public health issues.

Refer questions regarding this directive to Risk and Innovations Management Division through askFSIS at <u>http://askfsis.custhelp.com</u> or by telephone at 1-800-233-3935, then press 1 and then 4.

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