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

FSIS PHIS DIRECTIVE

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LABORATORY SAMPLING PROGRAM FOR IMPORTED MEAT, POULTRY, AND EGG PRODUCTS

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL MAY 29, 2012.

CHAPTER I

I. PURPOSE

This directive is addressed to import inspection personnel. It provides instructions on the FSIS sampling and testing of imported meat, poultry, and egg products under the Public Health Information System (PHIS).

KEY POINTS

- *How to collect, prepare, and submit samples for laboratory analyses*
- *How to interpret laboratory results and take appropriate action*

II. CANCELLATION

FSIS Directive 9500.5, Laboratory Sampling for Meat and Poultry, dated 8/13/09

III. [RESERVED]

IV. REFERENCES

9 CFR Parts 327 and 381 and 590
FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications
FSIS Directive 10,210.1, Unified Sampling Form
FSIS Directive 10, 230.6, Submitting Tissue Specimens for Pathological or Diagnostic Microbiological Evaluation to the Laboratory
FSIS PHIS Directive 13,000.2, Performing Sampling Tasks in Official Establishments using the Public Health Information System
FSIS Directive 9900.2 Import Reinspection of Meat, Poultry, and Egg Products
FSIS Directive 9900.8, Meat, Poultry, Egg Products, and Shell Eggs Refused Entry into the United States
The PHIS User Guide is available via the FSIS Intranet on the PHIS page under Resources

V. BACKGROUND

PHIS is programmed to assign laboratory Types of Inspections (TOI) for imported meat, poultry, and egg products. In some instances, PHIS may assign one or more TOI to a lot. Refer to the following FSIS Directives when TOIs are assigned for the following:

1. For abnormal containers see FSIS Directive 7530.1, "Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product."

2. For **MT08 and MT51** sampling see FSIS Directive 10,010.1, "*Microbiological Testing Program and Other Verification Activities for Escherichia coli O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components*."

VI. REINSPECTION ASSIGNMENTS

A. Assignment is the specific PHIS reinspection assignment for a lot of imported meat, poultry, or egg products.

B. Level of Reinspection is the intensity of reinspection assigned to a lot based on the compliance history of a foreign establishment and country for a specific TOI and product. There are three levels of reinspection that PHIS will assign:

1. Normal is a level of reinspection where randomly selected lots are assigned a TOI based on the FSIS annual sampling plan. Under the normal level of sampling, FSIS does not hold lots of imported meat, poultry, and egg products pending receipt of a laboratory analysis (exception: abnormal container).

2. Increased is a level of reinspection above the normal level that is directed by a management decision. Under the increased level, lots of imported meat, poultry, or egg products may or may be not held by FSIS pending receipt of a laboratory analysis.

3. Intensified ia a level of reinspection that is implemented automatically by PHIS when a TOI is reported as "Fail." Under intensified reinspection, lots are placed on mandatory FSIS hold pending results of the TOI that is performed at the intensified level.

C. Voluntary Hold is an option available to the importer of record whenever a lot is sampled for any laboratory analysis. If product is under voluntary hold, import inspection personnel are to verify that the lot is held at the official import inspection establishment where it was reinspected pending completion of the lab analysis. They are also to ensure that lots on voluntary hold are not stamped with the mark of import inspection until acceptable laboratory results have been reported in PHIS.

D. Laboratory TOI Not Performed: Import inspection personnel are to request through PHIS not to perform a laboratory sample TOI assigned by PHIS on lots under normal or increased reinspection when they determine that the TOI is not applicable to the product. They are to select a reason in PHIS for not performing the TOI.

NOTE: Upon reviewing the assigned TOI, import inspection personnel are to refer to the regulations, FSIS Directive 9900.2, "*Import Reinspection of Meat, Poultry and Egg Products,*" and the FSIS Food Standards and Labeling Policy Book if they have questions about assigning any specific laboratory analysis for presented product.

VII. SAMPLING

A. Ordering Sampling Supplies Through Outlook

1. Currently the function for inplant inspection personnel (IPP) or import inspection personnel to order sampling supplies through the PHIS Sample Collection and Management system is not operational. The ability to request sample supplies at the time of sample scheduling will be included in a future PHIS enhancement. Inplant personnel and import inspection personnel will receive official notification when this enhancement is initiated. Until that time, IPP and import inspection personnel are to continue to order sample supplies using the Outlook Sampling Mailboxes.

2. To find the sampling supply email address in the global address list in the search box, import inspection personnel are to enter "FSIS – Sampling" to see them. Import inspection personnel are to submit requests for sample supplies via Outlook using the following email addresses:

   FSIS - Sampling Supplies - Eastern Lab
   FSIS - Sampling Supplies - Midwestern Lab
   FSIS - Sampling Supplies - Western Lab

3. The majority of sample supplies are now shipped via ground. In rare instances, import inspection personnel may request the overnight shipment of supplies. In such cases, import inspection personnel are to indicate "Overnight delivery needed" in the subject line of the e-mail requesting supplies. In addition, to ensure timely delivery of supplies, the e-mail supply request is to include:

a. sampling project code (e.g., IMVRTE) see Note below,

b. establishment number and establishment name,

c. name of submitter, and

d. contact phone number.

NOTE: Sampling project code reference: FSIS Directive 10,210.1, Unified Sampling Form and amendments.

B. Selecting Samples

When PHIS assigns a laboratory TOI, import inspection personnel are to:

a. Identify each shipping container selected as a sample with "USDA OFFICIAL IMPORT SAMPLE;"

b. Observe import establishment personnel's handling and removal of the unit to be sampled.

c. Collect samples from one specific production code or date.

C. Sample Receipt

Import inspection personnel are to provide FSIS Form 9770-1, "*Official Receipt for Samples of Foreign Products Collected for Laboratory Analysis*," to the importer once all samples are collected from the lot. Import inspection personnel can print this form by hitting the "Send 9770-1" button on the laboratory sampling screen.

D. Completion of Sample Management – Sample Collection Form

1. Import inspection personnel are to complete the PHIS Sample Management – Sample Collection Form in PHIS.

2. Import inspection personnel are to print a copy of the form and submit the printed copy with the sample to the laboratory.

E. Sample Submission to Laboratories

1. Samples are to be submitted to an FSIS field service laboratory for analysis in accordance with the instructions in PHIS.

2. Import inspection personnel are to refer to FSIS Directive 7355.1 for directions on sealing sample shipping containers.

3. Import inspection personnel are to mail samples using the FSIS contract overnight delivery or courier service and to follow the instructions below for samples requiring refrigeration:

    a. Before the FSIS contract overnight delivery or courier service pickup Monday through Friday, samples are to be kept refrigerated and shipped that same day.

    b. After the FSIS contract overnight delivery or courier service pickup Monday through Thursday, samples are to be kept refrigerated overnight and shipped the next day.

    c. During the weekend (after the FSIS contract overnight delivery or courier service pickup Friday through Sunday night), samples are to be frozen and shipped on Monday.

NOTE: If Monday is a holiday, the FSIS contract overnight delivery or courier service does not pick up samples. In this situation, the samples are to be kept frozen until shipping on Tuesday.

NOTE: See Chapter V for egg products sample shipping instructions.

d. The Agency will issue instructions via e-mail during a special circumstance (e.g., holiday, emergency, etc.)

4. Import inspection personnel are to ensure that sample integrity and security are maintained at all times.

5. Import inspection personnel are to ensure that the product label or a copy of the label accompanies the sample to the laboratory.

F. Sanitation in Handling Samples- All Pathogens

1. Import inspection personnel are to use aseptic handling procedures identified in paragraph 2 below when taking non intact samples that will be analyzed for pathogens. Import inspection personnel are to properly clean and sanitize affected equipment before and after sample collection to prevent cross-contamination of the sample and of inspection lots after collection of the sample.

2. For each non-intact sample, import inspection personnel are to:

   a. Sanitize all non-disposable equipment before collecting the samples;

   b. Wash and scrub hands thoroughly to the mid-forearm, using antibacterial hand soap (or a hand sanitizer at 50 ppm chlorine equivalency, if available);

   c. Open the Whirl-Pak™ bag without contaminating the interior, by grasping the side with fingers;

   d. Peel open the package of sterile gloves from the top without contaminating the exterior of the gloves;

   e. Remove a glove by holding it from the wrist side opening inner surface. Avoid any contact with the outer surface of the glove;

   f. Insert hand without puncturing the glove;

   g. Discard glove and use another sterile glove if there is a concern that it may have been contaminated;

   h. Collect the sample with the gloved hand from the randomly identified sample unit located on the surface perimeter of the product. Place the sample into the opened bag; and

   i. Close the bag and discard the glove.

G. Laboratory Sample Discards

1. Import inspection personnel will be notified of any discarded samples through the Laboratory Electronic Application for Results Notification LEARN system.

2. If the discarded sample was a TOI that is on FSIS hold, import inspection personnel are to add an unscheduled TOI and select a new sample from the same lot and submit it to the appropriate laboratory for analysis.

3. If the discarded sample was a TOI that is not on FSIS hold, import inspection personnel are not to collect a sample to replace the discard.

H. Reporting Results- **Actions Taken Based on Results**

1. **Indeterminate Results-** Indeterminate results will show as such in the PHIS Lot Manager screen until the Subject Matter Expert (SME) has researched and determined a result of Pass or Fail. The SME will then enter the result in PHIS.

2. **Negative results** - When a sample tests negative or is identified as ”Pass” in PHIS for the requested analyses, and all other reinspection activities are acceptable, import inspection personnel are to release the lot if it was on FSIS Hold and complete re-inspection of the lot in PHIS. If the product was on voluntary hold, import inspection personnel are to notify official import inspection establishment management that the hold can be released and are to complete re-inspection of the lot in PHIS.

3. **Presumptive positive results** (Microbial results only)-

    a. When a sample is reported as presumptive positive, import inspection personnel are to retain the lot, if available: provide the Regional Import Field Office (RIFO) with copies of all documentation identifying the sample(examples: Slaughter Date, Pack Date, Production Date, Use by Date, Expiration Date, Production Code, Lot Code, Can Code, Bar code, Batch number, Serial number, Any other identifiers or codes) for the lot; and notify the RIFO of the lot has been retained.

    b. If the lot has not been held and has been distributed, import inspection personnel are to request that the importer:

        i. Contact the importer of record to inform them of the presumptive positive. The importer of record contact information is contained in the application in PHIS.

        ii. Request that the importer of record stop further distribution of the product and place the involved product on voluntary hold.

        iii. Request distribution information on the product from the importer of record.

    c. Import Inspection Division- head quarters (IID-HQ) is to notify the program officials of the exporting country as soon as a presumptive positive result is

reported in order to determine whether the producing establishment has exported any other product from the same production lot to the U.S.

d. IID-HQ is to query PHIS to identify any other shipments that may have entered the U.S. with the same production dates. If shipments are identified with the same production dates, IID-HQ is to notify the Director of IID.

4. Positive or Failed Results

a. When a sample is confirmed positive, import inspection personnel are to:

i. refuse entry on the lot, if on hold at the import establishment, as per FSIS Directive 9900.8.

ii. contact the RIFO to determine whether product is held or not. The RIFO and IID-HQ are to follow FSIS Directive 8080.1, "*Recall of Meat and Poultry."*

NOTE: Egg Product recalls are handled by the Food and Drug Administration.

b. IID-HQ is to issue an alert to import inspection personnel to refuse entry or hold similar product with the same production codes that the foreign country presents for FSIS import reinspection after the confirmed positive result. Import inspection personnel are to hold at the official import inspection establishment all lots of similar product that is inspected and passed or not yet inspected from the same establishment. IID-HQ is to notify the foreign government for identification of other shipments affected.

CHAPTER II – FOOD CHEMISTRY TESTING

I. INTRODUCTION

Import inspection personnel are to conduct food chemistry sampling on imported meat, poultry, and egg products when assigned by PHIS to determine whether ther imported products comply with FSIS food chemistry regulatory requirements (e.g. nitrite, total fat, added water).

II. SAMPLING

A. Sample Size

1. Import inspection personnel are to select a food chemistry sample unit of approximately one pound of product but not less than twelve ounces.

2. Depending upon how product is packaged, import inspection program personnel are to obtain a sample from one single package, a portion thereof, or several packages.

a. *Example 1*: When product is packaged in 12-ounce units, such as frozen meatballs, then a single package is one sample unit.

b. *Example 2*: When product is packaged in 10-pound immediate containers, such as frozen frankfurters, then enough frankfurters are to be withdrawn from the container to obtain an approximate 1-pound sample.

c. *Example 3*: When product is packaged in 10-ounce units such as canned hams, then two cans (20-ounces) are to be considered as one sample unit.

B. Sample Selection

1. Import inspection personnel are to submit one sample from the same production lot or code to a laboratory regardless of the number of food chemistry assignments assigned to a lot. For example, if a lot of dried, cooked, and cured beef has two food chemistry assignments, (e.g., sodium nitrite and Moisture/Protein Ratio (MPR)), import inspection personnel are to randomly select one sample for both analyses.

2. There are exceptions below to the practice of only taking one sample (FSIS Directive 10,210.1, Unified Sampling Form, Amendment 3, 7/01/02, Attachment 3):

    a. Lots subject to maximum internal temperature (MIT) - When a lot is the subject of a MIT TOI and at least one other chemistry assignment, two sample units need to be submitted to the laboratory with the lab form: one sample unit for MIT analysis and the other sample unit for all other food chemistry analyses.

    b. Lots of cooked sausage (9 CFR 319.180, 319.181) sampled for compliance with the 30% fat limitations - When a lot of cooked sausage is the subject of a food chemistry assignment for total fat or moisture fat analysis, 3 one-pound samples (or the equivalent) needs to be submitted to the laboratory from the same production lot or code.

NOTE: When submitting sausage products for chemistry analysis, import inspection personnel are to submit a copy of the inspection certificate identifying the Group II protein data, as defined in 9 CFR 318.22, with the lab form.

CHAPTER III – MICROBIAL SAMPLING OF READY TO EAT (RTE) IMPORTED PRODUCT (Intact Unit Sampling- IMVRTE) (FRTESALMONELLA) (FLISTERIA) (see Note for sampling project codes)

I. INTRODUCTION

A. Import inspection personnel are to sample imported ready-to-eat (RTE) meat, poultry, and egg products when assigned by PHIS. IMVRTE analyses includes *Listeria monocytogenes* and *Salmonella* testing for all RTE meat and poultry products. See Chapter VII for instruction on sampling egg products. All product that is intended to be

consumed without further preparation steps is eligible for IMVRTE sampling. Any product that is in a form that is edible, without additional preparation to achieve food safety, and that may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes, is subject to this testing.

B. Import inspection personnel are to collect samples following the instructions for sanitary sampling in Chapter 1, F. of this directive.

NOTE: For "sampling project codes" see FSIS Directive 10,210.1, Unified Sampling Form and amendments.

II. SAMPLING PROCEDURES

A. Sample Size and Selection

1. Import inspection personnel are to randomly select enough samples units so that they submit at least two (2) pounds of product to the laboratory for analysis. Follow the directions below when packages weigh:

    a. Three pounds or more (including bulk packed cartons or combos of intact packaged product): select sample units, using aseptic sampling methods outlined in Chapter 1, F. when sampling non-intact product. For example, if cooked beef is packaged in 10-pound units, then one 10-pound unit needs to be submitted to the laboratory for analysis. If combos of 4-pound salamis are packaged in a combo, then one 4 pound unit needs to be selected.

    b. More than 1 pound but less than three pounds: collect enough units for a total of at least 2 pounds of product. For example, if cooked ham is packaged in 18-ounce units, two cooked hams in intact packages needs to be submitted to the laboratory for analysis.

CHAPTER IV – MICROBIAL TESTING OF NON-INTACT PACKAGES (IMVRTE) (FRTESALMONELLA) (FLISTERIA)(see Note)

A. PRODUCTS ELIGIBLE FOR SAMPLING- RTE cooked meat or poultry product as defined in 9 CFR 430.1 is subject to microbial testing.

B. SAMPLING PROCEDURES

Import inspection personnel are to:

1. Use the sanitary sample selection directions in Chapter 1 of this directive;

2. Collect at least two (2) pounds of product for each laboratory analysis;

3. Have products subject to sampling moved to the import establishment's inspection room and select samples in the following manner when the product cannot be sampled as an intact package;

a. For large containers (e.g., combo bins) of RTE Product (cooked beef, fully cooked chicken nuggets, salamis), select the sample from the surface perimeter of the container.

b. Allow the product to air temper (defrost) while remaining covered, if necessary, in a controlled environment and use aseptic sample tools (tongs and scoop) to obtain the sample.

c. For liquids (drums and totes), use aseptic tools to remove liquids from the container.

d. For other bulk packed RTE product, import inspection personnel are to consult with the RIFO before taking a sample.

4. Refrigerate or freeze all samples before submitting them to a laboratory except for shelf stable products;

5. Do not refreeze thawed or tempered samples before submitting them to the laboratory; and

6. State that the sample is selected as a non-intact sample in the narrative section of the laboratory form.

NOTE: For "sampling project codes" see FSIS Directive 10,210.1, Unified Sampling Form and amendments.

CHAPTER V – MICROBIAL SAMPLING OF PASTUERIZED EGG PRODUCTS NOT SHIPPED IN BULK PACKED CONTAINERS (IMPEGG)(FEGGIMP)(see Note)

A. General Procedures

Import inspection personnel are to:

1. Sample imported pasteurized egg product for *Salmonella* when assigned by the PHIS;

2. Use aseptic sampling procedures as described in Chapter 1 of this directive and collect at least half pound of product; and

3. Sample units are to be REFRIGERATED or FROZEN when submitted to the laboratory. Note: Shelf stable egg product is not required to be refrigerated or frozen before submitting to the laboratory.

    a. Samples of liquid egg product collected are to be kept refrigerated and are not to be frozen. Samples are to be collected and submitted to the laboratory Monday through Friday and submitted in the liquid state with sufficient coolant to keep samples cold.

b. Samples of frozen egg product collected are to be kept frozen and not allowed to thaw. Samples are to be kept frozen and shipped to the laboratory on the first workday after the weekend or holiday with sufficient frozen coolant to keep samples frozen.

NOTE: Sampling project code reference: See FSIS Directive 10,210.1, Unified Sampling Form and amendments.

CHAPTER VI – PATHOLOGY TESTING

I. INTRODUCTION

Import inspection personnel are to conduct pathology sampling on any imported meat or poultry product whenthe product's tissue appears to be abnormal or a possible pathological lesion is identified. Pathology testing may also be performed when processed products are suspected to be out of compliance with labeling and formulation requirements. All lots of product being tested pathlogly are to be placed on FSIS hold until results are received.

II. SAMPLING PROCEDURES

A. When import inspection personnel detect abnormal tissue or pathological lesions during a product examination, the defects are to be scored as per the defect criteria.

B. When import inspection personnel are unable to identify the defect to score it, and there is a FSIS Public Health Veterinarian (PHV) in the local area, the import inspection personnel are to request that the PHV assist in scoring the defect. The PHV is to attempt to classify the defect and make a disposition based on the defect (any disposition or analysis made by the PHV is to be in writing and included in the Remarks/Comments block of the lot in the PHIS, as well as the case file).

C. If a PHV is not available, or if the PHV cannot make a determination to classify the defect, import inspection personnel are to submit the tissue or lesion to a FSIS laboratory as Pathology – Lab TOI for analysis. For intact products, submit the affected unit. The sample unit is not to be less than 12 ounces; however, if sample units weigh less than 12 ounces as packaged, sufficient intact sample units are to be submitted to equal 12 ounces. For abnormal tissue (e.g., lung tissue, salivary glands), import inspection personnel are to submit the entire section of abnormal tissue.
Place all lots of product sampled for pathology under FSIS control until results are received.

D. When a Pathology (PH) defect is scored on a product examination, PHIS automatically assigns a follow-up Pathology TOI. If a PHV makes the diagnosis, then import inspection personnel are to request through PHIS to not perform the Pathological TOI.

CHAPTER VII – RESIDUE TESTING

I. INTRODUCTION

Import inspection personnel are to sample imported meat, poultry, or egg products for residues when PHIS assigns the TOI.

II. SAMPLING PROCEDURES

A. Sample Size:

1. Import inspection personnel are to refer to the current FSIS Notice for Import Residue Sampling Requirements.

2. Other Residue TOIs = 1 lb of muscle/lean tissue.

Import inspection personnel are to attempt to submit a single piece of product for each residue sample. When a single piece of product is not available, import inspection personnel are to select enough adjacent pieces of product to obtain the required sample size.

B. Selecting, Preparing, Securing, and Submitting Samples: Import inspection personnel are to select samples assigned by PHIS.

1. An imported lot may be the subject of more than one residue analysis assigned by PHIS.

   a. Example 1: If two or more residue TOIs are assigned to a lot, and multiple residue TOIs are to be analyzed at the same laboratory, import inspection personnel are to collect and submit one sample for each sample form PHIS displays for the assigned laboratory.

   b. Example 2: If the assigned residue samples are to be analyzed at different laboratories, import inspection personnel are to collect separate one pound samples of each tissue and submit to the designated laboratories.

2. Import inspection personnel are to submit residue samples frozen or cold to the designated laboratory. Dried or shelf-stable products do not need refrigeration.

NOTE: All samples for Florfenicol must be frozen prior to submission to the laboratory.

C. Boneless Fresh or Frozen Manufacturing Meat or Meat Cuts

If product is in combo bins, import inspection personnel are to randomly select one combo bin from the lot and choose one selection site within the combo bin for each sample. Import inspection personnel are to remove a single piece of meat that equals the required sample size. When a single piece of product is not available, import inspection personnel are to select enough adjacent pieces to obtain the required sample size.

D. Processed Product

Import inspection personnel are to randomly select enough cans or packages to meet the required sample size.

E. Egg Products (Non Bulk Packed Product)

Randomly select enough cans or packages to meet the required sample size.

CHAPTER VIII – SPECIES TESTING

I. INTRODUCTION

When assigned by PHIS, import inspection personnel are to sample imported meat, and poultry for species verification.

II. SAMPLING REQUIREMENTS

A. Sample Size

1. Import inspection personnel are to randomly select one sample unit from the lot and remove a half pound sample, if possible. If this is not possible, import inspection personnel are to submit the whole unit.

2. When import inspection personnel remove the half pound sample from the unit, they are to place it in the plastic bag provided by the FSIS laboratory.

B. Preparing Samples for Laboratory Analyses

Import inspection personnel are to:

a. Submit samples to the laboratory designated by PHIS.

b. For lots with chemistry analyses also assigned, the chemistry and species sampling may be combined on one form, and only one sample need be submitted, if both analyses are to be performed by the same FSIS field service laboratory.

CHAPTER IX. - DATA ANALYSIS

Quarterly, the Data Analysis and Integration Group (DAIG) within the Office of Data Integration and Food Protection (ODIFP) will review and analyze the PHIS data on import laboratory sampling including factors such as country, establishment and product for each type of laboratory analysis, based on available data, and starting 90 days after full implementation of Import PHIS. Results from the analyses are to be shared with the Office of International Affairs (OIA), the Office of Policy and Program Development

(OPPD), and the Office of Public Health Science (OPHS). These offices will determine if the findings suggest improvements to import reinspection procedures, import reinspection guidance or potential follow up action with foreign countries.

Refer questions through supervisory channels or *askFSIS* at http://askfsis.custhelp.com.

Acting Assistant Administrator
Office of Policy and Program Development