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

FSIS DIRECTIVE

9900.6
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LABORATORY SAMPLING PROGRAM FOR IMPORTED MEAT, POULTRY, AND EGG PRODUCTS

CHAPTER I – GENERAL SAMPLING INSTRUCTIONS FOR ALL PRODUCTS

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) on the Food Safety and Inspection Service (FSIS) laboratory sampling and testing of imported meat, poultry, and egg products assigned by the Public Health Information System (PHIS). FSIS is issuing a new version of this directive to incorporate all laboratory sampling instructions for imported meat, poultry, egg products, and Siluriformes fish, including instructions from expired FSIS notices for raw beef and Shiga toxin-producing *Escherichia coli* (STEC) and *Salmonella* sampling, raw poultry *Salmonella* and *Campylobacter* sampling, and raw pork *Salmonella* sampling, and instructs IPP to use the cloth surface sampling method for imported fresh non-intact beef. This directive changes the packaging descriptions from intact to "product in the final package" and non-intact to "product not available in the final package," so imported product packaging descriptions are consistent with domestic product packaging descriptions. Additionally, this directive provides new instructions on accepting certified *Salmonella* and *Listeria monocytogenes (Lm)* negative analysis test results from foreign countries that are eligible to certify test results for egg products imported in tanker trucks and totes. Finally, this directive provides instructions for IPP to access IPP Help to view the current import laboratory sampling Type of Inspection (TOI) information on the new "Import Laboratory Sampling Types of Inspection (TOI) Chart" and to refer to the new "Import Laboratory Sampling User's Guide" for supplemental PHIS data entry instructions and other types of import laboratory sampling information.

II. CANCELLATION

FSIS PHIS Directive 9900.6, *Laboratory Sampling for Imported Meat, Poultry, and Egg Products*, 11/03/15
FSIS Directive 14100.1, *Siluriformes Sampling at Import Establishments,* 10/03/22

III. BACKGROUND

A. Import laboratory sampling TOIs for imported meat, poultry, and egg products are assigned through PHIS. In some instances, one or more import laboratory sampling TOIs are assigned to a lot. IPP are to refer to the information in this directive when PHIS assigns an import laboratory sampling TOI to imported product.

B. IPP are to refer to FSIS Directive 7530.1, *Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product* for instructions on sampling abnormal containers.

C. IPP are to refer to the Imported Product Categorization Guide for Imported Product for questions about product categorization.

IV. SAMPLING SUPPLIES

A. Sampling supplies are automatically sent out to official import inspection establishments (import establishment). IPP are to be familiar with the types of products on the import establishment grant of inspection to ensure required sampling supplies are available.

B. When required sampling supplies are not available, IPP are to refer to FSIS Directive 13000.2, *Performing Sampling Tasks in Official Establishments Using the Public Health Information System*, for instructions on ordering sampling supplies through PHIS or Outlook. All egg product and Siluriformes fish sampling supplies must be ordered through the specified laboratories:

1. Egg Products – Western Laboratory; or

2. Siluriformes fish – Eastern Laboratory or Western Laboratory.

C. When sampling supplies are needed immediately and are not available due to unforeseeable circumstances, IPP are to request the overnight shipment of supplies. In such cases, IPP are to indicate "Overnight delivery needed" in the subject line of the e-mail requesting supplies.

D. Chemical residue sampling supplies for egg products and Siluriformes fish may not be sent automatically and should be requested in advance to ensure availability.

E. When IPP request sampling supplies and kits for imported products through Outlook, they are to identify the following information in the e-mail:

1. The Import Laboratory Sampling TOI (e.g., IMVRTE, MT51, IMVRTE, EGGIMP, IMPRESFRESH, Metals, IMPFISH_CH);

2. The establishment name and number;

3. IPP's contact information (name, e-mail, and phone number where they can be reached); and

4. The import sampling supply kit, including the species and product category and temperature category when applicable (e.g., fresh or frozen).

F. Should IPP have questions or concerns regarding the sampling supplies, they are to submit them to one of the FSIS laboratories via Outlook by selecting one of the email addresses below from the Global Address List.

NOTE: The "Import Laboratory Sampling User's Guide," available in IPP Help, contains a list of imported product laboratory sampling TOIs and the names and the types of sampling supply kits available for imported products.

V. REINSPECTION CATEGORIES

A. Level of Reinspection (LOR) is the intensity of reinspection assigned for an imported lot based on the compliance history of the foreign establishment and the country for a specific TOI and product. TOIs are assigned at one of three LORs:

1. Normal is a LOR where randomly selected lots are assigned TOIs based on the FSIS annual

sampling plan. Under the normal level of sampling, the importer of record (IOR) is required to maintain control of products sampled for adulterants by FSIS and is not to allow such product to enter U.S. commerce until negative test results are received.

2. Increased is a LOR above the normal level that is directed by an FSIS management decision to address food safety concerns. FSIS may retain lots of imported products under increased reinspection pending receipt of a laboratory analysis. The determination to retain product is a management decision made on a case-by-case basis. If FSIS does not retain products, the IOR is still required to hold or maintain control of products tested for adulterants by FSIS and is not to allow such product to enter U.S. commerce until negative test results are received.

3. Intensified is a LOR that is implemented automatically by PHIS when a TOI is reported as "Fail." Under intensified reinspection, FSIS retains the sampled lot tested for adulterants by FSIS at the import establishment until negative test results are received. The sampled lot is not allowed to move off-site to be held.

B. When PHIS assigns the same import laboratory sampling TOI to a single lot at more than one LOR (e.g., Normal, Increased, and Intensified), IPP are to:

1. Perform only one TOI;

2. Select the TOI based on the following order of LOR priority: 1) Intensified, 2) Increased, and 3) Normal;

3. Identify each of the remaining TOIs as "Submit Not Performed;" and

4. Select "Agency Instruction" as the reason.

NOTE: The IOR is the individual or company named on the entry made with U.S. Customs and Border Protection (CBP). For locations where the local customs authority is not U.S. CBP, the IOR is identified on the FSIS Form 9540-1, *Import Inspection Application*.

VI. CONTROL OF PRODUCTS THAT ARE TESTED BY FSIS FOR ADULTERANTS (TEST AND HOLD)

A. IPP are to withhold a determination as to whether imported meat, poultry, and egg products are not adulterated and thus eligible to enter U.S. commerce until the results of all Agency testing that bears on the determination have been received (see 77 Federal Register 73401 (December 10, 2012), *Not Applying the Mark of Inspection Pending Certain Test Results* and the final rule *Egg Products Inspection Regulations* 85 FR 68640 (December 16, 2020)). When not retained by FSIS, the IOR must hold or control applicable lots of product that FSIS tests for adulterants until IPP receive the results of the testing. If unacceptable test results are reported, the product will be refused entry.

B. IPP are to be aware that test and hold instructions apply to imported:

1. Non-intact raw beef product or intact raw beef product that is tested for STEC that FSIS considers to be an adulterant;

2. Ready-to-eat (RTE) meat, poultry, and pasteurized egg product tested for *Lm* or *Salmonella;* and

3. Livestock carcasses and meat products tested for residues.

C. IPP are to be aware that test and hold instructions do not apply to:

1. Meat and poultry products assigned a residue laboratory sampling TOI to test for metals;

2. Non-intact raw meat and poultry or intact raw meat and poultry products tested for *Salmonella, Campylobacter,* or other pathogens that FSIS has not designated as adulterants in those products;

3. Poultry carcasses or raw poultry parts sampled for residues; and

4. Egg products assigned an EGGCHEM laboratory sampling TOI.

D. IPP are to be aware that the IOR has the following options for maintaining control of the product:

1. Keep the sampled product on the premises of the import establishment where the product was sampled until laboratory test results are received; or

2. If not retained by FSIS as part of an Intensified or Increased LOR, the sampled product can move from the import establishment, provided the IOR has effective measures in place to prevent the product from entering U.S. commerce until the results of the testing are received.

NOTE: When a lot is subject to an Increased LOR the Increased List, which is available on the Import Inspection Operations (IIO) SharePoint site, will identify when lots must be retained onsite. If IPP do not have access to the site, they are to refer to FSIS Directive 9900.5, *Label Verification of Imported Meat, Poultry, and Egg Products* on how to obtain access.

E. When a laboratory sampling TOI for an adulterant is assigned under a "Normal" LOR or an "Increased" LOR, and the sampled product is not retained by FSIS, IPP are to ask the import establishment management how they will control the product. When product is held off-site, IPP are to:

1. Ask the import establishment management to provide the name and address in writing of the off-site location where the IOR will hold the product;

2. Inform the import establishment management that when product is held off-site and unacceptable laboratory sampling test results are received, the IOR is responsible for bringing the product to an import establishment to be refused entry by FSIS; and

3. Inform the import establishment management that when product is held off-site, the IOR is responsible for providing IPP with a copy of the label when requested.

F. For Canadian imports, if the IOR intends to return the shipment to Canada after FSIS samples are collected, IPP are to use the instructions in Chapter IX and the "Import Laboratory Sampling User's Guide" to complete the entry in PHIS.

G. The agency may change import laboratory sampling TOIs or evaluation of results as needed. IPP are to refer to the "Import Laboratory Sampling Types of Inspection (TOI) Chart" to determine which laboratory sampling TOIs assigned by PHIS are applicable if they have questions.

VII. SELECTING SAMPLES

A. When an import laboratory sampling TOI is assigned through PHIS, IPP are to:

1. Notify import establishment management about the sample;

2. Clearly identify the product that will be sampled; and

3. Clearly identify the type of laboratory sampling TOI assigned.

B. When collecting samples of imported product for laboratory analysis, IPP are to:

1. Use random sampling which may include the use of random number tables, or use the FSIS computer Random Number Generator;

2. Consider personal safety when collecting samples and contact their frontline supervisor (FLS) if safety concerns are evident;

3. Select samples that can be submitted for laboratory analysis in their final package whenever possible. Samples submitted in final packages (i.e., consumer ready package) are not to weigh more than 20 pounds;

4. Request import establishment personnel move products subject to sampling to the import establishment inspection room;

    a. IPP are to notify their FLS for guidance if totes or combo bins cannot fit into the inspection room.

    b. If the product will not be sampled immediately, IPP are to ensure that import establishment personnel secure the product.

5. Use aseptic sampling technique when removing samples from product in final packages weighing more than 20 pounds for microbiological analysis. Resources for aseptic technique are available on IPP Help;

6. Collect samples for laboratory analysis in a sanitary manner when PHIS assigns:

    a. A microbiological sample for products available in their final package weighing less than 20 pounds;

    b. A residue sample for products available in their final package and products not available in their final package. FSIS Directive 10800.2, *Residue Sampling and Testing under the National Residue Program* contains additional information on collecting samples in a sanitary manner; and

    c. A chemistry sample for products available in their final package and products not available in their final packages.

7. Submit separate samples for each assigned sampling project. IPP are not to request food chemistry, microbiological, and pathology analysis on the same sample;

8. Place a "USDA OFFICIAL IMPORT SAMPLE" stamp on each shipping container selected as a sample. When a product exam is assigned to the lot in addition to the import laboratory sampling TOIs, double stamp the carton or cartons from which the laboratory samples are obtained;

9. Select samples from one single production code or date; and

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

C. When an aseptic sample is taken from products not available in their final package for laboratory analysis, the sample must be removed from a separate sample unit other than the product exam sample. When an aseptic sample is not required, IPP are to retrieve the sample in a sanitary manner after the product exam.

D. When samples are available in their final package, IPP are to:

1. Use the instructions in Section VII.B to collect a sample;

2. Select the number of packages to equal the desired weight or count for the assigned import laboratory sampling TOI and product; and

3. Place the product collected in its final packaging in the larger, non-sterile bag provided by an FSIS laboratory.

E. When samples are not in their final package, IPP are to:

1. Use the instructions in Section VII.B to collect a sample;

2. Select the sample from the surface perimeter of the containers when possible (e.g., combo bins and totes); and

3. Refer to Section VII.G. (below) for instructions on using roll top bags and cups supplied by an FSIS laboratory to collect samples.

F. When PHIS assigns a laboratory sampling TOI to frozen imported products, one of the following options are to be used to obtain frozen product samples:

1. Defrost or temper frozen meat and poultry products as directed in FSIS Directive 9900.2, *Import Reinspection of Meat, Poultry, and Egg Products* when frozen products are not available in their final package, and defrosted product is permitted to be submitted for laboratory analysis for the specific type of product. IPP are to:

    a. Temper only enough bulk packaged product or cuts to retrieve the required sample amount. Do not completely thaw the entire block of product; and

    b. Allow the product to air temper (defrost) while remaining covered, if necessary, in a controlled environment. When product is individually quick frozen (IQF), the air temper step is not needed.

2. The drilling sampling method for collecting applicable samples of frozen meat, poultry, and egg products in IPP Help under Sampling, Drill Sampling Method and the instructions in FSIS Directive 9900.2 for drill sampling pasteurized egg products. When an establishment elects to use the drill sampling method, IPP are to:

    a. Verify establishment personnel clean and sanitize the drill and drill bit before and after each use;

    b. Verify the establishment removes the frost and ice crystals from the top of the block of product and drill at a 45-degree angle to within 1 inch of the bottom of the product container, if possible, but not more than the drill bit safely permits;

    c. Verify establishment personnel avoid drilling through any hump that is caused by the freezing process; and

    d. Collect drilled shavings for laboratory analysis in a sanitary environment, using clean and sanitized equipment.

NOTE: The drill is to be a variable speed, heavy-duty electric drill with a rated capacity of not less than 1,800 RPM without a load. The drill bit is to be 11/16 inch or larger with not less than a 12-inch shank (thin-twist type), the type typically used only for wood and capable of producing large shavings. Since it is best to drill within 1 inch of the bottom of the frozen block of product, a 12-inch bit is only acceptable for blocks that are approximately 6 inches thick. An 18-inch bit is preferred for a block that is approximately 9 inches thick and a 24-inch or longer (if available) bit is recommended for a block that is 12 inches thick or more.

G. Collecting Samples.

1. When using sterile sample cups IPP are to:

    a. Open the sample cup without contaminating the interior;

    b. Ensure the sample cups are not overfilled;

    c. Ensure the lids are tightly closed; and

    d. Place the filled sample cups in the same secondary containment bag (large zipper lock bags supplied by FSIS laboratories), expel excess air, and use the zipper lock to close the bag.

2. When using roll top bags IPP are to:

    a. Open the roll top bag without contaminating the interior by grasping the side of the bag;

    b. Fill the bag to the fill-line indicated. Do not underfill or overfill the bag;

    c. Ensure that each roll top bag is properly closed by carefully squeezing out the air remaining in the bag and tightly folding over the top at least four times as trapped air and loose closures may lead to leakage. Do not wrap bag with tape. When folding over the tops of each bag, do not touch the bag near its opening. Fold over the side tabs to secure the folds

in place and do not tie the ends; and

d. Place the roll top bags in the same secondary containment bag (large zipper lock bags supplied by an FSIS laboratory), expel excess air, and use the zipper lock to close the bag.

3. Edible tallow packaged in bulk containers (e.g., totes or railway cars):

a. IPP are to notify their FLS verbally or by e-mail of the sample request. Based on IPP's description of the container size, construction, and location the FLS can determine if obtaining a sample is feasible.

b. When it is determined a sample can be collected, IPP are to provide designated import establishment personnel with FSIS sampling supplies and observe that import establishment personnel obtain samples in a sanitary manner from the correct product.

c. IPP are not to climb on tanker trucks and railway cars to retrieve samples.

H. When PHIS assigns an import laboratory sampling TOI that is not applicable to the product, IPP are to:

1. Refer to the "Import Laboratory Sampling Types of Inspection (TOI) Chart" to verify the TOI is not applicable; and

2. Select "Not Applicable" as the most appropriate reason in PHIS for not performing the assigned sample.

I. Sample Receipt – IPP are to provide FSIS Form 9770-1, *Official Receipt for Samples of Foreign Products Collected for Laboratory Analysis*, to the IOR once all samples are collected from the lot (9 CFR 327.11).

J. Before submitting the sample to the laboratory for analysis, IPP are to:

1. Complete the following:

a. Enter all the data required to complete the "Sample Management – Sample Collection" information in PHIS;

b. Print a copy of the completed laboratory sample form, sign it, and submit the printed copy with the sample to the laboratory; and

c. Place the applicable lot on hold in PHIS and select the appropriate reason.

2. When PHIS requires production dates for sampled products, IPP are to:

a. Record the date of the final process identified on the foreign inspection certificate (e.g., date of deboning or date of slicing) when recording the production date on the laboratory form in PHIS for complex products; and

EXAMPLE: When IPP submit a dry-cured ham sample to the laboratory for analysis, they are not to use the date of earlier salting and curing periods as the production date.

b. Select the date of sampling as the production date when a production code is on the product and not an actual production date and record the product code in the "Remarks" section of the laboratory form.

3. When product cannot be submitted to the laboratory in the final package, IPP are to state that the selected sample is not in the final package in the "Remarks" section of the laboratory form.

VIII. SAMPLE SUBMISSION

A. IPP are to submit samples to the FSIS laboratory designated on the form in PHIS, EXCEPT for products sampled in the Pacific Islands and Puerto Rico. For these samples, IPP are to:

1. Send laboratory samples taken from imported products in the Pacific Islands to the Western Laboratory, regardless of which laboratory is designated on the sample form in PHIS;

2. Send laboratory samples taken from imported products in Puerto Rico to the Eastern Laboratory, regardless of which laboratory is designated on the sample form in PHIS; and

3. Line through the laboratory name on the form and write in the correct laboratory name for samples taken in the Pacific Islands and Puerto Rico.

B. IPP are to:

1. Ensure that the gel coolants are frozen solid at least 24 hours before sample collection for refrigerated samples;

2. Keep refrigerated samples in the refrigerator (if shipping same day or next day) or in the freezer (if shipping later, such as collecting over a weekend before a Monday holiday) until the sample is picked up by the carrier, except for products and samples identified in paragraph C;

3. Ensure sample security is maintained at all times and that the samples collected remain under FSIS control before pick-up by carrier;

4. Ship samples on the day of collection or the next day, but are not to ship samples on a Saturday, or the day before a federal holiday; and

5. Refer to FSIS Directive 7355.1, *Use of Sample Seals for Laboratory Samples.*

C. Supplemental Instructions for submitting samples.

1. Egg product samples collected after the courier has picked up for the day are held overnight under the same condition as received (refrigerated or frozen) and submitted to the laboratory in the same condition as received.

2. Raw poultry products sampled for *Salmonella* and *Campylobacter:*

   a. Chicken part samples are to be held overnight under the same condition as received (refrigerated or frozen);

   b. Rinsate or swab samples for chicken or turkey carcasses are to be held overnight under

refrigeration and are not to be frozen;

c. Non-frozen samples of ground, or other comminuted, or mechanically separated chicken or turkey are to be held overnight under refrigeration and are not to be frozen; and

d. Samples of frozen ground, or other comminuted, or mechanically separated chicken or turkey collected by using the drill sample method, are to be kept frozen and not allowed to thaw.

3. Raw pork products sampled for *Salmonella* analysis collected after the courier has picked up for the day are held overnight under the same condition as received (refrigerated or frozen) and submitted to the laboratory in the same condition as received.

4. Frozen raw beef products sampled for STEC collected after the courier has picked up for the day are held overnight and must remain frozen under the same condition as received (refrigerated or frozen) and submitted to the laboratory in the same condition as received.

IX. LABORATORY SAMPLES IDENTIFIED AS DISCARDED NOT ANALYZED

A. IPP are to monitor LIMS-Direct for sample results.

B. When a laboratory sampling TOI is identified as discarded or not analyzed by the laboratory in LIMS-Direct for product sampled under an "Increased" LOR and the product is retained by FSIS, or the product was sampled under an "Intensified" LOR, IPP are to:

1. Collect a second sample for resubmission to the laboratory;

2. Add a replacement sample in PHIS using the instructions in the "Import Laboratory Sampling User's Guide"; and

3. Notify the import establishment management that a second sample is being submitted to the laboratory and ask them to notify the IOR.

C. When a sample is discarded by the laboratory for product sampled under a "Normal" LOR, IPP are to:

1. Verify the laboratory TOI is recorded in PHIS as "Complete" with a status of "Discarded Not Analyzed" for the lot; and

2. Notify the import establishment management that the sample was discarded and that the lot will not be resampled.

NOTE: Samples that meet discard criteria for one pathogen may still be tested for other import laboratory TOIs assigned to the lot by PHIS.

X. LABORATORY SAMPLING TEST RESULTS AND ACTIONS TAKEN BASED ON THE RESULTS

A. After a sample has been submitted, IPP are to:

1. Monitor PHIS for sample results; and

2. Release the shipment when acceptable results are posted.

NOTE: The result not posting in PHIS doesn't preclude IPP from releasing the product if LIMS Direct is acceptable, but it does prevent IPP from closing the application and PHIS from sending the "may proceed" to CBP & the Broker.

B. When an indeterminate result for chemistry or residue samples displays for a lot in the PHIS Lot Manager screen.

1. IPP are to:

    a. Send an e-mail to Office of Field Operations (OFO) Recall Management & Technical Analysis Staff (RMTAS) at foimports@usda.gov;

    b. Identify the e-mail subject as Indeterminate Laboratory Sample Test Results;

    c. Include the PHIS application-lot ID number, laboratory form number, and either a scanned copy of the product label with the ingredients statement or a typed product name and ingredients statement; and

    d. Identify the status of the lot.

2. Indeterminate sample test results will show as such in the PHIS Lot Manager screen until RMTAS has researched and determined a test result of Pass or Fail. RMTAS will then enter the result in PHIS.

    a. When RMTAS determines an indeterminate test result is a Fail, IPP are to follow instructions provided by RMTAS.

    b. RMTAS will notify FSIS' Office of International Coordination (OIC) of the result.

C. When Acceptable laboratory sample tests results (e.g., negative, passed, detected non-violative) are identified in PHIS for the requested analyses, and all other reinspection results are acceptable, and the lot was:

1. Sampled under a "Normal" LOR or an "Increased" LOR and held under IOR control, IPP are to:

    a. Notify the import establishment management that the laboratory sampling test results are acceptable, and the lot can be released, and

    b. Complete the reinspection of the lot in PHIS.

2. Sampled under an "Increased" LOR and retained by FSIS or the product was sampled under an "Intensified" LOR, IPP are to:

a. Notify the import establishment management the laboratory sampling test results are acceptable, and the lot can be stamped "U.S. Inspected and Passed" and released; and

b. Complete reinspection of the lot in PHIS.

D. When an import laboratory sampling TOI is reported as presumptive positive (microbiological results for adulterants only) in PHIS.

1. Lots sampled under a "Normal" LOR and the product is still at the import inspection establishment, IPP are to:

    a. Notify the import establishment management of the presumptive positive test result; and

    b. Verify the product is still under IOR control.

2. Lots sampled under a "Normal" LOR or an "Increased" LOR, and held under IOR control and the lot has been moved from the import establishment to an off-site location, IPP are to:

    a. Request the import establishment management to:

        i. Notify the IOR of the presumptive positive;

        ii. Confirm with the IOR that the product is still on hold;

        iii. Confirm the off-site location of the product; and

        iv. Notify the IOR no further movement of the product is permitted.

    b. Notify their FLS to report the presumptive positive result as well as the hold status and location of the lot; and

    c. Provide the FLS with a copy of the inspection certificate (for non-electronic Certification (eCert) countries), PHIS import application, and lot number.

3. The FLS is to e-mail these documents to RMTAS at foimports@usda.gov and the appropriate district office (DO) contact immediately.

4. RMTAS may issue instructions to retain applicable products from the same foreign establishment until further notice based on data review. This may include previously inspected and passed products.

E. When a sample is confirmed Positive, Failed, Detected – Violative or identified with any other unacceptable sample test results.

1. If the product is under IOR control at an off-site location, IPP are to:

    a. Confirm through the import establishment management that the IOR still has the product under control and the product has not entered U.S. commerce;

b. Notify the import establishment management to inform the IOR that the lot is refused entry and must be returned to an import establishment to be officially refused entry; and

c. Confirm the import establishment management and the IOR know that the import mark of inspection must be removed from all boxes.

2. When a sample is confirmed Positive, Failed, Detected – Violative, or identified with any other unacceptable sample test results, and the sampled lot is held onsite or confirmed to be held off-site by the IOR, IPP are to:

a. Initiate a refused entry in PHIS; and

b. Immediately send an e-mail to notify the FLS and DO of the unacceptable laboratory sampling test result and if the shipment is held off-site, indicate the status of the shipment returning to an import establishment. The e-mail is to include a copy of the inspection certificate (for non-eCert countries) and PHIS import application and lot numbers. The FLS or DO will send the e-mail notification and documents to RMTAS.

3. When IPP refuse entry on imported product, they are to:

a. Verify the import mark of inspection is removed from all applicable containers;

b. Verify all containers are stamped "United States Refused Entry," including products held off-site and returned to an import establishment to be refused entry;

c. Refer to FSIS Directive 9900.8, *Meat, Poultry and Egg Products Refused Entry Into the United States*, for further instructions on refusing entry on imported products; and

d. Refer to the "Import Laboratory Sampling User's Guide" in IPP Help to enter the refused entry data into PHIS.

4. When a lot tests Positive, Failed, Detected – Violative or identified with any other unacceptable test results for adulterants, and the IOR failed to maintain control of the product:

a. The DO will notify the appropriate Office of Investigation, Enforcement and Audit Regional Director and RMTAS.

b. RMTAS will follow the instructions in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*.

c. The lot cannot be refused entry in PHIS because the shipment is in U.S. commerce.

F. Imported products not required to be held pending receipt of laboratory testing results, and if Positive for *Salmonella* and *Campylobacter* in raw product or "Detected – non-violative" for Metals, are not to be refused entry.

1. Laboratory Sampling TOIs:

    a. Raw Beef products sampled for *Salmonella*;

    b. Raw Poultry products sampled for *Salmonella* and *Campylobacter*;

    c. Raw Pork products sampled for *Salmonella;* and

    d. Meat and poultry products sampled for metals.

2. When PHIS assigns one of the laboratory sampling TOI's as described in 1. above with a laboratory sampling TOI for an adulterant to the same lot:

    a. IPP are to withhold the test results of the laboratory sampling TOIs described in 1 above until after receiving the laboratory sampling test results for adulterants (e.g., STEC, *Lm*, residues); or

    b. When negative or acceptable test results for adulterants are received first, IPP are to advise the import establishment management the lot does not need to continue to be held until receipt of the exploratory sampling test results.

3. When test results are reported for the laboratory sampling TOI's described in 1. above as negative, acceptable, or "Not Detected" for Metals, IPP are to notify the import establishment management the sampling test results are negative and request that they notify the IOR.

4. When test results are reported as positive for *Salmonella* or *Campylobacter*, or "Detected – non-violative" for Metals, for the laboratory sampling TOI's in paragraph one, IPP are to notify the import establishment management the sampling test results are positive, and request that they notify the IOR, but that no further actions are required.

5. When test results are reported as positive for *Salmonella* or *Campylobacter*, or "Detected – Non -Violative" for Metals, and the IOR requests that the lot not be stamped "U.S. Inspected & Passed" because the IOR wants to drawback the entire lot or partial lot from the United States, IPP are to:

    a. Request that the IOR provide evidence that the drawback was completed with CBP;

    b. Review the information to verify the product and the amount of product coincides, at minimum, with the kind of product and the weight of the product being withdrawn for the lot;

    c. Attach any documents provided by the IOR to the case file; and

    d. Identify the appropriate "Type of Withdraw" in PHIS.

CHAPTER II – MICROBIOLOGICAL SAMPLING OF RTE MEAT, POULTRY, AND PASTEURIZED EGG PRODUCTS

I. INTRODUCTION

A. IPP are to collect and submit samples of imported RTE meat and poultry, and pasteurized egg products when IMVRTE and EGGIMP laboratory sampling TOIs are assigned by PHIS.

1. RTE meat and poultry products are assigned an IMVRTE laboratory sampling TOI for *Salmonella* and *Lm* testing.

2. Pasteurized liquid, frozen, and dried egg products are assigned an EGGIMP laboratory sampling TOI for *Salmonella* and *Lm* testing.

B. Eligible RTE products are described as:

1. All products that are intended to be consumed without further preparation steps; or

2. 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, aesthetic, epicurean, gastronomic, or culinary purposes.

II. SAMPLING PROCEDURES FOR PRODUCTS IN THEIR FINAL PACKAGE

A. When PHIS assigns a laboratory sampling TOI to RTE meat and poultry product that can be sampled by submitting products in their final package to the laboratory for testing, IPP are to use the instructions in Chapter I, Section VII to collect enough products in their final package so that at least 1 pound of product is submitted to the laboratory for testing and follow the directions below when packages weigh:

1. Less than 1 pound: collect enough packages for a total of at least 1 pound of product; or

EXAMPLE: If cooked ham is packaged in 12-ounce units, two cooked hams in their final packages must be submitted to the laboratory for analysis.

2. More than 1 pound: select one package for the sample.

EXAMPLE: If cooked beef is packaged in 10-pound units, then one 10-pound unit is submitted to the laboratory for testing.

B. When PHIS assigns a laboratory sampling TOI to pasteurized egg products that can be sampled by submitting products in their final package to the laboratory for testing, IPP are to use the instructions in Chapter I, Section VII to collect enough final packages so that the sample collected is equal to or greater than the following sample sizes:

1. Dried Egg Product – 8 ounces;

2. Liquid Egg Product – 8 ounces; and

3. Frozen Egg Product – 8 ounces.

III. SAMPLING PROCEDURES FOR PRODUCT NOT AVAILABLE IN THE FINAL PACKAGE

Sample Size and Selection.

1. When PHIS assigns a laboratory sampling TOI to RTE meat and poultry products that cannot be sampled in their final package (e.g., bulk packaging, or final package is greater than 20 pounds), IPP are to:

    a. Use the aseptic sampling instructions in Chapter I, Section VII to randomly select product not available in the final package; and

    b. Collect 1 pound of product.

2. When PHIS assigns a laboratory sampling TOI to pasteurized egg products that are not available in the final package (e.g., pails, totes without certified negative results), IPP are to:

    a. Use the aseptic sampling instructions in Chapter I, Section VII to randomly select samples; and

    b. Collect a product sample that weighs:

        i. Dried Egg Product – 8 ounces of dried product;

        ii. Liquid Egg Product – 8 ounces of liquid product; or

        iii. Frozen Egg Product – 8 ounces frozen shavings.

IV. SAMPLING PROCEDURES FOR PASTEURIZED EGG PRODUCTS SHIPPED IN TANKER TRUCKS OR TOTES

A. IPP are to verify the type of container is identified as a "foodtainer" in PHIS for imported egg product shipped in tanker trucks. When a tanker is not identified as a "foodtainer," IPP are to correct the entry in PHIS.

B. Pasteurized egg product shipped in tanker trucks or totes must be accompanied by certification issued by the foreign country central competent authority (CCA) that test results for *Salmonella* and *Lm* were negative. When negative test results for *Salmonella* and *Lm* are not certified by the foreign CCA on a certificate issued for pasteurized egg products shipped in tanker trucks or totes, IPP are to fail the Certification TOI regardless of whether an EGGIMP sampling TOI is assigned by PHIS.

1. When IPP fail the Certification TOI because the shipment is not accompanied by certified negative *Salmonella* and *Lm* laboratory test results, IPP are to:

    a. Refuse entry on the shipment;

    b. Immediately notify the import inspection establishment management the shipment was refused entry; and

    c. Immediately compose and send an e-mail to their FLS and the DO to report the refused

entry and the reason for the refusal and include a copy of the certificate (for non-eCert countries) and the PHIS import application number and lot number.

C. When PHIS assigns a laboratory sampling TOI for egg products shipped in a tanker truck or totes, IPP are to:

1. Accept the certified negative *Salmonella* and *Lm* results; and

2. Request through PHIS not to perform the assigned import laboratory sampling TOI for *Salmonella* and *Lm*.

D. When the DO receives an e-mail notification that egg products shipped in tanker trucks or totes were refused entry, they are to e-mail the information to RMTAS at foimports@usda.gov. RMTAS will notify OIC of the refused entry and provide them with the documentation received from the DO so they can officially notify the foreign country CCA of the refused entry.

CHAPTER III – RAW BEEF PRODUCTS SAMPLED FOR STEC

I. INTRODUCTION

IPP are to collect and submit samples of imported raw beef products for STEC testing when an MT08 or MT51 laboratory sampling TOI is assigned through PHIS.

II. IMPORTED RAW BEEF PRODUCTS ELIGIBLE FOR SAMPLING

IPP are to refer to FSIS Directive 10010.1, *Sampling Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products* to view a general description of eligible products for each of the routine import sampling programs (MT08 and MT51).

1. MT51 - Sampling program for imported beef manufacturing trimmings and other components. Imported beef manufacturing trimmings and other components are sampled for seven adulterant STEC serogroups (O157, O26, O45, O103, O111, O121, and O145) and *Salmonella.*

2. MT08 - Sampling program for imported raw ground beef products. Imported raw ground beef products are analyzed for seven adulterant STEC serogroups (O157, O26, O45, O103, O111, O121, and O145) and *Salmonella*.

III. SAMPLE SELECTION

A. When PHIS assigns a STEC MT08 or STEC MT51 laboratory sampling TOI, IPP are to:

1. Refer to the sampling instructions in Chapter I, Section VII of this directive and FSIS Directive 10010.1, *Sampling Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products* to select a random sample from one specific production code or date;

2. Use the cloth sampling instructions in FSIS Directive 10010.1 to collect fresh non-intact beef samples for laboratory analysis; and

3. Notify the import establishment management that a sample will be collected and analyzed for STEC and that all samples analyzed for STEC will also be analyzed for *Salmonella*.

B. The product is not required to be held pending receipt of *Salmonella* laboratory testing results, and if *Salmonella* positive, is not to be refused entry.

C. Sampling Resources:

1. Training video, STEC Sampling of Imported Raw Beef Products Video Training is available online.

2. Instructions for sampling imported raw beef can be found on IPP Help in Sampling – Raw Beef.

NOTE: Reporting of *Salmonella* test results may take 1-3 days longer than reporting of STEC test results.

CHAPTER IV - RAW POULTRY PRODUCTS SAMPLED FOR *SALMONELLA* AND *CAMPYLOBACTER* ANALYSIS

I. INTRODUCTION

IPP are to refer to the instructions in Chapter I, Section VII to collect random samples of imported raw poultry for *Salmonella* and *Campylobacter* testing when the Poultry-*Salm/Campy* TOI is assigned through PHIS.

II. SUPPLEMENTARY SAMPLING SUPPLY INSTRUCTIONS

A. Upon receipt of sampling supplies, IPP are to:

1. Open the shipping container and check to ensure that all supplies needed for sample collection are inside as listed in FSIS Directive 10250.1, *Salmonella and Campylobacter Verification Program for Raw Poultry Products*; and

2. Refrigerate (not freeze) the sampling broth in a secure refrigerator where the supplies will remain under FSIS control until use.

B. IPP are not to use broth that:

1. Is not included in the provided IMP_Poultry supplies;

2. Is packaged in a leaking container;

3. Is past the expiration date on the label; or

4. Is or was previously frozen.

C. If any of the conditions in paragraph B of this section exist, IPP are to discard the broth and submit a request to any of the laboratories for sampling supplies using the instructions in Chapter I Section IV for replacement supplies.

D. The broth received from the laboratory may be cloudy in appearance. IPP are **NOT** to discard based on cloudy appearance.

III. PRODUCT ELIGIBILITY AND SAMPLE COLLECTION

A. IPP are to refer to Chapters III, IV, and V of FSIS Directive 10250.1 to determine imported poultry carcass and parts sampling eligibility and sampling process

B. In addition to the instructions in FSIS Directive 10250.1, eligible chicken and turkey carcasses for sample collection include both intact whole birds with or without feet attached and non-intact whole birds injected or marinated with or in a liquid (e.g., broth or marinade that does not mask the raw nature of the product).

NOTE: The Poultry-*Salm/Campy* TOI will continue to be assigned by PHIS to all products in the IMP_Poultry project.

C. IPP are not to perform an import laboratory sampling TOI assigned by PHIS to products not eligible for sampling as described in FSIS Directive 10250.1. IPP are to not perform the TOI and select "not applicable" for:

1. Chicken necks, chicken feet and giblets;

2. Mechanically separated poultry; and

3. Battered or breaded raw poultry products and mixed species comminuted poultry.

D. In addition to the instructions in FSIS Directive 10250.1, PP are to:

1. Use IMP_Poultry Rinse sampling supplies;

2. Allow the fresh or tempered carcass to drip for approximately one minute before rinsing with the broth;

3. Ensure that frozen chicken carcasses are properly tempered to remove all ice crystals and that the broth is able to reach all the external and internal carcass cavity surfaces;

4. Use IMP_Poultry Ground/Comminuted poultry sampling supplies for raw ground comminuted or otherwise non-intact chicken and turkey and collect sufficient product to;

    a. Fill the two roll top bags (approximately 325 grams per bag); or

    b. Enough final packages to equal at least 2 pounds.

5. Use the instructions in Chapter I, Section VII of this directive to collect a sample when frozen product is not available in consumer-ready final packages weighing 2 pounds or less.

E. When PHIS assigns a Poultry-*Salm/Campy* laboratory sampling TOI to a lot of raw poultry, IPP are to notify the import establishment management about the sample collection, and that the sample will be analyzed for *Salmonella* and *Campylobacter.* IPP are to be aware that the IOR does not have to hold the product pending reporting of these test results.

CHAPTER V - RAW PORK PRODUCTS SAMPLED FOR *SALMONELLA* ANALYSIS

I. INTRODUCTION

Imported raw intact and non-intact pork products are sampled for *Salmonella* when the Pork – *Salmonella* laboratory sampling TOI is assigned by PHIS.

II. ELIGIBLE PRODUCTS

A. The following pork products are eligible for sampling:

1. Raw – Non-Intact, Raw ground, comminuted, or otherwise non-intact pork, product groups Ground Product, Mechanically Separated, Advanced Meat Recovery Product (AMR), Sausage and Other Non-Intact.

2. Raw – Intact, Raw Intact Pork, product group Cuts.

B. The following practices **Do Not Exempt** raw pork products from sampling:

1. Addition of ingredients such as spices, seasonings, rosemary extracts or vegetables to eligible pork products;

2. Application of an antimicrobial treatment or intervention (other than a treatment that achieves a full lethality); or

3. Addition of meat or poultry products from a different species to eligible pork products.

C. The following pork products are **Not Eligible** for sampling:

1. Battered or breaded pork products;

EXAMPLE: dumplings, egg rolls, potstickers, or breaded pork tenderloin.

2. Heat Treated – Not Fully Cooked – Not Shelf-Stable product containing pork; and

3. Carcass (including halves and quarters), primals and subprimals, edible offal and boneless manufacturing trimmings.

D. Instructions for sampling imported raw pork can be found on IPP Help in Sampling –Raw Pork.

III. SAMPLE SELECTION

A. When the Pork – *Salmonella* laboratory sampling TOI is assigned by PHIS to fresh and frozen intact and non-intact raw pork cuts, IPP are to:

1. Use IMP_Pork (Cuts) sampling supplies;

2. Collect enough fresh or frozen raw pork cuts to equal at least two pounds; and

3. Select only one type of cut for the sample when the imported pork lot includes more than one type

of eligible pork cut. An alternate type of cut should be chosen for subsequent sample collections for mixed lots to ensure representation of all eligible cuts.

B. When the Pork – *Salmonella* laboratory sampling TOI is assigned by PHIS to Fresh or frozen raw ground, mechanically separated, AMR, or comminuted pork products, IPP are to:

1. Use sampling kit:

    a. IMP_Pork (Ground); or

    b. IMP_Pork (Intact Frozen/Mechanically Separated Species (MSK).

2. Collect enough product to equal at least two pounds for laboratory analysis.

CHAPTER VI – FOOD CHEMISTRY AND SPECIATION TESTING

I. INTRODUCTION

A. When a food chemistry laboratory sampling TOI is assigned by PHIS, IPP are to conduct food chemistry sampling on imported meat, poultry, and egg products when assigned by PHIS to determine whether imported products comply with FSIS regulatory requirements.

B. Food chemistry testing may include the following analyses:

1. Added Water;

2. Moisture/Protein Ratio (MPR);

3. Total Fat;

4. Total Water;

5. Nutritional Labeling;

6. Maximum Internal Temperature (MIT); and

7. Other types of food chemistry testing the Agency deems necessary.

II. FOOD CHEMISTRY SAMPLING

A. When a food chemistry laboratory sampling TOI is assigned by PHIS, IPP are to collect a minimum of 12 ounces of product in their final package or from product not in the final package.

B. Depending on how the product is packaged, IPP are to obtain a sample from one single package, a portion hereof, or several packages.

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

EXAMPLE: When product is packaged in 10-pound immediate containers, such as frozen frankfurters, then enough frankfurters are to be collected from the container to obtain a 12-ounce sample.

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

C. When PHIS assigns multiple food chemistry laboratory sampling TOIs to the same production lot or code, IPP are to:

1. Review the exceptions in paragraph D to ensure that only one food chemistry sample is required to be submitted to the laboratory for analysis;

2. Collect one sample that weighs a minimum of 12 ounces using the examples provided in paragraph B;

3. Use one sample form to identify all food chemistry laboratory sampling TOI assigned by PHIS; and

EXAMPLE: If a lot of hot dogs is assigned two food chemistry laboratory sampling TOIs (e.g., Added Water and Total Fat), the sample form will identify both TOIs;

4. Submit the sample and sample form to the laboratory.

D. Exceptions to taking only one sample: When PHIS assigns the following chemistry TOIs, IPP are to use a separate form and collect more than one sample for laboratory testing:

1. Lots subject to maximum internal temperature (MIT) testing.

    a. When a lot is assigned an MIT laboratory sampling TOI, the MIT analysis requires a separate sample and sample laboratory form.

    b. The MIT TOI is assigned to fully cooked pork products from Animal and Plant Health Inspection Service restricted countries (9 CFR part 94) to verify cooking temperatures for animal disease concerns (e.g., foot-and-mouth disease).

2. Lots of cooked sausage (9 CFR 319.180 and 319.181) sampled for compliance with the 30% fat limitations. When PHIS assigns a food chemistry laboratory sampling TOI for Total Fat or Moisture Protein Ratio (MPR) to lots of cooked sausage, IPP are to:

    a. Collect three one-pound samples (or the equivalent) to be submitted to the laboratory from the same production lot or code; and

    b. Submit a copy of the inspection certificate identifying the Group II protein data, as defined in 9 CFR 318.22 with the laboratory form.

3. Food chemistry samples submitted for laboratory analysis are sent to the FSIS laboratory identified on the sample form unless instructed otherwise in this chapter or in Chapter I, Section VIII.

III. SPECIES SAMPLING

A. When a Species TOI is assigned by PHIS, IPP are to sample imported meat and poultry products for species verification. Species testing may include Species-Processed and Species-Raw.

B. When PHIS assigns an import laboratory sampling TOI for species verification, IPP are to:

1. Randomly select a sample weighing at least one-half pound but not more than 20 pounds; and

2. Submit the ingredient label (original or copy) with the sample in the separate plastic bag provided with the sample supplies.

C. When a species verification TOI is assigned by PHIS at a "normal" LOR for which IPP can easily identify the species is correct, IPP are to request not to perform the TOI in PHIS and select "Visual Species Identification" for the appropriate reason.

D. IPP are to submit laboratory samples for species verification to the Eastern Laboratory.

CHAPTER VII – PATHOLOGY

I. INTRODUCTION

A. The Pathology – Lab TOI can either be assigned by PHIS or added as an unscheduled TOI. An unscheduled Pathology – Lab TOI may be added for a lot in PHIS, after correlating with the FSIS supervisor, whenever the product tissue appears to be abnormal, a possible pathological lesion is identified, or the product is observed or suspected to contain ineligible ingredients (e.g., lung tissue or salivary gland in canned corned beef).

B. Pathology testing may include the following analyses: Pathology – Lab; AMR Panel – Beef, Veal.

II. SUPPLEMENTAL PATHOLOGY SAMPLING PROCEDURES

A. Pathology defects or abnormal tissue observed on product exam (PE) are to be examined by a Public Health Veterinarian (PHV) if possible. IPP are to:

1. Send an e-mail to notify their supervisor of the defects. If the defect cannot be classified, or if a PHV is not available, an unscheduled Pathology – Lab TOI is to be added to the lot in PHIS, and the defect sample submitted to the laboratory; and

2. Retain the lot pending the results of the laboratory analyses.

B. When IPP detect abnormal tissue or pathological lesions during a product examination, the defects are to be scored using the defect criteria designated for the specific product identified in FSIS Directive 9900.2.

C. When IPP are unable to identify the defect to score it, and there is a PHV in the local area, IPP are to request through their supervisor that a 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" block of the product examination TOI in PHIS for

the lot, as well as the case file.

D. If a PHV is not available, or if the PHV cannot make a determination to classify the defect, IPP are to add an unscheduled Pathology – Lab TOI and use sanitary sampling procedures and information provided in FSIS Directive 10230.6, *Submitting Tissue Specimens for Pathological or Diagnostic Microbiological Evaluation to the Laboratory* to collect the tissue or lesion and submit the sample to an FSIS laboratory for analysis.

E. For products in their final package, IPP are to submit one or more packages to equal at least 12 ounces from the affected unit.

F. For abnormal tissue (e.g., lung tissue, salivary glands), IPP are to:

1. Submit the entire section of abnormal tissue to the Eastern laboratory; and

2. Place all lots of products sampled for pathology under FSIS control until the results are received.

III. SUPPLEMENTAL PATHOLOGY RESULTS INSTRUCTIONS

A**.** RMTAS may provide additional disposition guidance for failed pathology results that are rectifiable, e.g., relabeling or sorting of product as appropriate.

B. The results reported by the laboratory must be interpreted by a PHV.

CHAPTER VIII – RESIDUE TESTING

I. INTRODUCTION

Import laboratory sampling TOIs for residues are assigned by PHIS to lots of imported meat, poultry, and egg products.

II. ELIGIBLE PRODUCTS

IPP are **not** to sample the following types of products for residues:

1. Fresh or frozen products (raw-intact or raw non-intact) that are multiple-ingredients, intestines, organs, offal, or primarily consists of fat, skin, or bones (without sufficient muscle tissue); or

2. Processed product that is a combination product containing non-meat components, such as a pastry shell, dough, or meat sauce (e.g., pizza, ravioli, and wonton), if product is multi-species; or if product is broth.

III. SAMPLE SELECTION

A. When PHIS assigns a laboratory sampling TOI for residue testing for meat and poultry, IPP are to:

1. Select an intact sample weighing greater than or equal to two pounds but not more than 20 pounds;

2. Select one or more final packages to equal at least 2 pounds when product is available in final packages weighing less than 2 pounds; or

3. Collect a 2-pound sample from one final package when packages weigh more than 20 pounds.

B. When PHIS assigns an Egg, CHEM laboratory sampling TOI for pasteurized liquid, frozen or dried egg products available in the final package, IPP are to:

1. Select an intact sample weighing greater than or equal to 8 ounces but not more than 20 pounds;

2. Select one or more final packages to equal at least 8 ounces; or

3. Collect an 8-ounce sample from one final package when packages weigh more than 20 pounds.

C. PHIS may assign multiple import laboratory sampling TOIs for residue to a single lot of product resulting in multiple sample forms for the sample. When multiple residues TOIs are assigned, IPP are to:

1. Submit the multiple printed sample forms, along with one sample unit, to the designated laboratory identified on the form; and

2. When the assigned residue analyses are run at different laboratories, collect a separate sample and submit the sample along with the form or forms to each designated laboratory.

D. Test and Hold instructions for products sampled for residues.

1. **Livestock carcasses and meat products**: The IOR is required to maintain control of livestock carcasses and meat products assigned a laboratory sampling TOI for residues pending receipt of acceptable laboratory test results.

2. **Meat and poultry products assigned a residue laboratory sampling TOI for metals**: The IOR is not required to hold meat and poultry products pending receipt of acceptable exploratory residue laboratory test results for metals.

3. **Poultry carcasses or raw poultry parts sampled for residues**: The IOR is not required to hold poultry carcasses or raw poultry parts pending receipt of acceptable laboratory test results for residues.

4. **Egg products** assigned an Egg, CHEM laboratory sampling TOI are not required to be held pending receipt of laboratory sampling test results.

E. IPP are to refer to Chapter I, Sections V and VI for additional instructions on holding or maintaining control of imported products.

CHAPTER IX - RETURN OF IMPORTED SHIPMENTS TO CANADA SUBJECT TO TEST AND HOLD PENDING RECEIPT OF LABORATORY RESULTS

I. ELIGIBLE PRODUCTS

A. FSIS allows imported meat and poultry products sampled and tested for adulterants to return to Canada provided:

1. The product was imported from Canada;

2. The product is eligible to be held off-site under an importer of record hold for the import laboratory sampling TOI analyses assigned; and

3. The product is fresh, not frozen, and packaged in a manner that could compromise the quality (freshness), and thereby the usability, of the product for its intended use if it is held in the United States pending reporting the result of the laboratory analyses.

EXAMPLE: Opened combos and fresh carcasses or parts.

B. Vacuum packaged products are not eligible to return to Canada.

II. IMPORT INSPECTION PERSONNEL RESPONSIBILITIES

A. Each time IPP have a laboratory sample TOI assigned to a lot that is eligible for an IOR hold, and the product meets the criteria in Section I of this chapter, they are to notify the import establishment management and inquire whether the IOR will be holding the lot in the United States or returning it to Canada.

B. If the IOR indicates the product will be returned to Canada and held, IPP are to allow the product to return to Canada after IPP:

1. Review a copy of the Canadian Food Inspection Agency's (CFIA) ANNEX (E) J, APPLICATION TO RETURN CANADIAN PRODUCTS EXPORTED TO THE USA, from import establishment management for completeness;

2. Review the Annex (E) J to ensure that the form contains CFIA Approval number;

3. Review that Part 2 is completed; and

4. Attach the Annex (E) J to the case file.

NOTE: The "Import Laboratory Sampling Users Guide" contains a copy of the Annex (E) J available in IPP Help.

C. When the documentation requirements are not met, IPP are to notify import establishment management that Annex (E) J is not acceptable, and that the product cannot be returned to Canada until an acceptable Annex (E) J is received.

D. When samples are collected, and the lot is not held onsite, IPP are to:

1. Access PHIS to record the specific location, including full physical address, when completing the questionnaire portion of the sample documentation or in the Remarks box of the laboratory form, as applicable; and

2. Access the Lot Manager page to place the applicable lot on hold.

III. LOT DISPOSITION

A. IPP are to access LIMS-Direct for sample results and e-mail a copy of the sample results to CFIA using the address provided on Annex (E) J. IPP are to remove the hold status on acceptable lots in PHIS after results have been received.

B. When a laboratory sample is discarded, IPP are to:

1. Send an e-mail copy of the discard notification to CFIA using the address provided on Annex (E) J; and

2. Request not to perform the TOI in PHIS and select "Discarded Sample" as the reason.

C. IPP are not to e-mail unacceptable laboratory test results to CFIA. When unacceptable laboratory test results (e.g., Positive, Detected – Violative) are received, IPP are to:

1. Request the import establishment management to notify the IOR the lot is refused entry;

2. Send an e-mail to notify their supervisor and provide a copy of the inspection certificate and PHIS import inspection application number and lot number. The supervisor will forward the e-mail notification to RMTAS headquarters; and

3. Initiate a refused entry in PHIS.

D. If IPP receive a message that the e-mail is undeliverable or a return message that indicates the e-mail could not be delivered, IPP are to:

1. Verify that the e-mail address they entered on the original e-mail was accurate, and correct and resend if necessary; or

2. Send an e-mail to RMTAS at foimports@usda.gov to let them know an e-mail for CFIA was undeliverable.

IV. OFO-HEADQUARTERS RESPONSIBILITIES

A. When RMTAS receives the e-mail notification that the e-mail to CFIA was not able to be delivered, RMTAS is to make OIC aware of the incorrect e-mail address so they can contact CFIA for an updated e-mail address.

B. When RMTAS receives notification that a laboratory sample result on product returned to and held in Canada has failed, they are to:

1. Immediately notify OIC of the failed laboratory sampling results;

2. Provide OIC with copies of the inspection certificate and failed test results; and

3. Follow FSIS Directive 9780.1, *Verifying the Ongoing Equivalence of Foreign Food Safety Inspection Systems*.

C. OIC will use the information provided by RMTAS to immediately notify CFIA of the failed laboratory sampling results.

CHAPTER X – DATA ANALYSIS AND QUESTIONS

A. The Office of Policy and Program Development (OPPD) will work with the Office of Planning, Analysis and Risk Management and RMTAS to track imported product sampling data every year. OPPD will analyze the data to determine whether new policy is needed to address positive results.

B. Refer questions regarding this directive to your supervisor or the OPPD through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select Import for the Inquiry Type.

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

Assistant Administrator
Office of Policy and Program Development