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

FSIS DIRECTIVE

9900.6 | 11/3/15

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

CHAPTER I - GENERAL

I. PURPOSE

This directive provides instructions to import inspection personnel on the Food Safety and Inspection Service's (FSIS) laboratory sampling and testing of imported meat, poultry, and egg products that is assigned by the Public Health Information System (PHIS). FSIS is reissuing this directive to address changes associated with the reorganization of import inspection personnel into the Office of Field Operations (OFO), as well as to incorporate instructions for control of products offered for import that are tested by FSIS for adulterants and for products sampled and returned to Canada, and to provide clarification of PHIS functions.

KEY POINTS:

- *How to collect, prepare, and submit samples for laboratory analyses*
- *How to interpret laboratory results and take appropriate action*
- *How to verify that import establishments control Agency tested imported products for adulterants*

II. CANCELLATION

FSIS PHIS Directive 9900.6, *Laboratory Sampling for Meat, Poultry and Egg Products, 5/25/12*

III. 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 laboratory TOIs to a lot. Import inspection personnel are to refer to the following FSIS Directives when TOIs are assigned for:

1. Abnormal Container, see FSIS Directive 7530.1, *Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product; and*

2. Shiga toxin-Producing producing *Escherichia coli* (*STEC*) sampling and testing of imported products (e.g., MT08, MT51), see FSIS Directive 10,010.1, *Verification Activities for Escherichia coli O157:H7 In Raw Beef Products.*

IV. REINSPECTION CATEGORIES

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

B. 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 levels:

1. Normal is a LOR where randomly selected lots are assigned TOIs based on the FSIS annual sampling plan. Under normal level of sampling, the importer of record (IOR) is required to maintain control of product tested for adulterants by FSIS and is not to allow such product to enter commerce unless and until negative results are received;

2. Increased is a LOR above the normal level that is directed by a FSIS management decision. Under increased reinspection, FSIS may hold, on a case-by-case basis, lots of imported meat, poultry, or egg products pending receipt of a laboratory analysis. If FSIS does not place the product on hold, the importer of record is still required to hold product tested for adulterants by FSIS and is not to allow such product to enter commerce unless and until negative results are received; or

3. Intensified is a LOR that is implemented automatically by PHIS when a TOI is reported as "Fail." Under intensified reinspection, FSIS holds the sampled lot at the official import inspection establishment pending receipt of laboratory analysis. The sampled lot is not allowed to move off-site to be held.

V. CONTROL OF PRODUCTS OFFERED FOR IMPORT THAT ARE TESTED BY FSIS FOR ADULTERANTS

A. Import inspection personnel are to withhold a determination as to whether imported meat, poultry, and egg products are not adulterated, and thus eligible to enter United States (U.S.) domestic 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"). When not under an FSIS hold, the IOR must hold or control applicable lots of product that FSIS tests for adulterants until import inspection personnel receive the results of the testing. If unacceptable test results are reported, product will be refused entry if the product has been maintained under the IORs control and not entered commerce.

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.

B. Imported products assigned a TOI for cause are under FSIS control and are not permitted to be stamped with the mark of inspection or to move off-premises from the official import inspection establishment prior to receipt of acceptable laboratory results. For cause sampling includes Intensified LOR or Increased LOR with Agency instruction that the lot be held under FSIS control.

C. If the sample is discarded by the laboratory, a reason for the discard will be provided to import inspection personnel. If the sampling of the lot was for cause, import inspection personnel are to collect a replacement sample from the lot. If the sampling was not for cause (e.g. Normal LOR), then import inspection personnel are to release the lot, and PHIS will randomly assign a replacement sample from a future lot.

D. The instructions in this section apply to imported:

1. Non-intact raw beef product or intact raw beef product intended for non-intact use that is tested for *Escherichia coli* O157:H7 (*E. coli* O157:H7) and other shiga-toxin producing *E. coli* (*STEC*) that FSIS considers to be adulterants;

2. Ready-to-eat products tested for *Listeria monocytogenes,* or *Salmonella; and*

3. Livestock carcasses and meat products tested for residues.

E. The instructions in this section do not apply to:

1. Raw meat or poultry products tested for *Salmonella* or other pathogens that FSIS has not designated as adulterants in those products; or

2. Poultry carcasses or raw poultry parts sampled for residues.

F. Import inspection personnel are to be aware that the IOR has the following options:

1. To keep the sampled product on the premises of the official import inspection establishment where the product was sampled until laboratory results are received; or

2. To move the sampled product from the official import inspection establishment premises provided the IOR has effective measures (e.g. company seals) in place to prevent the product from entering U.S. domestic commerce until the results of the testing are received.

G. Each time import inspection personnel have a laboratory sample TOI assigned to a lot, they are to notify the import establishment management and, if the TOI is not for cause, ask whether the IOR will be holding the lot on-site at the official import establishment or off-site under the IOR's control.

H. When completing the questionnaire portion of the sample documentation in PHIS, import inspection personnel are to select the appropriate option for the location where the product will be held. When the IOR informs them that the lot will be held off-site, import inspection personnel are to select the off-site option and record the name and address of the off-site location.

NOTE: If the IOR intends to return the shipment to Canada after FSIS samples are collected, import inspection personnel are to refer to Chapter VIII., "Return of Imported Shipments to Canada Subject To Test and Hold Pending Receipt of Laboratory Results."

I. Import inspection personnel are to monitor LIMS-Direct for sample results and are to notify the official import inspection establishment of sample results as soon as the results are reported. Import inspection personnel are to ensure that the sample results are also reported in PHIS.

1. When a sample report is negative or is identified as "Pass" in PHIS for the requested analyses, and all other reinspection activities are acceptable, import inspection personnel are to notify official import inspection establishment management that FSIS is releasing the lot.

2. For results other than negative or identified as "Pass," import inspection personnel are to follow instructions in Chapter 1, Section VI., I. Reporting Results.

J. If import inspection personnel become aware that an IOR failed to maintain control (i.e., product was released into commerce or further processed) of the product tested by FSIS for adulterants, import inspection personnel are to notify their supervisor. For shipments that IOR failed to maintain control that test positive for adulterants, because the shipment is in commerce, it cannot be refused entry in PHIS. The District Office (DO) is to notify the appropriate Office of Investigation, Enforcement and Audit (OIEA),

Regional Director (RD), as well as the OFO Recall Management and Technical Analysis Staff (RMTAS) staff to investigate or take enforcement action, when necessary.

VI. SAMPLING

A. Ordering Sampling Supplies through Outlook

1. Import inspection personnel are to order sample supplies using the Outlook Sampling Mailboxes.

2. To find the sampling supply e-mail address in the global address list in the search box, import inspection personnel are to enter "FSIS – Sampling" to view them. Import inspection personnel are to submit requests for sample supplies via Outlook using the following e-mail 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. To ensure timely delivery of supplies, the e-mail supply request is to include:

   a. Sampling supplies needed (e.g., *E. coli* MT08, MT51, IMVRTE, residues, chemistry);

   b. Establishment number and establishment name;

   c. Name of submitter, and

   d. Contact phone number.

B. Selecting Samples

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

1. Identify each shipping container selected as a sample with "USDA OFFICIAL IMPORT SAMPLE;" When PHIS assigns a product exam in addition to laboratory TOIs, identify the carton or cartons from which the lab sample was obtain by double stamping the carton or cartons with the sample stamp.

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

3. Collect samples from one single production code or date;

NOTE: When recording the production date on the laboratory form in PHIS for complex products such as aged, dry cured hams, import inspection personnel are to record the date of the final process (e.g., date of deboning or date of slicing; rather than salting or curing periods). When a production code is on the product and not an actual date, import inspection personnel are to select the date of sampling as the production date and enter the production code in the Remarks section of the laboratory form.

4. Have the import plant management make photo-copies, when practical, of the shipping container label and immediate package label (front and back) from the sample submitted for the case file for use in the event of follow up if there is a violative laboratory result; and

5. When the entire contents of the sampled container are submitted to the lab, import inspection personnel are not to permit the empty container to be discarded pending receipt of the laboratory results. They are to ensure that the empty container remains at the official import inspection establishment until the laboratory sample results are reported, as RMTAS may request information from the container when an unacceptable laboratory result is reported.

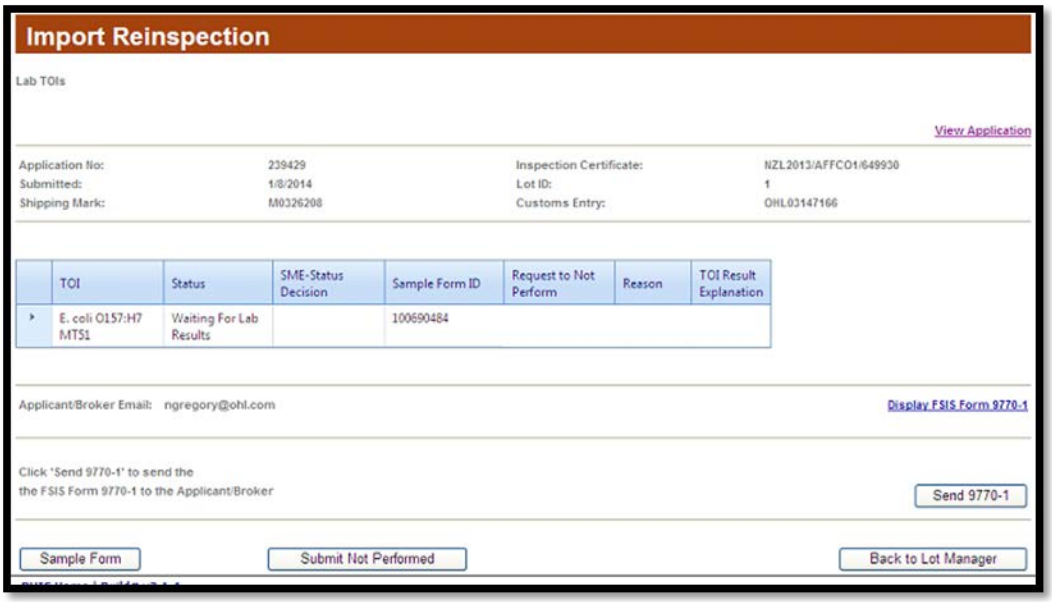
C. Laboratory TOI Not Performed

1. Import inspection personnel are to request through PHIS not to perform a laboratory sample TOI assigned by PHIS when they determine that the TOI is not applicable to the product. They are to select the most appropriate reason in PHIS for not performing the TOI; and

2. Import inspection personnel are to refer to the products and applicable TOIs document located on the import inspection SharePoint site for TOIs that are applicable to product groups.

D. 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 IOR once all samples are collected from the lot. Import inspection personnel can send this form to the IOR/applicant by clicking the "Send 9770-1" button on the laboratory sampling screen in PHIS. FSIS Form 9770-1 is also available in InsideFSIS.



E. 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 FSIS Form 8000-21, Sample Analysis Request Form, sign it, and submit the printed copy with the sample to the laboratory.

3. Import inspection personnel are to return to the Lot Manager page, and when applicable, select Lot Tracking, select "Place Lot on Hold," and select the appropriate reason.

F. Sample Submission to Laboratories

1. Samples are to be submitted to the FSIS field service laboratory designated on the form in the PHIS. Import inspection personnel are to ensure the form is submitted electronically in PHIS so that the sample results will post to LIMS-Direct.

NOTE: Pathogen samples from the Pacific Islands must go to the Western Laboratory, and pathogen samples from Puerto Rico must go to the Eastern Laboratory, regardless of which laboratory the PHIS designates on the form. Import inspection personnel are to line through the lab name on the form and write-in the correct laboratory name.

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. Samples are to be shipped Monday through Friday so that they arrive at the laboratory overnight. Samples are not to be shipped on Saturday or the day before a Federal holiday.

4. Import inspection personnel are to follow the instructions below for samples requiring refrigeration:

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

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

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

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

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

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

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

G. 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.

H. Laboratory Sample Discards

When import inspection personnel observe in LIMS-Direct that a sample is discarded, they are to:

1. For a lot that was sampled for cause and is under mandatory FSIS hold, access the Lab TOIs page for the lot, choose "Submit a 2nd sample," and notify the IOR through import plant management that a 2nd sample is being submitted to the lab; or

2. For a lot that was not sampled for cause and is under the IOR's control, access the Lot Manager page and verify that PHIS has recorded the lab TOI as "Complete" with a status of "Not Analyzed" for the lot. They are to choose "Submit Not Performed," select "Discarded Sample" as the reason, and notify the IOR through import plant management that the sample was discarded, and that the lot will not be resampled; and

3. Complete FSIS Form 9770-3, *Discarded Sample Report and Findings,* and submit it to their supervisor, who is to review and determine whether follow-up training or correlation is needed. If follow-up training or correlation is needed, the supervisor will ensure that it occurs. FSIS Form 9770-3 is available through the FSIS Home page, by selecting the "Programs & Services" tab and then selecting InsideFSIS for Employees.

I. Reporting Results - Actions Taken Based on Results

1. Import inspection personnel are to monitor LIMS-Direct for sample results and ensure that the results are also reported to PHIS. When sample results have not reported to a lot in PHIS, import inspection personnel are to submit a Footprints ticket and request that the laboratory results be pushed to PHIS again.

2. Indeterminate Results – When an indeterminate result displays for a lot in the PHIS Lot Manager screen, import inspection personnel are to send an e-mail to the RMTAS-Subject Matter Expert

(SME) at importinspection@fsis.usda.gov. The email is to include the PHIS Application-Lot ID number, Lab Form number, and either a scanned copy of the product label with the ingredients statement or a typed product name and ingredients statement. Indeterminate results will show as such in the PHIS Lot Manager screen until the SME has researched and determined a result of Pass or Fail. The SME will then enter the result in PHIS.

3. Negative or Passed Results - When a sample tests negative or is identified as "Pass" in PHIS for the requested analyses, and all other reinspection results are acceptable, and the lot was:

    a. Under IOR control, import inspection personnel are to notify official import inspection establishment management that the lot can be released and are to complete the reinspection of the lot in PHIS; or

    b. Held for cause under FSIS control, import inspection personnel are to complete the reinspection of the lot in PHIS and notify official import inspection establishment management to stamp the lot so it can be released.

4. Presumptive positive results (microbial results only) - When a sample is reported as presumptive positive,

    a. Import inspection personnel are to:

    i. Notify the import establishment management of the presumptive positive result;

    ii. If the lot is still at the import establishment, retain the product using FSIS Form 6502-1, U.S. Rejected U.S. Retained Tag;

    iii. If the lot has been moved from the import establishment to an off-site location, request import establishment management to:

        (a) contact the IOR to inform it of the presumptive positive;

        (b) confirm with the IOR that the product is still on hold and stop further movement of the product; and

        (c) confirm the off-site location of the product;

    iv. Compose an e-mail to their supervisor that reports the hold status and location of the lot;

    v. Provide the District Import Specialist (DIS) with a copy of the inspection certificate (for non-eCert countries) and PHIS import application and lot number. The DIS is to forward these documents to the RMTAS-Import staff and the appropriate District Office (DO) immediately.

    b. RMTAS are to:

    i. Determine whether the exporting country has approved lotting procedures that establish microbiological independence of the lot or container that preclude other lots from being associated with the presumptive positive. If the exporting country has approved lotting procedures, no action is to be taken on other lots from the same foreign establishment.

NOTE: OPPD-International Equivalence Staff (IES) will provide this information upon request.

    ii. When the exporting country does not have approved lotting procedures to establish microbiological independence,

(a) Notify the foreign central competent authority of the exporting country at the earliest opportunity after the presumptive positive result is reported and after receiving the documentation from the field in order to determine whether the producing establishment has exported any other product from the same production lot to the U.S.

(b) Query Business Objects as per the table below to identify other lots that have entered the U.S. with the same production dates. Production dates are not a required field in PHIS or on inspection certificates unless the foreign establishment has been delisted.

(c) Refer to the information provided by the foreign central competent authority and to the table below when determining what products may be placed on hold pending further investigation. When other lots with the same production date are identified, notify the DO and import inspection personnel to retain the lots.

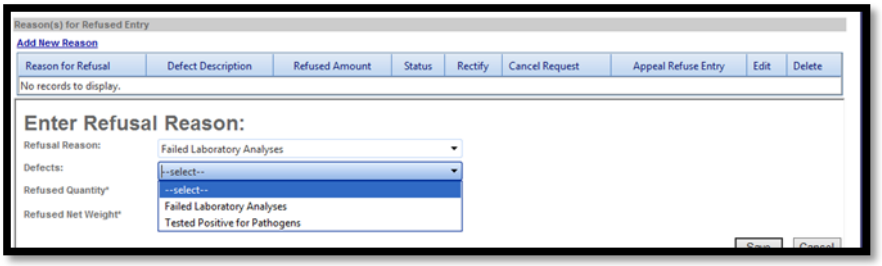
TOI Name	**Action on Presumptive Positive**
IMVRTE, FListeria mono., FRTESalmonella, EGGIMP	Products of the same process category/product category from the same processing establishment.
E.coli O157:H7 MT08, E.coli O157:H7 MT51	Products of the same process category, product category, product group and species from the same processing establishment.

c. RMTAS may issue instruction to retain applicable products from the same foreign establishment until further notice based on the information received and the table above. This may include previously inspected and passed product.

5. Positive or Failed Results

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

i. If the product is under the IOR's control and off-site, confirm through import establishment management that the IOR still has the product under the IOR's control, and that it has not entered commerce. If product is confirmed to be under the IOR's control, notify import establishment management to inform the IOR that the lot is refused entry and must be returned to the import establishment to be officially refused entry. Whether the lot is off-site or on-site at the import establishment, initiate a refused entry in PHIS from the Lot Manager page for the lot, select Add New Reason on the refused entry page, select Failed Laboratory Analyses and the appropriate reason from the drop down menu.



ii. When the product is held off-site and the lot is returned, ensure that the containers are stamped United States Refused Entry upon their return.

iii. Inform the DIS and DO of the unacceptable result and, if the shipment is held off-site, what the status of the shipment returning to the import establishment is, and whether the shipment is still on hold, or the IOR released it into commerce. If the shipment is not held, the DIS and RMTAS are to follow FSIS Directive 8080.1, *Recall of Meat and Poultry Products,* if the Agency determines that a request to recall the product is warranted; and,

b. RMTAS is to verify that PHIS has placed the foreign establishment on Intensified LOR for the failed TOI. If PHIS has not activated the Intensified LOR status, RMTAS-Import Staff is to add the Intensified status as per the Intensified Acton Table for the failed TOI.

c. RMTAS is to issue an alert to import inspection personnel with instructions pertaining to other lots from the same foreign establishment pertaining to the failed TOI.

d. RMTAS is to notify the foreign government of the violative result for identification of other shipments affected. If any lots are identified by the foreign country as affected product from the same producer with the same production code, RMTAS is to:

i. Follow FSIS Directive 8080.1; or

ii. Instruct import inspection personnel to refuse entry of the product if the product has not already been passed under import reinspection.

CHAPTER II – FOOD CHEMISTRY TESTING

I. INTRODUCTION

A. Import inspection personnel 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. Food chemistry testing may include analyses for Added Water; Moisture Protein Ratio (MPR); Total Fat; Total Water; Nutritional Labeling; or Maximum Internal Temperature (MIT).

B. Import inspection personnel may refer to the products and applicable TOIs located on the import inspection SharePoint site for TOIs that are applicable to product groups.

NOTE: Food Chemistry and Microbiological and Pathology analyses should never be requested on the same sample**.**

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 for each food chemistry assignment assigned to a lot. For example, if a lot of hot dogs has two food chemistry assignments (e.g., added water and total fat), import inspection personnel are to randomly select one sample for each analysis and submit the samples as one unit with one form.

2. There are exceptions below to the practice of only taking one sample:

    a. Lots subject to maximum internal temperature (MIT) - When a lot is assigned a MIT TOI, the MIT analysis requires its own lab form with its own sample unit. The MIT TOI is assigned to fully cooked pork products from Animal and Plant Health Inspection Service (APHIS) restricted countries (9 CFR Part 94) to verify cooking temperatures for animal disease concerns (e.g. Rinderpest or Foot and Mouth Disease)).

    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) are 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 (IMVRTE, FRTESalmonella, FListeria mono, EGGIMP)

I. INTRODUCTION

Import inspection personnel are to sample imported ready-to-eat (RTE) meat, poultry, and egg products when assigned by PHIS. IMVRTE analyses include *Listeria monocytogenes* and *Salmonella* testing for all RTE meat and poultry products. EGGIMP analysis is for *Salmonella* in pasteurized and dried egg products. See Chapter IV for instruction on sampling egg products. All products that are intended to be consumed without further preparation steps are eligible for IMVRTE or EGGIMP 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.

II. INTACT PACKAGE SAMPLING PROCEDURES FOR RTE PRODUCT

A. Sample Size and Selection

1. Import inspection personnel are to randomly select enough intact sample 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. More than one (1) pound but less than three pounds: collect enough intact units for a total of at least two (2) pounds of product. For example, if cooked ham is packaged in 18-ounce

units, two cooked hams in intact packages need to be submitted to the laboratory for analysis.

b. Three (3) pounds or more, select one intact sample unit. 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.

NOTE: If product is packaged in a manner that does not facilitate intact sampling, such as combo bins, refer to Chapter III below.

III. NON-INTACT PACKAGE SAMPLING PROCEDURES FOR RTE PRODUCT

A. Products Eligible for Sampling: Import inspection personnel are to make every effort to submit intact packages for analysis. However, there may be instances when product is packaged in a manner that makes the submission of intact samples impossible. For example: four (4) lb. salamis bulk packed in combo bins.

B. Sampling Procedures

Import inspection personnel are to:

1. Use aseptic sampling procedures as described in Chapter I, VI, G. 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 (e.g., cooked beef, fully cooked chicken nuggets, salamis), select the sample from the surface perimeter of the container.

    b. When product is frozen together in bulk, 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. When product is individually quick frozen (IQF), the air temper step is not needed.

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

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

4. Import inspection personnel are to submit sample units to the laboratory either refrigerated or frozen except for shelf stable products;

5. Thawed or tempered RTE samples prepared after the FSIS contract overnight delivery or courier service pickup are to be kept refrigerated until shipped; and

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

CHAPTER IV – MICROBIAL SAMPLING OF PASTEURIZED EGG PRODUCTS NOT SHIPPED IN BULK PACKED CONTAINERS (EGGIMP)

Import inspection personnel are to:

A. Sample imported pasteurized egg product for *Salmonella* when assigned an EGGIMP TOI by the PHIS;

B. Use aseptic sampling procedures as described in Chapter I. VI. G. of this directive and collect at least a one half (½) pound of product; and

C. Sample units are to be REFRIGERATED or FROZEN when submitted to the laboratory.

D. Shelf stable egg product is not required to be refrigerated or frozen before submitting to the laboratory.

1. Samples of liquid egg product collected are to be kept refrigerated and are not to be frozen. Samples are to be submitted to the laboratory in the liquid state following sample submission to laboratories guidance in Chapter I. VI. with sufficient coolant to keep samples cold.

2. Samples of frozen egg product collected are to be kept frozen and not be allowed to thaw. Samples are to be kept frozen and shipped to the laboratory following sample submission to laboratories guidance in Chapter I. VI. with sufficient frozen coolant to keep samples frozen.

CHAPTER V – PATHOLOGY TESTING

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 the PHIS lot whenever the product's 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, salivary gland, etc. in canned corned beef).

B. Pathology defects or abnormal tissue (e.g., abscesses or lesions in raw product) observed on product exam (PE) are to be examined by a Public Health Veterinarian (PHV) if possible. Import Inspection Personnel are to notify their supervisor of the defects and request examination by a PHV. 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. Import inspection personnel are to place the lot on FSIS hold pending the results of the laboratory analyses.

C. Pathology testing may include the following analyses: Pathology-Lab; AMR Panel-Beef, Veal; AMR Panel-Pork; Poultry MS Panel; or Red Meat MS Panel.

II. SAMPLING PROCEDURES

A. When import inspection personnel 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.

B. When import inspection personnel are unable to identify the defect to score it, and there is a PHV in the local area, the import inspection personnel 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 for 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 add an unscheduled Pathology -– Lab TOI and submit the tissue or lesion to a FSIS laboratory 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.

NOTE: The SME may provide additional disposition guidance for failed pathology results that are rectifiable, e.g., relabeling or sorting of product as appropriate.

CHAPTER VI – RESIDUE TESTING

I. INTRODUCTION

A. Residue sample TOIs will be assigned to a PHIS lot. Import inspection personnel are to complete and submit FSIS Form 8000-21, *Sample Analysis Request Form*, in PHIS for each residue TOI that is assigned.

NOTE: A single sample may have more than one form associated with the sample when there are multiple residue analyses of the sample. When this occurs, import inspection personnel are to submit the multiple printed forms representing the sample to the laboratory with the sample. If the residue analyses assigned are run at different laboratories, a separate sample must be collected for each of those laboratories.

B. Import inspection personnel are to refer to the most recent FSIS Notice on Import Residue Sampling Requirements, which provides detailed information for each specific residue TOI, including the applicable tissue, species, sample size requirements, and designated FSIS laboratories at which the analyses are performed.

C. In the situations described below, import inspection personnel 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-ingredient, intestines, organs, offal, or practically all fat, skin, or bones; or

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

II. SAMPLING PROCEDURES

A. Sample Size:

1. Import inspection personnel are to refer to the most recent FSIS Notice on Import Residue Sampling Requirements Table for the type, species, and amount of tissue to collect when assigned a residue TOI.

2. 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 immediately 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.

III. IMPORT INSPECTION PERSONNEL RESPONSIBILITIES

A. Import inspection personnel are to access the PHIS Sample Management – Sample Collection page from the Lab TOIs page by clicking on the Sample Form button. The Sample Management – Sample Collection page has three tabs:

1. Generate a Sample;

2. Sample Collection Data; and

3. Additional Info.

B. When completing the Generate a Sample tab, import inspection personnel are to place a check mark in the box next to each residue analyses listed, enter the sample weight as per Attachment 1, then select "Save and Continue."

C. Additional Info tab. This is the questionnaire portion of the residue sampling. Import inspection personnel are to respond to the questions, which are self-explanatory.

D. After completing the questionnaire and returning to the Lab Sample screen, import inspection personnel are to print, and sign the form, and submit with the sample.

E. When multiple residue TOIs are assigned for the same laboratory, import inspection personnel are to select one (1) sample unit and are to complete and submit all applicable forms with the sample.

F. When PHIS assigns the same TOI at different LOR (e.g., Normal, Increased, and Intensified) to a single lot, import inspection personnel are to:

1. Perform only one TOI. Import inspection personnel are to select the TOI based on the following order of LOR priority: 1) Intensified, 2) Increased, and 3) Normal; and

2. From the Lab TOIs page, choose "Submit Not Performed" for each of the remaining TOIs, selecting "Agency Instruction" as the reason.

G. Import inspection personnel are to return to the Lot Manager page, and when applicable, select Lot Tracking, select "Place Lot on Hold", and select the appropriate reason.

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

IV. LOT DISPOSITION

A. For residue test results reported as "Residue Detected – violative," import inspection personnel are to:

1. If the lot is on hold, whether on-site or off-site:

    a. If the product is under the IOR's control, confirm that the product is still under the IOR's control and not in commerce. If product is confirmed to be under the IOR's control or is on-site at the import establishment, initiate a refused entry in PHIS from the Lot Manager page for the lot, select Add New Reason on the refused entry page, select Failed Laboratory Analyses, and select the appropriate reason from the drop down menu.

    b. Notify the importer through import establishment management that the lot is refused entry,

and if the lot was held off-site, request that the lot be returned to the official import inspection establishment; and

c. Notify RMTAS through the supervisory chain and provide a copy of the inspection certificate (non-eCert countries) and PHIS import inspection application number.

2. If the lot is not on hold:

a. Notify the importer that a sample result was returned violative and request information as to the whereabouts of the lot; and

b. Notify RMTAS through the supervisory chain and provide copy of the inspection certificate (non-eCert countries) and PHIS import inspection application number.

B. For residue test results reported other than "Residue Detected – violative," the lot is eligible for release into commerce when all TOI results for that lot are "Passed." The hold status may be removed.

CHAPTER VII – SPECIES TESTING

I. INTRODUCTION

When assigned by PHIS, import inspection personnel are to sample imported meat and poultry products for species verification. Species testing may include the following analyses: Species-Processed and Species-Raw.

II. SAMPLING REQUIREMENTS

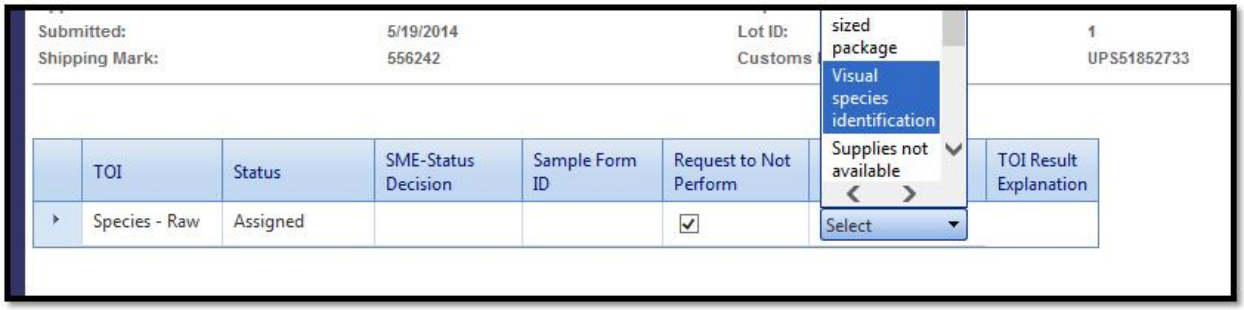
A. Sample Size

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.

3. Inspection personnel are to submit the ingredients label (original or copy) with the sample in a separate plastic bag.

NOTE: For samples assigned at a "normal" level of reinspection for which the import inspection personnel can easily identify the species is correct, they are to request not to perform the TOI, selecting "Visual species identification".



B. Preparing Samples for Laboratory Analyses

Import inspection personnel are to submit samples to the Eastern Laboratory as designated by PHIS on the form.

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

I. IMPORT INSPECTION PERSONNEL RESPONSIBILITIES

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

1. The product is fresh, not frozen, and packaged in a manner that will 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. Specific examples include:

    a. open combos;

    b. fresh carcasses or parts;

    c. not vacuum packaged, etc.; and,

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

B. Each time import inspection personnel have a laboratory sample TOI assigned to a lot that is eligible for an importer of record hold, and the product meets the criteria in Chapter VIII. I. A, 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.

C. If the IOR indicates the product will be returned to Canada and held, import inspection personnel are to receive a completed copy of the Canadian Food Inspection Agency's (CFIA) ANNEX (E) J, APPLICATION TO RETURN CANADIAN PRODUCTS EXPORTED TO THE USA, (Attachment 1) from import establishment management. Import inspection personnel are to review the Annex (E) J to ensure that the form contains CFIA Approval number, and that Part 2 is completed.

D. When I. C. above is met, import inspection personnel are to allow the product to return to Canada. When I.C. above is not met, import inspection personnel 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.

E. Import inspection personnel are 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, in the Public Health Information System (PHIS) when samples are collected, and the lot is not held on-site.

F. Import inspection personnel are to attach the Annex (E) J to the case file.

G. Import inspection personnel are to place the lot on hold in PHIS by:

1. accessing the PHIS Lot Manager page for the applicable lot;

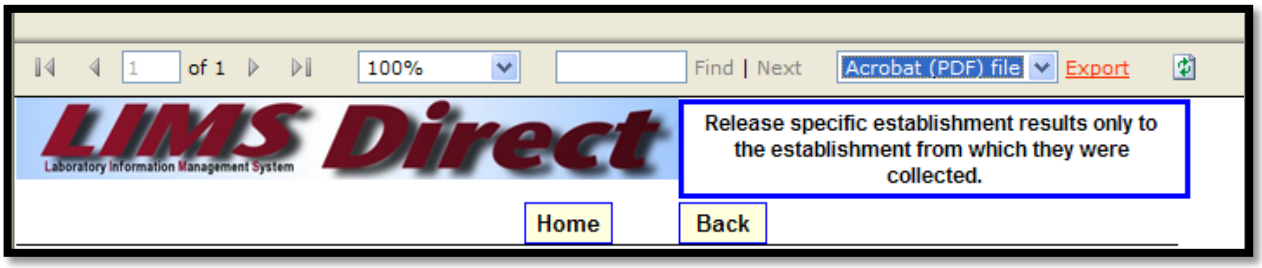
2. using the Lot Tracking feature, select "Place Lot on Hold;" and

3. select "Lab Sample/Lot Returned to Exporting Country."

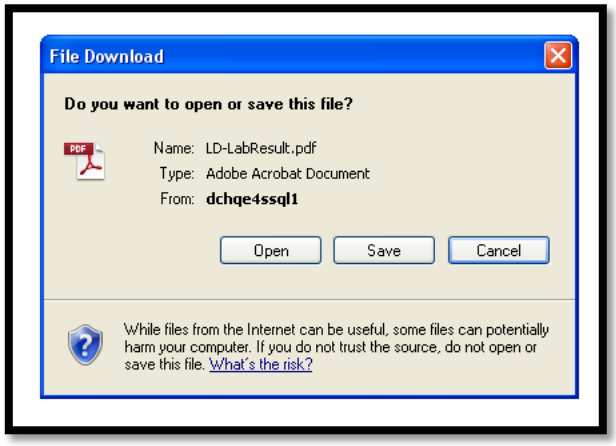
H. When laboratory sample results for the lot held in Canada are reported, import inspection personnel are to e-mail a copy of the results in LIMS-Direct to the e-mail address provided on Annex (E) J in Part 2. To accomplish this, when viewing the laboratory sample report, import inspection personnel are to save and e-mail a copy of the report from LIMS-Direct by:

1. Clicking the down arrow next to “Select a format”, and select “Acrobat (PDF) file”;

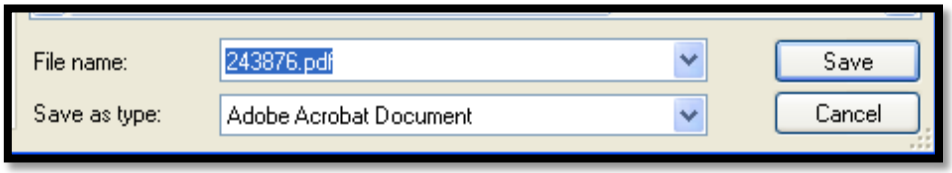
2. Clicking on “Export”.



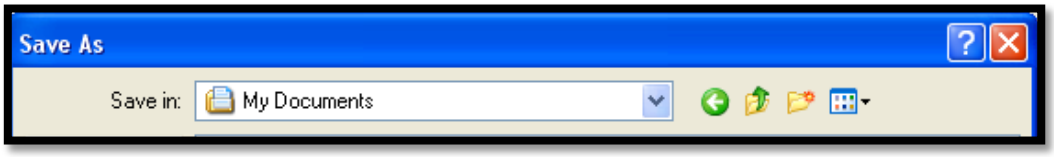
3. A pop-up will appear asking if you want to open or save the file. Choose “Save”.



4. Name the file with the inspection certificate number.



5. Select My Documents as the location to save the file to.



6. Opening a new Outlook e-mail message, complete as follows:

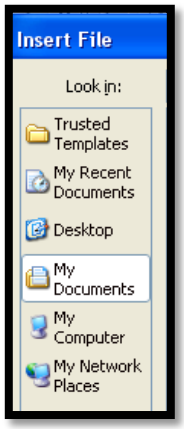
   a. To: type the CFIA e-mail address from Part 2 of Annex (E) J

   b. Cc: type your supervisor's e-mail address

   c. Subject: type "Laboratory Sample Result"

   d. Message: at the top of the new e-mail, click on Attach File

   e. Select My Documents from the left menu in the popup if not already selected



   f. Find the saved file name; highlight it by clicking on it; and click on Insert in the lower right hand corner. The file should appear in the e-mail message.

   g. Click "Send" in the upper left hand corner of the e-mail message.

   h. Go into your Sent Items folder, print a copy of the message and attach to the case file.

NOTE: If import inspection personnel receive a message that the e-mail is undeliverable or a return message that indicates the e-mail could not be delivered, they are to verify that the e-mail address they entered on the original e-mail was accurate, and correct and resend if needed. If the e-mail address was entered correctly, they are to then send the e-mail to importinspection@fsis.usda.gov, and type in the e-mail that the e-mail was undeliverable to CFIA.

I. When a laboratory sample for products returned to and held in Canada is discarded, import inspection personnel are to:

1. E-mail the discard notification to CFIA as in H above;

2. Access the Lab TOIs page for the lot in PHIS, choose “Submit Request to Not Perform” for the appropriate TOI, select “Discarded Sample” as the reason; and

3. Complete FSIS form 9770-3, *Discarded Sample Report and Findings,* and submit to their supervisor. The form may be found at ***Inside FSIS, for Employees*** from the FSIS homepage.

II. LOT DISPOSITION

A. For Unacceptable (e.g., Positive, Detected – Violative) laboratory results, import inspection personnel are to:

1. Notify the IOR through plant management that the lot is refused entry; and

2. Notify Office of Field Operations RMTAS headquarters through the supervisory chain and provide copy of the inspection certificate and PHIS import inspection application number.

3. Initiate a refused entry in PHIS from the Lot Manager page for the lot, select Add New Reason on the refused entry page, and complete a refused entry in the PHIS as follows:

    a. Reason for Refusal: Select “Failed Laboratory Analysis;”

    b. Defect Description: Select either “Failed Laboratory Analysis” or “Tested Positive for Pathogens”, as appropriate for the TOI;

    c. Click “Save;”

    d. In the “Enter remarks for applicant” box, type “This lot was returned to the exporting country prior to laboratory results being reported;”

    e. Click “Send To Applicant;”

    f. Click “Appeal Refuse Entry”, select “Accept FSIS's decision”, type “No appeal” in the “Reason for Appeal” box, and click “Submit;”

    g. Click “Add New Disposition” and select “Lab Sample/Lot Returned to Exporting Country;” and

    h. Place a check in “Disposition Complete” box, select the Disposition completed date,”, and click “Save.”

B. For Passed (e.g., Negative, Not Detected) laboratory sample results, import inspection personnel are to remove the hold status using Lot Tracking on the Lot Manager page for the lot. The lot is eligible for release.

III. OFO-HQ RESPONSIBILITIES

A. When RMTAS receives an e-mail from import inspection personnel that the e-mail to CFIA was not able to be delivered, RMTAS will contact CFIA for an updated e-mail address to send the e-mail to.

B. When RMTAS receives notification that a laboratory sample result on product returned to and held in Canada is failed, they are to follow their internal protocol for notifying foreign countries of a failed TOI. In addition, they are to communicate that this lot was returned to Canada to be held until acceptable laboratory results were received, and request information on the disposition of the failed lot.

CHAPTER IX - QUESTIONS

Refer questions regarding this directive through your supervisor or submit your questions through askFSIS. When submitting a question, use the "Submit a Question" tab, and enter the following information in the fields provided:

Subject Field:	Enter **Directive 9900.6**
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **Import** from the drop-down menu.
Category Field:	Select **Basic Import Answers** from the drop-down menu.
Policy Arena:	Select **International (Import/Export)** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question.**

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

Assistant Administrator
Office of Policy and Program Development

Attachment 1

ANNEX (E) J
CFIA APPROVAL # /APPROBATION ACIA _____

APPLICATION TO RETURN CANADIAN PRODUCTS EXPORTED TO THE USA/
DEMANDE POUR RETOURNER DES PRODUITS CANADIENS EXPORTÉS AUX ÉU

PART / PARTIE 1.	We hereby request permission to bring back into Canada the following product: Par la présente nous demandons permission de ramener au Canada la marchandise décrite ci-dessous :		
APPLICANT / DEMANDEUR	**NAME OF APPLICANT (Exporter as listed on the CFIA/ACIA 4546): NOM DU DEMANDEUR (Exportateur tel que sur CFIA/ACIA 4546) :**		
	Manufacturing establishment (# and name): Etablissement de fabrication (n° et nom) :		
	Product description: Description du produit :		Weight/Poids: # Cartons :
	No. of export certificate CFIA/ACIA 4546 / Numéro du certificat d'exportation CFIA/ACIA 4546 :		
	Location of product/emplacement du produit :		
	refused entry/entrée refusée ___ voluntary return/retour volontaire ____ Reasons for return : Raisons du retour :		
	We are attaching applicable official documents: CFIA-ACIA 4546, FSIS form 9840-3 or 9135-3 with FSIS statement.[1]/ Les documents officiels applicables sont ci-joints: CFIA-ACIA 4546, Formule FSIS 9840-3 ou 9135-3 avec attestation FSIS.[1]		
	Product to be returned to and inspected by CFIA at: / Le produit sera retourné et inspecté par l'ACIA à :		
	-est. # and name / n° et nom de l'établ. :		
	-address /adresse		
	-transport company / transporteur		
	- seal number on trailer / no de scellé		
	-projected date and time of arrival at inspection est. / date et heure prévues d'arrivée à l'établissement d'inspection		
	Firm's representative: / Représentant de la compagnie :		
	Name / Nom :	Signature :	Date :
	Tel/Tél.	Fax no/ email address/ courriel	
PART / PARTIE 2.	Permission granted by: Permission accordée par :		
	Date and email address / date et courriel :		
CFIA / ACIA	**Permission given to proceed to inspection destination / permission de se rendre au point d'inspection :**	Other conditions: Autres conditions :	

[1] Delete the mention(s) that are not applicable. / Biffer la(les) mention(s) inutiles.