FSIS Import Inspection Student Notebook and Course Materials

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Import Acronyms

ABI	Automated Broker Interface
ACE	Automated Commercial Environment
AMR	Advanced Meat Recovery
AMS	Automated Manifest System *or* Agricultural Marketing Service
APHIS	Animal & Plant Health Inspection Service
BMT	Beef manufacturing trimmings
BOL	Bill of lading
nBPW	Neutral buffered peptone water
CBP	Customs & Border Protection
CCA	Central Competent Authority (foreign government inspection agency)
CEN	Customs entry number
CFIA	Canadian Food Inspection Agency
COC	Condition of Container
EAN	Emergency Action Notification (CBP form)
EDA	Estimated date of arrival (outdated term, currently use “estimated date to present”)
F*Listeria*	Follow-up *Listeria* (sampling project)
FMD	Foot and mouth disease
FRTE	Follow-up Ready-to-Eat (sampling project, follow-up to positive IMVRTE)
FTP	Failure to Present
HTS	Harmonized Tariff Schedule
IAS	International Audit Staff
IES	International Equivalence Staff
IMVRTE	Sampling project for imported ready-to-eat products
IOR	Importer of Record
LIMS	Laboratory Information Management System
LOR	Level of Reinspection
LPDS	Labeling Program Delivery Staff (part of Office of Policy and Program Development)
LVP	Label Verification Pallet
OCP	Other Consumer Protection
OIC	Office of International Coordination
OIEA	Office of Investigation, Enforcement & Analysis
PDS	Policy Development Staff (part of Office of Policy and Program Development)
PE	Product Exam
PH	Public Health
PJT	Pink Juice Test
POA	Port of Arrival
POE	Port of Entry
POL	Port of Lading
POR	Place of Receipt
POU	Port of Unlading
RE	Refused Entry
RMTAS	Recall Management Technical Analysis Staff

RP	Rinderpest (livestock disease considered eradicated by World Organization of Animal Health)
SME	Subject Matter Expert
SP	Sampling plan
TOI	Type of Inspection
VS	Veterinary Services (branch of APHIS concerned with animal disease surveillance and eradication)

Importing Meat, Poultry, and Egg Products into the United States

The Acts (Federal Meat Inspection Act (FMIA) (21 U.S.C. 620), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 466), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1046) give FSIS the authority to regulate the importation of meat (including fish of the Order Siluriformes), poultry, and egg products into the United States. Imported egg products include liquid, frozen, or dried eggs products. With that authority granted by the Acts, FSIS is responsible for ensuring that imported meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged. All commercial shipments are subject to FSIS requirements.

On the **FSIS home page** (www.fsis.usda.gov) you will find numerous resources to help you in your daily routine as an Import Inspector, including the **Import Guidance** page, the **Import & Export Library**, the **International Equivalence** page, and information on **PHIS components**. Import Inspectors in the field are also granted access to an Import Operations SharePoint site (more on this later in the training) and have access to policy guidance via the **Recall Management & Technical Analysis Staff (RMTAS) email inbox** (importinspection@usda.gov) and **askFSIS**.

FSIS has reinspection authority over amenable species (cattle, swine, sheep, goats, Siluriformes fish, and poultry, as well as egg products) and products derived from them, though eligibility to import these products is determined on a country-by-country basis. There are certain exemptions from the requirement for FSIS reinspection of imported products, such as small quantities of product for personal consumption. These exemptions are discussed in the “Importation of Products for Other Than Commercial Purposes” section.

FSIS works cooperatively with other government agencies to ensure foreign products are imported in accordance with all Federal regulations:

Animal and Plant Health Inspection Service (APHIS)

- Responsible for regulating foreign animal disease/animal health issues
- Restricts some products from entering the U.S. because of animal disease conditions in the country of origin
- Contact APHIS Veterinary Services, National Center for Import and Export (www.aphis.usda.gov/vs/ncie/)

Food and Drug Administration (FDA)

- FDA has jurisdiction over seafood (except Siluriformes), denatured animal products not intended for human food, and meat and poultry products not amenable to FSIS
- Examples of *non*-amenable products include meat or poultry in small amounts (less than or equal to 3% raw, 2% cooked) and species under voluntary inspection

Customs and Border Protection (CBP)

- CBP has jurisdiction at all U.S. ports of entry
- Since reinspection does not occur at the port of entry, FSIS performs physical reinspection of shipments on behalf of CBP at approximately 160 official import establishments located throughout the continental United States, Hawaii, Puerto Rico, Guam, American Samoa, and the Northern Mariana Islands

U.S. Laws and Regulations related to Imports

- Federal Meat Inspection Act (FMIA)
- Poultry Products Inspection Act (PPIA)
- Egg Product Inspection Act (EPIA)
- Code of Federal Regulations - Title 9 Chapter III
  - Part 327 (meat)
  - Part 381 - Subpart T (poultry)
  - Part 590 - Subpart B (egg products)
  - Part 557 (Siluriformes)

FSIS Equivalence Process

Any country can apply for eligibility to export meat, poultry, Siluriformes, and/or egg products to the United States. There is an in-depth process that FSIS undertakes to determine whether foreign countries' food safety inspection systems are equivalent to our own. Note that these systems do not need to be *identical* to our domestic inspection system, but they must be found to be equally consistent and effective at producing a safe, wholesome product. This process is a prerequisite for trade.

Multiple FSIS Offices cooperate in the equivalence process:

- Office of Program and Policy Development (OPPD) - International Equivalence Staff (IES)
- Office of Investigation, Enforcement and Analysis (OIEA) - International Audit Staff (IAS)
- Office of International Coordination (OIC)
- Office of Field Operations (OFO) - Recall Management and Technical Analysis Staff (RMTAS)

There are three (3) main steps in the equivalence process:

Document Analysis - This part of the process is conducted by OPPD-IES. When a foreign country applies for eligibility to export to the United States, they must submit for review documentation that addresses six (6) equivalence components or risk areas:

- Government oversight;
- Statutory authority and food safety regulations;
- Sanitation;
- HACCP;
- Control of chemical residues; and microbiological testing programs.

On-site Audits - This part of the process is conducted by the OIEA-IAS. If the document review process shows the foreign country's system to be satisfactory, a technical team will visit the country for an on-site review to evaluate the above six risk areas, as well other aspects of the inspection system, including plant facilities and equipment, laboratories, training programs, and in-plant inspection operations.

Point-of-Entry Reinspection - This final step occurs when a foreign establishment exports product to the U.S. IPP at the import establishments perform types of inspection (TOIs) to determine whether foreign products meet regulatory requirements for entry into U.S. commerce. If the products do not meet the requirements, they are refused entry. At the headquarters level, evaluation of repeated instances of products not meeting FSIS import requirements (i.e., refused entry products) are factors that contribute to the determination whether a foreign establishment or foreign country maintains eligibility to export to the U.S. (**Note:** "Point-of-entry" refers to the official establishment where imported product undergoes reinspection; it is not to be confused with the "port of entry," the location where the products' certification paperwork enters the U.S. and is initially filed with CBP).

Statistics

As of July 2024, there are 36 countries eligible to export meat, poultry, and/or egg products to the United States. Fiscal year 2022 estimates are that the U.S. imported 4.84 billion pounds of meat products, 4.22 million pounds of poultry products, and 9.4 million pounds of egg products. Eligibility of countries and their establishments and the products they produce are determined on a case-by-case basis using the equivalence process described above.

Currently, only Canada, the Netherlands, and Lithuania are eligible to export egg products to the U.S. While *all* egg products from Canada are eligible, only certain products from the Netherlands and Lithuania are. Most of the egg products imported into this country are pasteurized—only Canada exports unpasteurized egg products to the U.S. These unpasteurized egg products may bypass FSIS official import establishments, provided they are transported directly to an official egg products establishment for further processing. Inspectors at these establishments will also perform import reinspection tasks to ensure U.S. regulations for imported products are met.

Terminology

Amenable - "Under the jurisdiction of" or "subject to reinspection, by regulation"

Denatured - to have a substance applied that make it clear that the product would not be confused with product that is fit for human consumption.

Manufacturer - The original supplier or seller of the goods.

Shipper/Exporter - Person or entity whose goods are being shipped.

Importer - Owner or purchaser of goods, or their legal agent. The party that is legally responsible for filing entry and paying duties. Often referred to as the **importer of record (IOR).**

Filer/Customs Brokers - Represent the interests of the importer by providing the following services:

(1) Prepare and file the necessary entries with Customs and Border Protection (CBP)
(2) Arrange for the payment of duties found due
(3) Take steps to effect the release of the goods in CBP custody

Consignee - Person or entity who is the true party in interest, receiving goods for the designated end user.

Applicant - This term is used throughout the training to refer generally to the interested party or parties involved in importing product (e.g., importer of record, filer, broker, etc.)

Port of Entry (POE) - Port where the application and certificate for an import shipment are initially filed with CBP. The port of entry is *usually* also the location where the product physically enters the U.S.; however, this might not always be the case.

Simplified Trade Process

- Manufacturer **>** Shipper/Exporter **>** Importer (U.S.)
- Product is shipped to Port of Entry (POE)
- Filer/Customs Broker files entry documents with Customs and Border Protection (CBP)
  1. CBP completes agriculture checks for restricted products (per APHIS requirements)
  2. Entry document data fed into PHIS via Automated Commercial Environment (ACE)
  3. CBP releases shipment for FSIS reinspection
  4. PHIS assigns reinspection activities (TOIs)
- If product passes FSIS reinspection, it is then released to the consignee

FSIS Import Reinspection - Process Overview

In FSIS, we use the term “reinspection” to describe the verification and certification of foreign product presented at official import establishments. This is because all such product has already been inspected at the foreign establishment prior to export to the U.S. As imported amenable product enters the United States, it must be moved to one of approximately 160 official import establishments (or “I-houses”) for FSIS reinspection. As we have already discussed, unpasteurized egg product from Canada may be routed directly to an FSIS-inspected official egg products establishment.

When the import establishment is ready to present a shipment (including one or more lots) for reinspection, they will provide the Import Inspector with the Customs Entry Number (CEN). The Inspector will then access the shipment in PHIS. IPP will select the **“Receive Lots”** action, which will simultaneously **“Draw Assignments.”** Assignments are the **Types of Inspection (TOIs)** PHIS automatically assigns to each lot, based on a number of factors, including FSIS’s routine schedule, level of reinspection (LOR), and other aspects of the foreign country/establishment profile. **IPP will perform the TOIs to verify that the importer has met U.S. requirements**. If all TOIs are marked as “Passed,” a lot can be designated as “Complete,” and the product may be released to be distributed in U.S. commerce. At that point, the imported product is treated as if it is domestic product. If one or more TOIs are marked as “Failed” in

PHIS, the Inspector will **refuse entry** of the product, **notify the applicant** using the "Send to Applicant" button, and the applicant will either correct the deficiency (rectify) or dispose of the product by an approved method.

Initially, Import Inspectors verify the following:

(1) Foreign country eligibility.
(2) Foreign establishment certification.
(3) Proper foreign health certification (when required).
(4) Import Inspection Application and Report, FSIS Form 9540-1 (either paper or electronic), which accompanies the shipment.

Note: Required statements and elements are defined in 9 CFR 327.4, 381.197, and 590.915. Only original foreign health certificates are acceptable. FSIS Form 9540-1 is typically from the broker. Import IPP may verify foreign country and establishment eligibility via the FSIS website or the Import Operations SharePoint Site.

Every shipment of foreign product that arrives at an I-house will be assigned, at a minimum, the Certification and Label Verification TOIs by PHIS (more on these tasks later in the training). During Certification and Label Verification, all shipments are reinspected for:

(1) Proper certification documentation (including accurate matching applications).
(2) Transportation damage (to the extent that product is exposed to the environment or otherwise spoiled).
(3) Proper labeling.
(4) General condition.
(5) Unit count.

An establishment receives and stages a shipment and informs IPP. IPP will then review the application and certificate to find the total declared count of the shipment. The inspector will then go out to the warehouse and will perform the unit counting based on that total number. Unit counting is done by multiplying the number of containers on a row by how many rows high multiplied by the number of pallets (including partial pallets when there is an uneven number).

Outside containers (shipping containers) of imported meat, poultry, and egg products that pass FSIS reinspection are stamped with the official import inspection legend* and can enter U.S. commerce for distribution and use as if they were produced domestically. Packages of Canadian product *do not* receive the mark of inspection. Outside containers of imported meat, poultry and egg products that fail to meet U.S. requirements are stamped "United States Refused Entry*" and, within 45 days, must be:

- Exported from the United States
- Destroyed, or
- Converted to animal food

*More on refused entry procedures in a later module.

Public Health Information System

Upon verification of proper documentation, import inspectors enter data into the Public Health Information System (PHIS), a centralized computer database that generates Types of Inspection (TOIs) and stores inspection results, links points of entry, captures results for each country, and tracks results from each establishment. As with domestic inspection, the value of PHIS is that it can serve a number of functions instantaneously and simultaneously across the United States and its territories:

- Confirms and acts on eligibility and status of foreign countries and establishments (focuses on performance and compliance history)
- Tracks public health and animal regulations
- Applies variable frequencies of reinspection for each type of inspection performed
- Provides the ability to increase/decrease reinspection of products by country or by establishment

Example: A shipment of beef manufacturing trimmings from Country A, Establishment 1 is imported and arrives at an I-house. Beef trimmings is part of a specific process category/product category/product group (PCPCPG) listed in the establishment's eligibility profile. The Import Inspector is tasked with submitting a sample for Shiga toxin-producing *Escherichia coli* (STEC), which comes back positive for *E. coli* O157:H7. The Inspector then goes into PHIS and enters a "Refused Entry" for that shipment, selecting "Failed Laboratory Analysis" as the reason. Once that entry is made, PHIS automatically adjusts the level of reinspection and sampling frequency for beef trim from Country A, Establishment 1 for a specified period of time. During this time, this product from Country A, Establishment 1 will be subject to a higher level of reinspection (intensified) regardless of which I-house it is presented to.

PHIS Inspection Tasks

PHIS assigns types of inspection (TOIs) for IPP to perform to determine whether shipments of foreign product meet U.S. regulatory requirements for entry and distribution in commerce. In addition to these TOIs, IPP are *also* assigned PHIS inspection tasks to perform. Just as with domestic inspection tasks, these tasks are part of the Establishment Profile and are scheduled routinely from the PHIS Task List/Task Calendar page. These tasks focus specifically on the **establishment's responsibilities** in the import process. When one or more regulatory requirements under these tasks are not met, IPP issue a noncompliance record (NR) addressed to the establishment:

- Sanitation
  (1) SPS Verification (Import)
  (2) Pre-Operational SSOP Review and Observation (Import)*
  (3) Pre-Operational SSOP Record Review (Import)*
  (4) Operational SSOP Review and Observation (Import)*
  (5) Operational SSOP Record Review (Import)*

  *In import establishments, the SSOPs typically apply only to the designated reinspection room where containers are opened for product examinations, laboratory sample

collection, and other activities where product is exposed or handled. As in domestic establishments, SPS verification applies to the entire facility and the official premises.

- Handling, Storage, and Segregation of Refused Entry Product
  (1) Import Refused Entry Verification

- Labeling
  (1) General Labeling (Import) - *addresses application of the marks of inspection*
  (2) General Labeling (Pre-Stamp) (Import)
  (3) Labeling (Scale Calibration) (Import)

- Food Defense/Emergency Response
  (1) Food Defense Task (I)

- Administrative
  (1) Update Establishment Profile (Import)
  (2) Meeting with Establishment Management (Import)

Each of these tasks will be discussed in more detail wherever relevant throughout the modules of this course.

Types of Inspection (TOIs)

As previously mentioned, PHIS assigns TOIs based on foreign country and foreign establishment eligibility, the type (PCPCPG) and volume of product imported, as well as the recent performance and compliance histories of the foreign countries and establishments. Every shipment (and every lot within each shipment) is assigned the Certification and Label Verification TOIs; however, other TOIs will be assigned based on either a routine frequency schedule or based on the factors mentioned above. Specifically, the TOIs are assigned when the Import Inspector performs the "Receive Lots/Draw Assignments" function in PHIS. When, during the process of reinspection, one or more regulatory requirements are not met, IPP are *not* to issue an NR to the establishment; rather, they will fail the TOI, refuse entry, and notify the applicant through PHIS, requiring the importer, broker, or other designee to take action on the product. More on this process later in the course.

We generally divide TOIs into four (4) broad categories:

(1) Certification TOI - Performed on all lots of imported product. This is where IPP verify the completeness and accuracy of applications and foreign inspection certificates, including accuracy of the count of shipping units in the lot.

(2) Label Verification TOI - Performed on all lots of imported product. IPP verify that labeling features on containers meet U.S. requirements for entry. It is also during Label Verification that IPP will perform a general condition examination of the staged product, looking for signs of transportation damage, spoilage, or tampering.

(3) Physical Examinations - There are several different physical examination TOIs that may be assigned to selected lots of product. These generally involve random selection of sample units from a staged lot; these units are then moved into a sanitary inspection room for further examination. Physical exam TOIs include:

- Product Examinations (PE1 - PE3)
- Condition of Container Examination (COCE)
- Net Weight Verification
- Pink Juice Test (PJT)

(4) Laboratory Examinations - FSIS performs sampling and laboratory analysis for imported products, including:

(a) Microbiological
- Shiga toxin-producing *E. coli* (STEC) (raw beef)
- *Listeria monocytogenes* (RTE products)
- *Salmonella* spp. (RTE products and raw Siluriformes)
- *Salmonella/Campylobacter* (raw poultry)

(b) Residues (drugs & pesticide)
(c) Species Identification
(d) Pathology (when requested)
(e) Food Chemistry (no longer routinely tested)

Levels of Reinspection

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

(1) Normal LOR

(a) Lots are randomly selected for reinspection/sampling according to an annual sampling plan pre-programmed into PHIS.
(b) The targeted number of lots is based on imported lots presented by country, species, and process category the previous year.
Lots are not held by FSIS at the establishment pending receipt of laboratory results. However, the importer may voluntarily hold the product. By voluntarily holding these lots, the importer eliminates the need to recall the product if the laboratory results are “unacceptable” (shipment rejected). Voluntary hold allows the importer to reexport refused entry product. Should the importer elect not to hold a shipment pending acceptable lab results, and subsequently stamp and ship the load, if the lab results were to fail, the importer would be unable to reexport the product. Product in commerce may be subjected to a recall and subsequent destruction.

(2) Increased LOR

(a) Sample frequency set above the normal level of reinspection/sampling

(b) This is an Agency management decision rather the result of a failed TOI. This is typically due to audits conducted in the foreign country by the International Equivalence Staff wherein deficiencies are found in the foreign establishment.

(3) Intensified LOR

(a) Level of reinspection for a TOI when a lot fails to meet U.S. requirements (failed TOI).
(b) Product is held by FSIS at the official import establishment pending test results.
(c) When a lot fails a physical examination TOI, the intensive of follow-up reinspection/sampling is based on whether the defect is a public health (PH) concern, a laboratory TOI failure, or other consumer protection (OCP) concern:
- For a PH defect or failure, IPP will sample a minimum of 15 subsequent lots or 15 times the weight sampled under normal LOR (whichever is achieved first)—all subsequent lots must pass the TOI at the intensified level before it can return to normal LOR.
- For a laboratory TOI failure, 15 subsequent lots of 15 times the weight sampled (whichever is achieved first) must pass for the TOI to return to normal LOR.
- When a TOI is failed for an OCP defect, 10 subsequent lots or 10 times the weight (whichever is achieved first) must pass at the intensified LOR before the TOI can return to normal LOR.

(d) Note that the intensified LOR is assigned specifically to the TOI that failed for the specific product, country, and establishment of origin.

Frequency of Product Examination

The frequency at which product is assigned additional examinations is set in PHIS at the FSIS headquarters level. The factors determining these frequencies include:

- Exporting country
- Process category/product category/product group (PCPCPG)
- Species
- Country performance

Process Category/Product Category/Product Group (PCPCPG)

Eligible products for import are entered into the foreign country profile by process category, product category, and product group (PCPCPG). You can find a link to a product classification table on the FSIS Website Import Guidance page.

Process Category - The broadest level of categorization. There are nine (9) process categories identified in 9 CFR 417.2(b) (HACCP processing categories). Of the nine (9) listed, Slaughter is considered an internal process that occurs in establishments where the animals or birds are slaughtered. *This category is not used for imported products*. An additional process category that is not contained in 9 CFR 417.2(b) is Egg Products.

Product Category - More specific than the Process Category, this links the product to the appropriate species (or predominant species in the product) so that the correct FSIS regulations can be applied.

Product Group - The most detail description of the imported product, this designation is used to ensure that PHIS assigns the appropriate types of inspection (TOIs) when the lot is received. When a laboratory sampling TOI fails, that specific sampling TOI for that specific product group will be sampled at an intensified level.

Import & Export Library

Requirements for importation of products can be found on the FSIS website here. FSIS has combined the requirements for certifying exports *to* foreign countries *and* the requirements for product imported *from* those countries on to single web pages, so be sure to scroll down to "Import Requirements" after selecting the country of origin. The library includes eligible establishments and PCPCPGs from each country, as well as information on APHIS animal disease restrictions and other documentation requirements. The information listed in the Import Library conforms to the information entered into each country's PHIS profile and is updated whenever there are changes in eligibility of foreign countries or establishments.

It is good practice for the Import Inspector to periodically review these pages, and if questions or concerns regarding eligibility or policy compliance arise, they should contact RMTAS for clarification. It is also good practice to always include the Frontline Supervisor in any such correspondence.

Import Applications
FSIS Directive 9900.4

Whenever a shipment is presented for reinspection, the establishment will provide the Import Inspector with the foreign inspection certificate and the corresponding application. The establishment should provide the Customs Entry Number (CEN) so that IPP can access the correct application and certificate in PHIS (this is because foreign countries may reuse certificate numbers, but the CEN is a unique identifier for each shipment that is generated by CBP when the application is first filed). Depending upon the country of origin and the particular applicant, these forms may be presented in paper form, or they may be presented as electronic data transmitted to PHIS. As you will see in this module, there are four (4) possible combinations of either paper or electronic applications and certificates.

Remember that applications and certificates are first filed with CBP at the port of entry. Applicants may choose to file their applications using the Partner Government Agency (PGA) Message Set. Though use of the PGA Message Set is entirely optional, it streamlines the filing process by automatically transmitting the *complete* application directly from CBP's Automated Commercial Environment (ACE) to FSIS's PHIS. Applicants who choose not to use the PGA Message Set continue to submit paper applications using the FSIS Form 9540-1, *Import Inspection Application*. In the latter case, the Import Inspector will need to manually enter some data elements from the form into PHIS to create the complete application.

Countries may file either paper (non-eCert) or electronic (eCert) inspection certificates. Currently, only Australia, New Zealand, the Netherlands, and Chile are eligible to use eCert, wherein the complete certificate data are transmitted directly into PHIS.

Prior Notice Requirements

The meat, poultry, and egg products import regulations require the applicant to apply for the reinspection of product that is to be offered for import in advance of the arrival of each consignment. Applicants must submit electronic or paper import inspection applications to FSIS in advance of the shipment's arrival but no later than when the entry is filed with U.S. Customs and Border Protection (CBP) (9 CFR 327.5(b), 381.198(b), 557.5(b) and 590.920(b)).

The purpose of the prior notice requirement is to help the Import Inspector readily identify shipments that fail to present by the declared estimated date (more on this in the Failure to Present module). Thus, it is important for IPP to check daily for shipments that are expected to arrive and, when necessary, to enter application data from FSIS Form 9540-1 into PHIS in a timely manner (to avoid the *appearance* of a delayed shipment).

4 Types of Applications

1. **CBP Entry in ACE <u>without</u> the PGA Message Set from a <u>Non-eCert Country</u>:** When applicants do not file entries with CBP in ACE that utilize the PGA Message Set, an application is created in PHIS by the data transfer from ACE based on the Harmonized Tariff Schedule (HTS) code used by the applicant. *This is an incomplete application, which must be accompanied by a paper FSIS Form 9540-1*. IPP are to

complete the rest of the application in PHIS manually using the data provided on the FSIS Form 9540-1 and the official paper inspection certificate. The application will show in PHIS as “Status Unsubmitted” and, if expanded, the Lot Status “CBP Received” or “No child records to display” (lots) will be shown.

2. **CBP Entry in ACE without the PGA Message Set from an eCert Country:** When applicants do not file entries with CBP in ACE that utilize the PGA Message Set, an application is created in PHIS by the data transfer from ACE based on the Harmonized Tariff Schedule (HTS) code used by the applicant. *This is an incomplete application, which must be accompanied by a paper FSIS Form 9540-1*. IPP are to complete the rest of the application in PHIS manually using the data provided on FSIS Form 9540-1. The application will show in PHIS as “Status Unsubmitted”, and, if expanded, the Lot Status “CBP Received” or “No child records to display” (lots) will be shown. FSIS does not require a paper inspection certificate from a participating eCert country as outlined in FSIS Directive 9900.1, *Imported Product Shipment Presentation*. Once IPP enter in PHIS the country of origin and the inspection certificate number provided on FSIS Form 9540-1, PHIS will populate the applicable eCert data in the import application.

3. **CBP Entry in ACE with the PGA Message Set from a Non-eCert Country:** When applicants file entries with CBP in ACE, including the PGA Message Set, an application is created in PHIS by the data transfer from ACE. The HTS code used by the applicant is irrelevant to file the entry in this instance. ACE is programmed to transfer FSIS data no matter which HTS code the applicant has identified. This is a complete application. The application status will show as “Submitted” and the lot status will show as “PGA Received.” If expanded, the individual lots in that shipment will be listed.

4. **CBP Entry in ACE with the PGA Message Set from an eCert Country:** When applicants file entries with CBP in ACE, including the PGA Message Set, an application is created in PHIS by the data transfer from ACE. The HTS code used by the applicant is irrelevant to file the entry in this instance. ACE is programmed to transfer FSIS data no matter which HTS code the applicant has identified. This is a complete application. When the applicant provides the official inspection certificate number from an eCert country, PHIS reaches out to the foreign government's server and transfers the certificate data into the import application. FSIS does not require a paper application (FSIS Form 9540-1), and IPP are not to request a paper application (FSIS Form 9540-1). FSIS does not require the inspection certificate when the country of origin is an eCert country. IPP are not to request paper copies of inspection certificates. The application will show in PHIS as “Status Submitted”, Lot Status “eCert Received” and, if expanded, the individual lots in that shipment will be listed.

To summarize, when the applicant uses the PGA Message Set, the application status will always show as “Submitted”, and the lot status will show as “PGA Received”, *unless* the shipment is from an eCert country, in which case the lot status will show as “eCert Received.” When the applicant *does not* use the PGA Message Set, the application status will always show

as “Unsubmitted”, and the Import Inspector will need to enter data manually from the paper form 9540-1.

Import Application Data Elements in PHIS

There are five (5) tabs for the import application in PHIS: Application, Importer/Applicant, Lots, Submit, and History. This section focuses on data elements within the Application, Importer/Applicant, and Lots tabs that are transferred from the entry with CBP in ACE, the PGA Message Set, and eCert. An asterisk (*) in the import application in PHIS denotes a required data field.

Application Tab:

(1) Country of Origin* - Comes from the entry with CBP in ACE. There may be instances when the country of origin in an electronic entry does not match the country listed on the paper certificate. In these instances, IPP are to correct the application in PHIS to match the country listed on the certificate.

(2) Inspection Certificate Number – Comes from the PGA Message Set. If the applicant enters this number incorrectly, IPP will not be able to search the corresponding application in PHIS.

(3) Exporting Establishment – Comes from the PGA Message Set or from eCert.

(4) Point of Entry* - Comes from the entry with CBP in ACE.

(5) Port of Unlading – Comes from the entry with CBP in ACE.

(6) Reference Number – This element is obsolete.

(7) Type of Establishment* - Selected by PHIS based on the official establishment provided by the PGA Message Set.

(8) Official Establishment* - Comes from the PGA Message Set.

(9) Estimated Date of Arrival* - Comes from the PGA Message Set.

(10) Bill of Lading Number – Comes from the entry with CBP in ACE. IPP are to accept the data in the application, i.e., there should be no need to change it.

Importer/Applicant Tab:

(1) 9 CFR 327.4, 381.197, 590.915, and 557.4 require the name and address of the importer or consignee and the name and address of the exporter or consignor to be certified by the foreign government’s Central Competent Authority (CCA) on the inspection certificate. These entities may change due to business decisions during transit. Except for the first names, last names, telephone numbers, fax numbers, and email addresses, the data elements in this tab are transferred from the electronic entry with CBP in ACE.

IPP are to accept the prepopulated data elements in this tab even if the information differs from that on the inspection certificate.

Lots Tab:

(1) Lot Number - Generated automatically by PHIS.

(2) Shipping Mark* - Comes from the PGA Message Set.

(3) Customs Entry Number (CEN)* - Comes from the entry with CBP in ACE.

(4) Production Dates - Comes from the PGA Message Set.

(5) Lot Net Weight* - Comes from the PGA Message Set.

(6) Shipping Container Package Type* - Comes from the PGA Message Set or from eCert.

(7) Shipping Container Units* - Comes from the PGA Message Set or from eCert.

(8) Immediate Container Package Type - Comes from the PGA Message Set or from eCert.

(9) Immediate Container Number Per Unit - Comes from the PGA Message Set or from eCert.

(10) Seal Number - Comes from the PGA Message Set (required for certain egg products).

(11) Process Country* - Comes from the PGA Message Set.

(12) Process Establishment* - Comes from the PGA Message Set.

(13) Source Countries and Establishments - Comes from the PGA Message Set.

(14) Harmonized Tariff Code - Comes from the entry with CBP in ACE. IPP are to accept the prepopulated data.

(15) Category* - Comes from the PGA Message Set. Note that PHIS will not map multiple species in a product; IPP will need to enter the additional information manually.

(16) Product Category/Product Group* - Comes from the PGA Message Set.

(17) Species* - Comes from the PGA Message Set.

(18) Supplemental Product Code - Comes from the PGA Message Set.

(19) Product Description - Comes from the PGA Message Set.

Correcting Missing or Inaccurate Data

Part of the initial certification process for any shipment that is presented is verification of the accuracy and completeness of both the application and the accompanying certificate. An important rule of thumb for the Import Inspector is that the data presented on the certificate takes precedence over the data on the application. That means that occasionally, you will have to edit the application data elements in PHIS to match what is declared on the certificate. In any of these situations, you have the flexibility to determine the best way to acquire the missing information and complete the Certification and Label Verification TOIs.

(1) Paper Applications (FSIS Form 9540-1)
- Review the application for the required data elements listed above.
- If data elements are missing or inaccurate, refer to the certificate.
- Enter the data from the certificate into the application in PHIS.
- Take no further action on the FSIS Form 9540-1.

(2) PGA Message Set Applications (electronic data)
- Review the application in PHIS for the required data elements listed above.
- If data elements are missing or inaccurate, refer to the certificate.
- Enter the data from the certificate into the application in PHIS.
- This applies to both paper (non-eCert) and electronic certificates (eCert).

(3) Missing data not found
- If the application is missing data, and IPP find no results after searching for the application in PHIS, request the applicant submit a correction in ACE.
- Note that applicants can only make changes to applications within 10 days of release by CBP—after 10 days, you will have to make the corrections.
- If after requesting a change, there is still missing data in PHIS, email importinspection@usda.gov with “PGA Message Set” in the subject line, providing as much detail as possible, and await further instructions.
- As always, cc the FLS with these requests.

Event Messaging

Just as PHIS supports incoming data from ACE, your actions in PHIS initiate event messaging back to ACE. Applicants in turn receive information from ACE through a system called the Automated Broker Interface (ABI). This is the method by which the parties involved in importing product receive notification of failed TOIs, refused entries, laboratory samples collected, failures to present, and release of product meeting U.S. requirements.

Shipment Presentation and Certification
FSIS Directive 9900.1

In 2014, FSIS issued a final rule that made some changes to import certificate regulations. The rule streamlined foreign inspection certificate requirements, including removing overly prescriptive formatting and narrative requirements and providing for an electronic alternative to paper certificates (eCert). In this module, we will review how the Import Inspector performs the Certification TOI for every lot of product presented for reinspection, how to verify proper presentation of shipments, how TOIs are assigned and prioritized, and how to verify the application of the official import mark of inspection.

The **Certification TOI** and **Label Verification TOI** are assigned by PHIS to *every* lot of product presented for import into the United States.

There is no standard format for paper foreign inspection certificates, nor is there a standard format for electronic certificates (each of the four eCert countries—Australia, New Zealand, the Netherlands, and Chile—has its own portal for entering certificate data). Your concern as an Import Inspector is to verify that all required data in PHIS is complete and accurate. FSIS Directive 9900.1 lists the contents required on *all* foreign inspection certificates, as well as the contents specifically required for paper certificates.

Contents on All Certificates

- Foreign country of export and producing foreign establishment number for each lot
- Species of meat or poultry
- Source country and foreign establishment number if source materials originated from a country other than the country of export
- Product description (PCPCPG)
- Name and address of importer or consignee
- Name and address of exporter or consignor
- Number of units (pieces or containers) and shipping or identification mark on the units
- Net weight of each lot
- Any additional information necessary to determine eligibility (as specified by the FSIS Administrator)
- Production dates—required when the producing establishment has had a past period of ineligibility (de-listment); PHIS will alert you when these must be entered
- Slaughter dates—FSIS issues notices to IPP when this is required

Specific Requirements for Contents on Paper Certificates

- Must be complete, accurate, and legible
- Exporting country's official seal, mark, or legend
- Date the certificate was issued
- Name, title, and signature of foreign official authorized to issue inspection certificates
- No items may have been erased or altered
- Identifies which product originated from which foreign establishment (when product from multiple establishments is listed on a single certificate)

- Must be in English (may also include the native or official language of the exporting country)

Errors or Omissions on Paper Certificates

When the Import Inspector discovers incorrect or missing data while reviewing a paper certificate, they will take the following steps in PHIS:

- Fail the Certification TOI, including the most applicable reason from the dropdown menu (this will activate the "Refuse Entry" option for the lot)
- Notify the applicant using the "Send to Applicant" button
- Receive a response from the applicant—they may choose to rectify the error (within 45 days) or they may allow the product to remain as Refused Entry

*Refused Entry procedures will be discussed in more detail later in the course.

Errors or Omissions on Electronic Certificates (eCert)

When the Import Inspector is concern about possible errors or omissions while reviewing an electronic certificate, they should request clarification through their chain of command (FLS). RMTAS will work to obtain the requested information from the foreign government.

Replacement Certificates

Under certain circumstances, when the Certification TOI fails, FSIS will accept replacement certificates (either paper or electronic) from the applicant.

Paper Replacement Certificates:

- IPP may accept either original paper replacement certificates or electronic files (e.g., PDF forms) emailed directly from the foreign government's central competent authority (CCA)…in other words, it must be received directly from a representative of the foreign government's inspection service via official government-to-government email.
- IPP are to maintain a copy of the voided original certificate on file.
- Foreign governments (inspection agencies or embassies) may request that original voided certificates be returned but must make such requests on official government letterhead.

Electronic Replacement Certificates:

- If certification data is incorrect, fail the Certification TOI.
- If applicant wants to replace the certificate, IPP will follow country-specific procedures:
  - Australia, New Zealand - Email RMTAS to request an extract from the foreign country's eCert portal
  - Chile - Access the Chile eCert Viewer (https://visualizadorecze.sag.gob.cl/) and enter the replacement certificate number
  - Netherlands - Though eligible, not currently using electronic certificates

- Print replacement, attach it to the case file, and stamp unacceptable certificate as "USDA VOID."
- Foreign governments (inspection agencies or embassies) may request that original voided certificates be returned but must make such requests on official government letterhead.

Additional Certifications

FSIS Directive 9900.1 describes some additional certifications specific to certain products:

(1) *Pasteurized Egg Products* - IPP are to verify that bulk packed shipments (e.g., tankers, totes) have foreign government documentation attesting that the product has been laboratory tested and found negative for *Salmonella*.

(2) *Poultry Grading Certificates* - The USDA Agricultural Marketing Service (AMS) recognizes Canadian Food Inspection Agency (CFIA) grade designations, so IPP are to accept them as accurate, so long as a grading certificate is provided. If no certificate is provided, IPP are to reject the shipment until either:

(a) A grade certificate is provided, or
(b) The applicant agrees to have the grade reference on the labeling obliterated or removed.

(3) *Production Dates* - IPP will be prompted to enter production dates for product from any country or establishment with a history of being ineligible (prior period of de-listment). If production dates are required but not provided by way of signed supplemental documentation (including the certificate number and production dates for each lot), IPP are to fail the Certification TOI.

(4) *BSE Certification* - APHIS regulations require that the importer provide documentation certifying that any beef product is free of specified risk materials (SRMs).

Unit Count

Verifying an accurate count of units as presented on the certificate is an essential part of the Certification TOI. IPP should physically verify the count every time a shipment is staged for reinspection—you should not rely on a count given by establishment personnel. When counting units, IPP should of course verify that the shipping marks on all units match what is declared on the certificate. FSIS *does* allow for minor deviations from the declared count, as explained in FSIS Directive 9900.1.

Count Less Than Certified (Underage):

- If the underage is less than 10% of the total declared count, accept the lot.
    - For example, if the certificate states that there are 500 cartons in Lot 1, a 10% underage would mean there are 450 or less cartons presented, so if 483 cartons are presented, Lot 1 is acceptable.

500 x 10% = 50 → 500 – 50 = 450 → 451 or more is acceptable

- If the underage is 10% or more of the total declared count, first request an explanation from the establishment.
    - If the missing units are on another conveyance, place the shipment on hold until they arrive.
    - If there is no explanation, inform the FLS, place the shipment on hold, fail the Certification TOI and refuse entry of the product.
    - Note that FSIS *does not* permit the applicant to simply issue a replacement certificate for ≥10% underage!

Count Greater Than Certified (Overage):

- FSIS allows for a limited number of additional units over the declared count on the certificate—this is to account for human error.
- Allowed overages (per lot) are presented in a table in FSIS Directive 9900.1.

Lot Size (Shipping Units)	Overage Allowed (Shipping Units)
50 and under	0
51 – 100	1
101 – 200	2
201 – 400	4
401 – 600	6
601 – 1,200	12
1,201 – 2,000	20
2,001 – 5,000	50
5,001 – 10,000	100
10,001 and over	150

- If the overage is within acceptable limits, accept the lot.
- If the overage exceeds the prescribed limit, fail the Certification TOI and refuse entry of the product.
- If the number of units in a lot deviates from what is recorded on the application in PHIS, make the necessary correction in PHIS.

Receive Lots and Draw Assignments

Official import establishment personnel should notify IPP when an import shipment has arrived and has been staged for reinspection. The Import Inspector should first access the application in PHIS, using the Customs Entry Number provided by the establishment, access the Lot Manager page, and select the “Receive Lots” action from the dropdown menu. This will simultaneously “Draw Assignments” for each lot in the shipment, thus assigning all applicable TOIs the Inspector will perform.

Presentation and Staging

FSIS regulations (9 CFR 327.6, 381.199, and 590.925) specify requirements for the presentation of shipments of imported product. Each lot must be presented in a manner that:

(1) Ensures safety of personnel;
(2) Provides adequate space to select samples and perform verification activities; and
(3) Ensures that each shipping unit has an equal chance of being randomly selected as a sample.

There is a unique exception for presentation of shipments of Canadian product. If lots of Canadian product are assigned *only* the Certification and Label Verification TOIs, those TOIs can be performed at the rear of the shipping conveyance backed up to a loading dock. In this situation, IPP will verify one shipping unit from each lot. However, any lots of product from Canada that are assigned *additional* TOIs (such as physical exams, laboratory sampling, etc.) must be staged as described above. Additionally, if IPP have concerns about any findings during performance of the Certification or Label Verification TOIs, they may direct the establishment to offload the product and stage it for more detailed reinspection.

Presentation of Palletized, Consumer-Ready Product

Some import shipments consist of individual consumer packaged product (immediate containers—usually cans, cartons, or tray packs) stacked on pallets and wrapped with a placard (often a large piece of corrugated cardboard) that bears the shipping mark and other shipping container label requirements. Therefore, the pallet serves as the shipping container. IPP verify that each pallet contains only one type of product and size of container (an exception to this rule is that shipments of Canadian product may be presented with different-sized containers of the *same* product). In any case, the placard must bear a designated space for application of mark of inspection.

Note: Canadian product, even if it passes all assigned TOIs, does not receive the "U.S. Inspected & Passed" mark. More on this in the Label Verification module.

Inspection certificates accompanying palletized product must identify all the retail package production codes (such as date codes imprinted on the cans or tray packs).

When palletized product fails a TOI and is refused entry, *every* immediate container contained therein must be stamped as "United States Refused Entry" (including Canadian product).

Bar Codes in lieu of Shipping Marks

As part of a pilot program, a limited number of Australian establishments are authorized to mark the placards of palletized product with bar codes in lieu of traditional shipping marks and ship such product to a limited number of participating U.S. official import establishments. This procedure will not be discussed in detail in the training, but the procedures and regulatory requirements are outlined in FSIS Directive 9910.1.

Note that *this* use of bar codes is different from the approved use of bar codes as a replacement for partially missing or illegible shipping marks (currently limited to Australia, New Zealand, and Namibia). Shipping marks will be discussed further in the Label Verification module.

Performing and Prioritizing TOIs

As previously mentioned, IPP will perform the Certification and Label Verification TOIs on *every* lot of product presented for import reinspection. Some lots will be assigned *additional* TOIs by PHIS. To ensure that the flow of product is not delayed, IPP are to prioritize those lots that are assigned additional TOIs before reinspecting those assigned only the Certification and Label Verification TOIs. All assigned TOIs must be complete before you can select "Release Acceptable Units", at which time the product may be marked and moved into commerce.

During marking, you will verify that all acceptable units (immediate containers, shipping containers, or placards) are stamped as "U.S. Inspected & Passed"). You will document this verification daily in PHIS under the General Labeling (Import) task.

When a lot fails a TOI, IPP will document the reason for failure in PHIS. This will initiate a Refused Entry. IPP will then be able to notify the applicant of the refused entry and the justification, allowing the applicant to take action on the product. Note that refused entry may apply to an entire lot, or to just a portion of the lot found to be unacceptable (partial refused entry). Refused Entry procedures will be discussed in detail in a later module.

<u>Unscheduled TOIs</u>

Some situations warrant the additional of an unscheduled TOI to a lot's assignments. Import Inspectors have the authority and latitude to recognize these situations and add the unscheduled TOIs without seeking permission; however, IPP are encouraged to consult with their Frontline Supervisors and reference the "Products and TOIs" link on the Import Operations SharePoint site (more on this later) to determine whether the TOI is applicable for the product.

We will provide several examples throughout the course; however, here is one:

> **Example:** An Import Inspector is performing an assigned Product Exam 2 (PE2) TOI on a lot of raw chicken breasts and discovers what appears to be fecal material in one of the boxes. The Inspector knows that fecal material is classified as a public health (PH) defect in FSIS Directive 9900.2 under the PE2 table. He/she also knows that this shipment included three (3) *additional* lots of the same product (raw chicken breasts) from the same producer. Therefore, the Inspector schedules a PE2 TOI for the three additional lots and details the reason for doing so when prompted by PHIS.

Important Note: In a situation where an unscheduled TOI is warranted, IPP are instructed to add the unscheduled TOI *rather than* selecting "Draw Assignments" again in PHIS. The latter method will make PHIS incorrectly think the TOI is being performed under Intensified LOR.

TOI Not Performed

Occasionally, the situation may warrant *not* performing a certain assigned TOI ("Request Not Performed" in PHIS). As with unscheduled TOIs, IPP are granted discretion when determining whether to mark a TOI as "Not Performed" (and as with unscheduled TOIs, IPP should consult with the FLS and the "Products and TOIs" link on the Import Operations SharePoint site when there are questions). Typically, this is done when an assigned TOI is determined to be "Not Applicable" to the product being reinspected. Otherwise, IPP are expected to manage their time and prioritize tasks to ensure all reinspection assignments are completed on any given day.

Completing TOIs

When Certification and all other assigned TOIs are completed, and the lot has met U.S. requirements for import, IPP will select "Release Acceptable Units" from the Lot Manager page in PHIS and notify the import establishment that the product may be moved into commerce.

Failure to Present
FSIS Directive 9900.1

Failure to Present (FTP) occurs when amenable products produced by a foreign establishment and properly certified by the foreign government are delivered into commerce, further processed, placed into storage, or otherwise distributed to the consumer *without* the benefit of FSIS import reinspection as required.

For products to be considered a failure to present it must meet the following standards:

1. Amenable
2. Produced by eligible foreign establishment
3. Certified by eligible foreign country
4. Eligible product
5. Moved into commerce

Meat or Poultry FTP - Any eligible shipment, not designated as a sample shipment, of meat or poultry products entering the U.S. that fails to stop for reinspection at an official FSIS import establishment.

- If imported product has not been presented for reinspection at an official import inspection establishment by the **estimated date to present** declared, and is off-loaded from the conveyance, it is declared as an FTP product. (You may hear the term "estimated date of arrival" or "EDA" used; this is an outdated term and is no longer considered correct).

Egg Products FTP - Any shipment of egg products that is not presented at either an official egg product establishment or import establishment and enters U.S. commerce.

FTP Warning - The expectation is that the shipment status update will be received within the workday, provided the notification is sent early enough in the day. Therefore, it is important that you monitor the expected arrivals menu in PHIS daily, so that if an FTP occurs, you have ample time to notify the applicant and receive a same-day response. The response from the applicant may come to the IPP via:

- Official import inspection establishment management
- Monitoring incoming shipments using PHIS: When a shipment has not arrived by the estimated date to present, access the Lot Tracking menu through the Lot Manager screen and select "Send FTP Warning". PHIS will send an email notification to the applicant requesting a status update on the shipment.

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Possible Responses

(1) Product is at the designated location (i.e., at the establishment)

- Verify the shipment's presence.

- Access the Lot Tracking menu through the Lot Manager screen and change the status to “On Premises.”
- If the location cannot be confirmed, IPP should notify the FLS.

(2) Delayed Arrival

- Ask for a revised estimated date to present
- Amend the estimated date to present on the application as follows:
    (a) Access the shipment using PHIS,
    (b) Access the application,
    (c) Revise the estimated date to present,
    (d) Click Save and Continue,
    (e) Select the Submit tab, and
    (f) Select Submit.

(3) Cancelled Shipment

- The broker/applicant should notify the import inspector.
- Document the reason for cancellation in PHIS and cancel the shipment.

(4) No Response, or Location cannot be confirmed:

- Search PHIS for the inspection certificate number. If certificate number is listed more than once,

    (a) Confirm it is the same product inspected elsewhere and do not issue an FTP Warning.
    (b) Request a cancellation notice from the applicant.
    (c) Delete the application and document the reason upon receipt of the cancellation notice.
    (d) If certificate number is listed once or if applicant responds that the load bypassed inspection, notify the FLS.

FTP Notifications

The District Office will notify the OIEA-Regional Director (RD) and RMTAS of the FTP. OIEA follows applicable directives. The FLS and RMTAS will be updated, as necessary. RMTAS reviews incoming data and verifies OIEA-RD was notified of the FTP. You will initiate the FTP process as follows:

- Email FLS and RMTAS
- Subject line must include FTP, date, import establishment number
- Attach PDF copy of application and inspection certificate to email
- Attach a copy of the email to the case file
- Provide a hard copy of the email to import establishment

Label Verification
FSIS Directive 9900.5

Exports to the U.S. must meet the labeling standards contained in the FSIS regulations and policies. Foreign establishments are responsible for complete and accurate labeling. Foreign inspection systems will verify that exporters maintain complete labeling records, that their practices result in compliance with FSIS regulations, and that their policies and claims (e.g., free range, grass fed, etc.) are truthful and accurate.

Just like domestic establishments, foreign establishments can use generically approved labels in accordance with 9 CFR 317.5 and 9 CFR 381.133 (e.g., single ingredient products, products that meet a standard of identity, products with no special claims, etc.). Labels with special claims about quality, nutrient content, health, negative geographic origin, and animal production must be submitted to FSIS's Labeling Program Delivery Staff (LPDS) for sketch approval.

On every lot, inspection personnel will verify the labeling of:

- Shipping containers - Any outside container box containing wholly or partly enclosing any product packed in one or more immediate containers (9 CFR 301.2)
- Immediate containers - Fully labeled consumer-ready containers (9 CFR 301.2)
- Protective coverings - Coverings that solely protect product against soiling or excessive drying during transportation and storage
- Primal parts - For example, chucks, rounds, loins, shoulders, briskets
- Carcasses

Of course, not all products will be packaged the same way and will not include all the above. In this section, we will review the label feature requirements for each of the above.

Label Verification of Staged Lots

Select the number of sample units (pallets, totes, carcasses) from the presented lots using Table A from FSIS Directive 9900.5 below. You will generate random numbers to determine which units in the presented lots are to be identified as the sample units and marked with the "USDA Official Import Sample" stamp. A random number generator can be accessed from the FSIS Applications >> Tools menu on every government computer desktop.

Once the sample units are identified—for example, a specified number of pallets—you will verify the labeling of *every container* on that pallet. In some cases, you may need to have cartons moved into the inspection room to be opened so that you can inspect protective coverings or immediate containers contained therein.

Based on the number of units in the presented lot, examine the designated sample units (e.g., 15 pallets in presented lot = 2 pallets) after the lot is staged for general condition examination.

TABLE A Labeling Verification Procedures (LVP) Sample Size	
Number of Units in Presented Lot	**Number of Sample Units (Pallets/Totes/Carcasses)**
1-10	1
11-20	2
21-30	3
31-40	4
41-50	5
51 or more	5 plus 1 additional sample unit for every increase in lot size by 10 units or parts thereof.

- If you had 18 pallets in the lot how many would you select for label verification? 2
- If you had 120 pallets, how many would you select? 5 + 7 (one for every 10 pallets above the initial five) = 12
- Generate random numbers to designate which pallets are to be examined for label verification.

Shipments should be staged for reinspection and organized by lot. It is during Label Verification that you will perform the general condition examination, observing primarily for transportation damage (product exposed to the environment), leakage, and off-condition product/spoilage.

Of course, the product should be staged in a manner that is safe for personnel, allows the Inspector to view the pallets from all sides, and allows the Inspector an equal chance of randomly selecting individual units for sampling (i.e., for additional TOIs).

Note: Even though there are regulatory requirements for staging, you are *not* to issue a noncompliance record (NR) for improper staging. Rather, you will simply decline to reinspect the shipment until it is properly presented.

Special Exceptions for Canadian Product

Shipments of product from Canada that are assigned *only* the Certification and Label Verification TOIs do not need to be off-loaded and staged like other product. For these shipments, IPP may perform these TOIs on one representative unit (shipping container) from each lot at the back of the shipping conveyance. You should still be able to get an accurate estimate of the unit count and general condition of the shipment on the conveyance. If you have concerns about the accuracy of the count or the condition of the product, if you must perform other TOIs, or if either the Certification or Label Verification TOIs are assigned at either the increased or intensified level of reinspection, the import establishment will need to off-load and stage the product.

Labeling Requirements

Shipping Containers

Labels on shipping containers may be mechanically printed, stenciled, stamped directly on to the containers, or printed on a self-destructive (cannot be removed and placed on another carton) sticker applied to the container. Handwriting is not acceptable, with two exceptions:

- Adding the value of random net weights in open net weight statements
- Marking checks in pre-printed check-off boxes

Labels must be in permanent ink and in English, except for products intended solely for distribution in Puerto Rico, which may be in Spanish.

Following are the specific required labeling features for shipping containers:

(1) Country of origin, preceded by “Product of ____”

- If the name of the country appears within the foreign country’s mark of inspection, or if the shipping container contains fully labeled immediate containers, the “Product of ___” statement need not appear on the shipping container.

(2) Establishment number assigned by the foreign country inspection system

(3) Name of product

(4) Name and address of the foreign producing establishment, manufacturer, distributor, or importer (unless this appears on fully labeled immediate containers)

(5) Complete and legible shipping mark or unique identifier;

- The shipping mark links the product to the foreign inspection certificate and/or other supporting documents
- FSIS regulations do not prohibit duplicate shipping marks

(6) Special handling statements (e.g., “Keep Frozen”, “Keep Refrigerated”, "Perishable, Keep Under Refrigeration")

- Required when special handling is required to maintain wholesomeness of the product

(7) Sufficient space on the main display panel for the USDA marks of inspection
- Not required for product from Canada
- Space must be sufficient to ensure the marks of inspection are legible and do not obscure other labeling features

(8) Weight expressed in terms of the avoirdupois system (pounds, ounces)

Immediate Containers

Immediate containers are boxes, bags, pouches, wraps, cans, or jars that are in direct contact with the product and wholly or partially enclose the product.

Following are the specific required labeling features for immediate containers:

(1) Name of product or descriptive designation

(2) Ingredient statement, if the product is fabricated from two or more ingredients

(3) Foreign establishment number

- For cans, 9 CFR 327.14(b)(2) specifies that the establishment number must be embossed or lithographed on the can and not be obscured by other label features

(4) Special handling statements (if applicable)

(5) Net quantity/weight of contents

(6) Name and address of the manufacturer, distributor, or importer

(7) Name of the country of origin, preceded by "Product of ____"

(8) Safe handling instructions for not-ready-to-eat (NRTE) meat and poultry products that have not undergone further processing that would render them ready-to-eat (RTE) and are destined for the consuming public

Protective Coverings

Products may be packaged or wrapped in protective coverings that do not bear any mandatory labeling features, provided the shipping container bears all required features of an immediate container. An example of this is when products like primal cuts, trimmings, patties, and poultry parts are packed in boxes with plastic liners, wherein the liner is the protective covering, and the box serves as the immediate container. Protective coverings are referenced in 9 CFR 317.1(a).

Following are the specific regulatory requirements for protective coverings:

(1) When protective coverings without required labeling features are used, the shipping container must bear all required features for immediate containers.

(2) Shipping containers should bear a statement of limited distribution (e.g., "Packaged for Institutional Use").

(3) Unlabeled product in protective coverings may not be removed from the shipping containers for further distribution nor displayed or offered for sale.

(4) When unprocessed cuts are packaged or wrapped in protective coverings, there are no required labeling features on those cuts; however, *they* may bear the foreign country mark of inspection, including the establishment number and name of the country of origin.

(5) Other optional features on protective coverings include company brand names, trademarks, and code numbers.

As a general rule, other than the optional foreign mark of inspection mentioned in (4) and (5) above, protective coverings should not bear any required labeling features. If such protective coverings *do* bear other labeling features, they must bear *all* required labeling features of an immediate container in order to be compliant.

Marked Carcasses and Primal Parts

When shipping containers hold carcasses or primal parts, IPP are to verify that the requirements of 9 CFR 316.9(b), 327.14(a), and 327.14(b)(1) are met by observing the surfaces of the product. The phrase "Product of ____" is not required on a carcass or primal (or sub-primal) cut that prominently displays the name of the foreign country within the marking (legend) itself. Products required to bear an inspection legend include: red meat carcasses, each primal part of a red meat carcass, beef livers, beef tongues, and beef hearts.

Unmarked Carcasses and Primal Parts

If the official mark is not present on the carcass or parts but is on the shipping container, the unmarked carcass and parts can move to an official establishment for further processing. If the product was *not* intended to go to an official establishment, then the product would be refused entry. As part of the disposition, the importer *can* change the destination to an official establishment. If the shipping container *nor* the carcass or parts bear the inspection legend, the products cannot go into commerce, and IPP would fail the Label Verification TOI.

Unmarked carcasses and primal parts may be transported in cargo containers or truck trailers and may be transported to an official inspected establishment for further processing, provided the containers are sealed to prevent tampering or substitution of product (the conveyance would need to be properly resealed after reinspection). You should fail the Label Verification TOI and refuse entry on shipments of unmarked carcasses and primal parts that are not tamper-resistant sealed or for which destination information is not provided. If there is evidence that a seal has been tampered with, or if there is no seal on the shipping container or conveyance, retain the product and notify the FLS.

Qualifiers, Claims, Grades, or Declarations

As with domestic products, the majority of labels may be generically approved and do not need sketch approval by the Labeling Program Delivery Staff (LPDS). It is the importer's responsibility to ensure that they meet U.S. requirements for supporting qualifiers, claims, grades, or declarations on their products prior to filing the application and certificate.

Labels with specific claims, such as “grass fed” or “free range,” or with specific certifications such as “Certified Halal” should be submitted to LPDS for approval prior to shipment. You may request a copy of the sketch approval from the importer if you are uncertain that proper procedures have been followed.

If you have concerns about other claims, qualifiers, grades, or declarations (for example, “For Cooking Only”, “Not for Grinding”, Certified Organic by ____”), retain the lot by placing it on hold (from the Lot Tracking page in PHIS) and contact the FLS for guidance.

Label Verification Procedures for Import Egg Products

Imported egg products may be presented in shipping containers or immediate containers. It is common for liquid or powdered egg products to be bulk packaged (such as in tankers or totes), in which case the shipping container must meet all the requirements of an immediate container (on tankers, the labels are usually presented as placards). Below are the labeling requirements for each type of container.

Shipping Containers

(1) Name of product
(2) Country of origin (may appear in the foreign mark of inspection)
(3) Foreign establishment number where the egg product was processed or packed
(4) Foreign country mark of inspection
(5) Lot number or production code
(6) Weight expressed in terms of avoirdupois (lbs./oz.)
(7) Shipping or identification mark (as listed on the foreign inspection certificate)

Immediate Containers

(1) Name of product
(2) Country of origin (may appear in the foreign mark of inspection)
(3) Ingredient statement
(4) Manufacturer’s, packer’s, or distributor’s name and address
(5) Net quantity of content (net weight)
(6) Foreign country mark of inspection
(7) Production date
(8) Handling statement (“Keep Refrigerated”, “Keep Frozen”, etc.)

Lot Disposition When Labeling Requirements Are Not Met

When imported product fails to meet one or more U.S. labeling requirements, you will fail the Label Verification TOI in PHIS, refuse entry, and notify the applicant. The lot should be retained pending disposition by the applicant (disposition is discussed in 9 CFR 327.13(a)(2), 381.202(a)(2), and 590.945). In many cases when Label Verification fails, the applicant may request to rectify the errors or omissions and ultimately get the product released. Alternatively, the applicant may appeal the refused entry decision (9 CFR 327.24).

However, **when IPP observe missing, incorrect, or completely illegible shipping marks, they are to fail the Certification TOI**, rather than the Label Verification TOI. This is because the purpose of the shipping mark is to link the physical product directly to the foreign inspection certificate. We will discuss disposition related to shipping marks later in this section.

Labeling Compliance Options

When a lot has been refused entry for failure of the Label Verification TOI, the applicant has several options to bring the shipment back into compliance:

(1) Sort non-compliant containers
- The applicant may request that the establishment sort non-compliant containers and segregate them from the lot until they can be rectified.
- The segregated refused entry product will be retained under FSIS control.

(2) Stencil, stamp, or obliterate incorrect labeling
- The applicant may that the import establishment replace or reprint incorrect labeling features.
- Shipping marks, foreign inspection legends, and foreign establishment numbers may *not* be replicated by the I-house (more on this coming up).
- Recall that handwritten labels are not acceptable.

(3) Movement to an official establishment
- For refused entry product that is not properly marked (e.g., missing processing establishment number), or shipments refused entry for label defects on protective coverings, the applicant may request to the District Office (DO) to correct the noncompliance by diverting the product to an official establishment for further processing.
- If approved, IPP are to seal the conveyance with a USDA seal, complete FSIS Form 7350-1, Request a Notice of Shipment of Sealed Meat/Poultry, and distribute copies of the form as noted on the form.
- IPP should retain a copy of the form in the case file at the official import inspection establishment.

(4) Sort and relabel immediate containers
- Approved on a case-by-case basis by the District Office.
- The applicant will need to submit a written plan describing how immediate container labels will be corrected.

(5) Other methods
- Any requests to correct labeling noncompliances by other means should be submitted to the FLS.

Correcting Shipping Marks

As mentioned previously, the shipping marks (along with the producing foreign establishment number and foreign inspection legend) are the purview of the foreign government central competent authority (CCA) and cannot be replicated by the official import establishment without the approval of

and supervision by a representative of the foreign government, as well as approval by the District Office. Whenever shipping marks are missing or illegible, either completely or partially, IPP are to fail the Certification TOI for that lot, refuse entry, and notify the applicant.

However, **when only a portion of the shipping mark is missing or illegible**, and IPP can confirm that the remaining legible digits match the shipping marks on the certificate, the applicant may request to have the import establishment sort noncompliant cartons and reapply or correct the partial shipping marks.

Currently, importers and establishments importing from Australia, New Zealand, and Namibia are authorized to use barcodes **in lieu of** seeking permission to reapply shipping marks in the presence of a foreign government representative. The bar code is a unique identifier that links the product to the certificate and may be used in situations where the shipping marks are missing or completely illegible. In these situations, IPP will first fail the Certification TOI, refuse entry, and notify the applicant. If the applicant requests to use these bar codes, IPP should:

- First review the “Country Eligibility for Use of Barcodes” page on the Import Operations SharePoint site.
- If the country or foreign establishment is not eligible, the product will remain as refused entry.
- If the country or foreign establishment is eligible, review the supporting documentation.
- Verify the affected shipping units are part of the lot on the certificate.
- Permit the import establishment to apply the bar codes.

Note: This use of bar codes as a replacement for missing or illegible shipping marks is *different* from the pilot program for use of bar codes in lieu of conventional shipping marks described in FSIS Directive 9910.1.

Conclusion

The correction (rectification) of missing or incorrect labeling features—including correction of shipping marks as described above—should be observed and verified by IPP as part of the Label Verification procedures, coded as voluntary reimbursable time. IPP should then complete documentation of the TOI in PHIS, including any disposition of noncompliant product.

Reinspection
FSIS Directive 9900.2

As has previously been discussed, each lot of imported meat, poultry, or egg products will be assigned *at least* the Certification and Label Verification TOIs. When an inspection certificate/application contains more than one lot, you will prioritize those lots that are assigned *additional* TOIs, such as physical exams and laboratory sampling projects, over those lots assigned only Certification and Label Verification.

In this section, we will review several of the types of physical examinations you will perform, including how to select the appropriate sampling plan, how to classify defects, and how to determine whether the lot passes or fails the TOI. For actual physical examination procedures, refer to the instructions in FSIS Directive 9900.2.

Adding Unscheduled TOIs

When a prioritized lot fails a physical exam TOI due to a food safety (public health) defect, and there are other lots of like product (i.e., the same PCPCPG) from the same establishment on the certificate, IPP should add an unscheduled TOI to the other lots. You will select "Public Health Defect on Related Lot" as the justification. Always add unscheduled TOIs rather than selecting "Draw Assignments" again—this ensures the intensified LOR is reserved for future certificates and applications from the same establishment.

Selecting Sampling Plans

FSIS Directive 9900.2 is roughly organized as follows:

When assigned a physical exam TOI, such as a Product Exam, Condition of Container Exam, or Pink Juice Test, IPP select the Product Exam (PE) from **Table 1** (page 2) based on the type of product in the lot. IPP will then reference **Attachment 1** of the directive to find the sampling plan (SP) for the TOI. Finally, after having selected samples and while performing the TOI, IPP will reference the defect classification tables in **Attachment 2** to determine the numbers of public health (PH) and other consumer protection (OCP) defects and determine whether the lot passes or fails.

There are a few exceptions to this pattern:

(1) When assigned a Condition of Container Exam (COCE) for thermally processed product, you will refer to **Section XV** of the directive to find Sampling Plan 7 (SP7). For metal and glass containers (cans and jars), you will then refer to the **COCE1 table**, and for flexible containers (e.g., sealed pouches), you will refer to the **COCE2 table**.

(2) For incubation of such hermetically sealed containers, you will refer to **Section XVI** of the directive, and then to either table **COCE1** or **COCE2**, depending on the type of container.

(3) When assigned the Net Weight TOI, you will refer to the **NIST Handbook 133, Appendix A, Tables 1-1, 2-1, and 2-9**.

For the sake of brevity, this handbook does not include the tables and procedures for all types of physical inspections. However, FSIS Directive 9900.2 includes detailed methodology for conducting physical inspections of several types of products. Refer to the following sections in the directive for instructions:

- VI. Physical inspection of carcasses, whole birds
- VII. Physical inspection of primals and subprimals, cuts, offals
- VIII. Physical inspection of finely textured trim, advanced meat recovery (AMR)
- IX. Physical inspection of cooked meat from restricted countries
- X. Physical inspection of Parma, Prosciutto, and Serrano hams
- XI. Physical inspection of meat extracts, bone, stock broth, and similar items
- XII. Physical inspection of semi-solid packed products (canned hams)
- XIII. Physical inspection of non-solid packed products (beef in gravy, stews)
- XIV. Pork skins intended for popping, rendering, or gelatin manufacturing
- XV. Condition of container examination
- XVI. Incubation of hermetically sealed containers
- XVII. Net weight reinspection
- XVII. Tanker shipment reinspection (edible fats and oils transported in bulk)
- XIX. Physical inspection of egg products
- XX. Sampling procedures for physical inspections
- XXI. Identification of defects during physical inspection
- XXII. Results based on defect identification during physical inspection

Identification and Retention of Defects

IPP are to use the appropriate defect table (Table PE1-A or Table PE1-B) for the product reinspected. Defects observed during physical inspections are classified as either public health (PH) or other consumer protection (OCP).

- Classify defects as Extraneous Material as an OCP for products not subject to zero tolerance
- Identify as feces or ingesta only when both characteristics are observed: color and texture
- Identify as milk only when both characteristics are observed: color and consistency
- Remove the sample defects from the sample unit and classify and identify the defects
- Defects from passed lots are to be denatured and discarded in an inedible container
- Defects from TOIs for which the TOI is entered as “Fail” are to be kept under FSIS control and, if necessary, refrigerated, or frozen until the final disposition of the lot.

Livestock Feces and Ingesta Contamination Identification Chart				
	Beef		Swine	Sheep and Goat
Color	Cattle	Calves	Yellow, tan, brown, or green.	Green, brown, to black
	Yellow, green, or brown	White, yellow, tan		
Texture	Fibrous or plant-like texture; may include grain particles depending on diet.		May include identifiable grain particles or fibrous plant material.	Fibrous or plant-like; feces or ingesta may also be tarry.

Livestock Milk Contamination Identification Chart			
	Beef	Swine	Sheep and Goat
Color	clear to white to light yellow		
Consistency	watery to ropy or curdy		

Note: The DO may request defects be held for correlation purposes.

Pathology Defects

When a pathology defect is identified, hold the lot. Pathology defects should be examined by a PHV if possible. If the defect cannot be classified by a PHV, submit a sample to the laboratory following FSIS Directive 9900.6.

Recording Public Health Defects

These descriptions are the official record of the defect, and, in the case of a failed TOI, they are used as the official description of the issue conveyed to importer and to the foreign government. Therefore, it is essential that these descriptions are as detailed as possible.

- Record all PH defects in PHIS
- “Fail” the TOI
- Clearly and accurately describe the defect(s)
- Size, color, texture, dimension, smell (if applicable), and any other details necessary to clearly describe
- IPP are to refuse entry on the lot
- When a lot fails a PI because of an observed public health defect and there are other lots on the inspection certificate in which the identified public health defects may also be present, add and perform an Unscheduled TOI for each such lot on the certificate (consult with FLS and RMTAS if uncertain)

Recording OCP Defects

These should be recorded in PHIS. A description of the defects should be detailed in the text box. These defects may or may not result in a failed TOI. However, the IIP should consider the rate of occurrence of the defect and the effect on safety and usability of the product. IIP should

determine whether the defect is isolated/widespread, whether it renders the product misbranded, or whether the product could not be effectively further processed or safely consumed, by reviewing the following pass/fail criteria:

- Does the number, type, and/or size of defects affect the safety of the product?
- Are defects severe or numerous enough to affect the usability of the product?
- If limited to one sample unit, after that carton and/or the defect itself is condemned, is there any additional evidence that the remainder of the lot is adulterated or misbranded? If not, safety and usability would not be affected once the defect and/or its carton are condemned.
- Was the lesion localized?
- If widespread throughout the sampled cartons, would presence of the defect in the lot result in misbranded or unwholesome product?
- If unable to make a determination based on the original sample, use SP3A, and take additional samples.

Passed TOI with OCP Defects

For any sample under SP3 (e.g.,12 lb. sample) identified with either an OCP pathological/parasitic lesion or OCP extraneous material, the defect and the corresponding sample carton (e.g., 60 lb. carton) is refused entry and entered into PHIS (see screen shots in Directive).

With any other OCP defect, if a container still otherwise passes the TOI, do not refuse the entire carton, just condemn and dispose of the defects.

Failed TOI

If IPP make a determination after reinspection of the additional samples to fail the lot, based on observation of OCP defects, and the additional criteria, IPP are to enter the failed TOI result in PHIS, and refuse entry on the entire lot.

Appeals

In accordance with 9 CFR 327.24 the IOR, owner, or their representative may appeal any inspection decision including a failed TOI. Appeals are to be made to the program employee's immediate supervisor. Supervisors may receive appeals orally or in writing. When this occurs, the inspector will click the appeal refused entry link and enter the appeal as communicated by the applicant. This is necessary because the applicant does not have PHIS access to enter an appeal. (The original plan was that they would have access). The inspector would then click "submit" and then click the link again to enter their decision.

> **Note:** Inspectors must be sure to click the radio button for" Appeal" when entering an appeal for the applicant. If applicant "Accepts FSIS Decision", PHIS closes the appeal process, and no further appeals may be entered into the system. If the inspector accepts the appeal, the amount refused changes to "0". If the appeal is denied, the applicant can appeal again to the next level supervisor in the OFO chain of command.

However, PHIS will not automatically escalate the appeal. The appeal process must proceed outside of PHIS. FYI: The import establishment can appeal domestic type tasks, but they do not own the product and therefore cannot appeal failed TOIs.

Laboratory Sampling
FSIS Directive 9900.6

Background

PHIS is programmed to assign Laboratory Types of Inspections (TOI) for imported meat, poultry, and egg products. Though it is not a frequent occurrence, more than one Laboratory TOI may be assigned to a given lot. In this module, we will review the various types of laboratory sampling projects that may be assigned. Most sampling projects are described comprehensively in FSIS Directive 9900.6; however, you will also need to refer to FSIS Directive 7530.1 (Abnormal Container TOI) and FSIS Directive 10,010.1 (sampling of raw beef components for Shiga toxin-producing *E. coli* (STEC)).

Laboratory TOIs Assigned

PHIS could assign any of the following types of laboratory TOIs (depending upon the type of product):

(1) Microbiological (RTE)
(2) Microbiological (pasteurized egg products)
(3) Pathology
(4) Residue
(5) Species
(6) Microbiological (STECs, *Salmonella*) - see FSIS Directive 9900.6 (pages 7-14). STEC sampling is further explained in FSIS Directive 10,010.1.

Review of Levels of Reinspection (LOR)

The IOR is required to maintain control of product tested for adulterants by FSIS and not allow such product to enter commerce until negative results are received.

- Normal - LOR where randomly selected lots are assigned a TOI based on the FSIS annual sampling plan.
- Increased - LOR above the normal level based on an FSIS management decision.
- Intensified - LOR assigned by PHIS in response to a TOI reported as “Failed”.

Note: 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 IOR is still required to hold product tested for adulterants by FSIS and is not to allow such product to enter commerce unless and until acceptable (negative) results are received.

For a TOI assigned at Intensified LOR, FSIS holds and does not allow product to be moved from the establishment until the Intensified TOI is “Passed”.

Control of Agency Tested Imported Products for Adulterants

As with any laboratory sampling project, IPP are to notify establishment management when a laboratory TOI is assigned.

- Withhold determination of adulteration and eligibility to enter commerce until testing is complete.
- Products tested "for cause" cannot receive the U.S. mark of inspection pending the availability of results or be moved off-premises. A "for cause" sampling project is one that is conducted for lots at Intensified LOR or Increased LOR with FSIS instructions to hold; in such cases, product may not be moved off-premises or stamped.
- For other sampling projects (i.e., not "for cause"), notify the establishment to determine whether the IOR will hold the lot on-site or hold it off-site with effective controls (e.g., company seals) to prevent entry into commerce.
- If lot is to be held off-site, record the location name and address in the lab sample questionnaire.

    - Not for cause samples may be stamped and moved off premises but must be maintained under IOR control pending results.
    - The IOR is the named individual or company 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 application.
    - If product ownership changes prior to results, product is considered to have entered commerce. The District Office (DO) is to notify the Office of Investigation, Enforcement and Audit (OIEA) Regional Director to investigate and take enforcement action or sanctions, as necessary.

Adulterant Tests Requiring Control

"Control" could be defined as either an Agency-required hold or the IOR maintaining control of the product, and would also apply during "for cause" food chemistry or pathology sampling. The following types of laboratory sampling projects bear a mandatory "test-and-hold" requirement:

- Non-intact raw beef product or intact raw beef product intended for non-intact use tested for *E. coli* O157:H7 and six other Shiga toxin-producing *E. coli* (STEC).
- RTE products tested for *Listeria monocytogenes* or *Salmonella.*
- Livestock carcasses and meat products tested for residues.

Tests Not Requiring Control

- Raw meat or poultry products tested for *Salmonella, Campylobacter,* or other pathogens that FSIS has not designated as adulterants in those products.
- Poultry carcasses or raw poultry parts sampled for residues (metals).

Laboratory TOI Not Performed

- Request not to perform lab samples and provide a reason if the TOI is not applicable to the product.
- May refer to the “Products and TOIs (PHIS)” document on the Import Operations SharePoint site for TOIs that are applicable to product groups.

Sample Supply Requests

- Verify Establishment Profile includes the correct physical mailing address (not P.O. Box) for the “Laboratory Sample Supplies Address”
- Order supplies through Outlook
- FSIS - Sampling Supplies - Eastern Lab
- FSIS - Sampling Supplies - Midwestern Lab
- FSIS - Sampling Supplies - Western Lab
- Include the following information:

  - Sampling supplies needed (e.g., MT08, MT51, IMVRTE, residues, chemistry)
  - Establishment number and establishment name
  - Name of submitter
  - Contact phone number

Sample Selection

- Randomly select shipping units from the lot for sampling
- Identify and stamp each shipping unit selected as "USDA OFFICIAL IMPORT SAMPLE”
- Observe handling and removal of the unit(s) to be sampled
- Collect samples from one specific production code or date
  - For products that undergo a long production process and have staggered production dates (e.g., dry cured hams), use the date of final processing
  - When production codes are used in lieu of dates, enter the date of sampling as the production date and add the production codes in the “Remarks” box
- When practical, obtain from establishment management a photocopy of the shipping container label and immediate package label (front and back) for the case file
  - Note stamp on carton. When PHIS assigns a Product Exam in addition to a Laboratory TOI, identify the carton(s) from which the lab sample(s) was (were) obtained by double stamping the carton or carton(s) with the “USDA OFFICIAL IMPORT SAMPLE” stamp.
  - Establishment management can take a photograph of the shipping container label if too big for the copy machine.
- If the entire contents of a container are submitted for sampling, ensure the establishment does not discard the container (in the event of an unacceptable/violative result, RMTAS may request additional information from the container)

Sample Receipt

Provide FSIS Form 9770-1 "Official Receipt for Samples of Foreign Products Collected for Laboratory Analysis" to the importer once all samples are collected from the lot.

Sample Collection Form

- Complete the PHIS Sample Management-Sample Collection Form in PHIS.
- Print the Sample Analysis Request Form, sign it, and submit it with the sample.
- When applicable, return to the Lot Manager page and select “Lot Tracking” and “Place Lot on Hold,” and select the appropriate reason.

Sample Submission

IPP should monitor LIMS-Direct for results within a day of shipping the sample. Ensure results are also being posted to PHIS Establishment Profile Sample History**.**

- Always maintain sample integrity and security.
- Submit product label or a copy of the label with the sample.
- Seal sample shipping containers per FSIS Directive 7355.1.
- Mail to the appropriate FSIS lab using the FSIS contract overnight delivery or courier service. Submission to the wrong lab will result in the sample being discarded.
  - All samples collected at establishments in Puerto Rico are submitted to the FSIS Eastern Laboratory
  - All samples collected at establishments in the Pacific Islands are submitted to the FSIS Western Laboratory
- Notify establishment management as soon as results are reported.
- Ensure the results are reported in PHIS.
- When results are reported as negative/acceptable, pass the laboratory TOI in PHIS, check “Release Acceptable Units,” and notify establishment the lot can be released (all other assigned TOIs must be completed and passed as well!).

Sanitation When Collecting Non-Intact Samples for Pathogens

- Properly clean and sanitize affected equipment before and after sample collection to prevent cross-contamination.
- Sanitize all non-disposable equipment before sample collection.
- Use aseptic handling procedures (clean and sanitize hands, carefully open bags without contaminating the insides, glove properly, use gloved hands to collect the sample and place it in the bags, then close the bag)
  - **Note:** In this context, “non-intact” samples are samples of product that is not packaged, whereas “intact” samples which are samples of product that is packaged.

Discarded Samples

- Reported in LIMS-Direct.
- For “for cause” samples on mandatory FSIS hold, add an unscheduled TOI and select a new sample **from the same lot** and submit it.
- For “not for cause” samples under IOR control, notify IOR through establishment management that the sample was discarded and that product will not be resampled. In PHIS, choose “Submit Not Performed” and reason “Discarded Sample”. Complete the TOI with status “Not Analyzed”.
- Submit completed FSIS Form 9770-3, “Discarded Sample Report and Findings” to the FLS. The directive says to access the laboratory TOIs page for the lot, choose “Submit a 2nd sample,” and notify the IOR through establishment management that a second sample is being submitted to the lab.
- FSIS Form 9770-3 is available on the FSIS Website (“Inspection Forms” page). The Inspector completes it, adds attachments, and sends it to the FLS, who determines if follow-up training or correlation is needed.
- The supervisor completes the bottom portion of the form, returns original for the case file, and keeps a copy for reference.

Negative/Acceptable Result

If all other reinspection activities are acceptable and the lot is on:

- IOR hold, notify establishment management of the results so that the hold can be released, and complete the lot reinspection in PHIS.
- FSIS hold, complete the lot reinspection in PHIS and notify establishment management to stamp the lot so it can be released.

Indeterminate Result

The designation “indeterminate” is reserved for species testing, meaning that the species of the animal protein in the product could not be determined. When this occurs, IPP are to email RMTAS with the following information:

- Application and lot number
- Lab form number
- Product name and ingredients statement (either scanned copy of the product label or type it out)

A subject matter expert (SME) will review the results, determine whether the TOI is passed or failed, and will update the results in PHIS accordingly.

Presumptive Positive Result (microbiological sampling only)

When a sample is reported as presumptive positive, there are going to be a lot of eyes on that result. It is the responsibility of the Import Inspector to notify, verify, and then notify again. You

will first notify the import establishment management of the presumptive positive result. Then you will verify:

- If the lot is still at the import establishment, retain the product (U.S. Retained tag);
- If the lot has been moved from the import establishment to an off-site location (under IOR control), request import establishment management to:

    (a) contact the IOR to inform them 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

Once you have verified the location of the sampled lot, email the FLS and RMTAS the lot status, location, inspection certificate number (for non-eCert countries), the application number, and the lot number. RMTAS will notify the program officials of the exporting country (CCA) as soon as a presumptive positive result is reported. This is to help determine whether the producing establishment has exported any *other* product from the same production lot to the U.S. RMTAS is to query PHIS to identify any other shipments of like product that may have entered the U.S. with the same production dates. If shipments are identified with the same production dates, RMTAS will notify the DO and the Import Inspector. RMTAS may provide further instruction to retain all like product from the same foreign establishment until further notice; this may include previously inspected and passed product.

Positive/Failed Result

If a laboratory result for an adulterant comes back as not acceptable/positive (or "violative" for residue samples), the Import Inspector must notify, verify, and notify…again!

As before, IPP should first notify establishment management, then verify the status of the lot:

- If under IOR control and off-site, confirm through establishment management the product is still under control and not in commerce. Notify establishment management to advise the IOR that the product is refused entry and must be returned. You should ask for a timeline on how soon the product will be returned.
- Whether on-site or off-site, initiate a refused entry in PHIS and select "Add New Reason" and "Failed Laboratory Analyses" and the appropriate reason from the drop-down menu.
- If and when the product is on-site, stamp containers "United States Refused Entry."

There are additional actions you will need to take when a lot fails one of these TOIs:

- Inform the FLS of the result and the status of the product.
- If the product entered commerce, FSIS would need to determine if a request to recall is warranted.
- RMTAS ensures the foreign establishment is under Intensified LOR and issues alert with instructions for other lots of like product from the same establishment.

- RMTAS notifies the foreign government of results, and if additional affected product is identified, the Agency will request recall or refuse product that has not already been passed.

Sampled Product Returned to Canada

There are a few unique provisions for when product from Canada is subjected to a laboratory TOI.

First, remember that Canadian product does not receive the U.S. mark of inspection, so there is no concern for removal of the marks (as would be necessary for product from other countries that had already been stamped).

Additionally, certain fresh products (e.g., open combos, fresh carcasses or parts, or other products which are not vacuum-sealed) which are sampled for adulterants may be returned to Canada for holding pending laboratory results. In this situation, FSIS would require a CFIA approval document with an approval number and a location where the product will be held (this information should be entered into PHIS when filling out the sample questionnaire).

There is more detail in FSIS Directive 9900.6; however, the overall point is that in the event of a laboratory TOI failure, the product held in Canada would *not* need to be returned to the U.S. for marking, removal of marks, or disposition. You *would*, however, still need to document the refused entry in PHIS.

Ready-to-Eat (RTE) Microbiological Sampling

Any product that is in a form that is edible without additional preparation to achieve food safety is eligible for either IMVRTE or EGGIMP sampling. Both of these sampling projects are regulatory, meaning that the lot being tested must be held pending results, and that FSIS will take action on positive/violative results.

- IMVRTE:
  - Tests for *Listeria monocytogenes* and *Salmonella* in any RTE meat or poultry products
  - Collect at least 2 lbs., intact (in packaging) whenever possible
- EGGIMP:
  - Tests for *Listeria monocytogenes* and *Salmonella* in pasteurized egg products
  - Collect at least ½ lb.

Collecting non-intact IMVRTE samples

There may be times when collecting an intact IMVRTE sample is not possible due to the nature of packaging (for example, you are presented with 4 lb. salamis in combo bins that are not individually packaged). In these situations, do the following:

- Have the products subject to sampling (randomly selected from the staged lot) moved into the inspection room.
- Use aseptic sampling procedures. Clean and sanitize equipment before and after sampling to prevent cross-contamination, wash hands up to the mid-forearm, carefully set up the collection supplies, and don gloves without touching their outer surfaces.
- Remember to collect at least 2 lbs. of product.
- Submit the sample either refrigerated or frozen (shelf-stable products do not require any refrigeration). Thawed or tempered RTE samples should be kept refrigerated until shipped.
- In the “Remarks” section of the lab form, include a statement indicating the sample is not intact.
- When collecting samples from large containers, such as combo bins, collect product from the top surface and from the perimeter of the product (areas which are in contact with the container).
- When product is frozen together in bulk, allow the product to air temper (defrost) while remaining covered, in a controlled environment, and use aseptic sample tools (tongs and scoop) to collect the sample.
- When product is individually quick frozen (IQF), the air temper step is not needed because the products are not frozen together as a single unit.
- For liquids (products in drums and totes), use aseptic sampling tools to remove liquids from the container.
- For other bulk-packed RTE product, consult with the FLS before taking a sample.

Egg Product Sampling

Pasteurized imported egg products are sampled for the adulterants *Listeria monocytogenes* and *Salmonella*. Remember that *un*pasteurized egg products (currently only from Canada) will proceed to an FSIS official egg products establishment for further processing before entering commerce and thus may bypass import establishments altogether.

Order sample supplies from the laboratory under the project code EGGIMP. Specify whether it is for EGGIMP (liquid egg) or EGGIMP (dried egg).

As with any sample, use aseptic technique. Collect at least ½ pound of product, maintaining its form—that is, if it is presented as liquid egg, it should be submitted as liquid egg (not stored in the freezer), and if it is presented as frozen product, submit it frozen. If the product is dried, it is shelf-stable and requires neither refrigeration nor freezing.

Sampling Egg Products in Large Containers

Sometimes, pasteurized egg products will be presented in tankers or combos that are too large to fit into the inspection room. When those shipments are presented, the testing results for *Salmonella* must be presented with the shipment and must be reported as “negative.” This information can be on the certificate or on official government letterhead and is verified as part of the Certification TOI.

For all other shipments of pasteurized egg products not in tankers or large containers, if an EGGIMP TOI is assigned in PHIS, inspectors will collect and submit a sample, even if the shipment is certified as "*Salmonella* negative."

Pathology Sampling

Occasionally, while performing a Product Exam (PE) TOI, IPP may observe abnormal tissues or lesions in the product. If IPP *can* positively identify the condition, they should classify it as either a Public Health (PH) or Other Consumer Protection (OCP) defect. This is important because a PH defect will result in refused entry of the lot, whereas an OCP defect usually does not (unless it is extensive enough to affect the safety or usability of the product). (For example: If a beef carcass presents with evidence of septicemia, that would be classified as a PH defect. On the other hand, a beef carcass presenting with what appears to be a chronic, localized abscess would be classified as an OCP defect).

Pathology sampling *may* be assigned by PHIS, but most often, the Pathology TOI is added as an unscheduled TOI when IPP observe an abnormal condition or lesion in product during a Product Exam TOI (tables PE1 to PE3) and they cannot identify or classify it. When this occurs, IPP should contact their supervisor to request examination by a PHV. If a PHV is not available, IPP are to add the unscheduled Pathology TOI, submit the abnormal tissue sample to the laboratory, and place the lot on hold pending results (again, you do not want the product to move into commerce until you have ruled out a PH defect).

Residue Sampling

When a residue TOI is assigned to a lot, you are to collect a sample from eligible products. residue TOIs are assigned to fresh and processed meat and poultry products, Siluriformes products, and egg products.

As a general rule, multi-ingredient raw products and multi-species processed products are not eligible for residue sampling. FSIS Directive 9900.6 has additional specific situations wherein Import Inspectors are not to collect residue samples (Chapter VI, Section I.C.1 and 2.).

Residue sample sizes:

- Meat and poultry products – 2 lb. sample
- Siluriformes – 1 lb. sample
- Egg – ½ lb. sample

More than one residue TOI may be assigned to a particular lot (e.g., Residue-Fresh (IMPFRESH) TOI and a Pesticide TOI). If the multiple residue TOIs are due to the same lab, then collect one 2-lb. sample, complete and submit the multiple lab forms, and include them in a single shipping container. If multiple TOIs are assigned to different labs, then collect a separate sample for each of the residue TOIs.

Additionally, a situation may arise in which a particular residue TOI will be assigned to a lot more than once, at different levels of reinspection. In this situation, perform only the TOI at the *highest* LOR (priority is Intensified > Increased > Normal), and document "Request Not Performed" for the sampling project(s) at the lower LOR(s).

> **Example:** Lot 2 of beef trimmings from Brazil is assigned two Residue-Fresh (IMPFRESH) TOIs—one at Intensified LOR and one at Normal LOR. In this case, you would collect *one sample* and document and submit the Residue-Fresh sample under *Intensified* LOR. You would document the Residue-Fresh sample under Normal LOR as "Request Not Performed."

When two *different* types of residue TOIs (e.g., IMPFRESH and Pesticides) are assigned to a lot and are due to the *same lab*, IPP are to collect a *single sample* (e.g., 2 lbs. for eligible meat or poultry products) and include *both sample request forms* in the sample shipping container.

Residue results may be reported as either **residue not detected**, **residue detected - non-violative**, or **residue detected - violative**. Residue detected - violative results are handled similarly to positive results for microbiological adulterants as described above (notify establishment management, verify the status of the lot (held by IOR, on-site or off-site, etc.), add refused entry in PHIS, mark product as "United States Refused Entry" if/when on-site).

Results *other than* residue detected - violative are eligible for release, provided that all other TOIs are passed.

Species Testing

When assigned by PHIS, IPP are to sample imported meat and poultry products for species verification. Species testing may include analysis for:

- Species-processed
- Species-raw

For species testing, IPP randomly select one sample unit from the lot and remove ½ lb. (if it is not possible to remove ½ lb., submit the whole unit). IPP are also to submit the ingredients list from the label (a photocopy is acceptable) in a separate bag along with the sample.

STEC Sampling

Imported raw, non-intact beef and beef components intended for use in non-intact product are tested for the adulterants *E. coli* O157:H7 plus six other non-O157 Shiga toxin-producing *E. coli* (this is the same as is done for domestic product). Since the STECs are considered adulterants in these beef products, these sampling projects are regulatory, which means there is a mandatory test-and-hold requirement. For the various STEC sampling projects, you will refer to FSIS Directive 10,010.1.

Note that these products are *also* analyzed for *Salmonella*, so you should notify the establishment and the IOR that the samples will be analyzed for both microorganisms. Since *Salmonella* is not considered an adulterant in these products, that aspect of the analysis is not regulatory, and it is not necessarily for the product to be held while only awaiting *Salmonella* results (be aware that *Salmonella* results may take 1-3 days longer to be reported). Additionally, you would not refuse entry of these products based solely on a positive result for *Salmonella.*

There are two primary raw beef STEC sampling projects:

- MT51 - Samples beef trimmings and components
- MT08 - Samples raw ground beef and veal

The following is an overview of how to collect samples for these projects:

- MT51
  - Beef Manufacturing Trimmings (fresh)
    - If lot is >5 containers, randomly select 5 containers and collect 12 pieces per container
    - If lot is ≤5 containers, follow chart
    - Aseptically collect a total of 60 exterior surface pieces (each 3”x1”x1/8th”) and package evenly into three WhirlPak™ bags
    - Note that we only use the N60 sampling method for collecting BMT in imported products—**the cloth sampling method does not apply!**
  - Beef Manufacturing Trimmings (frozen)
    - If ≥5 containers in the assigned lot, randomly select 5 with the same production code or date
    - Expose the top of the 5 blocks and aseptically remove twelve 15-gram slivers as shown
    - Use your knife to remove slivers. Do not use establishment equipment.
    - Repeat for additional blocks until sixty 15-gram samples are collected (900g is approximately 2 lbs.)
    - Sample as much surface area as possible
    - Package the sample evenly into three WhirlPak™ bags
  - Beef Components Sampling (includes esophagus (weasand) meat, head meat, cheek meat, beef from Advanced Meat Recovery (AMR) systems, low temperature rendered lean finely textured beef (LFTB), partially defatted chopped beef, partially defatted beef fatty tissue, and heart meat)
    - For smaller components, collect grab samples and fill each of the 3 bags to the fill line
    - For larger components (e.g., hearts), collect one or more slices to fill the bag 2-3” from the top (in this case, do not worry about the fill lines)

- MT08

  - Raw ground beef and veal (products that meet the standards of identity for ground and chopped beef (9 CFR 319.15(a)), hamburger (9 CFR 319.15(b)), and beef patties (9 CFR 319.15(c))

    - Intact sample: collect 2 lbs. of packages
    - Non-Intact sample: Collect grab samples to fill 3 bags to the fill line

    Collect a 2-pound intact sample unit from the assigned lot. If the intact packages <2 lb., then select intact packages to obtain an approximate 2 lb. sample. If necessary, select product from multiple open packages. If the immediate container is >2 lb., then select an entire intact package if it is practical to ship to the lab. If the immediate container is of a size that is not practical to ship to the laboratory as an intact unit, open the immediate container and select the sample using the aseptic methods.

Imported Raw Poultry Products Sampled for *Salmonella* and *Campylobacter*

Product Eligibility

- **Poultry Carcasses**: Intact and non-intact whole birds (chicken and turkey), can be injected or marinated.
- **Raw Chicken Parts (Not Turkey Parts)**: Cut-up chicken parts are eligible for sampling provided they are equal to or larger than 3/4 inch in size in at least one dimension and are of a type that would typically be available for consumer purchase.
  - Chicken Parts include chicken legs, breasts, wings, half and quarter carcasses, necks, and giblets (hearts, livers, gizzards).
  - Can be skin-on or skinless.
  - Bone-in or boneless
  - Intact or non-intact mechanically tenderized, vacuum tumbled, or injected or marinated with or in a liquid (e.g., broth or marinade that does not mask the raw nature of the product).
- **NRTE Comminuted Poultry**: Any NRTE comminuted poultry (chicken or turkey) product is any non-breaded, non-battered raw poultry product that has been:
  - ground, ○ mechanically separated, or
  - hand- or mechanically deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size.

Sample Size

- Chicken and Turkey Carcass = one whole bird
- Chicken parts = 4lbs. (±10%)
- Ground, comminuted or mechanically separated chicken and turkey
- Sufficient to fill two Whirl-Pak bags (approx. 325 grams per bag) OR
- Intact packages totaling 2 pounds

Laboratory Capacity Limits

Because laboratory capacity is limited in PHIS for the IMP Poultry project:

- Schedule the sample in PHIS before preparing the sample.
- Delay preparation of the samples until the appropriate day.

Collection Day

- Date Collected is the date that the inspector prepares the rinse, swab, or product sample, not when the inspector collects the product and removes it from the lot.
- These may or may not be the same date.
- Discard if held 3 or more days.

Sample Selection/Preparation

- Pre chill neutral buffered peptone water (nBPW)
- Freeze coolant
- Notify establishment management
- Inform them IOR does not have to hold product
- Ensure that all samples are properly tempered
- Follow the appropriate Attachment in FSIS Directive 10,250.1
- If frozen, follow FSIS Directive 9900.2 on how to temper • Chicken Carcasses:
    - Ensure BPW can reach entire bird
    - Allow carcass to drain for approximately 1 minute before rinsing with BPW ○ Aseptically collect rinsate from 1 carcass randomly from designated lot
- Turkey Carcasses:
    - Allow carcass to drain for approximately 1 minute before rinsing with BPW ○ Aseptically collect and submit 2 swabs ○ One 10 ml of BPW (*Salmonella)* ○ Other 25 ml of BPW (*Campylobacter*)
- Chicken Parts:
    - Collect only 1 parts type per sample (i.e., leg) ○ Sample enough parts to equal 4 lbs. (±10%) ○ Refrigerate rinsate sample within 5 minutes of collection

Raw Pork Sampling (Refer to **FSIS Notice 93-16**)

- Randomly assigned. Does not need to be held (IOR may voluntarily hold).
- Email any lab for supplies. Include:

(1) Contact information;
(2) Establishment name, street address (no P.O. Box), city, state and zip code;
(3) Project code IMP_Pork; and
(4) The specific name of the supply kit(s) that are needed:
(a) IMP_Pork (Cuts)
(b) IMP_Pork (Ground)

(c) IMP_Pork (Intact Frozen/Mechanically Separated Species (MSK))

- The following practices do not exempt the product 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).
  - 3. Addition of meat or poultry products from a different species to eligible pork products.

- The following products are exempted from sampling:

  - 1. Battered or breaded pork product. For example, dumplings, egg rolls, or pot stickers.
  - 2. Not-Ready-To-Eat (NRTE) products containing pork. For example, products in the HACCP processing category “Heat-Treated but not Fully Cooked - Not Shelf Stable”; and
  - 3. Raw pork products intended for use in ready-to-eat (RTE) products at a federally inspected establishment.

    - **Note:** If the Pork *Salmonella* TOI is assigned to these types of products, or to another product group where the presented product is not to be sampled, IPP are to “Not Perform” the TOI in PHIS and select “Lab Analysis Not Applicable for Product” as the reason.

- For intact and non-intact raw whole pork cuts, IPP are to collect fresh and frozen raw pork samples in final packaging, whenever possible, and an appropriate number of packages to equal 2 pounds.
- For raw whole (intact and non-intact) pork cuts not available in their final packaging, IPP are to use the single larger Whirl-Pak® bag and aseptically collect one or more cuts to fill the Whirl-Pak® bag leaving 2 to 3 inches of space at the top of the bag.
- For raw ground, mechanically separated, AMR, or comminuted pork products, IPP are to collect fresh and frozen raw pork in their final packaging, whenever possible, and an appropriate number of packages to equal 2 pounds.
- For raw ground, mechanically separated, AMR, or comminuted pork products not available in their final packaging, IPP are to aseptically collect grab samples.
- Attachment 3 for non-frozen or tempered.
- Attachment 4 for frozen.

***Salmonella/Campylobacter* Test Results**

- If positive for *Salmonella* or *Campylobacter:*

  - Advise IOR of result but TAKE NO ENFORCEMENT ACTION

- If negative for *Salmonella* or *Campylobacter*

  - Advise IOR of negative result

Salmonella/Campylobacter Positive Lots

- If IOR requests not to stamp product "U.S. Inspected and Passed" for all or part of lot, request through the import establishment that the IOR provide one of the following completed CBP forms:

  - Form 7551, DRAWBACK ENTRY
  - Form 7552, DELIVERY CERTIFICATE FOR PURPOSES OF DRAWBACK
  - Form 7553, NOTICE OF INTENT TO EXPORT, DESTROY OR RETURN MERCHANDISE FOR PURPOSES OF DRAWBACK

- Review the CBP form to verify the product and the amount of product coincides with product being withdrawn for the lot.
- Attach the form to the case file.

Salmonella/Campylobacter Positive Lots Documentation in PHIS

- Access the Lot Manager
- Select Lot Tracking
- Select, as appropriate

  - Entire Lot Withdrawn - *Salmonella* Positive
  - Partial Lot Withdrawn - *Salmonella* Positive
  - Entire Lot Withdrawn - *Campylobacter* Positive
  - Partial Lot Withdrawn - *Campylobacter* Positive

- When all TOIs are completed, select "Release Acceptable Units" to close out the lot in PHIS.

Cooked Meats
FSIS Directive 9900.7

Background

This module discusses how to conduct import reinspection physical examinations of cooked meat products from countries or regions where foot and mouth disease (FMD) is known to exist. We do these physical inspection TOIs on behalf of APHIS based on a memorandum of understanding (MOU) between the agencies.

APHIS restricts the eligibility for import of products from countries and regions affected by FMD and therefore has ultimate jurisdiction over the product. Customs and Border Protection (CBP) also has inspection authority at the port-of-entry and plays a significant role in these TOIs.

The PHIS foreign country profile includes the animal health status for each eligible country and will automatically assign the appropriate TOI associated with the FMD animal health restriction.

FSIS reports the results of its examinations to APHIS and CBP. If a violation or a defect is discovered upon inspection, FSIS fails the applicable TOI in PHIS, refuses entry of the product, and notifies APHIS and CBP. CBP takes regulatory action against the product, although we (FSIS) are still tasked with observing and verifying appropriate disposition of the product.

Establishment Profile

Review the Establishment Profile to confirm that the establishment is approved for reinspection of APHIS-restricted products from countries and regions affected by FMD. The **Import Guidance** page of the FSIS website includes a list of which import establishments serve as APHIS-approved Rapid Defrost Facilities.

Certification

Verify that the foreign inspection certificate meets the requirements in 9 CFR 327.4.

- Fail the Certification TOI when the information related to the batch codes on the certificate does not match the batch codes identified on the indicator piece packaging.
- Samples for research or evaluation not presented with an APHIS Veterinary Services import permit are considered as commercial and must be reinspected by FSIS.
- Verify equipment is cleaned and sanitized before and after use to preclude cross contamination of other product.
- Defrost tank water must never be reused for other product.
- Defrost tank with restricted cooked meat cannot be used to thaw any other product simultaneously.

CBP Notification

- Contact CBP if Form AI-629 (Notification for Perishable Cooked Ruminant or Cooked Swine Meat from Restricted Countries) was not received and request that it be forwarded.
- Do not reinspect product until you receive the form.
- CBP can email or fax the form. If email is down, CBP can also send sealed envelope by courier.
- Notify your supervisor if:

    - There is evidence of tampering with the envelope.
    - If the anticipated shipment is not presented.
    - If the container seal on the shipment was broken during transit.
    - If there are issues requiring notification of the applicant regarding the shipment's location.

- Complete Section B of form AI-629 (after reinspection)
- Email or fax the AI-629 to the CBP office in Section A confirming reinspection was completed.

    - Send the *same day* as reinspection.
    - Copy the completed AI-629 and keep in the case file.

Pink Juice Test (PJT) for Cooked Product Packed in Tubes from FMD Countries

- Conduct a PJT on every lot of cooked meat from a restricted country even if PHIS has not assigned the TOI.
- If not assigned, add unscheduled PJT TOI and email RMTAS to investigate. Provide the application-lot number and a copy of the inspection certificate.
- Verify the tubes weigh ≤5 kg (11.05 lbs.). If any tube weighs more than 11.05 lbs.
    - Place the lot on hold in the PHIS.
    - Contact APHIS for guidance.
        - At APHIS request, fail the pink juice test TOI and document the reasons for the failure.
- Select the number of sample units using SP6 in FSIS Directive 9900.2.
- Remove and defrost one tube from each carton.
- Thaw using water temperature that is as cool as possible to reduce the possibility of cooking of the indicator pieces or affecting product appearance.
- Table SP6 details the sampling plan for a product examination of frozen cooked meat in tubes from an APHIS restricted country.
- Make sure the sample is placed in a plastic bag suitable for low temperature thawing
- Examine each sample unit of cooked meat and verify:

    - At least 1 solid piece is located in the cold spot.
    - The piece is no smaller than a 1.5 cubic inches in size.

PJT for Tubes with Indicator Piece

- After thawing, manually separate and remove the indicator piece.
- Slice the indicator piece in half, squeeze the juices onto a white impermeable tray.
- Observe for the presence of pink juice on the tray.
- Look for any bone or bone fragments.

PJT Utilizing Representative Batch Samples

- Verify containers of ground, flaked, or cubed cooked beef are accompanied by representative sample packages (test pieces) of cooked meat that are placed in separate bags along with the shipment.
- Verify there is a representative indicator piece from each cooker batch code identified on the inspection certificate.
- Verify it corresponds to a specific batch identified on the inspection certificate.
- Verify that the shipment cooker batch code certified on the inspection certificate is consistent with the number of cases for each lot of product.
- Verify that lots presented for reinspection do not contain product with cooker batch codes that are not identified on the inspection certificate.
- Indicator pieces are:

    - Individually sealed
    - Properly labeled with the cooking date and cooker and batch number
    - Enclosed together in one sealed box that accompanies the shipment

- Use the sealed representative test piece to determine thoroughness of cooking.
- Thaw the test pieces using a water temperature as low as possible to reduce the possibility of further cooking.

Pink Juice Test

Cut the middle of each test piece, squeeze the juice on a white impermeable tray, and observe for the presence of pink juice on the tray.

Disposition of Defects

- If you observe pink juice:
    (1) Place the lot on hold in PHIS
    (2) Notify local CBP
    (3) Notify APHIS VS, Import Animal Production Staff at headquarters for guidance and disposition of the lot
    (4) Fail the PJT TOI in PHIS if APHIS refuses entry on the lot
    (5) Defer to APHIS VS regarding final disposition of the lot because of animal health risks to U.S. livestock
    (6) Verify that the establishment addresses sanitation issues to prevent cross-contamination

- If bones are found during PJT:

  (1) Place the lot on hold in PHIS
  (2) Notify local CBP
  (3) Notify APHIS VS, Import Animal Products Staff, at headquarters for guidance and disposition of the lot
  (4) Fail the PJT TOI in PHIS and identify reasons in comment block
  (5) Refuse entry of the shipment if instructed by APHIS VS; APHIS is to make disposition on the lot due to animal health risk
  (6) Verify that establishment addresses sanitation issues to prevent cross-contamination

Fresh Meat Inspection Certificates

APHIS has negotiated an exemption from the Pink Juice Test for fully cooked intact skeletal muscle for meat from Northern Argentina, Uruguay, and 14 states in Brazil. When such products are accompanied by a Fresh Meat Inspection Certificate, IPP will not need to perform the PJT (mark the TOI as “Not Applicable” in PHIS). Fully cooked head meat, such as cheek meat and tongues, are not eligible for this exemption. Contact APHIS at FSIS.PJT.Results@usda.gov if head meat products are presented with a Fresh Meat Inspection Certificate.

Condition of Container Examinations (COCE)
FSIS Directive 9900.2 & FSIS Directive 7530.1

The Condition of Container Examination (COCE) TOI is performed to assess the integrity and safety of imported thermally processed - commercially sterile products, including ready-to-eat product packaged in cans, jars, pouches, or other hermetically sealed containers.

Canned Product Definition - A meat or poultry food product with a water activity (A_w) above 0.85 which receives a thermal process either before or after being packaged in a hermetically sealed container (e.g., cans, glass jars, plastic containers, laminated pouches, paperboard containers, etc.).

Significant Microbes in Canned Food

- Public health microbes of concern
    - *Clostridium botulinum* - Pathogen of concern in canned foods because if the process is inadequate to destroy the spores, the spores will germinate into growing vegetative cells which produce a potentially deadly paralytic toxin.
    - *Staphylococcus aureus* - Although rare, this organism has grown in canned product prior to processing. When *S. aureus* grows, it produces a heat stabile toxin that is not destroyed during normal thermal processing. The toxin can cause severe gastroenteritis when ingested.
- Spoilage microbes
    - Coliforms
    - Butyric anaerobes
    - Putrefactive anaerobes
    - Yeast
    - Mold

Canned foods must be commercially sterile and shelf stable. That means that they will not spoil during storage and distribution. So, thermal processes must be adequate to eliminate not only pathogens, but also spoilage organisms, some of which are very heat resistant.

Purpose of COCE - To determine whether the containers have any abnormal, critical, or non-critical defects that may indicate under-processing of the products, or whether the defects themselves may substantially affect the integrity or usability of the containers. Inspection personnel must know how to classify critical defects and major defects.

Abnormal Container Definition - A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled (9 CFR 318/381.300(a)). An abnormal container is a critical defect.

Swelling - Possible causes include under-processing, growth of microbes between sealing the containers and processing (incipient spoilage), poor vacuum at mechanical vacuum capper or steam flow capper, post-processing contamination (leaker spoilage), and thermophilic spoilage from inadequate cooling after processing or storage at elevated temperatures.

- Often indicates microbiological growth.
- May be due to production of hydrogen gas through interaction of the food with the container (chemical spoilage).
- Overfilled containers may appear swollen (may result in under-processing).
- Any container that is bulged by excess internal pressure.
- Also includes any burst or leaking containers.

Lot Disposition Criteria

Begin the COC TOI by determining the sample size and selecting samples based on the Normal Plan in Table SP7 (p. 8 of FSIS Directive 9900.2). Identify and classify any defects and use Table A (p. 13) to determine if the lot passes or fails. If the lot passes, document the results in PHIS, and if all other TOIs are completed and passed, release the lot.

At this point, if the lot has failed under the Normal Plan, you will notify the establishment of the failed TOI, and you will refuse entry, but you will *not* notify the applicant that the lot is refused entry ("Send to Applicant" button), because further examination and analysis may be required before they will be required to render a disposition (recall that they only have 45 days from the time notification).

Next, refer to Table B (p. 13) to determine if the lot is sortable. If the lot is not sortable, or if the lot *is* sortable but the applicant declines to do so, proceed with notifying the applicant of the refused entry and await disposition.

If the lot *is* sortable, and the applicant wishes to proceed with sorting, rectify the refused entry in PHIS and proceed with reinspection under the Tightened Plan in Table SP7 (you will need to draw an entirely new set of containers to examine). If the lot fails the COC TOI under the Tightened Plan, it is ineligible for further sorting, and you will proceed with the refused entry notification.

> **Note:** Your worst case scenario is burst containers. They are easily detected by odor, maggots, stained cases, and sound (explosions). Exercise care when handling these. If a container is under-processed and contains botulinum toxin, it could get into your eyes, mouth, and nose if the container ruptures! Do not ever freeze these because it makes the contents expand (could burst) and affects lab analysis.

CONDITION OF CONTAINER EXAMINATION 1 (COCE1 TABLE)

Defect Criteria for Cans and Glass - Thermally Processed Commercially Sterile Containers

Abnormal Containers (Critical Defects) (Refer to FSIS Directive 9900.2; Table 1A; p. 14)

- Swells
- Springer
- Flipper
- Loose tin
- Overstuffed
- Crooked cap
- Other (any other critical defect that compromises the hermetic seal of the container or shows evidence of possible spoilage of contents)

Defective Containers (Non-Critical (Major) Defects) Cans and Glass – COCE1 (FSIS Directive 9900.2, Table 1B; p. 14)

- Punctured cans
- Fractured glass (jars)
- Dent
- Improper seams
- Buckled seams
- Cable cuts
- Rust
- Missing label
- Other (any other major defect that may compromise the integrity or usability of the container)

CONDITION OF CONTAINER EXAMINATION 2 (COCE2 TABLE)

Defect Criteria for Flexible Pouches and Plastic Trays and Cups - Thermally Processed Commercially Sterile Containers (Refer to FSIS Directive 9900.2, Tables 2A and 2C; p. 15)

Abnormal Containers (Critical Defects)

- Swollen package
- Leaker
- Non-bonding
- Cuts
- Fracture
- Notch leaker
- Hole/puncture
- Channel leaker
- Other (any other critical defect that compromises the hermetic seal of the container or shows evidence of possible spoilage of contents)

Defective Containers (Non-critical (Major) Defects)

- Abrasion/scratch

- Blister
- Compressed seal
- Contaminated seal
- Delamination
- Rooked, short, or misaligned seal
- Seal creep
- Burning
- Wrinkle
- Crushed package
- Uneven impression
- Other (any other major defect that may compromise the integrity or usability of the container)

Metal Container Examination

- Examine the label (if paper) for stains that may be evidence of leakage or rust.
- Apply slight end pressure on one end and observe for movement of the other end.
- Repeat on the other end.
- Use fingernail along all double seams to detect sharp seams.
- Visually examine the double seams or seams, the side seam, and any container score lines on easy-open and pull-top containers for defects or leakage.
- Check whether the container has a foreign establishment number embossed or lithographed on the container (9 CFR 327.14 (b)(2)).
- Check for production code on container (9 CFR 318/381.301(e)).
- Check any embossing impressions on container for metal fracture or stress.

Glass Container Examination

- Examine jar surfaces for obvious defects or crooked cap.
- Examine the exterior of the jar closure for food particles or foreign materials.
- Place slight pressure on the center of the cap and observe any movement that may be an indicator of a swell, loose cap, or short vacuum.
- Check the safety button, if present, on the cap.
- Check for production code on container (9 CFR 318/381.301(e)).

Pouches/Plastic Trays/Cups Examination

- Examine all surface areas for defects.
- Examine the edges of each seal for any evidence of product in the seal area.
- Test for seal creep by grasping the unsealed area of the container and exerting a steady pressure.
- If retorted, check whether the container is marked with a permanent, legible code (9 CFR 318/381.301(e)) for product, day, and year packed.

Abnormal Container TOI

When critical defects are identified when performing the COC TOI, these defects by default imply the containers are abnormal based on visual inspection. Laboratory analysis is needed to confirm that the containers in question are technically abnormal.

You will enter the results into PHIS and fail the COC TOI, then notify the establishment. However, at this step, you will *not* send the refused entry notification to the applicant, since laboratory analysis—which can take several weeks—will be required to yield a final determination.

FSIS Directive 7530.1 provides instructions on coordinating and performing sampling with the Western Laboratory (when recommended). Scheduling the Abnormal Container TOI in PHIS will generate the option to schedule a laboratory sample. Place the lot on hold, submit the sample according to instructions in the directive, and await laboratory analysis and a final recommendation by a subject matter export (SME) from the Policy Development Staff (PDS). Abnormal container samples shipped to the laboratory should be kept under refrigeration *but never frozen*.

Alternatively, after contacting the laboratory, they may instruct you to perform incubation at the import establishment (more on this later).

A third possibility is that the laboratory may not recommend sampling if the cause of the abnormal container is already clear. In this case, contact PDS directly for guidance.

<u>Possible Outcomes</u>

- Laboratory confirms abnormal container
  - Refuse entry of the lot without sorting
  - COC TOI fails at this step because the foreign establishment's canning process was inadequate
- After review, PDS reclassifies the defect observed by the inspector
  - Will be reclassified as "Critical" or "Major" defect
  - Not considered an "Abnormal Container"
  - Will either recommend sorting and Tightened COC TOI, or to release the lot

<u>Sample Collection Guidance</u>

If abnormal containers are observed and/or seam defects are evident, sample collection may be indicated.

- Refer to 9 CFR 327.6(j), 381.199(b) and (d)
- FSIS Directive 7530.1, *Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product* gives instructions on

coordinating sampling with the FSIS Western Laboratory, completing appropriate forms, and follow-up procedures
- Hard/soft swells shipped refrigerated (not frozen)
- Lab normally requests collection of both normal and abnormal cans
- Contact supervisor for directions if sample collection is not feasible
- Severely dented cans and rusted cans:
    - Collect representative number of each type of dent
    - Collect cans representing different degrees of rusting (check for pitting)—if pitting is found, take a sharp piece of metal and see if it can be easily penetrated or scrape off rust to see if it is pitted.

Sample Collection Report

- Sample collection report should indicate reason for sampling and analysis needed
- Number of cans in the lot
- Total number of containers examined
- Number of each type of abnormality noted（correlate with sub-samples (lab must confirm investigator's observations), as swollen cans can change over time.
- FSIS Directive 7530.1 identifies the collection forms to complete
- Number and location of each type of defect noted
- Location in lot where sampled (correlate with can codes if mixed)
- Sub-identification example:
    - Sub 1 - soft swell from pallet 1, case 1
    - Sub 2 - normal container from pallet 1, case 1
    - Sub 3 - hard swell from pallet 2, case 5

        - **Note:** Do not place identification on the code or label. Place off-center on code end or non-code end. Lab must open can from non-code end. Explain can coding system. It may be different for different container types, and it may be different for different customers. Explain all parts of the code. Lab needs to analyze cans, swells, abnormal and defective cans from all production days sampled. Sample at least 2 cans of each type of defect.

Incubation of Hermetically Sealed Containers

PHIS no longer schedules routine Incubation TOIs; however, you may be directed to perform in-house incubation by the Western Laboratory or PDS. IPP are to verify that official import establishments that receive thermally processed commercially sterile containers can provide an incubator (they must do so if such products are listed on their grant of inspection).

> **Note:** In actuality, neither PDS nor the Western Laboratory have been recommending in-house incubation in recent years. Generally, if they believe a potential abnormal container requires an incubation protocol, they will request that you send samples to the laboratory.

If in-house incubation is recommended, add an unscheduled Incubation TOI and select the appropriate number of containers for incubation as recommended by PDS. FSIS Directive 9900.2, Table SP8A, p. 16, is the sampling plan for when PHIS assigns the Incubation TOI.

Incubation Sample Selection & Documentation

- Randomly select 48 normally appearing containers from the lot. 24 of the sample units are used as the initial sample, and 24 are kept under FSIS control as the reserve sample.
- Randomly select the incubation samples, when applicable, from those samples selected for a COC examination.
- Incubation samples may be selected during or after the COC examination.
- Follow the incubation time and temperature requirements identified in 9 CFR 318.309.
- Use FSIS Form 9550-1, *Incubation Log*, to document incubation start time, monitoring dates, and finish time and results.
- Maintain all recording charts used during the incubation.

Incubation Procedures

- Verify that the containers are placed in the incubator in an acceptable manner.
- Verify that the incubator and the recording charts are under FSIS control.
- Check the sample containers in the incubator for abnormalities at least twice during the incubation period and at the completion of the incubation.
- Check the high and low thermometer inside the incubator and the recording chart daily, if practical, but at least twice during the 10-day (240 hours) period verifying the incubator temperature has not exceeded 100°F or gone below 90°F.
- Inspect the containers for abnormal containers using the appropriate criteria (Table COCE1 or COCE2).
- If abnormal containers are identified during or at the end of the incubation period, have the containers removed and allow them to cool to room temperature for 24 hours under FSIS control.
- After 24 hours, re-examine. If the containers still exhibit abnormal container characteristics, select “Fail” as the Incubation TOI result in the PHIS and describe the container defects in the Remarks box. A follow-up Abnormal Container Laboratory TOI is assigned in PHIS, and IPP are to collect and submit containers to the lab per FSIS Directive 7530.1.
- Disposition of the lot is determined when the lab results are forwarded to the FSIS subject matter expert (SME) who will interpret the results and ensure that the result is entered in the PHIS.
- Take the action indicated by the SME.
- See Table B and C of FSIS Directive 9900.2 Results (“Pass” or “Fail” Criteria). These are based on Defect Identification During Physical Inspection, for direction on whether a lot is sortable, and for “Pass” or” Fail” criteria if the lot is sorted.

Refused Entry
FSIS Directive 9900.8

Background

Imported meat, poultry, and egg products, that do not comply with U.S requirements are not allowed to enter U.S. commerce and are to be identified as "United States Refused Entry." Products that may be identified as "Refused Entry" include those that are:

- Not eligible for importation into the U.S.
- Eligible for importation into the U.S. but in a condition that causes them to be refused entry

Ineligible Product - Products are to be refused entry when:

- The source or producing country is not eligible to export to the U.S.
- The source, processing/preparing establishment is not certified to export to the U.S.
- The product is ineligible under FSIS or APHIS regulations.
- Production date shows that the product was sourced or produced when the producing or exporting establishment or country was not eligible to export to the U.S.
- Product is derived from a species that the exporting or source country is not eligible to export to the U.S.
- Product (PCPCPG) is not eligible for export to the U.S.
- Foreign inspection certificate is incorrect or invalid.

Failed TOI - Lots may be failed for one or more of the following:

- Certification
- Label Verification
- Physical Examinations
- Laboratory Analysis

Failed Certification TOI

- The Certification TOI may fail if it does not meet all the requirements in Part IV of FSIS Directive 9900.1, which covers what an inspection certificate must contain.
- Part VII A of FSIS Directive 9900.8 details the timeframes for the disposition of the product.
- Regulatory citations which cover a failed Certification TOI include 9 CFR 327.13(a)(2) for red meat, 381.202(a)(2) for poultry, and 590.945(a) for eggs.

Failed Physical Exam TOI - Eligible lots of meat, poultry, and egg products that are re-inspected may be refused entry for failure of the following TOIs which are addressed in FSIS Directives 9900.1, 9900.2, and 9900.7:

- Physical Examinations (Product Exam, COCE)
- Net weight
- Condition of Container Examination (COCE)
- Pink Juice Test (PJT)

Failed Laboratory TOI

- Food Chemistry (e.g., added water, nitrite, total fat) (no longer performed on a regular basis)
- Pathogen Sampling (*E. coli* O157:H7/STECs, *Salmonella*, *Listeria monocytogenes*)
- Pathology (pathology, species, CNS)
- Residue (pesticides, metals)

A failed laboratory analysis TOI will not automatically initiate a refused entry in PHIS for the lot; this must be manually initiated by the inspector. You must select the appropriate reason for the failure.

Partial Lot Refusals

When a portion of a lot of product presented for reinspection is noncompliant with FSIS requirements, the noncompliant units may be sorted and removed from the lot before continuing with the reinspection. The most common reasons for partial refused entries are that shipments include:

- Transportation damage (product exposed)
- Spoilage or off-condition of product
- Missing shipping marks
- Illegible shipping marks

If the applicant or import establishment personnel decline to sort the lot, the entire lot will fail and be refused entry.

Ineligible Product - When a lot is submitted in PHIS and is deemed to be ineligible product:

- Review the accuracy of the data entry in PHIS.
- If data entry errors are found, but the certificate is accurate, correct the application in PHIS.
- If no data entry errors are found, submit the application as ineligible, then:
  - Retrieve the application in PHIS
  - Access the Lot Manager page for the lot
  - Receive the Lot (if lot has restrictions, one or more error messages will appear, and only “Receive Lot” appears in the lot event log; “Draw Assignments” will not be available). Example:

- Click the “Refused Entry” button in Lot Manager.
- Click “Add New Reason” and select reason from dropdown menu.

- Select most appropriate defect and save.
- Send notification to applicant (click “Send to Applicant” button).

Failed TOI

- Products that fail a TOI for any of the reasons are to be identified as “United States Refused Entry” product.
- Access PHIS and enter defects/comments as applicable.
- Enter all data concerning a lot that fails a TOI in PHIS following the completion of the reinspection.
- If PHIS is not accessible, enter the data as soon as PHIS is accessible.

Transportation Damage or Missing/Illegible Shipping Marks

- Identify the noncompliant product and have the official import establishment sort and remove the noncompliant product from the lot before continuing with reinspection.
- If the official import establishment refuses to sort the lot, refuse the entire lot.
- Control the sorted product until it is marked “United States Refused Entry” or brought into compliance.
- Record all data concerning partially refused entries in PHIS as soon as possible following completion of reinspection.

Refused Entry Procedures

- Ensure that the refused entry product is stamped “United States Refused Entry” and verified while at the import facility.
- Notify import establishment management of each refused entry.
- Verify that the application of the refused entry stamp occurs in a designated staging area
  - When livestock carcass shipments or tankers from Canada are labeled with a placard, the placard, not the product or the conveyance, is to be stamped “United States Refused Entry.”
- Maintain control of the “United States Refused Entry” stamp at all times.
- Keep an accurate count of the number of units stamped for each refused entry occurrence.
- Send notification through PHIS to the applicant of refused entry of the lot.
- Print and submit copy of FSIS Form 9840-3 to CBP at the local Port of Entry.
- Notify APHIS and when a lot or any portion of a lot from an APHIS restricted country fails an animal health-related TOI (e.g., Pink Juice Test) or other APHIS requirement.
- Stamp the paper foreign inspection certificate with the “U.S. Refused Entry Amount” and record the amount of refused entry in units and pounds in the blank area of the stamp.
- Retain paper foreign inspection certificates in the FSIS in-plant files by country and calendar year.
- Verify that there is proper disposition of product designated as “refused entry.”
- When final product disposition of the refused entry occurs, access PHIS, enter the disposition status of the product.

- All TOIs and all refused entry dispositions must be complete before lot can be completed in PHIS.
- PHIS will warn of any TOIs that were not complete.

IMPORTANT NOTE: Do not mark units with the "United States Refused Entry" stamp until you are *100 percent certain* the deficiency either cannot or will not be rectified by the applicant. Remember that certificates can generally be replaced when errors or omissions are found, and most label features (*except* shipping marks, foreign inspection legends, and foreign establishment numbers) can be replaced or corrected at the l-house. In these situations, obtain the applicant's intent before proceeding with marking, because once the refused entry mark is applied, the applicant must dispose of the product.

Storage of Refused Entry Product

- Verify that refused entry product is stored and segregated from other product at the official import inspection establishment until final disposition occurs, or permission to move the shipment is granted by the District Office.
- Approximately once per month, schedule the **Import Refused Entry Verification** task on the PHIS task calendar, and document that you have located and accounted for any refused entry product being held on-site at the time.
- Record verification of monitoring on Lot Manager Screen (Lot Tracking function, Verified Refused Entry).
- If product cannot be located, contact establishment management for location.

Unauthorized Movement - Until you have authorized movement of refused entry product for export or other disposition, such product must be held on-site at the import establishment. Unauthorized movement of refused entry product violates 9 CFR 500.3(a)(5).

- Withhold the marks of inspection for imported products.
- Notify the FLS.
- Notify import establishment management and issue an NR citing 9 CFR 500.3(a)(5)
- Provide a copy of the NR to the establishment and inform inspection supervision of the NR.
- Await instruction through supervisory channels.

Time Period for Disposition - After notice is given by FSIS to the Director of Customs at the original port of entry, the owner or consignee must take action on the product that is refused entry as required by 9 CFR 327.13(a)(2), 381.202(a)(2), or 590.945(a)).

- **45 calendar days** for meat, poultry, and egg products.
- If final disposition of the refused entry product has not been accomplished within the regulatory timeframe, take control of refused entry product using FSIS Form 6502-1 (U.S. Rejected/Retained tag).
- Notify DO by phone or e-mail (through supervisory channels).
- Follow instructions provided by DO to ensure that proper disposition of the product occurs.

Methods of Disposition

- Returning the product to the originating country or to a third country (export)
- Destroying the product via landfill, rendering, incineration, denaturing the product
- Converting the product to animal food (requires FDA approval)
- Rectification (certification or labeling errors/omissions)

The applicant should notify IPP (through establishment management) of their intended disposition in a timely manner, at which time IPP will document the intended disposition in PHIS and will observe and verify the disposition.

Export of Refused Entry Product Procedures (General)

- Access PHIS and document that the applicant has requested re-export.
- The applicant will make arrangements for export and request approval from the DO.
- Once you are notified of approval, select the "Released to Port Date" in PHIS and Save.
- Notify import establishment management that the lot may be moved for export
- Receive required "proof of export" documentation from the importer or consignee through DO.
- Attach proof of export documentation to appropriate case file.
- Access PHIS and check "Disposition Complete" for lot disposition.
- Re-export requests for Canadian product (returning to Canada) can be made directly to the Import Inspector. For other countries, request is made to DO.
- FSIS Directive 9900.8 includes additional requirements for:

    - Exporting of Canadian refused entry product back to Canada
    - Exportation from a port other than the original port-of-entry (requires FSIS HQ approval)
    - Refused entry product transiting *through* Canada to a third country

Exportation of Canadian Refused Entry Product back to Canada - Additional steps are required.

- Applicant completes and print FSIS Forms 9135-1 and 9840-3
- Copy inspection certificate
- Place forms in sealed envelope "Attention: CFIA"
- Place prominently in rear of shipping conveyance
- Seal conveyance with USDA Foreign Meat Seal (red ball seal)
- Notify appropriate CFIA contact by e-mail with cc to FLS

Refused Entry Product Transiting *Through* Canada to a Third Country

- Perform general export of refused entry product procedures (see above)
- Verify conveyance is sealed with USDA Foreign Meat (red ball) seal at the import establishment
- Enter the seal number in PHIS
- Email FLS/DO the following information:

- Name of trucking company
- License # of truck/trailer
- Container number
- Red ball seal number

Destruction

- In PHIS, enter destruction as method of intended disposition
- Verify that the product is eligible for destruction (APHIS may have restrictions)
- Observe the destruction (record during voluntary reimbursable time)
- Access PHIS and complete the disposition, or await documentation that product has been disposed of at a landfill or rendering facility
- Note that for animal disease-related issues, APHIS may specify a method and timeframe for destruction

Conversion to Animal Food

- Receive from IOR or agent written approval from FDA authorizing movement to animal food manufacturer
- If acceptable, enter the intended disposition in PHIS, check the FDA approval box, enter the released for conversion date, and Save
- Inform management that product may be moved
- Review records to verify product was received and converted to animal food within 45 days
- Verify forms certifying conversion are complete
- In PHIS, enter the disposition as complete

Note that this method of disposition is infrequently used.

Rectification

Recall that certificates with errors or omissions may be replaced by the applicant, and that most missing or inaccurate labeling features may be corrected at the import establishment, with the exception of:

- Completely missing or illegible shipping marks
- Foreign inspection legends
- Foreign establishment numbers

If the applicant intends to rectify the failed TOI, document their intent in PHIS and await a replacement certificate and/or verify that the labeling corrections have been made before releasing the product.

Voluntary Reimbursable Time

All activities that IPP perform related to verifying the disposition of product should be coded as voluntary reimbursable time (either 01 time during regular operating hours, or overtime code when performed after hours). Such activities might include:

- Observing denaturing or tanking of refused entry product for destruction
- Reviewing documentation stating that product has been dumped, rendered, or otherwise destroyed
- Observing loading and sealing of conveyances when product is to be re-exported
- Reviewing proof of export documentation
- Reviewing FDA approval of movement of product for conversion to animal food

Appeals

As with any failed TOI, any refused entry may be appealed by the IOR (the import establishment may not make such appeals, since they do not own the product). When IPP refuse entry of imported product, the IOR will appeal first to the FLS, and, if denied, the appeal will proceed up the OFO chain of command to the Administrator level.

Pre-stamping
FSIS Directive 9900.3

Pre-stamping

Import inspection establishments may stamp the official inspection legend on imported meat and poultry products before the completion of official import reinspection. However, the establishments must have a pre-stamping procedure approved by the District Manager (DM).

In accordance with procedures approved by the District Manager, an import establishment may apply the official inspection legend on imported meat and poultry products for which the physical reinspection will be completed before the completion of official import reinspection on the same day.

Canadian product is not eligible for pre-stamping, since the mark of inspection is not applied.

Procedure Approval Process

- The import establishment submits the procedures to FLS.
- The FLS reviews and verifies the procedures meet the requirements.
- The FLS submits the procedures and recommendation to approve to the District Manager (DM).
- The DM reviews the procedure and FLS recommendation and, if approved, prepares, signs, and transmits a letter to the inspector to be given to the establishment.

    - Requirements are in 9 CFR 327.10(d), 381.204(f), 557.10, and 590.940(e).
    - The DO is to retain a copy of the letter and the pre-stamping procedure and send a copy of the approval letter and approved procedure to the Import Inspector.
    - If the procedure is not approved, the FLS is to coordinate with the requesting official at the import establishment to address any outstanding issues.

- Limits pre-stamping to lots that can be reinspected the same day.
- Provides that lots subject to Intensified LOR will not be pre-stamped.

    - Lots at Intensified LOR are on FSIS hold and not eligible for pre-stamping or off-site storage.

- Provides that product will not be pre-stamped until after the FSIS inspector verifies the product condition, count, documentation, and labels.
- Lists the name of the official ensuring compliance with the pre-stamping procedure.
- Provides all pre-stamped product remains on the official premises of the I-house until the physical reinspection is completed.
- Includes a control procedure for removing or obliterating the official inspection legend from pre-stamped lots that fail reinspection.
- Describes how the import establishment will maintain a daily pre-stamping log.

- Includes storage of lots during incubation and lots requiring “second-step” reinspection.
- Recall that pending receipt of lab results for adulterants, the IOR may hold/control product off-site if it is at Normal LOR or at Increased LOR without instructions to hold (i.e., sample is not “for cause”). If adulterated, the IOR must return the product, and the stamp must be removed/obliterated.

Pre-stamping Log Requirements

- Date the lot was pre-stamped/reinspected
- Country of origin
- Foreign establishment number
- Name of product
- Number of units
- Shipping mark
- Certificate number
- PHIS application and lot number
- A procedure for retaining the log per 9 CFR 320.3 and making it available to Import Inspectors daily, if requested

Establishment Profile - Upon approval, activate the General Labeling (Pre-Stamp)(Import) task in the Establishment Profile.

PHIS Task List - 1/month, Priority 6 task

General Labeling (Pre-Stamp)(Import) Task

- Verify the import establishment performs and monitors pre-stamping in accordance with the approved procedure.
- Verify the import establishment maintains their pre-stamping log.
- Record verification results in PHIS.
- Observe the mark of inspection being applied to imported products. Observe the cartons for legible and complete stamps. Look for any cartons that may have been missed.
- Verify that the pre-stamping log is being properly maintained by comparing the completed shipment documents to the shipments entered in the log. After the lots have been presented for the day, the establishment should make the log available to the inspector.

Noncompliance - When the import establishment fails to comply with the approved procedures, there is noncompliance with 9 CFR 327.10(d), 381.204(f)(2), 557.10, or 590.940(e):

- Retain any affected product and require correction of the noncompliance
- Document the noncompliance in PHIS and issue the NR
- Pre-stamping privileges may be cancelled orally or in writing after consultation with the FLS
- Examples of noncompliance:

- The establishment fails to maintain pre-stamping records accordingly
- The establishment pre-stamps ineligible product; or
- The stamps are improperly applied to containers (over other markings, illegible)

Appeals

Import establishment management can appeal NRs and regulatory control actions.
If appealed, refer to FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, Chapter VI, II, F. Follow through with the appeals process in PHIS.

Importing Fish of the Order Siluriformes
FSIS Directive 14,950.1

FSIS began reinspecting all Siluriformes fish and fish products imported into the U.S. on August 2, 2017. The regulations governing importation of Siluriformes are found in 9 CFR part 557. Currently, only 3 countries are eligible to export these products to the United States:

Country	Product Type(s)
Vietnam	• Raw-Intact • Raw-Not Intact • Heat Treated/Not Fully Cooked/Not Shelf Stable
Thailand	• Raw-Intact • Raw-Not Intact
China	• Raw-Intact • Raw-Not Intact

IPP can find instructions for reinspection of Siluriformes products in FSIS Directive 14,950.1; however, note that the procedures are largely similar for those involving imported meat, poultry, and egg products, and you will refer to the relevant 9900 series directives for most steps in the process.

Applications - Refer to FSIS Directive 9900.4.

Shipment Presentation, Certification, and Failure to Present (FTP) - Refer to FSIS Directive 9900.1

Label Verification - Refer to FSIS Directive 9900.5.

Note that the fish which are appropriately termed “catfish” are specifically those belonging to the Family Ictaluridae; however, the Order Siluriformes includes a number of other fish species as well. FSIS Directive 14,000.1 includes guidance on speciation and acceptable common or usual names for Siluriformes.

Net Weight Verification - Refer to FSIS Directive 9900.2.

Instructions on verifying that scales used by the import establishment comply with the regulations, the tare weight is determined using NIST Handbook 133, along with determining sample size and calculating Maximum Allowable Variation (MAV).

Condition of Container Examination (COCE) - Not applicable; there are currently no thermally processed-commercially sterile Siluriformes products eligible for import.

Pre-stamping - Refer to FSIS Directive 9900.3.

Laboratory Sampling - Refer to FSIS Directive 9900.6.

Selected lots of Siluriformes products will be assigned the chemistry sampling TOI (IMPFISH_CH). A certain percentage of samples will also be analyzed for species testing (products labeled “catfish” that do not contain fish of the Family Ictaluridae are considered misbranded).

IPP are to collect 1-lb. samples, in the final packaging, whenever possible.

Note that Siluriformes sampling can only be performed on single-ingredient products.

Refused Entry - Refer to FSIS Directive 9900.8.

Product Examination (PE) - Refer to FSIS Directive 9900.2.

IPP conduct the Product Examination TOI to identify defects such as:

- Filth
- Mold
- Extraneous materials (wood, glass, plastic, chemicals, insects, etc.)
- Stains
- Off-condition

When identified, defects will be classified into one of two categories:

- Public Health (PH) defects
- Other Consumer Protection (OCP) defects

In selecting sample units for PE TOI, Siluriformes products are categorized as follows. Refer to Table 1 in FSIS Directive 14,950.1:

- Category 1 - Single-ingredient fresh or frozen
  - Raw fish
  - Further processed fish
- Category 2 - Multi-ingredient fresh or frozen
  - Raw fish (including fish with added solutions)
  - Further processed fish

Selection of samples should be based on a random, unbiased selection process. IPP should also take care to maintain sample security and integrity (ensure selected samples are stamped “U.S.D.A. Official Import Sample” and have a system to ensure that examined product remains associated with its original shipping carton).

<u>PE TOI Procedures</u>:

- Tempering

  Samples are to be tempered in a rapid and efficient manner *only* to a point that allows for examination of outside surface of the product. This includes having the outer or cut

surfaces free of ice (defrosted) for visual inspection. Fish products are very sensitive to heat, so tempering at too high a temperature can easily change the color and odor of the product. Place the samples in water-tight food-safe plastic bags and either immerse them in room temperature water or hold them under running room temperature water until just tempered.

- Examination

  Begin the examination immediately after tempering—and before any other assigned TOIs—as fish can quickly spoil or become off-condition at room temperature.

  Note: Do not use samples selected for PE for laboratory samples. If a laboratory sample TOI is assigned, draw that sample separately.

  - First, examine the external surfaces of the fish, and document any defects found. Refer to **FSIS Directive 14,950.1, Chapter III, Section VII** for *specific* instructions on examination procedures, which will vary based on the specific type of product being examined (e.g., whole fish, whole un-gutted fish, fillets, loins, bulk frozen, breaded, etc.).

  - Second, break the surface and smell for any putrid or foul odors (off-condition). You may need to break the surface in more than one location to confirm your finding. If off-condition odors are detected, be sure to change your gloves and/or wash your hands to avoid cross-contamination with other samples. Note that off-condition odor may be harder to detect in frozen product, so some additional thawing time may be needed.

Examined portion	Product type(s)
External and cut surfaces	• All fish
Internal surfaces	• Steaks, loins, chunks, filets, strips • Fish blocks • Breaded fish (make lengthwise cut)
Body cavity	• Whole, gutted fish
Off-condition	• All fish

  - Samples used for the examination from passed lots are to be discarded in an inedible container, unless defects are identified. The remainder of the fish from the sample container not selected for the examination is to be returned to the lot.

- Classification of Defects

  - Remove defects from the sample units.
  - In PHIS, select defect classification Physical Examination 3 (PE3).
  - Only classify the “TYPE” of defect using the criteria in Attachment 1 of FSIS Directive 14,950.1 (“Product Examination 3 (PE3)(Modified for Siluriformes Fish)”).
  - If the lot has passed, discard the defects into an inedible container.

- If the lot has failed the TOI based upon the classification of the defects (more on this shortly), keep the defects under FSIS control under refrigeration or freezing until final disposition of the lot. The District Office may request defects be held for training or correlation purposes. Off-condition fish should be frozen, so as to be effectively used (after thawing) for training or correlation purposes.

- Recording Results ("Pass" or "Fail" Criteria)

  - Public Health (PH) defects – If one or more PH defects are found, record the defects by type and describe them in detail (size, color, dimension, texture, smell (if applicable), other characteristics) in the free text section. Fail the TOI and refuse entry of the lot. It is important to be accurate, because your description of the defect(s) resulting in the failed TOI is what is going to be conveyed to the foreign government.

  - Other Consumer Protection (OCP) defects – Identification of OCP defects will not necessarily result in a failed TOI and refused entry of the lot. IPP should consider the following criteria when making a pass/fail determination for OCP defects:

    - Does the number, type, and/or size of defects affect the **safety** of the product?
    - Are defects severe or numerous enough to affect the **usability** of the product?
    - If limited to one sample unit, after that carton and/or the defect itself is condemned, is there **any additional evidence that the remainder of the lot is adulterated or misbranded?** If not, safety and usability would not be affected once the defect and/or its carton are condemned.

    If IPP are uncertain as to whether they should pass or fail a lot for OCP defects, they should consult with the FLS, and they should obtain the concurrence of the FLS if deciding to fail the lot.

    IPP should also consider, based on their visual observations, if a defect is an isolated occurrence or if it appears to be widespread throughout the samples examined), and if the defect results in misbranded product or product that cannot be further processed or consumed.

Importation of Products for Other Than Commercial Purposes
FSIS Directive 9500.8

FSIS has reinspection authority over amenable species (cattle, swine, sheep, goats, Siluriformes fish, and poultry, as well as egg products) and products derived from them, though eligibility to import is determined on a country-by-country basis. However, there are two classes of products that are exempt from FSIS reinspection:

(1) Products for personal consumption – Small quantities of meat, poultry, or egg products (not to exceed 50 lbs. each) of any product may be imported for personal use but cannot be sold or otherwise distributed in commerce. Such products may still be subject to restrictions imposed by the Animal and Plant Health Inspection Service (APHIS) or by Customs and Border Protection (CBP).

(2) Product samples for laboratory analysis, research, or evaluative testing or samples for trade show exhibition – FSIS must be notified prior to the importation of these samples but does not have to reinspect them. Products imported for these purposes must be accompanied by FSIS Form 9540-5, which is reviewed by RMTAS. If RMTAS has concerns about the intended purpose of the product, they may refer the case to OIEA for further investigation. This class does not include product samples for consumer test marketing or sales promotions.

Additionally, under the North Atlantic Treaty Organization (NATO) Agreement, products from NATO member countries may be imported to be used in foreign government commissaries (for example, an embassy kitchen) located within the U.S. These products are also not subject to FSIS reinspection.

Animal Disease Restrictions

Remember that we share responsibility for import reinspection with CBP and APHIS. When APHIS has placed an animal disease restriction on specific products from specific countries (for example, cooked meat from a country affected by FMD, which must normally undergo the Pink Juice Test TOI), such product must be accompanied by a VS import permit that is first presented to CBP at the port-of-entry. This applies even if it is a small consignment imported for personal use. If no permit is provided, CBP and APHIS will likely direct that the consignment be treated as a commercial shipment and sent to an I-house for FSIS reinspection.

Contingency Plan
FSIS Directive 9500.1

Your duties as an Import Inspector are heavily dependent upon access to a functional PHIS. Data must be entered in a timely manner so as not to interrupt commerce. PHIS is essential for tracking shipments, reviewing electronic applications and certificates, receiving reinspection assignments, collecting and submitting samples, and communicating information with brokers, importers, and other government agencies.

Definition of "Assignment"

In import reinspection, the term "assignment" refers to the types of inspection (TOIs) assigned to any given lot of import meat, poultry, or egg products. Of course, the assignment for every lot will include Certification and Label Verification TOIs, but some lots will have additional TOIs assigned (e.g., Product Exam, laboratory sample, etc.).

Review of Levels of Reinspection (LOR)

The LOR is determined based on the compliance history of each foreign establishment (and country) for a specific product (PCPCPG) and TOI. For example, if a lot of raw pork sausage from establishment S-43 in Hungary fails a Product Exam TOI, the LOR will go to intensified *only* for raw pork sausage from establishment S-43.

It is important to understand the LORs, because during contingency plan—when PHIS is not available to issue lot assignments—IPP will have to determine the frequency at which additional (non-Certification or Label Verification) TOIs must be performed.

- Normal LOR - TOIs are assigned at a pre-determined frequency based on FSIS's annual sampling plan. FSIS only requires that the IOR maintain control of the product (either on-site or off-site) pending certain lab results (i.e., testing for adulterants).

- Increased LOR - This is based on FSIS management decisions. TOIs will be assigned at some frequency above the Normal LOR frequency. Depending on FSIS guidance, either IPP may be directed to hold product pending lab results, *or* the IOR will be responsible for holding the product, pending tests for adulterants.

- Intensified LOR - This is the LOR that is *automatically* assigned when a lot fails a TOI. It applies exclusively to the producing foreign country/establishment, product type (PCPCPG), and TOI that failed, and it remains in effect until either 10 consecutive lots or 10 times the weight of the initial lot pass the same TOI (for OCP defects), or 15 consecutive lots or 15 times the weight of the initial lot pass the same TOI (for PH defects). FSIS is responsible for holding lots, pending tests for adulterants.

Information Required During PHIS Outage

When operating under a PHIS outage (either locally or nationwide), there is certain information IPP will need to acquire in order to properly "assign themselves" reinspection TOIs. These can be accessed from the Import Operations SharePoint Site and from the FSIS website:

(1) List of foreign countries and establishments eligible to export to the U.S.
(2) List of foreign countries and establishments currently on increase LOR.
(3) List of foreign countries and establishments currently on intensified LOR.
(4) APHIS animal disease restrictions table – this will indicate, for example, whether IPP are to perform a Pink Juice Test on certain lots.
(5) Foreign Country Contingency Sampling Table – This table is essential because it dictates how frequently IPP will perform certain TOIs (not Cert or LV) based on the country, establishment, and current LOR for that PCPCPG and TOI).
(6) List of U.S. import facilities with contact information – This is especially useful when the PHIS outage is local. The FLS may coordinate for IPP at other import establishments with PHIS access to either perform reinspection (if product can be rerouted) or, at a minimum, document TOI results for you.

PHIS Connectivity

When IPP discover that they do not have PHIS connectivity, their first action should be to contact the FSIS CEC Help Desk to determine the nature of the outage (local or system-wide), and whether it will be short term (e.g., scheduled maintenance) or of extended duration. This will dictate how to proceed.

The next step is to contact the FLS and RMTAS (importinspection@usda.gov) for guidance and assistance, as TOI assignment, reinspection, and documentation will need to continue during the outage.

Throughout the outage, if you are uncertain about the status of a shipment based on the contingency documents available and other documentation provided to you, you should place the shipment on hold and consult the FLS and RMTAS for guidance.

Obtaining Assignments (without local PHIS connectivity)

Without PHIS connectivity, IPP will need alternate means of drawing assignments.

If the outage is due to scheduled maintenance (IPP should note warning emails from OCIO), IPP should draw the assignments in advance, but do not notify the establishment of the TOIs assigned until the shipment is presented.

If the outage is due to unexpected loss of local connectivity, correlate with the FLS and try to get in contact with other import inspectors in the area. They can assist by accessing the lots and finding out the assignments for you. They can also assist by entering results for you after reinspection, if necessary.

Obtaining Assignments (system-wide PHIS outage)

In the event of an unplanned, system-wide outage, IPP are to use printed or saved information to from the Import Operations SharePoint Site and the FSIS website to:

- Verify presented shipments are from an eligible foreign country and establishment
- Determine if the product species bears APHIS animal disease restrictions
- Reinspect according to frequencies in the Contingency Table
- Follow any additional guidance regarding laboratory sampling from FSIS management
- Identify foreign establishments under Increased or Intensified LOR
- Maintain a list of all TOIs performed under the Contingency Plan
- Report results of any TOIs performed under Increased or Intensified LOR, or failed TOIs* to RMTAS as soon as possible

  ***Note:** You do not need to make a special effort to report failed Certification or Label Verification TOIs under contingency plan, because they are performed at 100% frequency on all lots regardless of LOR.

When PHIS Connectivity is Restored…

- Document reinspection results as soon as possible…this must be done regardless of other duties!!

- Enter and submit applications in PHIS and “Receive Lots”/ ”Draw Assignments”

- Enter results for all TOIs performed while PHIS was unavailable (add Unscheduled TOIs)

- For TOIs not performed during Contingency Plan – enter “Contingency Plan” as the reason not performed

Import Operations SharePoint Site

All Import Inspectors in the field will be granted access to the Import Operations SharePoint site. The site contains information that is essential for operating under a contingency plan, as well as a number of other documents and resources the inspector may need to reference on a routine basis. Features of the SharePoint site will be demonstrated during the Import Inspection Training class.

Once an inspector is assigned to cover duties at one or more official import establishments, the Frontline Supervisor should contact RMTAS (importinspection@usda.gov) to request SharePoint access for the inspector.