



FSIS Import Inspection Refresher Student Notebook



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Import Acronyms

ACE	Automated Commercial Environment
AMR	Advance Meat Recovery
AMS	Automated Manifest System <u>or</u> Agriculture Marketing Service
APHIS	Animal & Plant Health Inspection Service
BITES	Biological Information Transfer E-mail System
BMT	Beef Manufacturing Trimmings
BPW	Buffered Peptone Water
BOL	Bill of Lading
CBP	Customs & Border Protection
CCA	Central Competent Authority (foreign meat inspection)
CEN	Custom Entry Number
CFIA	Canadian Food Inspection Agency
COC	Condition of Container
DIS	District Import Specialist (not currently an active position)
EAN	Emergency Action Notification CBP Form
EDA	Estimated Date of Arrival
<i>F</i>Listeria	Follow up <i>Listeria</i>
FMD	Foot and Mouth Disease
FRTE	Follow up RTE
FTP	Failure to Present
HTS	Harmonized Tariff Schedule
IAS	International Audit Staff
IE	Immediate Exportation (bond)
IES	International Equivalence Staff
IOR	Importer of Record
IT	Immediate Transportation
LFTB	Lean Finely Textured Beef
LIMS	Laboratory Information Management System
LOR	Level of Re-inspection
LVP	Label Verification Pallet
MID	Manufacturer ID
MIT	Maximum Internal Temperature
MPR	Moisture/Protein Ratio
MRM	Multi-Residue Method
NVOCC	Non-vessel Operating Common Carrier
OCP	Other Consumer Protection
OIC	Office of International Coordination
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
RP	Rinderpest (currently considered eradicated by OIE)
SME	Subject Matter Expert

SP	Sampling Plan
T&E	Transportation & Exportation (bond)
TID	Temperature Indicating Device
TOI	Type of Inspection
USITC	US International Trade Commission

IMPORTING MEAT, POULTRY, AND EGG PRODUCTS INTO THE UNITED STATES

Food Safety and Inspection Service

- Ensures the nation's supply of meat, poultry and egg products is safe, wholesome, and properly labeled and packaged
- Responsible for public health issues concerning meat, poultry and egg products
- **FSIS home page** www.fsis.usda.gov

Animal and Plant Health Inspection Service (APHIS)

- Responsible for controlling 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
- **APHIS home page** www.aphis.usda.gov/vs/ncie/

Food and Drug Administration

- FDA is responsible for 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
- Certain products containing meat or poultry in small amounts (less than or equal to 3% raw, 2% cooked)
- Reference: 9 CFR 381.15 (poultry)
- Species under voluntary inspection

U.S. Laws and Regulations

- Federal Meat Inspection Act (FMIA)
- Poultry Products Inspection Act (PPIA)
- Egg Product Inspection Act (EPIA)
- Code of Federal Regulations
 - Title 9 Chapter 3
 - *Parts 300-500 (meats)
 - *Parts 362, 381 (poultry)
 - *Parts 590, 592 (egg products)
 - *Parts 530 (Siluriformes)

Terminology

Amenable- "Under the jurisdiction of"

*Poultry exemptions are listed under 9 CFR 381.15. However, the raw ingredients used in these products must still come from an approved or equivalent country.

*It is the importers responsibility to prove that all requirements are being met

*Species under Voluntary Inspection are such as “venison or bison”

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.

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

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

Port of Entry (POE)- Port where the paperwork for an import shipment enters the U.S. and hence, where the goods enter U.S. commerce.

FSIS Equivalence Process

- Any country can apply for eligibility to export meat, poultry, Siluriformes, and/or egg products to the U.S.
- Equivalence evaluations of foreign meat, poultry, and/or egg products regulatory systems are a prerequisite for trade.
 - Not necessarily identical, but FSIS verifies whether foreign meat and poultry food regulatory systems.
- Document Analysis-Focus on six equivalence components: Government oversight, Statutory authority and food safety regulations, Sanitation, HACCP, Chemical Residues, and Microbiological testing program.
- On-site Audits- If the document review process shows the country’s system to be satisfactory, a technical team will visit the country for an on-site review to evaluate the six risk areas as well a other aspects of the inspection system including plant facilities and equipment, laboratories, training programs, and in-plant inspection operations.

Simplified Trade Process

- Manufacturer > Shipper/Exporter > Importer (US)
- 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
 3. CBP releases shipment for FSIS reinspection
 4. PHIS assign reinspection activities
- If passes reinspection, released to Consignee

FSIS Import Reinspection

- * The shipment must be reinspected at an FSIS-approved official import establishment or alternative location.
- * About 65 Import Inspectors carry out reinspection at approximately 113 official import establishments.
- * Unpasteurized egg product shipments must move for reinspection to an FSIS egg products plant.
- * Import Inspection personnel verifies the following:

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

Note: Statements and required elements 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 have electronic access to verify country and establishment eligibility within that country.

- All shipments are reinspected for:
 - (1) Proper certification documentation.
 - (2) Transportation damage.
 - (3) Proper labeling.
 - (4) General condition.
 - (5) Box count

An Establishment receives a shipment and lets the IPP know, they either provide the health certificate and Form 9540 or if it is a country that has e-Certs then the IPP will draw the e-Cert to check on the total count of the shipment. The inspector with the total count 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. With the addition of partial pallets to give the full number of containers that will be presented.

- Outside containers of imported meat, poultry and egg products that pass FSIS reinspection are stamped with the official 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
 - Importers wishing to export refused entry product must apply and obtain permission to do so with OIA Headquarters
- Destroyed, or
- Converted to animal food
 - With approval of the U.S. FDA

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 (TOI) and stores inspection results
 - Links points of entry
 - Captures results for each country
 - Tracks results from each establishment
- Confirms and acts on eligibility and statuses of the country and establishment
- Tracks public health and animal regulations
- Applies different frequencies of reinspection for each type of inspection performed
- Provides the ability to increase/decrease reinspection of products by country or establishment
 1. Performance based
 2. Compliance history of country and establishment

Note: If an ineligible country, establishment, or product is entered, PHIS generates an error message. If the import inspector received an error message, they will forward a screenshot to headquarters RMTAS, DIS. If the import inspector cannot correct the error, they will need to forward the screen shot to the import librarian and cc the FLS.

Type of Inspection (TOI)

- **Physical examinations**
 - Product examinations
 - Net weight verification
 - Condition of container
 - Pink juice test (cooked beef) - Required on all cooked beef shipments from countries that are affected with Food and Mouth Disease (FMD). This examination is an APHIS requirement. FSIS reports all findings of these examinations back to CBP.
- **Laboratory Examinations** – Laboratory results are fed directly into the PHIS from LIMS
 - Microbiological
 - Shiga toxin-producing *E. coli* (STEC) (raw beef)
 - *Listeria monocytogenes* (RTE)
 - *Salmonella* spp. (RTE)
 - *Salmonella/Campylobacter* (raw poultry)
 - Residues (drugs & pesticide)
 - Food Chemistry (no longer routinely tested)
 - Species Identification
 - Pathology

Levels of Reinspection

- **“Normal” Level**
 - Lots are randomly selected for in-depth reinspection according to an annual statistical schedule
 - 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 point of entry (POE) pending receipt of laboratory results. However, the importer may voluntarily hold the product pending results. 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.

- **“Increased” Level**
 - Sample frequency set above the “normal” level of reinspection/sampling
 - Agency management decision rather than from a failed TOI. This is typically due to audits conducted in the foreign country by the International Equivalence Staff which documents deficiencies found in the foreign establishment.

- **“Intensified” Level:**
 - Level of reinspection for a TOI when a lot fails to meet U.S. requirements
 - Held by FSIS at POE pending test results
 - Physical reinspection failures
 - Public Health (PH)-15 subsequent lots
 - Other Consumer Protection (OCP)-10 lots
 - Laboratory TOI
 - Minimum of 15 subsequent lots and 15 times the weight subject to intensified reinspection.
 - 10 consecutive lots from the failed establishment within the foreign country must pass FSIS reinspection, for a product exam failure, before the establishment can go back to the “Normal” status in PHIS.
 - For a “laboratory” failure, 15 consecutive lots must pass FSIS reinspection (at or above the same weight of the failed shipment) in order to go back to a “normal” status.

Frequency of Product Examination

- **Frequency of reinspection based on:**
 - Exporting country
 - Process category, product category and product group
 - Species
 - Country performance
 - POE physical failure factor

Pathogen Testing

Sampling currently conducted for:

1. *E. coli* O157:H7 and STECs – Beef (MT08)
 2. *E. coli* O157:H7 and STECs – Beef (MT51)
 3. *Listeria monocytogenes* & *Salmonella* – all species RTE (IMVRTE)
 4. *Salmonella*/*Campylobacter* – Raw Poultry
 5. *Salmonella* – Raw Siluriformes
- Annual sample target numbers are determined by an average of the number of lots submitted over the previous 24 months
 - The target may be adjusted based on a country's performance

References/Contact information

<http://www.fsis.usda.gov/internationalaffairs>

FSIS Office of Field Operations

Recall Management and Technical Analysis Staff (RMTAS)

importinspection@fsis.usda.gov

IMPORT APPLICATIONS

FSIS Directive 9900.4

Except for an application that IPP create and completely enter manually from a paper FSIS Form 9540-1, all import applications are automatically created by the interface between PHIS and ACE. IPP are to be aware that applicants who do not file the PGA Message Set data electronically with CBP in ACE can continue to submit paper applications to FSIS inspection personnel at an official import inspection establishment. Paper applications must be provided to FSIS at the time the entry is filed in advance of the shipments' presentation at the official import inspection establishment (9 CFR 327.5, 381.198, 590.920, and 557.5). Applicants are not required to file data electronically by means of the PGA Message Set—it is voluntary.

1. **CBP Entry in ACE Without the PGA Message Set from a Non-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 the FSIS Form 9540-1 and the official 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 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, lots will be shown(590.920, and 557.5).

Applicants are not required to file data electronically by means of the PGA Message Set—it is voluntary.

Import Application Data Elements in PHIS

There are five (5) tabs for the import application in PHIS. 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. A red asterisk (*) in the import application in PHIS denotes a required data field.

Country of Origin*, Inspection Certificate Number, U.S. Point of Entry, Reference Number*, US Port of Unlading, Type of Establishment*, Official Establishment*, Estimated Date of Arrival*, Bill of Lading Number, Lot Number, Shipping Mark*, Customs Entry Number* Harmonized Tariff Code: Process Category*: Product Category/Product Group*, Product Code: Product Description Process Category, Product Category and Product Group in the Product Description

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 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.

Establishments can generically approved labels in accordance with 9 CFR 317.5 and 9 CFR 381.133 (e.g. products that meet a standard of identity provided there are no special claims, single ingredients products, etc.).

Labels with printing, lithography, embossing, stickers, seals, or other written matter upon an immediate container (except for inspection legends, foreign establishment numbers on casings, bags, or wrappers must be submitted for approval to FSIS, LPDS (Labeling Program Delivery Service). Sketch labels with special claims about quality, nutrient content, health, negative geographic origin, and animal production must be submitted.

Reference FSIS Directive 9900.5

- Provides instruction for conducting label verification (LV) on imported meat, poultry, and egg products
- Provides instruction for Canadian shipments
- Clarifies verification of nutritional labeling
- Clarifies verification of products for further processing (intended use)
- Addresses documentation in the Public Health Information System (PHIS)

Label Verification - On every lot, IIP 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
- Protective coverings - Coverings that solely protect product against soiling or excessive drying during transportation and storage
- Primal parts
- Carcasses

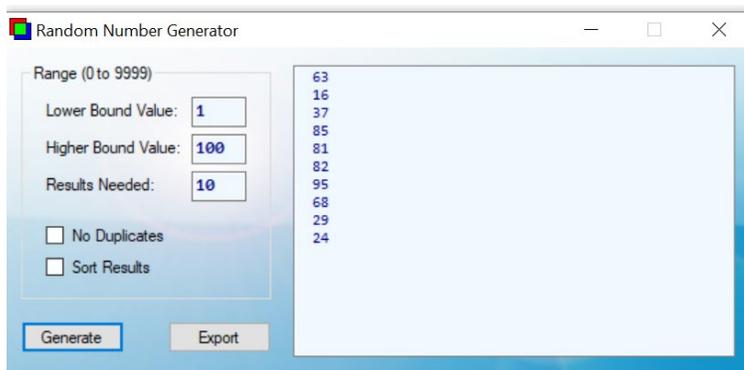
Label Verification of Staged Lots

- Select the number of sample units (pallets, totes, carcasses) from the presented lots using **Table A** below
- Generate random numbers to determine which units in the presented lots are to be identified as the LVP sample units

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

Number of Units in Presented Lot	Sample Units (Number of 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? $5 + 7 = 12$
- Generate random numbers to designate which pallets are to be examined for label verification.



*Random number generator is accessed by going to **Start Menu/Tools/FSIS Applications**.

Shipping Container LV

- Handwritten labels are not acceptable.
- Spanish is allowed if distributed only in Puerto Rico.
- Verify that labels are:
 - Mechanically printed
 - Stenciled
 - Stamped directly on shipping containers, or on a self-destructive adhesive sticker affixed directly to the shipping container
 - Language should be English
- Verified labels should include:
 - Country of origin preceded by “Product of”
 - “Product of” is not required if the name of the country appears in the country’s mark of inspection, or if the shipping container contains fully labeled immediate containers (9 CFR 327.14).
 - Foreign establishment number
 - Name of product
- Name and address of foreign establishment, distributor, or importer (unless on labels of immediate containers, if applicable)
- Shipping mark - A unique mark used to link the product to the foreign inspection certificate
- Special handling statement (“Keep Refrigerated” or “Keep Frozen”)
- Period of ineligibility of country, establishment, or product at the time the application is submitted or when the lot is received
- Space for USDA mark of import inspection (except Canada) on the main display panel
- Production dates when required by PHIS
- Weight of shipment expressed in pounds or, if liquid, in ounces
- Labels must be facing out—the containers must be properly staged where inspector can walk around to examine the labels. The inspector would not document an NR if not properly staged. We simply will not inspect it.
- If any of the required labeling is not on the principle display panel, IPP are *not* to reject the lot. The I-House has the option to show all sides of the shipping container to IPP. Inspectors examine the labels of all cartons on the selected pallets. In addition, Inspectors may need to open one shipping container from one of the selected pallets to verify the labeling of the immediate containers, protective coverings, etc. This carton may need to be moved into the inspection room and opened to prevent contamination of the product.

Immediate Container LV (9 CFR 301.2)

The receptacle or other covering in which any product is directly contained or wholly or partially enclosed. If the product inside the box is not fully labeled, then the outside container (i.e., shipping container) needs to bear all required labeling features or an immediate container including those stated in section B above.

- Immediate container label requirements are in 9 CFR 317.2 and 9 CFR 381.116.
- Verified labels include:
 - Name of product
 - Ingredient statement (if applicable)
 - Foreign establishment number
 - Special handling statements
 - Net quantity of contents (if applicable)
 - Manufacturers' or distributors' name and address
 - Nutritional labeling (if applicable)
 - Name of country (preceded by "Product of")
 - Safe handling instructions (if applicable)
 - *** Some features may not be included because of the type of product (e.g., if the product is fully cooked, it does not need safe handling instructions; if the product is not sold at retail, and it does not bear a nutrient content claim, then it does not need nutrition labeling); or if the product is going to an official establishment for further processing it does not require the safe handling statement.

Canadian Shipment LV

If assigned only Certification and Label Verification TOI, IIP will perform only one shipping unit from each lot. Lots assigned with additional TOIs or that are on increased/intensified LOR are to be staged.

- Perform Label Verification at the rear of open shipping conveyance at the dock of an official establishment
- Do not off load unless you have a concern.
- Import establishment management may rearrange the containers to facilitate the label verification.
- For carcasses, sides, or quarters on a pallet or tote, one unit from each pallet or tote represents a sample unit.
- For hanging carcasses, one side represents a sample unit.

Protective Coverings LV

Verified protective coverings on unprocessed meat products should include:

- Name of country of origin ("Product of" is not required)
- Foreign establishment number
- Optional information is permitted such as company brand names, Trademarks, and/or Code numbers
- Protective coverings do not need to be marked with an official mark of inspection if the product is marked with the official mark of inspection and is clearly visible through the transparent covering.
- If any other mandatory labeling information is on the protective covering, consider it an immediate container and verify it meets the regulatory requirements for an immediate container.

Marked Carcass Parts and Primals LV (9 CFR 316.9(b), 327.14(a), and 327.14(b)(1))

- If shipping containers hold carcass or primal parts, IIP must verify:
 - The container holding the carcass or primal parts meet the labeling requirements of an immediate container.
 - The primal and carcass parts must have the official inspection legend on each part.
- “Product of” on carcasses, primals, or sub primals do not have to be included if the country is identified within the mark of inspection.
- Products requiring inspection legend include red meat carcasses, red meat primals, beef livers, beef tongues, and beef hearts.

Unmarked Primal Parts and Other Products for Further Processing LV

- Movement is allowed to official FSIS establishments for further processing, provided the shipping conveyance (truck) or shipping containers are sealed to prevent tampering or substitution of product.
- Label Verification TOI will fail if the seal is not “tamper resistant” or the final destination is not provided.
- Retain any unmarked carcass or primal that is not sealed, then notify FLS and RMTAD.

Note: All labels and claims or certifications must be evaluated by FSIS and LPDS prior to use. (e.g. “For Cooking Only” or “Not for Grinding”). If there are concerns about qualifiers, claims, grades, or declarations on the lot tracking page, place the lot on hold and contact the District Office.

Egg Product Immediate Containers and Placards on Tankers LV

Immediate containers must include:

- Country of origin
- “Product of” before the Country of origin.
- Plant number where processed/packaged.
- Inspection mark of the country of origin
- Date of production
- Handling statement (e.g. “Keep refrigerated” or “Keep frozen”)

Lot Disposition (FSIS Directive 9900.8 and 9 CFR 327.13(a)(2), 381.202(a)(2), or 590.945(a))

- The entire lot fails if the labeling issue is found on an LVP sample unit. The LV will not fail if a label deficiency is found on a container not selected for LV. However, corrective action is still required.
- Print FSIS Form 9840-3 and mail/fax to CBP at the local Port of Entry.
- Disposition Options: Export (return), Destroy (landfill, render, incinerate, denature); convert to animal food with written FDA approval thru the District Office; Rectified (corrected-e.g. new inspection certificate, re-labeling).
- Per Dir. 9900.8 the intended disposition needs to be communicated in writing to FSIS (9 CFR 327.13(a)(5)). Import Inspectors are to verify that final refused entry product disposition is completed (similar to domestic policy). Import Inspectors are to enter the method of disposition in PHIS and retain the documentation (FSIS Form 9840-4 Voluntary Disposition of Imported Meat and Poultry Products) in the case file.

- If final disposition of the refused entry product has not been accomplished within the regulatory timeframe (45 days, unless otherwise specified), Import Inspectors are to:
 1. Take control of refused entry product using FSIS Form 6502-1,
 2. Notify the DO by phone or e-mail the FLS, and
 3. Follow instructions provided by the DO to ensure that proper disposition of the product occurs.

*****Note: The applicant may appeal or submit written request to correct the labeling to the FLS.**

Labeling Compliance Options (FSIS Directive 9900.8)

- Partial Lot Refused Entries - When Import Inspectors identify that a portion of a lot of product presented for reinspection is non-compliant with FSIS requirements, the non-compliant product can be sorted and removed from the lot before continuing with the reinspection. The most common reasons for partial refused entries are that shipments include immediate containers that have transportation damage, missing shipping marks, or illegible shipping marks.
- When refused entry for transportation damage or missing or illegible shipping marks, identify the non-compliant product and have the official import establishment sort the product and remove the non-compliant product from the lot before continuing with reinspection. Refuse the entire lot if the official import establishment refuses to sort the lot. Control the sorted product until it is marked "United States Refused Entry." Record all data concerning partially refused entries in PHIS as soon as possible following completion of reinspection.
- No handwritten labels - For not properly marked, or label defects on protective coverings, notify RMTAS, who can follow up with the foreign country.

For all options, notify your FLS of the option being proffered (keep the supervisor in the loop).

Shipping Mark Noncompliance (FSIS Directive 9900.8)

- When a portion of the mark is missing or illegible and the remaining identifying characters are the same as the other containers, fail the Label Verification TOI and send the FSIS Form 9840-3 to the importer. The Importer has the option to rectify the shipping mark before the shipment can be released.
- When the entire shipping mark is missing, is completely illegible, or incorrect, fail the Certification TOI and refuse entry. The import establishment must sort and remove the containers from lot. And they must handle the sorted product as per FSIS Directive 9900.8 unless the importer requests to re-apply the shipping mark in writing to the import inspector.

Note: When products are refused entry, the shipping marks must be applied in the presence of the official representative of the foreign government inspection system.

Shipping Mark Corrections (FSIS Directive 9900.5, Rev. 1)

- FSIS will allow authorized import establishment personnel to apply the shipping mark to shipping units that are missing shipping marks or to those that have completely illegible marks if the shipping units have bar codes that tie them back to the certificate. This is in lieu of a CCA representative having to be on-site. The Import Inspector will use supporting documentation from the foreign country to verify the unique identifier within the barcode on the shipping units. Documentation on eligible countries and establishments and the bar code identifiers is on the SharePoint site.

Note: Charge voluntary reimbursable services for supervising remarking.

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” product.
- 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 for export to the U.S.
- Product 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 9900.6.

- Physical Examination
- Net weight
- Condition of container

- Pink juices
- Physical TOI failures will automatically initiate a Refused Entry in PHIS for the lot.

Failed Laboratory TOI

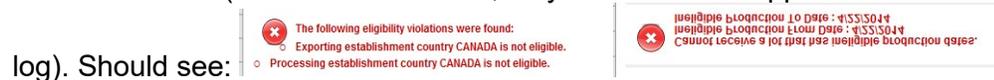
- Food Chemistry (e.g., added water, nitrite, total fat) (no longer performed on a regular basis)
- Pathogen Sampling (*E. coli* O157:H7/STECs, *Salmonella*, *Listeria monocytogenes*)
- Pathology (pathology, species, CNS)
- Residue (pesticides, metals)
- A fail laboratory analysis TOI will not automatically initiate a refused entry in PHIS for the lot. This must be manually initiated by the Import Inspection personnel
- 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, noncompliant product can be sorted and removed from the lot before continuing with the reinspection.
- The most common reasons for partial refused entries are that shipments include:
 - Immediate containers that have transportation damage
 - Missing shipping marks
 - Illegible shipping marks

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, 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, only “Receive Lot” appears in the lot event



log). Should see:

- Click the “Refused Entry” button in Lot Manager.
- Click Add New Reason and select reason from drop down 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 the RIFO when a lot or any portion of a lot from an APHIS restricted country fails an animal health TOI 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.

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.
- Record verification of monitoring on Lot manager Screen (Lot Tracking function, Verified Refused Entry).
- If product cannot be located, contact official establishment management for location.

Unauthorized Movement - Unauthorized movement of refuse entry product violates 9 CFR 500.3(a)(5).

- Withhold inspection of imported products.
- Notify DM or designee.
- Meet with establishment management to discuss this finding and document the meeting in a MOI in PHIS.
- Provide a copy of the MOI to the establishment and inform inspection supervision of the MOI.
- 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 for the product that is refused entry as required by 9 CFR 327.13(a)(2), 381.202(a)(2), or 590.945(a)).

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

Types 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)
- Rectifying

General Export of Refused Entry Product Procedures

- Access PHIS and document that the applicant has requested re-export.
- 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 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 to Canada
 - Exportation from a Port Other than the original Port-of-Entry (requires IID-HQ approval)
 - Refused Entry Product Transiting Through Canada

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

- Complete 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/DO

Refused Entry Product Transiting Through Canada

- Perform General Export of Refused Entry Product Procedures (see above)
- Verify conveyance is sealed with USDA Foreign Meat (red ball) seals 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
- Observe the destruction (record during voluntary reimbursable time)
- Access PHIS and complete the Disposition
- 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 timeframe (i.e., 45 days)
- Verify forms certifying conversion are complete
- In PHIS, enter the disposition as complete