



FSIS Import Inspection Student Notebook and Course Materials



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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
FL <i>Listeria</i>	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 as 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

Failure to Present

FSIS Directive 9900.1

OBJECTIVES

- Define Failure to Present (FTP)
- Describe how FTPs are to be handled

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 re-inspection at an official import inspection establishment by the estimated date of arrival declared, and is off-loaded from the conveyance, it is declared as a FTP product.

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. The response from the applicant may come to the IIP via:

- Official import inspection establishment management
- Monitoring incoming shipments using PHIS
 - When a shipment has not arrived by the estimated date of arrival (EDA), 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.

Response: At the designated Location

- (1) Verify the shipment's presence.

- (2) Access the Lot Tracking menu through the Lot Manager screen and change the status to "On Premises"
- (3) If the location cannot be confirmed, IPP should notify the FLS

Response: Delayed Arrival

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

Response: Cancelled Shipment

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

No Response or Location cannot be confirmed:

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

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

FTP Notifications:

The DO will notify the OIEA-RD and RMTAD of FTP. OIEA follows applicable directives. FLS and RMTAD will be updated, as necessary. RMTAD reviews incoming data and verifies OIEA-RD was notified of FTP.

- Email FLS and RMTAD
- 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 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

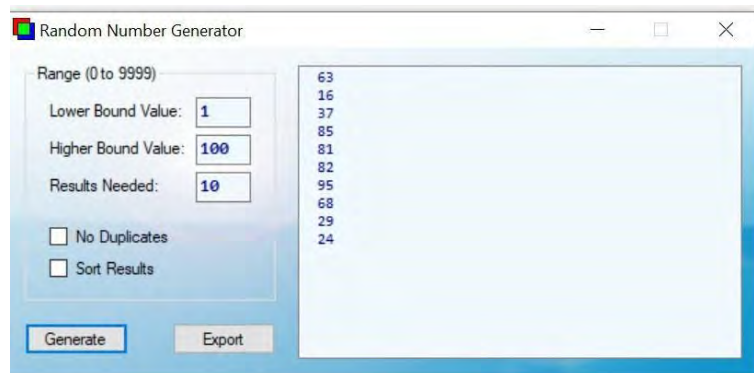
Label Verification of Staged Lots

- 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 = 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	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 principal 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 subprimals 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

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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.

Reinspection

FSIS Directive 9900.2, Rev. 2

OBJECTIVES

- Prioritize re-inspections
- Describe when to add unscheduled TOIs
- Choose the appropriate sampling plans
- Decide whether OCP defects should result in a TOI failure

Prioritizing Reinspections

Example: Reinspecting lots assigned additional TOIs with public health ramifications prior to inspecting lots only assigned Certification and Label Verification TOIs.

- * Each lot of meat, poultry, or egg products will be assigned at least a Certification and Label Verification TOI.
- * When an inspection certificate/application contains more than one lot, prioritize lots assigned additional physical TOIs first (e.g., physical exam, COC) over lots assigned only Certification and Label Verification TOIs.

Adding Unscheduled TOIs

Add unscheduled TOIs rather than redrawing assignment to ensure the intensified LOR is reserved for future certificates and applications from the same establishment.

- When a prioritized lot fails a physical TOI due to a food safety defect, and other lots of like-product (e.g., same process category and product group) from the same processing establishment are on the certificate, assign an unscheduled TOI to the other lots for the same physical inspection that failed.
- Select the justification “Public Health Defect on Related Lot”.

Physical Inspections (PI) Table 1 - Use FSIS Directive 9900.2 Table 1 (page 2) for a specific product to determine the Sampling Plan (SP) in Attachment 1 (page 27) and Defects Classification in Attachment 2 (page 30).

Table 1: Summary of Products, Sampling Plans and Defect Tables

TABLE 1: SUMMARY OF PRODUCTS, SAMPLING PLANS, AND DEFECT TABLES

Product	Sampling Plan (SP) (Attachment 1)	Defect Table (Attachment 2)
Beef, Equine, and Veal Carcasses	SP1	Product Exam 1 - A (PE1 - A)
Goat, Lamb, Mutton, and Pork Carcasses	SP2	Product Exam 1 - A (PE1 - A)
All Red Meat Species – Primals/Subprimals, Cuts, Offal, and Miscellaneous Parts	SP3	Product Exam 1 A or B (PE1 - A or PE1 - B) as applicable for Specified Product and Species
Boneless for Manufacturing (Trimming), Mechanically Separated, Advanced Meat Recovery (AMR), Finely Textured Trim and Bulk Ground Products	SP3A	Product Exam 1 A or B (PE1 - A or PE1 - B) as applicable for Specified Product and Species
Whole Birds and Poultry Parts	SP4	Product Exam 2 (PE2)
Ground, comminuted, processed, canned, packaged, and all other products not covered by Plans SP1 to SP4	SP5	Product Exam 3 (PE3)
Cooked Meat in Tubes (for Pink Juice Test only)	SP6	Product Exam 3 (PE3)

TOI/Product	Sampling Plan	Defect Table
Condition of Container (COC) - Glass and Metal Containers with Double Seams	See Section XV Condition of Container Normal/Increased/Intensified SP7	Condition of Container Examination 1 SP8 (COCE1 Table)
Condition of Container (COC) - Flexible Containers	See Section XV Condition of Container Normal/Increased/Intensified SP7	Condition of Container Examination 2 SP8 (COCE2 Table)
Incubation	See Section XVII Incubation of Hermetically Sealed Containers SP8A	Condition of Container, COCE1 or COCE2 Table, as applicable for the type of container; <u>FSIS Directive 7530.1</u>
Net Weight	<u>(NIST) Handbook 133</u> Tables 1-1, 2-1 in <u>Appendix A</u>	<u>(NIST) Handbook 133</u> Tables 1-1, 2-1, and 2-9 in <u>Appendix A</u>

NOTE: The defect classification to select in PHIS for product subject to defect criteria from Table PE1-A, or PE1-B is PE1

Physical Inspections-Defect Tables (refer to FSIS Directive 9900.2, Attachment 2 (page 34))

- Defects are classified as either Public Health (PH) or Other Consumer Protection (OCP).
- OCP would be a quality concern and not a safety concern.

Product Examination (PE)

An organoleptic inspection for defects such as fecal material, ingesta, blood clots, bruises, bone fragments, and extraneous materials.

- PE1-Raw Intact and Raw Non-Intact products, **excluding** poultry and ratites
- PE2-Raw Intact and Raw Non-Intact poultry and ratite products
- PE3-Further processed products of all amenable species, including egg products
- What are PH defects for beef carcasses when performing PE1? What are the OCP defects?

PE1 and PE3; Specified Risk Materials (SRMs) in Beef/Beef Products - Examine product for SRMs.

- If found, follow instructions in the Defect table (see slide).
- You can go to the APHIS website to determine the country's or region's BSE risk status.
- If negligible risk, PHIS will not allow you to Refuse Entry for the SRM defect.
- Status of some countries (e.g., Australia and New Zealand) are listed as "Negligible BSE Risk" which is equivalent to the U.S.
- Both PE1 and PE3 require reinspection of beef/beef products for SRMs.

• <u>All Cattle</u>	<u>≥ 30 Months of Age</u>
Tonsils	Tonsils
Distal ileum	Distal ileum
	Brain
	Skull
	Eyes
	Trigeminal ganglia
	Vertebral column (spine, except bones of the tail)
	Spinal cord
	Dorsal root ganglia



This [image] is bone-in loin.

Question: What do you see? **Answer:** Spinal cord and part of vertebral column.

Question: Is it an SRM? **Answer:** Depends on the age of the animal. If the animal was older than 30 months, the spinal cord and vertebral column are SRM.

Ask yourself: Does the certificate or label identify the age class of animal? If not, notify your supervisor.

Physical Inspection (PI) Methodology

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 (page 4)
- VII. Physical inspection of primals and subprimals, cuts, offals (page 4)
- VIII. Physical inspection of finely textured trim, advanced meat recovery (AMR) (page 4)
- IX. Physical Inspection of cooked meat from restricted countries (page 4)
- X. Physical Inspection of Parma, Prosciutto, and Serrano hams (page 5)
- XI. Physical inspection of meat extracts, bone, stock broth, and similar items (page 5)
- XII. Physical inspection of semi-solid packed products (canned hams) (page 5)
- XIII. Physical inspection of non-solid packed products (beef in gravy, stews) (page 6)
- XIV. Pork skins intended for popping, rendering, or gelatin manufacturing (page 6)
- XV. Condition of container examination 1 (page 6)
- XVI. Incubation of hermetically sealed containers (page 12)
- XVII. Net weight reinspection (page 14)
- XVII. Tanker shipment reinspection (edible fats and oils transported in bulk) (page 15)
- XIX. Physical inspection of egg products (page 16)
- XX. Sampling procedures for Physical inspections (page 18)
- XXI. Identification of defects during physical inspection (page 19)
- XXII. Results based on defect identification during physical (page 20)

Egg Product Entry Requirements

Canada and the Netherlands are currently the only countries eligible to export egg products to the United States.

- Bulk packed egg products imported into the U.S. must meet 9 CFR 590.910 (i.e., must be from an eligible foreign country).
- All egg products must be presented for reinspection at the location indicated on the application (FSIS Form 9540-1).
- All pasteurized egg products must stop at an import establishment for reinspection.
- Non-pasteurized egg products may proceed directly to an official egg product plant that conducts a pasteurization process for tankers and totes greater than 1000 lbs. (**Note:** Currently, only Canada is shipping unpasteurized egg product to the U.S.).
- Interim procedures for Unpasteurized Egg Products: Applicant emails/faxes application and certificate to HQ. HQ enters data and emails cert and app (including EDA) to IPP. If product has not arrived by the close of the EDA, IPP notify HQ immediately. Product examination assignments are received through PHIS.
- Prior to arrival, RMTAS enters application data and obtains the assignments.
- When notified the shipment has arrived, IPP use Import Inspector role to review the electronic application in PHIS and compare the information to the hard copy certificate that accompanies the shipment.
- IPP perform the assigned TOIs and enter the results in PHIS per FSIS Directive 5030.1.

Import Establishment Eligibility for Egg Product Reinspection

- Verify “Egg Products” will be checked Under “Import Inspection” on the Grant of Inspection (FSIS Form 5200-2) https://www.fsis.usda.gov/wps/wcm/connect/c7512904-07cf-46e2-bdfd-2a48e61b588b/Form_5200-2.pdf?MOD=AJPERES
- If unchecked:
 - Inform establishment it does not have approval for egg product reinspection.
 - Do not reinspect the product and advise the establishment that it may resubmit a revised form.

Import Establishment Facilities and Equipment for Frozen Egg Product PE

Verify adequate equipment and facilities for defrosting samples or core drilling samples (see FSIS Directive 9900.2, page 17).

Bulk Packed Egg Products Presented at an Import Establishment

Tanker trucks or portable totes weighing approximately 1,000 pounds or more. IIP should verify the following:

- The application information is accurate
- The certificate complies with 9 CFR 590.915
- The seal numbers on the transport vehicle match the seal numbers on the certificate or on official letterhead containing the exporting country’s official seal
- The labeling complies with 9 CFR 590.955
- For pasteurized egg products, test results for *Salmonella* are presented with the shipment and identified as negative on the certificate or on official letterhead for the production lot for tankers and totes only.
- The product matches information identified on the inspection certificate

PE of Egg Products (FSIS Directive 9900.2 (see page 16, “XIX. Physical inspection of egg products” for actual methodology)

- Assignments are made through PHIS
- Request to have the sample unit removed from the container and placed it in a sanitary container for examination
- Refer to Attachment 2, PE3 for classification of defects

Identification and Retention of Defects Zero Tolerance

- Use the appropriate defect table (Table PE1 -A or Table PE1-B for the product reinspected
- 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 sample to the lab 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 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.

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 defect and the effect on usability of the product. IIP should determine whether defect is isolated/widespread, whether misbranded, whether could not be further processed or 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's 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. However, PHIS will not automatically escalate the appeal to the next level supervisor. 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 fail product TOIs.

Laboratory Sampling

FSIS Directive 9900.6

OBJECTIVES

- Learn how to collect, prepare, and submit samples for laboratory analysis
- Learn how to interpret lab results and take appropriate action
- Learn how to verify import establishment control Agency tested imported products for adulterants.

Background

- Assignment is the specific Type of Inspection (TOI) assigned by PHIS for a lot of imported meat, poultry, and egg products
- Level of Reinspection (LOR) is the intensity of reinspection assigned to a lot based on the compliance history of a foreign country, establishment, and/or product.

Levels of Reinspection (LOR)

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

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 negative results are received

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

Control of Agency Tested Imported Products for Adulterants

- Notify OIIE management when you get a laboratory sample TOI
- 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. “For cause” (Intensified or Increased LOR with FSIS instructions to hold) may not be moved off-premises or stamped.
- For other samples (i.e., not “for cause”), notify OIIE 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 9540-1, Import Inspection 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 either Agency hold or IOR control and would also include “for cause” food chemistry or pathology sampling.

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

Tests Not Requiring Control

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

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 SharePoint site for TOIs that are applicable to product groups.

Sample Supply Request

- Verify Establishment Profile includes the correct physical mailing address (not PO 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

- Identify each shipping container selected as a "USDA OFFICIAL IMPORT SAMPLE"
- Observe handling and removal of the unit(s) to be sampled
- Collect samples from one specific production code or date
- When practical, obtain from plant management a photocopy of the shipping container label and immediate package label (front and back) for 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.
 - Plant management can take a photograph of the shipping container label if too big for the copy machine.

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", "Place Lot on Hold," and select the appropriate reason.

Sample Submission

Monitor LIMS-Direct. 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 wrong lab will result in the sample being discarded.

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, glove properly, use gloved hand to collect sample and place sample in bags, close bag)
 - **Note:** “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. Monitor receipt and status there.
- 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 OIIE management that sample was discarded, and product will not be resampled. In PHIS, choose “Submit Not Performed” and reason “Discarded Sample”. Complete the TOI with status “Not Analyzed”.
- Submit completed Form 9770-3 “Discarded Sample Report and Findings” to supervisor. Directive says to access the Laboratory TOIs page for the lot, choose “Submit a 2nd sample,” and notify the IOR through import plant management that a 2nd sample is being submitted to the lab.
- Form is available at InsideFSIS. Inspector completes, adds attachments, and sends to supervisor who determines if follow-up training or correlation is needed.
- The supervisor completes the bottom portion of the form, returns original for case file, and keeps a copy for reference.

Indeterminate Result

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

Negative/Passed Result

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

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

Presumptive Positive Result (Micro only)

- Notify OIIE management.
- If on-site, retain (tag).
- If off-site under IOR control, request OIIE management notify IOR of result and confirm the lot still being held and the location.
 - BITES notifications are sent to DO and HQ who should notify you.
 - The IOR contact information is contained in the application in PHIS. The FLS should

follow up with the inspector to ensure that the DIS and DO are informed of the presumptive positive result.

- Email supervisor and RMTAD the lot status, location, inspection certificate (for non-eCert countries, the application number, and the lot number).
- RMTAD may issue instruction to retain additional lots which may include previously inspected and passed product.
 - The FLS should follow up with the inspector to ensure that the DO and RMTAD are informed of the presumptive positive result.
 - FYI: RMTAD is to notify the program officials of the exporting country as soon as a presumptive positive result is reported in order to determine whether the producing establishment has exported any other product from the same production lot to the U.S. RMTAD is to query PHIS to identify any other shipments that may have entered the U.S. with the same production dates. If shipments are identified with the same production dates, RMTAD is to notify the DO and the import inspector. RMTAD 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 under IOR control and off-site, confirm through OIIE management the product is still under control and not in-commerce. Notify OIIE management to advise the IOR that the product is refused entry and must 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. • Stamp containers “United States Refused Entry.”
- Inform FLS of result and status.
- If product entered commerce, Agency would determine if a request to recall is warranted.
- RMTAD ensures the foreign establishment is under Intensified LOR and issues alert with instructions for other lots from the same establishment.
- RMTAD 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.

Laboratory TOIs Assigned

PHIS could assign the following types of Laboratory TOIs:

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

STEC Sampling (FSIS Directive 10,010.1)

BMT/Components for Raw Ground Beef/Non-Intact Beef Products (MT51)

Beef Manufacturing trimmings (BMT) - Collect samples of imported beef trimmings when the product is destined for use in raw ground beef or other non-intact raw beef product.

Components for Raw Ground Beef - Components for Raw Ground Beef/Non-Intact Beef Products - Raw 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.

Fresh BMT N60 Sampling (MT51) (refer to FSIS Directive 10,010.1)

- If lot is >5 containers, randomly select 5 containers and collect 12 pieces/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 WhirlPaks
- Complete sample collection data in PHIS

Frozen BMT N-60 Sampling (MT51)

- 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 approx. 2 lbs.)
- Sample as much surface area as possible
- Package the sample evenly into three WhirlPaks
- Enter sample collection data in PHIS and "Submit" to laboratory
- Identify samples, identify, and sign collection form, properly pack and seal container
- Complete shipping form to the assigned lab

Component Sampling (MT51)

- For smaller components, collect grab samples and fill each of the 3 bags to the fill line
- For larger components (e.g., hearts), collect 1 or slices to fill the bag 2-3" from the top (don't worry about the fill lines)

Raw Ground Beef Products (MT08)

Raw beef food 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)).

Sample Size (MT08)

- 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.
 - 1. 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.
 - 2. If the immediate container is >2 lb., then select an entire intact package if it is practical to ship to the lab.
 - 3. 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*

FSIS Notice 19-17

Key Points – Issued March 20, 2017, for poultry-*Salmonella/Campylobacter* TOI ○

Training - Review FSIS Directive 10,250.1, Attachments 1,2,3,4, and 5 ○ Order training video Sampling Raw Meat and Poultry @ CEDL@fsis.usda.gov.

- **Supplies** - Submit requests for sample supplies from a FSIS laboratory by email specifying the project code IMP_Poultry
- Request the appropriate sample kit for the specific products to be sampled. Import inspection personnel are to include in their request their contact information, establishment name, street address (no P.O. Box), city, state and zip code; the project code IMP Poultry; and specific name of the supply kits needed for the products sampled as indicated in the following tables: Refer to tables starting on page 3 of the Notice. Go over tables. ○ **Upon receiving the supplies:**
- Refrigerate (not freeze) the Buffered Peptone Water (BPW) until use ○ Freeze coolant at least 1 day before use
- **Buffered Peptone Water** – Do not use if it is not included in the IMP Poultry supplies or if it is out of date. Also, it may be cloudy when received. **Do not discard for cloudiness.**

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. ($\pm 10\%$)
- 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 BPW
- 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. ($\pm 10\%$)
 - 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 Hazard Analysis and Critical Control Point (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 OIIE that IOR to 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 rinderpest or Foot-and-Mouth (FMD) are known to exist (note that rinderpest is currently considered to be “eradicated” by the World Organization for Animal Health (formerly known as the “OIE”), though it is still referred to in the Directive). We do these reexaminations on behalf of APHIS based on a memorandum of understanding (MOU) we have with them.

- * FSIS Directive 9900.7 instructs Import Inspector on how to conduct import reinspection physical examinations of cooked meat products from regions where rinderpest (RP) or Foot-and-Mouth (FMD) disease exists.

- * APHIS restricts the eligibility for import of products from these countries, and FSIS performs examinations of these products, as part of a MOU between the agencies.

- * APHIS is responsible for the importation of perishable cooked meats from countries known to be affected by RP and FMD.

- * Customs and Border protection also has inspection authority at the port-of-entry.

- * The PHIS foreign country profile includes the animal health status for each eligible country and will automatically assign the appropriate TOI associated with the RP and 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 to the product, and notifies APHIS and CBP. * CBP takes regulatory action against the product.

Establishment Profile

Review profile to confirm that the establishment is approved for reinspection of APHIS restricted products from RP and FMD countries.

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 RP/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 and the DIS for guidance.
 - At APHIS request, fail the pink juice test TOI and document the reasons for the failure.
- Tubes have either:
 - An indicator piece (one solid piece of meat) no smaller than a 1½ inch cube in size at the cold spot of the tube (normally the center of the tube), or
 - A heat sensitive disk at the approximate center

Note: APHIS does not currently recognize the valid use of heat sensitive disks; therefore, Inspectors must only perform the PJT using the indicator piece as described above.

- 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 ½" cube in size.
 - Heat sensitive disk is available in the center of the tube.

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 for Tubes with Heat Sensitive Disks

No country currently approved by APHIS to use heat sensitive disks. Nevertheless, Inspectors perform the PJT using the semi-frozen indicator piece as described above.

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 the pink juice or the heat-sensitive disk (not currently applicable) has not turned black:
 - (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 US livestock
 - (6) Verify that the OIIE 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

Heat Sensitive Disk for Cooked Patties Temperature Indicating Devices for Cooked Patties

Heat-sensitive disks or other temperature indicating devices are not currently approved by APHIS.

Condition of Container Examinations (COCE)

FSIS Directive 9900.2 & FSIS Directive 7530.1

Objectives

- Describe the purpose of a condition of container exam.
- Define abnormal, critical, and major defects.
- Identify container defects.
- Utilize the sampling plans.
- Utilize criteria in the tables to pass or fail a lot.
- Utilize criteria in the tables to permit or refuse sorting and to pass or fail a sorted lot.

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
 - *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 Staph grows, it produces a heat stable 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/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. IIP 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

- Note the disposition (Pass/Fail) and eligibility for sorting is based on the number of abnormal containers, critical defects, and major defects, and the types of defects found (examples: hard swells, blown containers, loose tins).
- Worst case is burst containers. They are easily detected by odor, maggots, stained cases, and sound (explosions). ◦ Exercise care when handling. If under-processed and contains botulinum toxin, it could get into your eyes, mouth, and nose if the container ruptures. Not good! 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; page 9)

- Hard/Soft Swell * Flipper * Springer * Loose Tin * Overstuffed

Defective Containers (Non-Critical Defects) Cans and Glass – COCE1 (FSIS Directive 9900.2, Table 1B; page 9)

- Punctured Cans * Dents * Improper Seals * Cable Cuts * Rust * Missing Label * Other

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, Table 2A; page 10)

Abnormal Containers (Critical Defects) Table 2A; page 10

- Swollen Package * Leaker

Defective Containers (Critical Defects) Table 2B; page 10

- Non-bonding * Cuts * Fracture * Notch Leaker * Hole/Puncture * Channel Leaker

Defective Containers (Non-critical Defects) Table 2C; page 10

- Abrasion/Scratch * Blister * Compressed Seal * Contaminated Seal * Delamination * Crooked/Short/Misaligned Seal * Seal Creep * Burning * Wrinkle * Crushed Package * Uneven Impression

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.

Sample Collection - If abnormal containers are observed and/or seam defects are evident, sample collection is 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 Western Lab, 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 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 investigators observations). 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:
 - 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. 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 abnormal or defect.

Sorting - Lots determined to be sortable may be sorted at the applicants' request and presented for tightened reinspection under reimbursable services.

- Refer to 9 CFR 327.6(j).
- Refer to Table B and Table C on page 14 of FSIS Directive 9900.2

PHIS Data Entry Demonstration

- Lot 1: Defective containers only - If you find non-abnormal defects, you will use the charts in the directive to determine whether it is sortable and whether it passes or fails. If it fails and is sortable, PHIS fails the first step and creates a refused entry record. If the importer elects to sort the lot, you would enter that as a rectification. Once the Refuse Entry is rectified and recorded in PHIS, the tightened reinspection TOI is unlocked, and the results of the tightened reinspection can be entered.
- Lot 2: Abnormal containers - Per 9900.2 "When an Abnormal Container Defect is recorded in PHIS, IPP are to indicate whether the lot is sortable based on the table below and fail the condition of container TOI. If the lot is sortable, IPP are to add an

Abnormal Container TOI as Unscheduled, retain the lot, and contact the Western Lab for further instruction on submitting samples. If the lot is not sortable, record the TOI as "Fail." A follow-up Abnormal Container laboratory sample will assign automatically. Retain the lot and contact the Western Lab for further guidance on submitting containers to the laboratory."

Incubation of Hermetically Sealed Containers

- Verify that official import establishments that receive shelf stable containers can provide an incubator.
- When necessary, add unscheduled Incubation TOI and select the appropriate number of containers for incubation.
- If grant application shows the establishment will handle thermally process products, they must have access to an incubator.

Incubation Sample Selection

- 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 after or during the container 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 (Annex 2, 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 Import Inspection Personnel 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” 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 failed 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.
- 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 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

Pre-stamping

FSIS Directive 9900.3

OBJECTIVES

- Identify the appropriate pre-stamping procedures of the establishment
- Describe the approval process for the pre-stamping plan
- Identify which lots are not eligible for pre-stamping
- Describe the protocols for revoking/suspending pre-stamping privileges

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). Establishments are to submit pre-stamping requests and procedures to the DO.
- 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.

Procedure Approval Process

- The OIIE 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) or 381.204(f).
 - 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 import inspection establishment to address any outstanding issues.
 - A template of the approval letter is on the FSIS Import Inspection SharePoint site.
- Limits pre-stamping to lots that can be reinspected the same day.
- Provides that lots subject to Intensified LOI will not be pre-stamped.
 - Lots at "Intensified" LOI 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 label.
- 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 OIE 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 OIE 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 “Normal” LOI or “Increased” LOI w/out 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.

Prestamping 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 on a daily basis

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):

- Retain any affected product and require correction of the noncompliance

- Document the noncompliance in PHIS and issue a 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, not readable).

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.